CANADIAN RHEUMATOLOGY ASSOCIATION MEETING

The 68th Annual Meeting of The Canadian Rheumatology Association (CRA) was held at the Fairmont Chateau Laurier, Ottawa, Ontario, Canada, February 13–16, 2013. The program consisted of presentations covering original research, symposia, the Dunlop-Dottridge Lecture, workshops, the Great Debate, and a special spotlight on Canadian excellence in rheumatology by the CRA Distinguished Rheumatologist, Distinguished Investigator, Teacher-Educator, and Young Investigator. The contributions presented at the meeting are reflected in the abstracts of the meeting, which we are pleased to publish in this issue.

Podium

1

Tensegrity: The Importance of Mechanical Forces in Scleroderma Fibrosis

Andrew Leask (University of Western Ontario, London); Katherine Thompson (London); Shangxi Liu (University of Western Ontario, London)

Objective: The main cause of lethality in the autoimmune connective tissue disease scleroderma is organ fibrosis. Cellular behavior is altered by their local microenvironment, which includes enhanced local stimulation of mechanical signaling pathways. Fibrotic lesions are, by their nature, characterized by significantly enhanced mechanical forces relative to healthy tissue. Previous evidence from our laboratory has identifed the myofibroblast (a highly adhesive and contractile fibroblast that exerts mechanical tension on surrounding tissue) as the critical effector cell in the fibrosis observed in scleroderma. This observation led us to test the hypothesis that enhanced mechanosignaling was required for fibrogenesis. The signaling receptors required for mechanotransduction are the integrins, and we have previously shown that a neutralizing antibody to integrin beta 1 reverses the fibrotic phenotype of lesional scleroderma fibroblasts and that integrin beta 1 knockout mice are resistant to bleomycin-induced skin fibrosis.

Methods: We use fibroblast-specific integrin beta1 knockout mice as well as primary dermal fibroblasts to assess the effect of loss of integrin b1 on skin homeostasis and connective tissue sythesis and deposition. Specific chemical inhibitors were used to identify the mechanism underlying the basis for integrin beta activity in fibroblasts.

Results: We show that integrin beta 1 is an essential mechanosignaling receptor required for connective tissue production and deposition. We also show that integrin beta 1 promotes this activity through a focal adhesion kinase/ rac1/NADPH oxidase/reactive oxygen species-dependent mechanism.

Conclusion: Inhibitors of the integrin beta 1/focal adhesion kinase/rac1/NADPH oxidase/reactive oxygen species pathway, which are currently being considered as anti-cancer regimens. May be useful to prevent excessive connective tissue deposition and remodeling seen in scleroderma. Our data further suggest that altering how fibrotic cells perceive their microenvironment via mechanosignaling receptors may be prove to be a crucial, novel paradigm in treating chronic connective tissue disease.

2

Imbalance of Prevalence and Specialty Care for First Nations with Osteoarthritis in Alberta

Cheryl Barnabe (University of Calgary, Calgary); Allyson Jones (Departments of Physical Therapy and School of Public Health, University of Alberta, Alberta); Ed Enns (Calgary); Don Voaklander (Edmonton); Christine Peschken (University of Manitoba, Winnipeg); Joanne Homik (University of Alberta, Edmonton); John Esdaile (Arthritis Research Centre of Canada, Richmond); Sasha Bernatsky (McGill University, Montreal); Brenda Hemmelgarn (University of Calgary, Calgary); Deborah Marshall (University of Calgary, Calgary)

Objective: To compare osteoarthritis (OA) prevalence and healthcare use in Alberta First Nations (FN) and non-First Nations (non-FN) populations.

Methods: Using population-based healthcare administrative data (years 1993 to 2010), a prevalent OA cohort was determined based on diagnosis codes (2 physician claims within 2 years or 1 hospitalization with ICD9 code 715x, or ICD10 codes M15-19). FN patients were identified based on premium payer status and represent 3.8% of the Alberta population. OA prevalence (fiscal year 2007/2008) and visits to primary care physicians, orthopedic surgeons, and rheumatologists, and hospitalizations (joint replacement and all-cause) were calculated.

Results: Age and sex standardized prevalence of OA in FN persons was 160.0 cases/1,000 population, compared to 78.2 cases in non-FN persons (standardized rate ratio 2.06; 95% CI 2.00-2.12). Age and sex standardized prevalence was highest for rural residents (186.7/1,000 FN, 88.5/1,000 non-FN) and females (184.9/1,000 FN, 93.1/1,000 non-FN). Primary care physician contact for FN persons was more frequent than for non-FN (16.7 vs 10.8 visits/1,000 person-years (py), respectively), with 15% of these visits being coded for OA. FN persons with OA were less likely to see an orthopedic surgeon (290.4 FN vs 460.3 non-FN visits/1,000py; rate difference -0.170, 95%CI -0.175 to -0.165). Rheumatology visits were also less frequent for FN persons (39.0 FN vs 51.4 non-FN visits/1,000py; rate difference -0.012, 95%CI -0.014 to -0.010). FN with OA were less likely to have hip or knee replacements (6.2 FN vs 20.0 non-FN surgeries/1,000py; rate difference -0.014, 95% CI -0.015 to -0.013). All-cause hospitalization rates were highest in FN females with OA (355.8 admissions/1,000py) followed by FN males, non-FN males and non-FN females, and for rural compared to urban residents.

Conclusion: Our work suggests disparities in OA care in FN persons given an estimated 2-fold higher disease prevalence. This finding may be driven in part by an increased probability of diagnosis through frequent primary care contact. Use of rheumatology and orthopedic services is lower in FN compared to non-FN persons. This may be due to access barriers for FN patients.

3

TNF Inhibitors Slow Radiographic Progression of Ankylosing Spondylitis

Nigil Haroon (University of Toronto, University Health Network, Toronto); Robert Inman (University of Toronto, Toronto); Thomas Learch (Cedars-Sinai Medical Center, Los Angeles, Los Angeles); Michael Weisman (Cedars-Sinai Medical Center, Los Angeles); Michael Ward (National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, Bethesda); John Reveille (University of Texas Health Science Center at Houston, Houston); Lianne Gensler (University of California, San Francisco, San Francisco)

Objective: Tumor necrosis factor-alpha (TNF) inhibitors are excellent in giving symptomatic relief for patients with spondyloarthritis. Yet to date, there is no evidence that it has a disease-modifying effect. The use of nonsteroidal anti-inflammatory drugs (NSAID) has recently been proposed to have a disease-modifying effect. Our objective was to determine whether TNF inhibitors slow spine damage in AS patients.

Methods: All patients satisfied the modified New York criteria for AS and were enrolled in prospective observational cohorts in five tertiary care centers across North America. All 334 patients who had at least two sets of spinal radiographs available at a minimum gap of 1.5 years were included.

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Disease activity at baseline was assessed by a validated patient reported index, Bath AS Disease Activity Index (BASDAI) as well as by erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP). Baseline predictors including HLA-B27, gender and smoking (pack-years) were studied. Radiographic disease severity in AS was assessed by the validated scoring method, modified Stokes Ankylosing Spondylitis Spine Score (mSASSS). Patients with a rate of mSASSS progression more than 1 mSASSS unit per year were considered progressors. Univariate regression analysis followed by multivariate analysis was done to identify predictors of progression. Propensity score matching (PSM) was performed.

Results: There was a 50% reduction in the odds of progression of radiographic damage (OR: 0.50; CI: 0.27-0.91; p = 0.02) in AS patients treated with TNF-inhibitors. Patients who started TNF inhibitors within 10 years of disease onset had the greatest reduction in odds of progression (OR: 0.36; CI: 0.15-0.91; p = 0.03). Males had higher rate of progression than females but after correcting for baseline mSASSS, none of the baseline demographic factors independently predicted radiographic progression. Baseline CRP, ESR, smoking and mSASSS were significant independent predictors of progression. There was no effect of NSAID use on radiographic progression even after correcting for baseline ESR or CRP values.

Conclusion: This is the first study to show the disease-modifying potential of TNF inhibitor therapy in AS patients. Early initiation of TNF-inhibitors was associated with a greater likelihood of slowing progression arguing for earlier diagnosis. Smoking and baseline inflammation are important baseline predictors of radiographic progression in AS.

4

Long-term Outcomes of Children Born to Women with Systemic Lupus Erythematosus

Evelyne Vinet (McGill University Health Centre, Montreal); Christian Pineau (McGill University Health Centre, Montreal); Ann Clarke (McGill University Health Centre, Montreal); Susan Scott (Montreal); Caroline Gordon (The Medical School, University of Birmingham, Birmingham); Robert Platt (Montreal); Sasha Bernatsky (McGill University, Montreal)

Objective: SLE can cause considerable morbidity during pregnancy. Although several studies have evaluated fetal outcome in lupus pregnancy, few have examined the longterm outcome of children born to mothers with SLE. We aimed to determine if children born to women with SLE have an increased risk of major congenital anomalies, serious infections, and cardiac conduction disturbances compared to children born to women without SLE.

Methods: We identified all women who had ≥1 hospitalization for delivery after SLE diagnosis using Quebec's administrative databases (1989-2009). Women were defined as SLE cases if they had: 1) ≥ 1 hospitalization with a diagnosis of SLE prior to the delivery, 2) a diagnosis of SLE recorded at the time of their hospitalization for delivery, or 3) ≥ 2 physician visits with a diagnosis of SLE, occurring 2-24 months apart, prior to the delivery. We randomly selected a general population control group, composed of women matched at least 4:1 for age and year of delivery, who did not have a diagnosis of SLE prior to or at the time of delivery. We identified children born live to SLE cases and their matched controls and obtained information on all physician visits and hospitalizations incurred by these children. We ascertained major congenital anomalies (i.e. ≥ 1 hospitalization or physician visit for a major congenital anomaly < 12 months of life), serious infections (i.e. ≥ 1 hospitalization with a primary diagnosis of infection), and cardiac conduction disturbances hospitalization or 2 physician visits within 2-24 months) through to end of database followup. We performed multivariate analyses to adjust for maternal demographics, sex and birth order of child, major maternal comorbidities and/or obstetrical complications, and relevant maternal medication.

Results: 509 women with SLE had 719 children, while 5824 matched controls had 8493 children. Compared to controls, children born to women with SLE experienced slightly more major congenital anomalies [13.5% (95% CI 11.1,16.2) vs 10.4% (95% CI 9.8,11.1)], serious infections [23.9% (95% CI 17.6,31.5) vs 16.3% (95% CI 14.6,18.1)], and cardiac conduction disturbances [3.1% (95% CI 2.0,4.7) vs 1.2% (95% CI 1.0,1.4)]. In multivariate analyses, children born to women with SLE had substantially increased risks of major congenital anomalies (OR 1.35, 95% CI 1.07,1.70). Serious infections (HR 1.88, 95% CI 1.17,3.03) and cardiac conduction disturbances (HR 4.52, 95% CI 1.23,16.59) compared to controls.

Conclusion: Compared to children from the general population, children born to women with SLE have an increased risk of major congenital anomalies, serious infections, and cardiac conduction disturbances.

5

The ACR/EULAR Classification Criteria for Systemic Sclerosis (SSc)

Janet Pope (University of Western Ontario, London); Dinesh Khanna (University of Michigan, Ann Arbor); Jaap Fransen (University Medical Centre Nijmegen, Netherlands); Sindhu Johnson (Toronto Scleroderma Program, Toronto Western Hospital, Mount Sinai Hospital, University of Toronto, Toronto); Murray Baron (McGill University and Jewish General Hospital, Montreal); Alan Tyndall (University Hospital and Felix Platter Spital, Basel); Marco Matucci-Cerinic (Instituto di Clinica, Florence); Raymond Naden (National Women's Hospital, Auckland); Frank van den Hoogen (Sint Maartenskliniek, Maartens)

Objective: A joint EULAR and ACR committee was established to develop new classification criteria for SSc.

Methods: A nominal group technique were used to create potential items for SSc classificaiton. The validity was tested in databases of SSc cases and controls. Next, 20 cases were prospectively collected to represent the spectrum of SSc (low probability to high probability) which were ranked by SSc experts. Conjoint analysis (1000 Minds®) was used to assign weights to the items resulting in 17 items in 13 domains. Experts agreed that all patients with sclerodactyly and scleroderma skin involvement proximal to the MCP were considered SSc; patients with skin involvement due another scleroderma-like disorder (e.g. scleromyxedema) were excluded. A threshold was established to classify definite SSc based on the sum of weights of 17 items. To test the algorithm, data on the items were prospectively collected in cases and controls. To refine the threshold, a subset of cases (n=25) within the range of borderline probability of SSc was selected from the collected data. Experts were then asked to determine whether each case had "definite SSc" or not, leading to a new threshold. During a face-to-face meeting of the Steering Committee, the 17 items were reduced to 9 while maintaining adequate sensitivity and specificity, tested in a random sample of cases and controls of 100 from North America and 100 from Europe (derivation sample). Cases of SSc and mimickers were collected at several sites in NA and Europe where about half of SSc had early disease. Weights were simplified by dividing each weight by 5 and rounding to the nearest whole number. The data were then re-analyzed in the remaining cases and controls (validation set; n=405).

Results: Mimickers of SSc need to be excluded. If sclerodactyly with involvement proximal to MCP, then SSc is classified. Otherwise, only the maximum score in each domain is counted (skin: puffy fingers=2 or sclerodactyly entire fingers=4, finger tip ulcers=2 or digital pits=3, telangiectasia=2, nailbed abnormal capillaries=2, PAH or ILD=2, RP=3, SSc antibody (centromere, topo1, RNApol3)=3. Nine or more (out of 19) had a sensitivity of 91% and specificity of 92% in the validation cohort (n=405). The sensitivity and specificity of the former 1980 ARA criteria in this database were 75% and 72%, respectively.

Conclusion: The ACR/EULAR classification criteria for SSc performed better than 1980 Preliminary ARA Criteria for SSc. These criteria can be endorsed for epidemiological studies and clinical trials.

6

2010 ACR/EULAR Rheumatoid Arthritis Classification Criteria Predicts Radiogical, but Not Clinical Outcomes at 18 Months into Disease in a Canadian Early Arthritis Cohort

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Objective: Analyze the potential of the 2010 ACR/EULAR rheumatoid arthritis (RA) classification criteria to discriminate early arthritis patients according to their clinical and radiological outcomes at 18 months

Methods: Consecutive patients with at least 3 swollen joints (SJC≥ 3) were recruited; duration of disease was more than 1 and less than 12 months; microcrystalline arthritides and connective tissue diseases were actively excluded. All patients were treated with the target of SJC= 0, using whatever disease-modifying antirheumatic drug was required. According to the 2010 RA criteria, our cohort was classified in two groups: RA and non-specific inflammatory arthritis (NSIA). Both groups were compared at baseline and at 18 months into disease according to radiological and clinical outcomes: Sharp erosion score (classified erosive if ≥ 3), Health Assessment Questionnaire (HAQ), Disease Activity Score in 28 joints (DAS28-CRP), and pain (0-100 mm VAS). Remission rates at 18 months were calculated based on DAS 28 and ACR 2011 remission criteria.

Results: A total of 422 patients were available at baseline. Of these, 319 (75.6%) were classified as RA. Based on clinical outcome measures, RA patients had more severe disease than NSA patients at baseline (higher DAS 28, HAQ and pain scores measures – p< 0.001). At 18 months, this initial clinical discrepancy had now disappeared, but more RA patients had progressed to erosive status than NSIA patients (54% vs 33%; p< 0.001). Using two different definitions of remission, there was no difference in remission rates.

Conclusion: In this early arthritis cohort actively treated to SJC= 0, there was no difference in the 18-month clinical outcomes (HAQ, DAS 28, Pain, Remission rates) between 2010 ACR/EULAR criteria-defined RA and NSIA patients. Patients with RA had a worse radiological outcome, but significant joint damage occurred in one-third of NSIA patients. Early intensive treatment of NSIA patients, and not only of early RA patients, thus appears warranted.

7

Microparticle-Associated Immune Complexes Derived from Platelets are Elevated in the Plasma of Patients with Systemic Lupus Erythematosus and Discriminate between Levels of Disease Activity

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Objective: Immune complexes (IC) are implicated in the pathogenesis of several autoimmune diseases including systemic lupus erythematosus (SLE). In SLE, submicron extracellular vesicles, called microparticles (MP), are thought to serve as an antigenic surface promoting the deposition of immunoglobulins and the formation of MP-associated immune complexes (mpIC). However, the cellular origin of these mpIC and whether they correlate with disease activity and particular clinical features remains to establish.

Methods: The concentrations of mpIC in platelet-poor plasma from 193 women with SLE were determined using high sensitivity flow cytometry. Considering the recently revealed role of platelets in SLE, we further scrutinized the contribution of platelets to mpIC formation. The platelet and non-platelet MP and mpIC were tested for association with lupus disease activity, damage, history of previous arterial disease, and the carotid intima-media thickness and plaque area on ultrasound. To assess if disease activity and damage are associated with levels of MP and mpIC, univariate and multivariate negative binomial models were built using the SLE disease activity index 2000 (SLEDAI-2K) and the SLICC/ACR damage index (SDI) as outcome variables. In all models, the predictor variable was the level of MP or mpIC. When necessary, models were adjusted for covariables such as age, disease duration, menopausal status, hypertension, diabetes, anticoagulant or anti-platelet medication, antimalarial medication, prednisone use, smoking status, and ethnicity.

Results: The clinical characteristics of the 193 women studied were age of [mean (sd)] 46.3 (14.7) years; disease duration 18.5 (12.0) years; ethnicity (% white) 57%; ever-smoker 34%; menopausal in 55%; hypertentive 30%; diabetic 5%; prescribed anticoagulant or anti-platelet medication 25%; prescribed antimalarial medication 74%; prescribed prednisone 44%. Univariate analyses for activity revealed that platelet-derived mpIC, but not mpIC from other cells, were associated with SLEDAI-2K. In the multivariate model, this association remained significant (p=0.02 for annexin V+ platelet mpICs and p=0.0006 for annexin V-platelet mpIC) after adjusting for disease duration, hypertension and currently on prednisone. There was no association between platelet mpIC and SDI.

Conclusion: Platelets are a major source of MP serving to mpIC formation in SLE. Platelet-derived mpIC are associated with lupus disease activity level on the SLEDAI-2K but not with damage. This is the first report of an association between platelet mpIC and clinical marker of activity in SLE and in any autoimmune disease. Platelet mpIC as a possible biomarker of lupus disease activity needs to be further considered.

8

Survival in Rheumatoid Arthritis-associated Pulmonary Arterial Hypertension is Comparable to Idiopathic Pulmonary Arterial Hypertension

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Objective: To evaluate survival in rheumatoid arthritis-associated pulmonary arterial hypertension (RA-PAH) compared to idiopathic PAH (IPAH) population. Secondary outcomes included differences in sex predisposition, age of diagnosis, disease severity, comorbid diseases and pulmonary hypertension treatment.

Methods: Data were collected by a single abstractor from charts, standardized protocols, and hospital electronic records using a standardized abstraction form from the University Health Network Pulmonary Hypertension Programme, Toronto, Canada. PAH based on a mean pulmonary artery pressure ≥25 mmHg and a pulmonary capillary wedge pressure < 15 mmHg on cardiac catheterization. Mortality data was obtained from electronic records and obituaries. Student's t-test and Pearson's Chi-squared test were used to evaluate baseline differences between groups. Unadjusted survival was evaluated using Kaplan-Meier survival curves. Differences in survival distributions were evaluated using the log rank test. Propensity score models were used to adjust for differences in baseline covariates. Propensity score adjusted Cox proportional hazards models were used to estimate survival.

Results: Eighteen RA-PAH and 155 IPAH patients were identified. RA-PAH patients had a lower proportion of males (17% versus 30%), and had an older median age of onset (64.0 years versus 53.7 years). RA-PAH patients more frequently had coronary artery disease (33% versus 16%), lower baseline mPAP (43 mmHg versus 51 mmHg), lower proportion of WHO functional class III or IV (39% versus 52%), lower median baseline BNP (58.4 pg/mL versus 95.0 pg/mL) and longer 6-minute walk distance (478 m versus 381 m), less use of calcium channel blocker (22% versus 29%), phosphodiesterase-5 inhibitors (11% versus 19%) and prostaglandin analogs (6% versus 15%). There were 35 deaths, 2/18 (11%) RA-PAH patients and 33/155 (21%) IPAH patients. The unadjusted 1-year survival for RA-PAH patients was 93% and for IPAH was 94%. RA-PAH patients had improved survival compared to IPAH patients, with increasing separation of the survival curves over time. The unadjusted hazard ratio comparing RA-PAH to IPAH survival was 1.52. A propensity score matched cohort matching 18 RA-PAH patients to 18 IPAH patients resulted in significant reductions in the standardized differences of baseline characteristics. In the

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matched cohort there were 7 deaths, 2/18 (11%) RA-PAH patients and 5/18 (28%) IPAH patients. The propensity score adjusted hazard ratio was 1.53.
Conclusion: PAH is a life-threatening manifestation of RA. Despite milder disease at presentation, survival is comparable to IPAH.

9

Association of Clinical Findings with MRI-based Cartilage Damage in an Asymptomatic Population

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Objective: Cartilage damage is an important feature of osteoarthritis (OA) but has not been extensively explored in asymptomatic populations. This cross-sectional study will determine the prevalence of MRI-defined cartilage damage of the knee in an asymptomatic population-based cohort, and evaluate clinical correlates of cartilage damage.
Methods: Subjects aged 40-79 years without knee pain (n=73) were recruited as a random population sample from the Greater Vancouver area. Recruitment and cross-sectional assessments were performed identically to a previous study of symptomatic knee subjects and included comprehensive evaluation with questionnaires, standardized knee examination, radiograph, and MRI. Six knee joint surfaces were assessed on MRI, including the medial and lateral tibial plateaux and femoral condyles, patella, and trochlear groove. Using magnetic resonance cartilage (MRC) scores (range 0-4), subjects were classified into 2 groups: those with normal cartilage (< 2) and those with cartilage damage (≥ 2) on at least one surface. Univariate logistic regression analysis was used to evaluate the association of each clinical variable with cartilage damage, followed by backward stepwise multivariable logistic regression, with adjustment for age and gender. Assessment of OA risk factors included age, gender, body mass index (BMI) currently and at age 25, history of mild and severe knee injury, duration of regular sports activity after age 20, and family history of OA or of knee/hip arthroplasty. Other predictor variables included physical examinations for gait, quadriceps weakness, quadriceps atrophy, knee effusion, flexion contracture by goniometer, and smoking pack-years.
Results: Of 73 subjects, 48 (66%) had cartilage damage on MRI, while 25 (34%) had normal cartilage. The frequency distribution of MRC scores in ascending order from 0-4 were as follows: 34%, 1%, 37%, 21%, 7%. On univariate analysis, cartilage damage was associated with current BMI (OR 2.60, 95% CI 1.22-5.54, per 5 unit increase), while change in BMI since age 25 was of borderline significance (OR 2.33, 95% CI 0.99-5.49, per 5 unit increase). In the multivariable model, only current BMI was significantly associated with cartilage damage (OR 2.63, 95% CI 1.17-5.89, per 5 unit increase). There was no significant association with other clinical variables.
Conclusion: MRI-based cartilage damage was highly prevalent (66%) in this asymptomatic population-based cohort. Prevalent cartilage damage was significantly associated with self-reported current BMI but not with BMI at age 25 or change in BMI. Based on our findings and the literature, BMI is a risk factor for early asymptomatic cartilage damage.

10

The Impact of Reaching Low Disease Activity in the First Year on Future Disability and Damage in Patients with Early Rheumatoid Arthritis

Pooneh Akhavan (Mount Sinai Hospital, University of Toronto, Toronto); George Tomlinson (Toronto General Research Institute, Toronto); Paul Fortin (CHU de Québec Research Centre - CHUL, Québec); Claire Bombardier (University of Toronto)

Objective: The objective of this study was to assess the impact of achieving low disease activity (LDA) at one year on patient function and radiograph progression.
Methods: We used data from The Study Of New Onset Rheumatoid Arthritis (SONORA), a North American prospective cohort of patients with early RA. Our analysis is based on 3 years of followup. The Simplified Disease Activity Index (SDAI) and patients' function (HAQ-DI) were measured at baseline, years 1, 2 and 3. Hand radiograph was performed yearly up to year 2; a modified Sharp score of ≥3.5 indicated important radiograph progression[1]. Multivariate linear regression analysis was performed to assess the impact of reaching LDA (yes/no) at year 1 on future HAQ. Logistic regression was used to assess the impact of reaching LDA at year 1 on radiograph progression (yes/no) at year 2. Both analyses were adjusted for potential clinical confounders. Missing data were imputed using Multiple Imputation.
Results: Baseline characteristics of 984 eligible patients included: mean (SD) age 53 (14.8), disease duration 5.3 (3.1) months, swollen joint count (SJC) 9.4 (7.1), tender joint count (TJC) 10.1 (8.0), CRP 1.4 (1.5), SDAI 30.5 (16.6) and median (IQR) HAQ 1.0 (0.37-1.63) and modified Sharp score 3.0 (0.0-7.0). Year 1 LDA was achieved in 37% of patients and radiograph progressed in 17%.Year 1 LDA was strongly associated with lower HAQ at 3 years (p=0.0003). Other predictors included higher baseline HAQ (p<0.0001), older age (p=0.002), higher Joint space narrowing (JSN) score (p=0.03) and gender (female; p=0.007) which were associated with higher HAQ. Complete case and imputed analyses showed similar results. Year 1 LDA was significantly associated with less radiograph progression at year 2 (OR 0.68, 95% CI 0.47-0.98; p=0.04) in the imputed case analysis (was not significant in complete case analysis). Baseline Sharp score (1.06, 1.01-1.12; 0.03), positive rheumatoid factor (1.98, 1.2-3.2; 0.01), positive anti-CCP (1.95, 1.1-3.4; 0.03), higher CRP 1.15 (1.01-1.30; 0.03) were also predictors of radiograph progression.
Conclusion: Reaching low disease activity is associated with improved long-term outcomes in early RA. This provides strong supports for the current treat to target recommendations. An assessment of prognostic factors at baseline is essential and can help clinicians stratify patients and individualize RA treatment. Reference: [1]Bruynesteyn K, Boers M, et al. Deciding on progression of joint damage in paired films of individual patients: smallest detectable difference or change. Ann Rheum Dis 2005;64:179-82.

11

Epidemiology of Rheumatoid Arthritis in a Universal Public Health Care System: Results from the Ontario RA Administrative Database

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Objective: To describe trends in incidence and prevalence of rheumatoid arthritis (RA) in a universal public healthcare system over the past 15 years.
Methods: We used the Ontario Rheumatoid Arthritis administrative Database (ORAD), a validated population-based research database that includes all individuals with RA living in Ontario. Patients are included in ORAD if they are admitted to a hospital with an RA diagnosis or have at least 3 Ontario Health Insurance Plan (OHIP) physician service claims over two years on which RA is the recorded diagnosis, with at least 1 of these claims made by a musculoskeletal specialist (rheumatologist, orthopedic surgeon or internist). ORAD has a high sensitivity (80%), specificity (100%) and positive predictive value (78%) for identifying RA patients according to medical record reviews of both primary care and rheumatology charts. We used ORAD to calculate crude and age/sex-standardized

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incidence and prevalence rates among men and women aged 15 years or older over the period of 1995-2010. Age/sex-standardized rates by area of patient residence also were determined. A 5-year run-in period was used to distinguish between incident and prevalent cases.

Results: As of 2011, there were 99,130 patients (72% female) with RA living in Ontario, corresponding to a cumulative prevalence of 0.9% (females 1.3%, males 0.5%). Age/sex-standardized RA prevalence per 100,000 population increased steadily over time from 469 in 1996 to 782 in 2010 (0.5% to 0.9%). Prevalence increased with age: 15-24y (0.1%), 25-34y (0.2%), 35-44y (0.5%), 45-54y (0.9%), 55-64y (1.5%), 65-74y (2.1%), 75-84 (2.6%) to ≥85y (2.7%) as of 2010. Prevalence was higher in northern rural communities (835-1035/100,000) than southern urban areas (e.g., Toronto: 687-748/100,000). Age/sex-standardized incidence per 100,000 decreased gradually over time from 63 in 1996 to 55 in 2010. Despite increasing prevalence observed among seniors (>65y) over time, after adjusting for sex, incidence was stable among adults < 65y, but decreasing among seniors.

Conclusion: RA prevalence rates have increased significantly over time and may be partially attributable to an increase in the aging background population. Incidence appears to be slowly declining over time (with a shift toward fewer patients with elderly age at onset); however, this may be partly due to prevalent cases being misclassified as incident cases during the early years of study. Regional prevalence rates illustrate the high burden of RA in all locales, especially in northern communities, highlighting the importance of regional differences for planning for health care provisions for RA.

12

Recognizing Childhood Inflammatory Brain Diseases in Canada

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Objective: Childhood inflammatory brain diseases are life-threatening diseases causing devastating brain damage in previously healthy children, if left untreated. In 2000, the diagnosis was only made on autopsy. Over the past decade recognition has increased. Since 2007, the BrainWorks network prospectively captures children with inflammatory brain diseases around the world. The aim of the study was to determine the spectrum of inflammatory brain diseases in Canadian children and identify presenting features of distinct subtypes.

Methods: Consecutive pediatric patients enrolled into the BrainWorks study at Canadian centers from January 2007 until September 2012 were identified. Children with inflammatory brain disease were included, if predetermined information at the baseline visit were complete. Demographic characteristics, diagnosis at enrollment, baseline clinical, laboratory and neuroimaging features and brain biopsy characteristics were reviewed.

Results: In total 247 Canadian children were included; these were 132 boys and 115 girls; mean age at diagnosis was 9.33 years. The most common inflammatory brain diseases were primary CNS vasculitis with 90 children having non-progressive large vessel vasculitis (63 boys, 27 girls, mean age 8.15 years), 57 having small vessel vasculitis (19 boys, 38 girls, mean age 11 years) and 25 progressive large vessel vasculitis (21 boys, 4 girls, mean age 10.3 years). Anti-NMDAR-encephalitis was diagnosed in 25 children (7 males, 18 females, mean age 9.9 years), and other neuronal antibody mediated diseases in 6 children. Secondary CNS vasculitis was present in 29 children (12%); of whom 13 were associated with infection, 10 had an underlying rheumatic disease and 6 a systemic vasculitis. Rare inflammatory brain diseases were found in 15 children. At presentation focal deficits were most commonly seen in large vessel CNS vasculitis (79% non-progressive, 84% progressive), while diffuse deficits were reported in small vessel CNS vasculitis and NMDAR encephalitis (61% and 72%). Seizures were seen in all inflammatory brain diseases, more frequently in NMDAR encephalitis and small vessel CNS vasculitis (80% and 61%) compared to large vessel CNS vasculitis subtypes (non-progressive 18%, progressive 18%).

Conclusion: Inflammatory brain diseases are increasingly diagnosed in Canadian children of all ages. In this study the majority presented with primary inflammatory CNS diseases. Vasculitis is the most common childhood inflammatory brain disease; however NMDAR encephalitis is increasingly recognized and has to be considered given the widely overlapping clinical presentation.

13

Interferon-associated Cytokine and Chemokine Expression in Patients with Serologically Active Clinically Quiescent (SACQ) Systemic Lupus Erythematosus (SLE)

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Objective: Interferon-α (IFN-α) plays a prominent pro-inflammatory role in SLE. Studies suggest clinical/serologic discordance may illuminate SLE pathophysiology: peripheral IFN-α production is blunted in autoantibody-producing, clinically quiescent SLE mice despite abundant IFN-α-producing plasmacytoid dendritic cells (pDC); continuous pDC stimulation yields reversible blunting of the IFN-α response *in vitro*. Thus SACQ patients, who exhibit persistent autoantibody production despite durable clinical quiescence, may provide unique insights. We thus measured IFN-associated cyto/chemokines in SACQ patients, compared to serologically and clinically active (SACA) and serologically and clinically quiescent (SQCQ) patients.

Methods: We defined SACQ and SQCQ as ≥2-year periods without clinical activity, with/without persistent serologic activity, respectively, by SLE Disease Activity Index 2000 (SLEDAI-2K), over which antimalarials were permissible; corticosteroids/immunosuppressives were not. SACA was defined as disease activity, by SLEDAI-2K, which compelled immunosuppression. Clinical and lab data were collected at each visit. Plasma cyto/chemokines were measured by 65-plex Luminex panel, with the 16 most relevant selected a priori for analysis. Bonferroni correction was applied. Non-parametric univariate and logistic regression analyses were conducted.

Results: We identified 25, 28 and 48 SACQ, SQCQ and SACA patients, respectively. IFN-α, IL-6, IL-10, IP-10 and MCP-1 levels were lower in SACQ vs SACA patients (p = 0.006, 0.0018, and < 0.0001 (last three), respectively). There were no differences in cyto/chemokine levels between SACQ and SQCQ patients. IFN-α and IP-10 moderately correlated (r=0.79). Disease duration at study start differed between SACQ and SACA patients (18.5±12.1 vs 7.4±7.3 yrs, p=0.0002) as did proportion with anti-Ro, -La, and –RNP positivity (84.0 vs 53.6%; 48 vs 32.1%; 40 vs 28.6%, p=0.005, 0.004 and 0.023, respectively). There were no clinical differences between SACQ and SACA patients. Logistic regression revealed increased levels of IL-10 (OR 7.35 [1.04,51.93]) and MCP-1 (OR 2.33 [1.23,4.41]) were associated with SACA status. Increased disease duration (OR 1.12 [1.03, 1.23]) and anti-Ro positivity (OR 20 [2.38,166.67]) were associated with SACQ status. When SACA patients with disease duration < 6 years were excluded, MCP-1 elevation remained associated with SACA (OR 1.95 [1.28,2.97]) and anti-Ro positivity with SACQ (OR 7.14[1.47,33.33]). Regression analysis applied to SACQ vs SQCQ patients similarly revealed anti-Ro positivity was associated with SACQ status (OR 4.55[1.23,16.67]).

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Conclusion: IFN-associated cyto/chemokine profiles differed between SACQ and SACA, but not SACQ and SQCQ, patients. Elevations in MCP-1 and IL-10 were associated with SACA status; there were no cyto/chemokines associated with SACQ status. These findings warrant further pursuit as they may facilitate clinical prediction.

14

Involvement in Leisure Activities among Children and Youth with Arthritis

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Objective: To describe leisure activities in terms of diversity, intensity and enjoyment, as well as to identify potential socio-demographic and disease-related determinants.

Methods: Fifty children and youth aged 8 to 18 years diagnosed with juvenile idiopathic arthritis (JIA) and their families participated in this cross-sectional study. Children and youth were administered the Children's Assessment of Participation and Enjoyment (CAPE), which measures involvement in leisure activities (recreation, physical, social, skill-based, self-improvement). The disease characteristics were abstracted from the child's medical file (JIA sub-type, active joint count, age of diagnosis) and pain perception was obtained through self-report (visual analog scale). Parents completed questionnaires on sociodemographic data and family structure.

Results: The most popular activities (>90%) were playing board games, playing computer/video games, watching television, hanging out with friends, doing chores and doing homework. Least popular activities were (<10%) martial arts and horseback riding. The level of enjoyment was highest for social activities (mean: 4.2 ±0.5). Involvement in informal leisure activities showed a significant negative association with age (β= -0.421, 95% CI= -0.148, -0.032, p=0.003), and with disease activity (β= -0.401, 95% CI= -0.732, -0.133, p=0.006).

Conclusion: Greater disease activity may dissuade children and youth from participating in more active pursuits, which places them at greater risk for adopting sedentary lifestyles. The identification of determinants of leisure activities in children and youth with arthritis may allow healthcare professionals to assess children's health needs with more precision and promote a healthier lifestyle.

Posters

1

Systemic Sclerosis in Canada's North American Native Population: an Assessment of the Clinical and Serological Manifestations

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Objective: North American Native (NAN) populations are known to have higher rates of systemic sclerosis (SSc) compared to non-NAN, however, little is known of the specific disease characteristics in this population. This study compares the clinical and serological manifestations of SSc in NAN and white patients.

Methods: This cross-sectional, multicenter study included patients enrolled in the Canadian Scleroderma Research Group (CSRG) registry between September 2004 and June 2012. Patients were evaluated with complete medical histories, physical examinations, and self-administered questionnaires; ethnicity was by self-report. Descriptive statistics were used to summarize disease characteristics. ANOVA were used to assess the relationship between clinical and serological variables between NAN and white patients.

Results: Of 1278 patients, 1038 (81%) were white, 71 (6%) were NAN, and 169 (13%) were classified as Other. NAN had a younger age of disease onset (41 yrs vs 45 yrs), higher rates of diffuse cutaneous involvement (dcSSc; 46.5% vs 35.6%), greater severity of Raynaud's phenomenon (3.9 vs 2.8 on a 10 point scale), more digital ulcers (63.4% vs 52.1%), higher rates of inflammatory polyarthritis (44.8% vs 30.5%), more GI symptoms (5.8 vs 4.1 on a 14-item checklist), including greater rates of GI dysmotility (36.6% vs 14.8%) and severity [severe GI symptoms (2.9 vs 1.7 on a 10-point scale)], and increased rates of overlap with mixed connective tissue disease (9.9% vs 1.9%) compared to white patients.

Conclusion: NAN patients with SSc have a distinct clinical phenotype. This study provides strong rationale to pursue further research into genetic and environmental determinants of SSc. New insights into the pathogenesis of disease may lead to new targets of intervention for this as yet incurable disease.

2

Hospitalizations and Reasons for Admission in a Clinical SLE Cohort

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Objective: Data published from several countries have suggested that patients affected by systemic lupus erythematosus (SLE) may have high annual hospitalization rates. However, there is a lack of data regarding the incidence and causes of hospitalization in Canadian SLE patients. Our objective was to provide recent estimates for hospitalization rates, and reasons for admission, in a clinical systemic lupus (SLE) cohort.

Methods: We performed a retrospective study of patients followed at the McGill University Health Center Lupus Clinic from the year 2000 till 2006. Each patient undergoes a yearly clinical assessment, which includes documentation of hospital admissions in the past year.

Results: Our SLE cohort consisted of 316 female patients and 27 males, with an average age of 46.3 years. Over the interval studied, there were 234 reported admissions. SLE-related causes accounted for the highest proportion of hospitalizations (29.5%), and infections were the next most common reason for hospitalization (13.8%). Other categories included surgical and gynecological reasons for hospitalization (12.9% each), hospitalizations for cardiac and gastrointestinal causes (7.9% each) and other causes.

Conclusion: Canadian annual hospitalization rates are about 1.1 hospitalizations per 10,000 residents. Our results suggest much higher hospitalization rates in SLE. Previous authors have emphasized disease flares and infections as common reasons for hospitalizations in SLE, and our data seem consistent with this. Further work is in progress, to provide more detailed comparisons with general population data.

3

Rheumatoid Arthritis Prevalence Across Regions in Quebec

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Objective: Our objective was to assess the prevalence of rheumatoid arthritis (RA) in Quebec based on administrative health data, and to determine if any differences could be detected within two regions, Les Iles de la Madeleine (in the Gulf of Saint Lawrence), and the Saguenay/Lac-St-Jean census metropolitan area, in the northern-east of Quebec. For

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historical and geographical reasons, these two regions have been relatively isolated. In both regions, the vast majority of residents originate from a relatively small number of French settlers. The reduced genetic variation of these populations, compared to the rest of Quebec, might potentially put them at risk for diseases like RA, an autoimmune rheumatic condition that is driven at least in part by genetic risk profiles.

Methods: Cases of RA were ascertained from provincial physician billing and hospitalization data from 1992 to 2008. The databases contain International Classification of Diseases (ICD) billing and hospitalization diagnostic codes for all reimbursed medical encounters in Quebec. We considered a case as any Quebec resident who fulfilled one or more of three case definitions: 1) Two or more billing code diagnoses, submitted by any physician, at least 2 months apart, but within 2 years; or 2) At least one billing diagnosis, by a rheumatologist; or 3) One hospitalization diagnosis (all based on ICD-9 code 714, and ICD-10 code M05).

Results: In Les Iles de la Madeleine, we defined 139 RA cases in 13,110 individuals, (10.6/1000). In Saguenay/Lac-St-Jean, there were 1,094 RA cases in 138,671 residents (7.9/1000). In the rest of Quebec, there were 74,527 cases, within a population of 7,464,237 (10.0/1000).

Conclusion: With our case definition based on administrative health data, we did not find an excess of RA cases in either Les Iles de la Madeleine or Saguenay/Lac-St-Jean. Limitations include the fact that the cases were not clinically validated, and that the data reflect only persons seeking medical care, who are given an RA diagnosis on billing or hospitalization data. Thus less rheumatology access, in remote areas, could lead to falsely low estimates in these regions. Other mediating influences could be regional variations in pollution emissions, which might have complex mediating effects. These influences will be further studied in the next phase of our work.

4

Do Rheumatologists Debride Digital Ulcers in Systemic Sclerosis?

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Objective: Digital ulcers (DU) are common in systemic sclerosis (SSc) and are an important cause of morbidity. DU have been described in up to 46% of patients with limited and 67% of patients with diffuse SSc, negatively impacting quality of life. Therapeutic trials for DU treatment and prevention require assessment of the ulcer stage. Often, DU are covered with a crust preventing visualization of the base which is necessary to determine if the DU is "active". As debridement may be useful in the assessment of ulcer stage, we aimed to determine if requiring debridement to assess DU stage would be a reasonable request of rheumatologists participating in DU studies. We thus determined how often rheumatologists who take care of SSc subjects debride.

Methods: We sent an online survey to 334 rheumatologists with a particular interest in SSc using the mailing lists of the Scleroderma Clinical Trials Consortium, the Canadian Scleroderma Research Group and the EUSTAR Group. The survey included the following question: "For DU in scleroderma, how often do you debride or remove the crust or scab that may form over the ulcer?" and provided a 5-option answer including never, rarely, sometimes, often and always. The survey also asked whether the responder thought that removing the crust has no effect, improves, or delays ulcer healing.

Results: In total, 137 (41%) completed the questionnaire. The majority of respondents are currently practicing in Europe (52%) and North America (35%) with 85% affiliated to a university hospital. In terms of the frequency of ulcer debridement, 31% of rheumatologists never debride, 28% rarely debride and 22% sometimes debride whereas only 9.5% often do or almost always debride the DU. Further, 40% of the respondents believed that DU debridement improved ulcer healing, while 29% believed it had no effect on healing and 28% felt that it delays healing. Of note, DU debridement was more common among European than North American rheumatologists.

Conclusion: DU are an important cause of morbidity in SSc and the usefulness of ulcer debridement is unclear. In this study, we found a significant number of rheumatologists specializing in the treatment of SSc that do not often debride and are ambivalent about debridement and improved healing. Therapeutic trials that require assessment of the ulcer base will need to take into account the reluctance of most rheumatologists to debride ulcers in which the base is covered by overlying material.

5

A Roadmap to Personalized Medicine in Rheumatoid Arthritis using Anti-Sa Antibody Titers to Monitor the Immunopathologically Driven, Clinical Disease Activity

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Objective: Previously, in a Canadian early RA cohort, serum anti-Sa (citrullinated vimentin) antibodies have been shown statistically to be specific biomarkers for diagnostic and better tools than RF and anti-CCP combined to predict severe erosive evolutions. Here, we ask if anti-Sa levels can be used to monitor RA in real world, N-of-1 observations.

Methods: Anti-Sa positive patients with early RA were followed for 2 years as part of a hospital-based, academic practice (HAM). Patients received aggressive standard-of-care treatment, aiming at remission. Joint counts and anti-Sa levels (Euroimmune anti-Sa ELISA) were obtained at baseline and at regular intervals. Patients were stratified into low, medium, and high-titer anti-Sa at baseline. We calculated mean joint counts (tender/swollen) and mean anti-Sa levels within each subgroup and looked at their non-parametric correlation in each patient.

Results: Twenty-three (23) patients with early RA tested positive for anti-Sa (cutoff 0.2 Arbitrary Units [AU]). In the low-range subgroup (0.2-0.75 AU, mean 0.4 AU), anti-Sa levels had declined by 75.0% to 0.10 AU within the first year of treatment, and by 80.0% to 0.08 AU at the end of second year. In the same period, the mean joint count declined 60.0% (20.3 to 7.91) and 90.0% (20.3 to 1.82), respectively. In the medium-range subgroup (0.75-1.5 AU, mean 0.92 AU), the anti-Sa levels had declined by 56.5% to 0.40 AU within the first year and by 71.5% to 0.26 AU at the end of the second year. Mean tender/swollen joint count declined 86.8% (19 to 2.5) and 85.3% (19 to 2.8), by the first and second years, respectively. In the high-range subgroup (1.5-2.5 AU, mean 1.81 AU), the anti-Sa levels had declined by 59.9% to 0.73 AU within the first year and 79.9% to 0.40 AU by the end of the second year. Mean tender/swollen joint count declined 93.8% (16.2 to 1) and a further 100% (16.2 to 0), in the first and second years, respectively. In all 23 patients, variations of anti-Sa titers and joint counts were concordant. In the majority of patients where anti-Sa became negative, the joint score was zero.

Conclusion: In contrast to anti-CCP and RF titers, anti-Sa titers can be used in N-of-1 settings to monitor the most RA-specific immune mechanism. As it may represent true (serological and clinical) remission, could normalization of anti-Sa titers be a firm therapeutic goal to pursue? Further longitudinal studies in personalized medicine are needed to explore that proposition.

6

Association of Extra-articular Features and HLA-B27 with Recently Identified UGT2B17 Copy Number Variants in Ankylosing Spondylitis

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Objective: Recently a genome-wide microarray interrogation of a large multiplex AS family revealed segregation of the UGT2B17 gene CNV among all affected family members. The association of the UGT2B17 CNV with AS is particularly interesting given the proposed function as it encodes

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a key enzyme that inhibits androgens. The objective of our study was to determine if UGT2B17 CNV can affect disease expression of AS and assess its relationship to HLA-B27.

Methods: 285 AS patients from two well ascertained AS cohorts (Newfoundland and Alberta cohorts) were selected. All AS patients satisfied the modified New York Criteria. Clinical information regarding presence of psoriasis, uveitis and IBD along with HLA-B27 was assessed for each patient. CNV was detected using real-time quantitative fluorescence polymerase reaction (QF-PCR). The frequency of copy number variation for the UGT2B17 CNV gene was then performed. Fisher's exact test was performed to quantify the association.

Results: 94 of the 280 AS patients had self reported uveitis. For patients with uveitis prevalence of deletion or one copy of UGT2B17 CNV was 0.37 and for two copies of UGT2B17 CNV the proportion of patients with uveitis was 0.28 (p=0.14). 58 of 285 AS patients had self-reported inflammatory bowel disease (IBD). For patients with IBD, the proportion of AS patients with deletion or one copy of UGT2B17 CNV was 0.21 and for two copies of UGT2B17 CNV was 0.19(p=0.63). 212 of 256 AS patients carried the HLA-B27. For patients with deletion or no copy of UGT2B17 CNV, the proportion of patients with HLA-B27 was 0.75 and for two copies of UGT2B17 CNV it was 0.70 (p=0.57).

Conclusion: Although UGT2B17 gene CNV was associated with disease susceptibility in a large muliplex family, there is no convincing evidence to suggest that the copy number variants are associated with extraarticular features of AS. Also there is no interaction between UGT2B17 CNV and HLA-B27.

7

Longterm Safety of Rituximab in Rheumatoid Arthritis Clinical Trials: A 10-Year Followup Study

Ronald van Vollenhoven (Karolinska Institute, Stockholm); Alfred Cividino (McMaster University, Hamilton); Paul Emery (University of Leeds and Leeds Teaching Hospitals, Leeds); Clifton Bingham (Johns Hopkins University, Baltimore); Edward Keystone (The Rebecca MacDonald Center for Arthritis and Autoimmunity, Toronto); Roy Fleischmann (University of Texas Southwest Medical Center, Dallas); Daniel Furst (University of California at Los Angeles, Los Angeles); Nicola Tyson (Roche Products Ltd, Welwyn Garden City); Abdul Mehbob (Roche Products Ltd); Patricia Lehane (Roche Products Ltd)

Objective: To assess rituximab (RTX) longterm safety in rheumatoid arthritis (RA) patients (pts) in clinical trials.

Methods: Safety data from a global clinical trial programme were pooled and analyzed to evaluate safety in moderate-to-severe active RA pts treated with RTX plus methotrexate (MTX). Pts received either 2x1000 mg or 2x500mg of RTX (IV infusions, 2 weeks apart), preceded with IV methylprednisolone (100 mg). All pts received stable doses of MTX weekly (10-25mg). RTX retreatment was offered based on physician's decision of clinical need, including active disease evidence.

Results: As of September 2011, 3595 pts had been treated with RTX, for a total exposure of 14 008 pt-years (pt-yrs). The analysis contained >10 yrs of followup with up to 19 courses of RTX. Baseline demographics and disease characteristics were similar across the longterm, the all-exposure, and the pooled placebo populations, although the former patients had a longer mean RA disease duration and a greater number (n=2.4) of previous disease-modifying antirheumatic drugs, not including MTX. The safety profile of RTX was comparable to the pooled placebo population, with the exception of infusion-related reactions (IRR), which occurred after the first infusion of the first course (22%), with 0.5% reported as serious (over all courses). Generally, rates of adverse events (AE), serious AE (SAE), and serious infectious events (SIE) remained stable over time. SIE rates in the RTX all-exposure, RTX long-term, and pooled placebo populations were 3.80, 2.76, and 3.79 events/100 pt-yrs, respectively. SAE that occurred in >1% of pts comprised osteoarthritis, pneumonia, falls, and exacerbations of RA. Lower respiratory tract infections were the most frequent serious infections, with pneumonia being predominant (2%). Serious opportunistic infections were rare, with a rate comparable to the placebo population (0.05 vs. 0.09 events/100 pt-yrs, for all-exposure vs. placebo respectively). The most frequent cardiac AE was myocardial infarction, with a rate of 0.40 events/100 pt-yrs consistent with rates in the general RA population (0.48-0.59 events/100 pt-yrs). No evidence of an increase in malignancy over time or RTX course was found.

Conclusion: Data from longterm followup of RA pts treated with RTX in clinical trials indicate that RTX continued to be well tolerated over time and over multiple courses, with safety profiles similar to that of the placebo population and consistent with published data on pts with moderate-to-severe RA. No new safety signals were observed with increasing duration of exposure, including inpatients with >5 yrs of followup.

8

Are Needs Being Addressed? Mapping the Evolution of Canadian Rheumatologists' Gaps and Challenges in the Last Decade

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Objective: To characterize the evolution of Canadian rheumatologists' educational needs and practice gaps in the care of patients with rheumatoid arthritis (RA) over the last decade, in order to identify areas of progress and areas where educational efforts need to be increased.

Methods: Secondary analysis of three National Needs Assessments (2003, 2008, 2012) was conducted. The needs assessments (NA) targeted the screening, diagnosis, treatment, and management of RA (2003), rheumatic diseases (2008), and RA and spondyloarthropathies (2012) among Canadian rheumatologists. The 2008 and 2012 NA used mixed-methods research designs (qualitative and quantitative), while the 2003 NA was qualitative only. All three studies combined the perspectives of healthcare professionals and patients.

Results: Two gaps appear to be consistent across the three studies. First, primary care providers are struggling in timely recognition of RA symptoms, and consequently patients are not referred early enough to benefit from early initiation of treatment. In addition, managing patients' stress and psychosocial issues was a challenge for rheumatologists in all three studies. An evolution of needs was mapped out for three areas: rheumatologists' challenges in using imaging for diagnosis and monitoring of RA appear significantly different across the three NA. Rheumatologists reported no such gap in the 2003. However, in 2008, rheumatologists (81%) indicated moderate to low levels of knowledge interpreting MRI tests. In 2012, rheumatologists reported a lack of confidence in having an informed discussion with radiologists about MRI results, and a lack of knowledge in ordering the proper MRI sequence. Rheumatologists reported challenges with special access to biologics in 2003; in 2008, they reported lack of knowledge and confidence on specific aspects of biologics (longterm effects, discontinuation, early introduction); in 2012, the challenges revolved around prescription of biologics to special populations (immunocompromised, high cardiovascular risk), and communication of risks to patients. Rheumatologists reported inconsistent and incomplete patient education in 2008, but only a lack of followup on the provided education in 2012 (no data for 2003).

Conclusion: This analysis highlighted areas where important progress have been made, but also areas in which gaps identified a decade ago remain significant. Communication appears as an overarching theme across the gaps: providing psychosocial support, information on risks or any other education to patients, having informed discussions with radiologists, and collaborating with primary care for early diagnosis, all have important communication aspects. Development of evidence-based educational interventions, to help rheumatologists overcome these sustained challenges, is essential.

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9

Subcutaneous Methotrexate Safety in the Community: A Systematic Review of the Literature

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Objective: Low-dose methotrexate (MTX) is the cornerstone of treatment for RA, juvenile idiopathic arthritis, and other inflammatory conditions. Subcutaneous (sc) administration is often preferred due to its superior bioavailability and diminished side effects. Also used at high doses in chemotherapy, the injectable form of MTX is classified as an antineoplastic cytotoxic drug that has raised concerns regarding the safety of sc MTX administration. The primary objective of this study was to evaluate the safety of sc MTX administration in doses used for rheumatic diseases. A secondary objective was to determine the safety and toxicity of injectable high-dose MTX administration.

Methods: A systematic review using a predefined search was performed. Relevant English and French articles included assessments of MTX exposure, biomonitoring, and toxicity of injectable MTX preparation and administration. ACR and EULAR abstracts for the last 2 years were also searched.

Results: A total of 5805 articles were evaluated from the database search; 53 were included (some examined more than one outcome). Excluded articles were duplicates (n=1064), were not in English or French (n=337), did not focus on injectable MTX (n=2106), did not examine safety and toxicity (n=1885), or did not have an outcome of interest (n=360). All studies were small and cross-sectional so quality of evidence was low. For the primary objective, there was only 1 study examining the safety of low-dose MTX. This study, wherein 6 individuals were treated with an intentional skin exposure of 25 mg MTX, found very little measurable systemic absorption as measured both by serum and urine MTX levels. Regarding the secondary objective, 15 articles addressed environmental contamination and 10 articles examined glove surface contamination in pharmacies and oncology units. No MTX air contamination was detected but surface swipe testing did occasionally find low levels of MTX contamination. Seven articles addressed glove permeability of MTX and an additional 6 studies examined urine levels of MTX in nurses and pharmacists exposed to high-dose MTX. Only 1 study found positive urinary levels of MTX in oncology nurses handling high-dose MTX. Some studies examined genetic abnormalities (22 studies) or urine mutagenicity (6 studies) in nurses administering or preparing multiple chemotherapy agents. Results regarding urinary mutagenicity or genetic abnormalities in chemotherapy nurses were highly variable, were often influenced by factors such as smoking, and could not be attributable solely to MTX.

Conclusion: Although limited, the current evidence does not indicate substantial toxicity of low- dose MTX administration by healthcare workers.

10

Urate Lowering Therapy in Gout: A Systematic Literature Review

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Objective: To evaluate the efficacy and safety of urate lowering therapy in gout.

Methods: A systematic literature search as part of the 3e Initiative (Evidence, Expertise, Exchange) on gout was performed in Medline, EMBASE and the Cochrane library from 1950 to October 2011, and the ACR and EULAR abstracts (2010-2011). Efficacy was analyzed using randomized and controlled clinical trials and safety was further assessed with cohort studies, case-control studies, and case series of greater than 20 patients. Two reviewers screened the titles and abstracts of the identified references independently. Subsequently, included articles were reviewed in detail and data collected. A hand search was completed by reviewing the references of the included studies and all the publications or other information provided by experts were examined. Risk of bias was evaluated using the Cochrane for therapeutic trials.

Results: Of the 1594 efficacy references and 2486 safety references retrieved, 21 studies and 31 studies fulfilled the criteria respectively and were initially included. After excluding high risk of bias studies, a metaanalysis was performed as follows: allopurinol (4 studies), febuxostat (4 studies), benzbromarone (2 studies), and pegloticase (2 studies). Twenty studies assessed allopurinol safety, 9 studies for febuxostat, 4 for benzbromarone, 1 for probenecid, and 4 for pegloticase. When assessing serum urate response, allopurinol (up to 300 mg) and febuxostat at reported trialed doses is more effective than placebo at lowering serum uric acid. Efficacy did not differ significantly between allopurinol (up to 300 mg) and febuxostat 40 mg, but febuxostat 80 mg, 120 mg or 240 mg were more efficacious. When using step-up therapy, allopurinol 300-600 mg or benzbromarone 100-200 mg are equally effective at lowering serum uric acid. In patients who have failed to reach target uric acid level on allopurinol, benzbromarone is more effective than probenecid at reducing serum uric acid level below 5 mg/dL. Pegloticase biweekly or monthly can reduce serum uric acid < 6 mg/dL more effectively than placebo. During the first 8 weeks of initiating treatment and while on colchicine prophylaxis, allopurinol (up to 300 mg) causes no more acute gout flares than placebo or febuxostat 80 mg but has significantly fewer acute gout attacks than febuxostat 120 mg, 240 mg. Further adverse events will be presented.

Conclusion: The efficacy of allopurinol, febuxostat, benzbromarone, probenecid, and pegloticase is supported by studies in the literature. These medications differ in their degree of serum urate response as well as in propensity to cause acute gout attacks and side effects.

11

Isolated Angiitis of the Vasa Vasorum: A Comparison Series of Fourteen Patients

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Objective: To compare cases of isolated angiitis of the vasa vasorum (IAVV). Diagnosis of IAVV was made incidentally on temporal artery biopsy while investigating the patient for giant cell arteritis (GCA).

Methods: Fourteen patients (nine female and five male) with IAVV were compared retrospectively. All were seen by rheumatologists at St. Joseph's Health Care in London, Ontario. Data were compiled from the patients' first encounter with the rheumatologist at the time of diagnosis.

Results: Temporal artery biopsies showed mononuclear infiltration of the vasa vasora, with no inflammation observed in the artery. Two biopsies showed perivascular lymphocytic infiltration in the loose connective tissue adjacent to the temporal artery. GCA-type symptoms were present in 86% of patients, with 50% of patients meeting the 1990 ACR criteria for GCA. Symptoms of trigeminal neuralgia were present in two patients. Polymyalgia rheumatica symptoms were found in 36% of patients, and systemic symptoms were described by 21%. Other presenting symptoms included ocular inflammation and sicca symptoms. At first presentation (before the initiation of corticosteroids), the average erythrocyte sedimentation rate was 44 mm/h (range 28-70 mm/h) and C-reactive protein was 23 mg/L (range < 0.6-68 mg/L). Anemia and/or reactive thrombocytosis were present in 29%. One patient required no treatment. Thirteen patients were

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prescribed corticosteroids, with a mean initial dose of 41 mg/day (range 10-70 mg). The average duration of prednisone was 16 months (range 1-53 months). Methotrexate was required as a steroid-sparing agent for six patients (mean starting dose of 17.5 mg/week) for an average duration of 13 months. One patient required further immunosuppressive medications to control his systemic cytoplasmic antineutrophil cytoplasmic antibodies (cANCA) vasculitis. Disease duration was greater than one year in 64% of patients, with longterm immunosuppression required in 50% of cases. None of the studied cases resulted in an ocular crisis, ischemic event, aneurysm, or death. However, two cases did result in hospitalizations because of another complication. Two patients developed a systemic vasculitis, including a cANCA vasculitis and a case of polyarteritis nodosa vs MPA.

Conclusion: IAVV is an important diagnosis to recognize, as greater than 90% of patients required corticosteroid treatment, and 50% required longterm immunosuppression. Consideration of other systemic vasculitides in these patients is also important, as they require significantly more aggressive treatment, and were associated with an increased morbidity and hospitalization.

12

A Retrospective Study to Evaluate the Efficacy, Safety, and Drug Survival of Etanercept in Elderly Patients with Rheumatoid Arthritis

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Objective: Biological drugs have dramatically improved the prognosis of rheumatoid arthritis (RA) but treatment has been focused on early disease, often in younger patients with fewer comorbidities. As the Canadian population ages, the number of Canadians with RA is expected to increase and be highest among those over 60 years of age. Currently, 2.3% of the Canadian population over 60 years of age live with RA; this will increase to 3.3% by 2040 (a 40% increase). The purpose of this retrospective real-world study is to evaluate efficacy, safety, and durability of etanercept initiated in patients over the age of 65 (inclusive) and to know if etanercept treatment decreased the use of concomitant disease-modifying antirheumatic drugs (DMARD).

Methods: This study is a retrospective analysis of all elderly RA patients (age ≥ 65 years), started on etanercept between Jan 2004 and Dec 2011 at Bensen's Rheumatology Clinic, Hamilton, Canada. The overall drug survival was computed using survival data with Kaplan-Meier plots. Efficacy was assessed by change in the disease activity, swollen and tender joint counts (SJC and TJC) over a period of time in the age group of 65-80 and above 80 years, and early versus longstanding RA.

Results: A total of 72 patients were included in the analysis. 58% were receiving etanercept at the study endpoint, with median drug survival rate of 42 months. Significant improvement in the mean SJC (p value < 0.001) from baseline (8.45 ± 4.81) to treatment at 3 months (4.56 ± 3.92), at 13 months (2.56 ± 2.84), and 23 months (1.85 ± 2.06) was observed and maintained at the low level. Mean TJC was improved within 3 months of etanercept treatment from baseline (11.08 ± 7.93) to 5.38 ± 6.77 and was 2.39 ± 5.13 at 23 months of treatment. Similar efficacy was observed in patients between age group of 65-80 and over 80 years. Patients with early as well as longstanding RA showed sustained improvement in disease activity over a period of time. Concomitant use of DMARD reduced significantly (p-value < 0.05) after treatment with etanercept. Etanercept was well tolerated, although injection site reaction, respiratory infections, and other infections were reported.

Conclusion: In this study of real-world practice, elderly RA patients (age ≥ 65 years), treated with etanercept, had significant improvement, no unexpected safety concerns, long durability and diminished use of concomitant DMARD even when they had longstanding disease or were over the age of 80.

13

Prevalence and Clinical Significance of Isolated Leukopenia in Systemic Lupus Erythematosus

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Objective: To determine the prevalence and importance of isolated leukopenia in otherwise quiescent systemic lupus erythematosus (SLE) patients, and compare these patients with those with inactive disease or those with active serology.

Methods: Patients with isolated leukopenia were identified from the cohort of SLE patients followed at the Lupus Clinic. Isolated leukopenia was defined as leukocytes < $3{,}000 \times 10^9$/L on ≥2 consecutive visits (≤18 months apart) in the absence of other criteria for active disease, that is SLEDAI-2K=1 from leukopenia alone (referred to as the IL cohort), or =3 or =5 from leukopenia and active serology (referred to as the ILS cohort). Patients taking cytotoxic drugs were excluded. IL cases were then compared to a cohort of 180 "control" SLE patients who had serologically and clinically quiescent disease (SQCQ), having SLEDAI-2K=0 for ≥1 year. Comparisons were made on the basis of demographics, organ damage accrual (measured by the Systemic Lupus International Collaborating Clinics/ American College of Rheumatology Damage Index (SDI)), and the prevalence of infection over 1 year of follow-up. Fisher's exact and Wilcoxon rank sum tests were used. The IL cohort was then compared to the ILS cohort in the same manner.

Results: The overall prevalence of isolated leukopenia in the cohort was 70/1645 (4.3%). After 26 patients taking cytotoxic drugs were excluded, the prevalence of isolated leukopenia alone, and isolated leukopenia plus active serology was 0.9% (15/1645), and 1.8% (29/1645), respectively. A statistically significant difference in the proportion of black patients was detected between IL cases and controls (40.0% of IL cases vs 6.1% of controls, p = 0.0005). No other statistically significant differences were detected in demographics, organ damage accrual characteristics, or infections. ILS patients were similar to IL patients.

Conclusion: Patients in our SLE cohort rarely present with leukopenia as the sole clinical manifestation of "active disease", according to the SLEDAI-2K. Patients with IL were more likely to be black compared to quiescent controls, but did not display an increased prevalence of infection or organ damage accrual at 1-year followup.

14

Do Patients with Psoriatic Arthritis Fall into Distinct Clinical Subgroups – A Cluster Analysis?

Arane Thavaneswaran (University of Toronto, Toronto); Vinod Chandran (University of Toronto); Dafna Gladman (University of Toronto)

Objective: To determine if demographic and disease characteristics of patients with PsA at presentation to a PsA clinic cluster into distinct groups.

Methods: 1058 patients with psoriatic arthritis (PsA) were included from an observational cohort. Cluster analysis using Ward's method was conducted to identify groups of patients based on the following characteristics at baseline: gender, type of psoriasis (type I or II), duration of PsA, race, family history of psoriasis, ESR, PASI, psoriasis vulgaris, nail disease, dactylitis, swollen joint count, damage joint count, axial disease, presence of arthritis mutilans and presence of arthritis prior to psoriasis. 5 clusters were formed and matched to non-overlapping arthritis patterns at first clinic visit: distal arthritis, oligoarthritis, polyarthritis, axial arthritis, distal and axial arthritis, oligoarthritis and axial arthritis, and polyarthritis and axial arthritis. Comparisons between the clusters and arthritis patterns were conducted using t-tests and Chi-square analysis.

Results: The baseline characteristics of the 1058 patients were as follows: 613 (56.5%) males, mean age at diagnosis of PsA 37.1 (13.5) years, mean age at first visit 44 (13.1) years, mean duration of PsA 6.8 (8.2) years, mean active joint count 11.0 (9.8), mean PASI 5.8 (8.3), mean Steinbrocker score

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12.9 (25.5), HLA-B*27 116(17.7%), with an average follow-up of 8.4 (8.4) years. Two main clusters of patients were identified. The first consisted of distal arthritis, oligoarthritis and polyarthritis and the other cluster included patients with axial arthritis only, distal and axial arthritis, oligoarthritis & axial arthritis, and polyarthritis & axial arthritis, thus clearly clustering patients into peripheral and axial arthritis groups. Comparison of the two clusters showed a higher duration of disease (10.2 vs. 5.7 years, p< 0.0001), more psoriasis vulgaris (94% vs. 85%, p=0.0001), worse PASI (25% vs. 16%, p=0.006), higher damage joint count (12.8 vs. 4.3, p< 0.0001), higher swollen joint counts (5.1 vs. 4.2, p=0.0009), more arthritis mutilans (54% vs. 4%, p< 0.0001), and more axial arthritis (77% vs. 18%, p< 0.0001) in patients within the axial arthritis cluster. Patients falling in the peripheral disease cluster had more patients with a family history of psoriasis (48.6% vs. 19.4%, p< 0.0001).

Conclusion: Based on patients' characteristics at baseline, cluster analysis separated PsA patients into two main arthritis patterns — axial and peripheral. The study provides further evidence to classify patients into just two groups based on the presence or absence of axial arthritis.

15

Severe Joint Damage in Psoriatic Arthritis: Mutilans and Ankylosis

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Objective: Patients with psoriatic arthritis (PsA) who develop severe joint damage have severe functional disability and increased mortality risk. The most severe form of PsA, termed arthritis mutilans, is associated with severe erosions, osteolysis, and pencil-in-cup change. Ankylosis is also a feature of severe PsA. The modified Steinbrocker method of scoring radiographic damage to peripheral joints in PsA recognizes grade 4 damage as severe damage, but does not explicitly distinguish between severe erosions, pencil-in-cup change, subluxation, and ankylosis. We aimed to describe the prevalence and disease association of these features of severe joint damage in such patients.

Methods: Patients with PsA duration < 5 years were identified. Patients are evaluated every 6-12 months and plain radiographs are obtained every 2 years. Radiographs are reviewed according to the modified Steinbrocker method by consensus of at least 2 rheumatologists. Radiographs scored as 4 were retrieved and rescored to indicate disorganization (4.0), subluxation (4.1), pencil-in-cup (4.2), and ankylosis (4.0). Subsequently, clinical characteristics at first visit of patients who developed at least 1 joint with severe joint damage were compared to those without such damage.

Results: 664 patients enrolled in the cohort within 5 years of diagnosis were subjects of this study. 116/664 (17.5%) were observed to have at least one joint with 4.0, 4.1, 4.2 or 4.3 of the 42 scored. Patients with severe joint damage were older at diagnosis of psoriasis and had longer PsA duration, but shorter psoriasis duration. They had higher active and damaged joint counts and ESR. There was a trend toward higher prevalence of female sex, axial disease, and HLA-B*27 in those with severe damage. Of the 116 patients observed to develop severe damage, 34 (29%), 63 (54%), 36 (31%), 58 (50%) patients were observed to have '4.0', '4.1', '4.2' and '4.3', respectively, at baseline or during followup. The mean (SD) number of joints with '4.0', '4.1', '4.2' and '4.3', were 0.3 (0.7), 1.1 (2.1), 0.6 (2.0), and 0.7 (1.4), respectively. Only 15 (13%) patients were observed to have ankylosis without lysis. These patients had lower modified Steinbrocker score [mean, (SD) 31 (18) vs 53 (43), p=0.001] compared to those with subluxation or pencil-in-cup change.

Conclusion: PsA patients who develop severe joint damage have higher disease activity at presentation. The most common form of severe joint damage observed is subluxation. Only 13% have exclusive ankylosis. Further phenotypic characteristic of radiographic damage in PsA will facilitate genetic and mechanistic studies.

16

Lung Transplantation in Rheumatoid Arthritis Compared with Idiopathic Pulmonary Fibrosis and Scleroderma

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Objective: Lung transplantation is a potentially life-saving treatment used in the treatment of interstitial lung disease, but may be underused in patients with rheumatoid arthritis-associated ILD (RA-ILD) due to concerns about poor outcomes. The purpose of this study was to compare post-transplant survival rates in RA-ILD patients with those in patients with interstitial pulmonary fibrosis (IPF) and scleroderma-associated ILD (SSc-ILD).

Methods: We identified all patients with RA-ILD who had undergone lung transplantation at a single Canadian Centre from 1989 until November 1, 2011. As a control, we used a randomly selected group of patients with IPF who had a lung transplant in the same time period as our RA-ILD patients. As a second control, we used all SSc-ILD patients without pulmonary hypertension who had received a lung transplant from 1989 to November 1, 2011. We then performed a retrospective chart review of all patients to assess survival following lung transplantation. The primary endpoint was death from any cause. Cumulative survival rates were calculated using the Kaplan-Meier method and compared between patient groups using the log-rank test.

Results: We identified 12 patients with RA-ILD who had undergone lung transplantation. Our control groups consisted of 53 patients with IPF and 17 patients with SSc-ILD. The mean age in years (± SD) was 58.4 ± 5.9 for the RA-ILD group, 60.9 ± 3.9 for the IPF group, and 44.5 ± 13.1 for the SSc-ILD group, with the RA-ILD group being significantly older compared to the SSc-ILD group (p value=0.02). The percentage of females was 58% in the RA-ILD group, 27% in the IPF group, and 67% in the SSc-ILD group, with significantly more females in the RA-ILD group compared to the IPF group (p value=0.05). Median survival was 5.84 years for RA-ILD patients and 5.01 years for IPF patients. We found no statistically significant difference in the post-transplant cumulative survival rate in RA-ILD patients as compared to that in IPF patients (p value= 0.46). There was a trend toward improved cumulative survival in SSc-ILD patients as compared to RA-ILD patients, but this did not reach statistical significance (p value=0.08).

Conclusion: Patients with RA-ILD have post-transplant survival rates similar to those in patients with IPF and SSc-ILD. Lung transplantation should be considered a viable treatment option in patients with endstage RA-ILD.

17

Induced Abortions in Women with Systemic Sclerosis

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Objective: In North America, up to half of pregnancies are unplanned and almost half of unintended pregnancies are terminated. Because of several disease-related factors, such as teratogenic drug exposure and disease complications, women with systemic sclerosis (SSc) facing an unplanned pregnancy may be more likely to undergo an induced abortion (IA) than their general population counterparts.We assessed IA events in women with SSc onset during their reproductive years and compared this with general population rates.

Methods: Within the Canadian Scleroderma Research Group (CSRG) cohort, between 2004-2011, we identified women with SSc symptom who were < 45 at cohort entry. We first determined the number of IA occurring during followup, and summed the years accrued during followup until age

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45 (or the oldest age attained if >45 at the last visit).We applied age-specific and province-specific Canadian population rates for each relevant calendar-period, to determine the expected number of IA during followup. In further analysis, we adjusted for fertility, which may be decreased in SSc.We then calculated the standardized incidence ratio (SIR) of observed to expected IA during followup.We also assessed potential disease-related predictors of IA, including teratogenic drug exposure and specific disease complications.
Results: We identified 89 women 45 years at SSc symptom onset and at baseline who had ≥1 followup visit.At baseline, limited and diffuse diseases were present respectively in 48% and 42% women, and mean time since symptom onset was 10.0 years (SD, 7.7). During a mean followup of 5.2 years (SD 5.2), the number of IA (5) was greater than what would be expected (2.5), although, because of the small number of events, the CI around the results included the null value (SIR 2.01; 95% CI 0.65, 4.68). However, when adjusting for fertility rates, women with SSc had a substantially increased number of IA (5) compared to what would be expected (1.2; SIR 4.04; 95% CI 1.35, 9.42). All IA during followup occurred in women without prior diagnosis of pulmonary hypertension, interstitial lung disease, or prior exposure to methotrexate, mycophenolate mofetil, bosentan, or cyclophosphamide.
Conclusion: Although the small number of events precludes strong conclusions, we noted more IA in women with SSc, which suggests inadequate attention to pregnancy planning in affected women. Regardless, these events appeared not to be triggered by organ involvement/severity or drug exposures.

18

Tofacitinib, an Oral Janus Kinase Inhibitor: Effects of Baseline Glucocorticoid Use on Selected Infections in Pooled Phase 3 and Longterm Extension Rheumatoid Arthritis Study Populations

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Objective: Tofacitinib (CP-690,550) is a novel, oral Janus kinase inhibitor investigated as a disease-modifying therapy for rheumatoid arthritis (RA). Glucocorticoid (GC) therapy continues to be used in treating RA and although effective, uncertainties about safety outcomes remain. We explored whether there is any association between baseline GC therapy and infection risk in tofacitinib-treated RA patients in the clinical development program.
Methods: Data were pooled from 5 randomized Phase 3 (P3) and two open-label longterm extension (LTE) studies (data cutoff 29 Mar 2011). Tofacitinib, 5 mg or 10 mg twice daily was administered as monotherapy or in combination with nonbiologic disease-modifying antirheumatic drugs (DMARD), mostly methotrexate. Oral GC (≤10 mg prednisone/day) was allowed in P3 with possible dose adjustments in LTE. We compared the overall incidence rate (IR; per 100 pt-yr) of selected infections between patients treated with GC at baseline and those who were not receiving GC.
Results: A total of 2430 patients from P3 and 3227 from LTE studies were included in the analyses, representing 1814.09 and 3118.32 pt-yrs, respectively. 57% and 53% were treated with GC at baseline in P3 and LTE, respectively. The overall IR of serious infection (SI) was 3.09 (95% CI 2.38, 4.02) in P3 and 3.00 (95% CI 2.45, 3.68) in LTE. The IR of SI was 3.85 (95% CI 2.81, 5.27) and 2.13 (95% CI 1.33, 3.43) in P3 and 3.50 (95% CI 2.70, 4.52) and 2.43 (95% CI 1.74, 3.38) in LTE, for patients receiving and not receiving GC at baseline, respectively. During P3, baseline GC use did not appear to influence the incidence of herpes zoster (HZ) infection; however in LTE baseline GC use appeared to modestly increase the risk. The overall IR of HZ in LTE in patients receiving GC at baseline was 5.12 (95% CI: 4.12, 6.36) as compared to 3.69 (95% CI: 2.82, 4.85) in patients not receiving GC at baseline. Events of opportunistic infections, including tuberculosis, were uncommon and baseline GC use did not appear to be associated with an increased risk for these infections.
Conclusion: In P3 and LTE, the rate of SI was consistent with the rate reported in the literature for RA patients treated with nonbiologic and biologic DMARD, whereas the rates of HZ infections in tofacitinib trials were higher than previously reported. Systemic GC use was associated with a modest increase in SI (P3/LTE) and HZ (LTE) rate, but not opportunistic infections, including tuberculosis in RA patients treated with tofacitinib.

19

Safety and Effectiveness of TNF-Alpha Inhibitor Therapy with Certolizumab Pegol Observed in Daily Practice in Adult Rheumatoid Arthritis Patients in Canada – First Interim Analysis of the Noninterventional FasT CAN Study

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Objective: Certolizumab pegol (CZP), a PEGylated Fc-free anti-TNF, has demonstrated a fast response and acceptable safety profile in rheumatoid arthritis (RA). This 2-year prospective, observational, noninterventional, noncomparative, postmarketing study was designed to assess the safety and efficacy of long-term CZP use in routine clinical practice for RA treatment in Canada. The primary objective is achievement of 28-joint count Disease Activity Score (DAS28) remission after 2 years in adult RA patients. Secondary objectives include patients' physical function and clinical disease activity index (CDAI).
Methods: This interim analysis includes data from all visits up to either week (wk) 20 or wk24. At the cutoff date for this analysis (17 January 2012), 150 patients were enrolled, all of whom received ≥1 CZP dose and were included in the safety analysis. Of these 150 patients, 113 were included in the full analysis set (FAS), defined as all patients who took ≥1 dose of CZP and had ≥1 valid post-baseline Disease Activity Score 28 joints (DAS28) value. Primary endpoint was DAS28 remission at wk20/wk24 [where available DAS28 CRP (C-reactive protein) was used, if not DAS28ESR (erythrocyte sedimentation rate) was used]. Efficacy data are reported for all patients who attended each visit and had non-missing observations.
Results: The mean age of enrolled patients (n=150) was 55 yrs and 83% were female. Median disease duration at baseline was 5.5 yrs (range 0-34 yrs). Baseline disease characteristics of the 113 FAS patients (median [min-max]) were: tender joint count 10.0 (1-28); swollen joint count 8.0 (0-22); DAS28(CRP) 5.2 (3-8); DAS28(ESR) 5.4 (2-8); CDAI 30.0 (10.7-66.9); Health Assessment Questionnaire-Disability Index (HAQ-DI) 1.5 (0.0-2.9). DAS28 remission (< 2.6) was achieved by 11/95 (11.6%) patients at wk12, and 23/78 (29.5%) at wk20/24. DAS28 low disease activity (≤3.2) was achieved by 31/95 (32.6%) patients at wk12 and 37/78 (47.4%) at wk20/24. Mean (SD) change from baseline, at wk12 and wk20/24 respectively, in CDAI was -15.2 (12.2) and -17.2 (13.6), DAS28(CRP) -1.3 (1.0) and -1.7 (1.2), DAS28(ESR) -1.3 (1.2) and -1.8 (1.3), and HAQ -0.4 (0.5) and -0.5 (0.6). Among all 150 patients, 46/150 (30.7%) reported an adverse event (AE), 9/150 (6.0%) withdrew because of AE, 17/150 (11.3%) reported infections, 2/150 (1.3%) reported serious AE, and 1/150 (0.7%) reported a serious infection. There were no deaths and no cases of tuberculosis.
Conclusion: In the FasT CAN study, RA patients treated with CZP achieved a rapid reduction in disease activity and improvement in physical function during the first 12 weeks of treatment, with further improvement up to wk24. AE incidence and severity were consistent with previous CZP reports.

20

Corticosteroid use in Rheumatoid Arthritis Patients Taking Infliximab: Treatment Implications Based on a Real-world Canadian Population

Boulos Haraoui (University of Montreal, Montreal); Algis Jovaisas

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Objective: According to the recent recommendations of the Canadian Rheumatology Association, addition of corticosteroids can be considered for the shortest period possible in rheumatoid arthritis (RA) patients treated with a traditional or biologic DMARD based on the patient's clinical status. The aim of the current analysis was to examine the effect of chronic systemic corticosteroid treatment at different doses on the incidence of infections in RA patients treated with infliximab in a real-life, Canadian, routine clinical practice setting.

Methods: BioTRAC is an ongoing, prospective registry of patients initiating treatment for RA, AS, or PsA with infliximab or golimumab as first biologics or after having been treated with a biologic for less than six months. In this analysis, a total of 838 RA patients treated with infliximab who were enrolled between 2002 and 2012 were included. Cox regression was used to examine the time-dependent association between systemic steroid dose (no steroid, ≤5 mg, >5 mg) and the incidence of first infection, while adjusting for possible confounders.

Results: Mean (SD) age of the patient cohort was 56.6 (13.5) years and mean (SD) duration since diagnosis was 10.5 (9.8) years. At initiation of treatment, 38.2% were treated with a systemic corticosteroid. After a mean (SE) followup of 51.3 (1.7) months, a total of 310 infections were reported for 19.7% of the patients (19.6 per 100 PYs). Among these, the vast majority (90.0%) were non-serious infections. Multivariate survival analysis using Cox regression showed that, upon adjusting for enrollment period, age, disease duration, number of steroid administrations, and HAQ-DI, the hazard ratio (HR; 95% CI) for acquiring an infection was 2.48 (1.24, 4.98) in patients treated with high dose (>5 mg) corticosteroids compared to patients not receiving corticosteroids. Treatment with low-dose corticosteroids was also associated with an increased hazard for infection [HR (95%CI) = 2.12 (0.97, 4.66)], which, however, did not reach statistical significance. In accordance with previous studies, increased HAQ-DI [HR (95% CI) = 1.51 (1.15, 1.92)] and disease duration [HR (95% CI) = 1.01 (1.00, 1.03)] were also identified as significant predictors.

Conclusion: Treatment with systemic corticosteroids was associated with an increased hazard ratio for acquiring an infection upon adjusting for possible confounders. The results of this analysis show that treatment with systemic corticosteroids is an independent predictor of infection in patients treated with anti-TNF agents and suggest that the use of concomitant medications should be considered in the interpretation of safety data.

21

Improving Osteoarthritis Outcomes Using a Multidisciplinary Model of Care; Experience in a Diverse Multicultural Urban Teaching Hospital

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Objective: In 2008, a multidisciplinary osteoarthritis (MOA) clinic was established at St. Michael's Hospital (SMH), a tertiary care academic teaching facility, serving a diverse social, economic, and cultural urban population in Toronto. The team (rheumatologist, advanced practice physiotherapist) designs a comprehensive treatment plan which consists of one or more of the following: patient education, exercise program, weight loss, intraarticular corticosteroid or hyaluronic acid injection, use of unloader braces or orthotic wedges, and discussion about referral for joint replacement surgery. All patients complete two questionnaires at each visit: (1) the Multi-Dimensional Health Assessment Questionnaire (MDHAQ) and (2) the Western Ontario and McMaster Universities Arthritis Index (WOMAC). Our goal was to evaluate the outcomes of patients who attend the SMH MOA clinic.

Methods: A retrospective chart review was completed on all patients who attended the MOA clinic between January 2010 and April 2012. Information collected from the chart included demographics, comorbidities, clinically assessed information, and patient-completed questionnaire data (MDHAQ and WOMAC). Paired t-test for statistically significant changes from baseline to 12 weeks (plus or minus 3 weeks) was used. The analysis was repeated on patients (group 2) with moderate to severe baseline pain (greater than 4 out of 10). We also performed a logistic regression to determine what factors predict response to treatment.

Results: Most patients attended the clinic for knee OA (86.2%). About one-third of the patients were recommended for surgery consult. There was baseline and followup data that was analyzed for patients with knee OA (group 1) and a subset (group 2) with moderate to severe baseline pain. In group 1, statistically significant improvements in function (WOMAC p = 0.0061) and fatigue (MDHAQ p = 0.0372) but not pain (WOMAC p = 0.656 and MDHAQ p = 0.3137) were observed. When the analysis was repeated on group 2, the results were similar, with the exception of the change in pain, which was statistically significant as measured by the MDHAQ (p = 0.0004) but not the WOMAC (p = 0.5059). A change in WOMAC stiffness was higher for group 2 (p = 0.07), but the change in duration of stiffness was similar in both groups (p = 0.0513 and p = 0.0608).

Conclusion: These results reflect actual clinical situations, and validate a multidisciplinary approach to OA management that uses a coordinated assessment by both rheumatologist and advanced physiotherapy practitioners in a 1-stop shop model to substantially improve overall OA management.

22

Methodological Reporting of Clinical Trials in Lupus Cochrane Reviews

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Objective: Since results of randomized clinical trials depend on the credibility of the methods reporting to support study findings, the reporting of the studies should contain credible methodologic criteria to support the findings.

Methods: 24 trials from those in the Cochrane Database of Systematic Reviews with "lupus" in the title and were printable. Each paper was scored by one reviewer using methodological criteria for design, allocation, blinding, reporting and imputation. Scores used Yes, No, or ? when it was unclear. Yes n (integer %) for all 24 papers are reported for each criterion.

Results: Design: 4 (17%) papers had a sample size justification; 22 (92%) contained 2 groups and 2 (8%) contained 3. 5 (21%) stratified patients; yet 2 (8%) used stratification in the analysis. Allocation: 6 (25%) stated random numbers generated and 3 (12%) blocked the balance associated with the allocation ratio; yet 0 (0%) used blocking in the analysis. 6 (25%) used a randomization list concealed from the person deciding patient eligibility, 0 (0%) provided an audit trail for randomization, 1 (4%) stated randomization integrity. 7 (29%) mentioned the randomization constructed with a computer program or random number table. Blinding: 4 (17%) stated the person deciding on the patient eligibility was blinded to block structure and 8 (33%) claimed the study was double blinded, even though it was not clear who the 2 were; indeed one was really triple blinded. For 3 (12%) patient blinded, 6 (25%) therapy, 4 (17%) therapist, 1 (4%) other care givers; 2 (8%) the outcome assessor; 0 (0%) data analyst, 0 (0%) manuscript writer. Reporting/Analysis: 1 (4%) checked statistical assumptions, 23 (96%) provided baseline data, not all for every patient randomized. 21 (88%) provided p values for group comparisons, 4 (17%) provided confidence intervals and 0 (0%) provided Numbers Needed to Treat. 1 (4%) specified subgroups in advance, 6 (25%) adjusted for baseline differences as one of the reported analyses. 4 (17%) stated statistical software, but not version, 0 (0%) provided the computer used for analyses. Imputation: 17 (71%) had missing data, yet 1 (4%) mentioned using last observation carried forward, 0 (0%) used multiple imputation and 0 (0%) mentioned impact on study conclusions. 2 (8%) provided a flowchart as suggested by CONSORT.

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Conclusion: Lupus trials did not report many of the methodological criteria that give paper credibility and validity to the study being reported. Reporting should be improved in future reports of studies of patients with lupus and related health problems. Possibly using the CONSORT check sheets would help make lupus papers more credible.

23

Yoga in Systemic Lupus Erythematosus: Qualitative Results of a Pragmatic Pilot Trial

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Objective: To assess the feasibility of a yoga program adapted for systemic lupus (SLE).

Methods: This qualitative study was performed in the context of a single-blinded, randomized control pilot study of standard treatment (control group) or standard treatment plus yoga (intervention group). The yoga intervention focused on gentle poses and 60-minute yoga classes, twice weekly for eight weeks, along with home practice. Evaluation included post-intervention surveys and focus group discussions.

Results: 57 persons were recruited; the primary reasons given for declining enrollment included not being interested, a lack of time, and feeling unwell. Most (96%) patients were female, average age was 38.6 (standard deviation, SD 12.6) years, mean disease duration was 9.8±7.9 years, and mean SLE Disease Activity Index (SLEDAI-2K) score was 4.0±4.0. Prior to allocation of the intervention, 23 recruited subjects withdrew because of timing or scheduling issues, primarily due to the long wait time (mean=62±33 days) between recruitment and intervention allocation. There were no differences in baseline characteristics between those who withdrew and those (N=34) who participated in the study. There were no baseline differences in these variables among those assigned to the intervention (N=17) versus the controls (N=17). Of the 17 randomized to the yoga intervention, one experienced upper back discomfort following the second class and discontinued. No further adverse events occurred. Class attendance averaged 63% (range 39-87%); home practice averaged 1.2±1.3 hours/week. Three focus groups conducted within one week after completion of the intervention consisted of 3, 4, and 5 participants respectively. All focus group participants perceived an improvement in sense of well-being after the program. Other reported benefits included improved stress and pain management, healthier relationships, and better sleep. Participants expressed satisfaction with the program content and teacher, agreeing that the tailored yoga program was essential. Most participants stated that they first began to notice benefits well into the program and would have preferred a duration of longer than 8 weeks. All participants wished to continue yoga but were hesitant to try programs that were not designed for SLE.

Conclusion: Our adapted yoga program was well tolerated in the SLE patients who participated, and positive effects were experienced. Because of self-selection, we cannot extrapolate our results to all patients, such as those with very active SLE. Regardless, it is clear that an adapted program can provide some persons with SLE an opportunity to experience yoga and its accompanying benefits.

24

Cutaneous Manifestations Associated with Systemic Lupus Erythematosus Disease Activity

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Objective: This study examined the pattern of cutaneous manifestations in a cohort of patients with systemic lupus erythematosus (SLE) and evaluated their association with disease activity as measured by the SLE Disease Activity Index 2000 (SLEDAI-2K). Lupus-related cutaneous findings were recorded based on Gilliam's classification where they are divided into "specific" and "non-specific" categories based on their histopathology. Lupus-specific findings are further divided into acute (ACLE), subacute (SCLE), and chronic (CCLE). Lupus-non-specific findings are cutaneous manifestations that can be seen in lupus as well as in other diseases, and include livedo reticularis, urticarial vasculitis, Raynaud's phenomenon and telogen effluvium.

Methods: Consecutive patients meeting ACR criteria for SLE were recruited from a multispecialty SLE clinic. All patients underwent a total body skin examination by a dermatologist. SLE disease activity was assessed at the same visit using the SLEDAI-2K which was modified by eliminating all muco-cutaneous items. Patients reported on sun exposure, medications, and smoking. Multiple linear regression models were run to estimate the effects of cutaneous manifestations on the SLEDAI-2K while adjusting for potential confounding variables.

Results: Eighty subjects were recruited, of which 75 (93.8%) were women. The mean age was 42.9 years (SD 13.4), mean disease duration was 12.6 years (11.4) and mean SLEDAI-2K was 5.85 (5.64). Of these patients, 24 (30%) had one or more lupus-specific cutaneous manifestations, of which 9 patients (11.3%) had ACLE, 6 (7.5%) had SCLE, and 10 (12.5%) had CCLE. No association could be demonstrated between the presence of lupus-specific skin findings and modified SLEDAI-2K scores. There were 59 patients (73.8%) who had lupus-non-specific cutaneous manifestations, the 3 most frequent ones being periungual telangiectasias (37 patients, 46.3%), Raynaud's (34, 42.5%) and livedo reticularis (27, 33.8%). Multivariate analyses estimated that the presence of any lupus-non-specific finding is associated with a higher modified SLEDAI-2K (difference of 4.11 points on the SLEDAI-2K scale, 95% CI 1.39-6.84). Among individual lupus-non-specific findings, livedo reticularis and periungual telangiectasias were associated with increased SLE disease activity (differences of 3.67, 0.96-6.38 and 2.61, 0.14-5.07, respectively).

Conclusion: Lupus-non-specific cutaneous findings as a whole, and individual manifestations such as livedo reticularis and periungual telangiectasias, are associated with increased SLE disease activity. No association was demonstrated between lupus-specific cutaneous manifestations and SLEDAI-2K. Careful examination of SLE patients for lupus-non-specific manifestations may aid clinicians in assessing global disease activity.

25

The 15% Rule in Scleroderma: The Frequency of Severe Organ Complications in Systemic Sclerosis (SSc). A Systematic Review

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Objective: The prevalence of organ complications in scleroderma (SSc) varies by definition used. This study was done to determine the frequency of several SSc features.

Methods: A search of Medline-OVID/EMBASE, PubMed, and Scopus databases from 1980 to November 30, 2011, was conducted to identify relevant articles with at least 50 SSc patients extracting prevalence of each organ complication. Study quality was assessed using the STROBE checklist. Pooled prevalence was calculated using the random effects method. Heterogeneity was quantified using I squared.

Results: 5,916 articles were identified (913 from Medline-OVID/EMBASE, 1,009 from PubMed and 3,994 from Scopus). 5,665 were excluded as 4,912 were irrelevant, 237 did not report organ prevalence, 193

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were reviews, 183 were case reports, 111 had fewer than 50 patients, 24 were not in English and 5 were not accessible; leaving 251 articles for full text review with 69 included. Where available, frequencies were also included from the Canadian Scleroderma Research Group. Many severe complications in SSc occur approximately 15% [95%CI] of the time including: cardiac involvement (15% [6-24]), diastolic dysfunction (16% [14-17]), estimated PA pressure > 40 mmHg (18% [14-21]), PAH by right heart catheterization (15% [12-17]), FVC< 70% predicted (15% [12-17]), FVC< 80% predicted (17% [12-21]), myositis (13% [10-17]), inflammatory arthritis (12% [9-16]), Sjögren's overlap (13% [10-16]) and digital ulcers (DU) (15% [10-20]); and 15% of DU have complications (amputations 12% [8-16]); hospitalizations (13% [6-21]). SRC is uncommon but occurs in almost 15% (12% [5-19%]) of dcSSc. There is no 15% rule within skin and GI tract for SSc.

Conclusion: This is a helpful '15%' rule for frequency of significant organ involvement in SSc.

26

A Novel Approach to the Early Detection of Axial Spondyloarthritis in Patients with Inflammatory Bowel Disease: The Implementation of an Advanced Practice Physiotherapist Led Screening Program

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Objective: Spondyloarthropathy (SpA) can affect 3.1 - 10% of patients with inflammatory bowel disease (IBD), compared to < 1% in the general population, defining IBD patients as high risk for developing SpA. Traditional referral pathways to rheumatologists are associated with lengthy wait times. One method to improve access to care has been to train advanced practice physiotherapists (APP) in the assessment/treatment of patients with inflammatory arthritis. The purpose of this study was to implement and evaluate a unique APP led screening program for IBD patients with suspected SpA. Objectives were to: measure wait times; measure a) the clinical agreement for screening results and b) agreed recommendation of MRI for further assessment between the APP and three rheumatologists with expertise in SpA, and compare the confidence of clinical judgment between the APP and rheumatologists.

Methods: Patients attending gastroenterology clinics with a diagnosis of IBD and ≥ 3 months of back pain were referred to the program. Patients demostrating signs and symptoms of inflammatory back pain (i.e. positive screen) were referred to the Rheumatology Clinic. Patients who screened negative were provided with education on appropriate back care. Descriptive statistics, Kappa coefficient (k), Pearson's Correlation and Bivariate analyses were used for data analysis.

Results: A total of 20 patients were referred to the screening program. Most patients were men (55%). Mean age was 40.9 years ±11.8. Average duration of back pain was 9.8 years; 65% reported insidious onset. Mean Oswestry disability index was 20.3 ±13.5, indicating minimal disability from back pain. The median wait time was 13 days. The APP agreed with the rheumatologists' screening results an average of 71.4% (k=0.5; CI: 0.07-0.87). The APP agreed with the rheumatologists to recommend MRI for further assessment an average of 66.7% (k=0.6; CI: 0.23-0.94). Comparison of confidence of screening results was 6.8/10 (higher values indicating higher level of confidence) for the APP versus an average confidence level of 6.4/10 for the three rheumatologists (Pearson's = 0.3).

Conclusion: Using an APP to screen for inflammatory back pain in patients with IBD demonstrates clinical judgment aligned with that of rheumatologists with expertise in SpA. The level of confidence of the APP was similar to the rheumatologists'. Wait times to be screened by the APP are shorter than traditional referral pathways. This screening strategy has the potential to improve access to care and act as a care model for patients at high risk for SpA.

27

Improving the Effectiveness of Delivery of Educational Information: Meeting the Needs of People Affected by Arthritis

Lynn Moore (The Arthritis Society, Toronto); Deanna Bowlby (Toronto)

Objective: This study was designed by a charitable organization to inform the development of a five year plan to increase effectiveness in providing information and education to Canadians living with arthritis.

Methods: A Canadian national marketing firm was recruited to conduct a Canada-wide survey of adults affected by arthritis (patients) and adults who provided support to a friend or family member with arthritis (caregivers). The survey was taken either online or by phone. Participants were asked about their education/information needs, information received from their healthcare provider at the time of diagnosis and the sources of information they relied on most.

Results: 1300 patients and 319 caregivers responded to the survey. The majority of participants completed the survey online with 400 completing by phone. At the time of diagnosis, the top three most useful types of information provided by physicians to patients and caregivers were identified as general information about their type of arthritis (37% patients/24% caregivers); medication being/ might be prescribed (33%/33%); and pain management techniques (29%/24%). However, there was a discrepancy between the information that patients and caregivers said they received from their physicians at time of diagnosis. Caregivers reported not receiving any information from their physicians much less frequently than did patients (3%/17%). There was also a discrepancy in the reported receipt of information on dealing with stress/emotional/psychological affects (caregivers 13%/patients 4%), self-management (caregivers 20%/patients 12%), and pain management techniques (caregivers 40%/patients 30%). In addition, more caregivers than patients reported receiving some information in writing (42%/19%). In the search for information, both patients and caregivers most frequently relied on health care providers (68%/62%), and the internet/online (54%/56%). Patients and caregivers reported seeking information from their health care providers because they considered the source trustworthy, and from the internet/online because it was considered easy to access. Overall, patients and caregivers agreed that it was easy to get information (79%/80%), however about half reported not knowing which information they could trust (43%/50%).

Conclusion: This study has identified gaps and opportunities for improvement in arthritis education. These results will help shape a five year plan to improve the effectiveness of the educational resources being provided to Canadians living with arthritis.

28

Lower than Expected Levels of DMARD Acquisition Immediately Pre and Post Biologic Initiation in RA Patients

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Objective: Reports suggest that a large proportion of patients who acquire and use biologic disease-modifying antirheumatic drugs (DMARD) to treat rheumatoid arthritis do not acquire or adequately consume traditional DMARD. However acquisition rates of biologics and DMARDs at the point of biologic initiation remains to be determined. The study explores the level of DMARD acquisitions in Canadian RA patients in the 6 to 12 months both immediately prior to and post-biologic initiation to quantify the levels of biologic monotherapy vs. biologic + DMARD combination consumption.

Methods: Biologic and DMARD concomitant therapy based on actual patient purchases was examined by tracking a cohort of 1,652 anonymous RA patient records from public and private drug plans in Canada via unique drug plan identifier numbers. All patients who were initiated on a biologic between August 2009 and July 2010 were tracked for a one-year period prior to and post their biologic initiation date. All cohort patients were compliant on biologics post initiation. Rheumatologist prescribing frequencies of RA therapies were assessed through randomly recruited surveys (n=100).

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Results: Physicians prescribed a biologic without a DMARD only 12% of the time. 25% of cohort patients did not purchase any form of DMARD within the 6 months prior to starting a biologic (41% for MTX). 29% did not acquire DMARDs at any point in the 6 months post-biologic initiation (43% for MTX). Data 12 months pre-biologic initiation showed that 22% did not acquire DMARDs (37% for MTX). Data 12 months post-biologic initiation showed that 26% did not acquire DMARDs (41% for MTX). Prescriptions supplied to 2-3 months worth of drug.

Conclusion: A large proportion of Canadian patients do not acquire any form of DMARD in the 6-12 months prior to being initiated on a biologic for the first time. This may negatively influence compliance on DMARDs once a biologic is initiated. Six months post-biologic initiation, 29% do not acquire any form of DMARD (43% for MTX) despite the general physician prescribing rate of biologic monotherapy (12%). These results are consistent with other registries, however this study isolates biologic monotherapy levels immediately prior to and post-biologic initiation. Many patients report reluctance or refusal to take DMARDs due to side effects that include headache, GI discomfort, malaise, fatigue, nausea, hair loss, and lifestyle restrictions. Close monitoring of DMARD intake is recommended and/or management of patients on monotherapy. Patient education is of prime importance as sustainability, clinical and radiological efficacy of biologic treatment may be compromised.

29

Real-world Effectiveness of Infliximab in the Treatment of Rheumatoid Arthritis over 5 Years: The Canadian Experience

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Objective: The efficacy of anti-TNF in the management of rheumatoid arthritis (RA) has been demonstrated in numerous controlled clinical trials. Longitudinal observational studies assessing the real-world effectiveness of anti-TNF agents are essential in order to demonstrate the true benefits. The objective of this study was to assess in Canadian routine clinical practice the 60-month outcomes in patients with RA treated with infliximab.

Methods: BioTRAC is an ongoing, prospective registry of patients initiating treatment for RA, ankylosing spondylitis, or psoriatic arthritis with infliximab or golimumab as first biologics or after having been treated with a biologic for less than six months. People with RA treated with infliximab who were enrolled between January 2002 and June 2011 and had at least one follow-up assessment were included in the six month analyses. People with follow-up assessments over 60 months were included in analyses of remission at five years. The probability of achieving remission was assessed with the Kaplan-Meier estimator of the survival function. Asymptomatic 95% CI around the survival estimate were produced with Greenwood's method.

Results: A total of 628 RA patients with a mean (SD) age of 55.8 (13.6) years and mean (SD) disease duration of 10.2 (10.0) years since diagnosis comprised the analysis cohort. Among these, 96 (15.3%) had completed five years of follow-up. At initiation of treatment, 90.9% were treated with disease-modifying antirheumatic drugs (72.1% with Methotrexate), 56.1% with nonsteroidal antiinflammatory drugs, and 40.0% with steroids. Mean (SD) patient parameters at baseline were: C-reactive protein (CRP) = 19.5 (24.9) mg/L, erythrocyte sedimentation rate (ESR) = 32.2 (24.0) mm/h, morning stiffness = 70.4 (43.6) min, tender joint count (TJC28) = 12.5 (7.9), swollen joint count (SJC28) = 10.6 (7.1), health assessment questionnaire (HAQ) = 1.7 (0.7), patient global assessment of disease activity (PtGA) = 6.0 (2.4) cm, physician global assessment of disease activity (PhGA) = 6.6 (2.1) cm, and DAS28-CRP = 5.4 (1.3). Upon six months of treatment, statistically significant ($P < 0.05$) and clinical meaningful improvements were observed in all parameters analyzed, which were sustained over 60 months of treatment. By 60 months, the cumulative probability (95% CI) of achieving remission as defined by the DAS28-CRP, CDAI, and SDAI definitions was 0.75 (0.63, 0.85), 0.54 (0.42, 0.66), and 0.45 (0.35, 0.57), respectively.

Conclusion: The results of this Canadian longitudinal observational study have shown that infliximab is effective in reducing symptom severity and improving outcomes in people living with rheumatoid arthritis over a five-year period.

30

What is the Impact of Rheumatoid Factor Positivity on the Real-world Effectiveness of Infliximab Treatment in Rheumatoid Arthritis?

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Objective: In addition to being a risk factor for the development of rheumatic diseases, the rheumatoid factor (RF) may also be a predictor of response to treatment (1). It is therefore hypothesized that patients with rheumatoid arthritis (RA) that are RF+ may be a subgroup with disease that may be less responsive to some treatments, and may therefore require more diligent management (2,3). This analysis examines whether presence of RF has an impact on the real-world effectiveness of infliximab in RA patients.

Methods: BioTRAC is an ongoing Canadian registry of RA, AS or PsA patients initiating treatment with infliximab (IFX) or golimumab (GOL) as first biologics or after having been treated with a biologic for less than six months. This analysis is based on 751 RA patients initiating IFX with known RF status. Within-group changes from baseline and between-group (RF+ vs. RF-) differences in clinical parameters were assessed for statistical significance using the one-sample t-test and independent samples t-test, respectively, using an α level of 0.05.

Results: A total of 556 (74.0%) RA patients treated with IFX were RF+. Disease duration was comparable for RF+ and RF- patients; however, mean (SD) age was significantly higher in RF+ patients treated with IFX compared to RF- patients (56.8 vs. 53.1; years $P = 0.001$). At initiation of IFX treatment (baseline), RF+ patients had significantly higher physician global assessment of disease activity (PGA), pain, DAS28-ESR and physical disability as measured by the HAQ-DI. After six months of treatment with IFX, clinically meaningful and statistically significant ($P < 0.05$) improvements were observed in all parameters studied. These improvements were sustained for 24 months of treatment with IFX. Although there were differences between the RF+ and RF- patients with respect to the crude-unadjusted changes over time in the parameters studied; after adjusting for baseline values these differences were not statistically significant.

Conclusion: The results of this analysis have shown that RF+ patients with RA may have more severe disease when compared to RF- patients at the time of anti-TNF initiation. However, treatment with IFX is equally effective in reducing disease severity and symptoms in both RF+ and RF-RA patients. These improvements were sustained for 24 months of treatment with IFX.

31

Updated Results of National Survey on Immunology Curriculum for Adult Rheumatology Residents: Improvement is Needed

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Objective: Immunologic mechanisms play an integral role in the understanding and management of rheumatic conditions. Currently, there is limited access to standardized formal instruction in immunology for trainees across Canada. A comprehensive immunology curriculum is essential for adult rheumatology trainees to meet the competencies mandated by the Royal College of Canada. The objectives of this project were as follows: (1) to describe the structure of current immunology curricula amongst adult rheumatology training programs across Canada and (2) identify and compare the perceived learning needs of rheumatology trainees from the perspective of program directors and trainees. These results will help develop a focused nationwide immunology curriculum for rheumatology training programs.

Methods: Rheumatology trainees and program directors from adult rheumatology programs across Canada completed an online questionnaire. Information on student demographics, past immunology training and overall satisfaction with current immunology training was collected in an anonymous manner. Participants ranked a comprehensive list of immunology topics by order of perceived importance. A modified Delphi approach was used to obtain consensus on immunology topics.

Results: Fifteen program directors and 38 rheumatology trainees were contacted between March 1 to May 2012. From this group, 42% of trainees and 66% of program directors responded, with a total 49% response rate. Of the rheumatology trainees, 67% had prior experience in immunology, which consisted of undergraduate and graduate courses. Teaching format and formal teaching hours varied between sites. Notably, only 42% of program directors and 31% of trainees felt the current method of teaching immunology was effective. Preliminary results illustrate concordance between program directors and trainees for the highest ranked topics, which include innate immunity, adaptive immunity, and cells and tissues of the immune system. However, there was discordance among other topics. Notably, diagnostic laboratory immunology and therapeutics were ranked higher by program directors as compared to trainees. Part two of the modified Delphi is currently in progress.

Conclusion: There is a need to improve immunology teaching in rheumatology training programs. Preliminary results show high concordance between the majority of topics ranked by trainees and program directors. However, discordance is seen with other topics, including diagnostic immunology and therapeutics. Final completion of the Delphi will allow for a national consensus and definitive conclusions. This study provides the groundwork for development of future immunology curricula.

32

Arthritis Coping Strategies used by On-reserve British Columbia First Nations Communities – Focus Groups Results

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Objective: Arthritis is more prevalent and more severe in Canadian First Nations' (FN) people. Self-management programs have emerged as an effective means of providing patients with information and tools to manage arthritis symptoms. However, it is beneficial if self-management programs are adapted to the specific cultural contexts of the communities where they are used. In collaboration with FN communities in BC, we are developing a self-management program for inflammatory arthritis (IA) that will involve family members, enhance family support and be consistent with the culture and values of our FN partners. To understand the needs of the community, we conducted focus groups with people living with arthritis and their family members. The primary objectives of the focus groups were to identify coping strategies used by FN people in the communities and barriers and facilitators to arthritis self-management.

Methods: Participants with IA were recruited from a previous household survey and asked to identify a family member. Focus groups were recorded, transcribed and analysed with inductive content analysis using Corbin's approach of Grounded Theory.

Results: Six focus groups (N=31) were conducted in three communities; three with people living with arthritis and three with family members. Four major coping strategies emerged. The most common coping strategy reported was "mind over matter", which involved persevering through pain. People living with arthritis did not want to burden family members by "complaining" about pain and often chose to suffer in silence. Second, listening to one's body, which included slowing down and respecting one's physical and emotional boundaries was used to deal with pain and fatigue. Participants spoke of the difficulty in taking care of one's own needs before family obligations. Third, humour was common during the focus groups and was expressed as a specific strategy that people used for emotional relief. Fourth, people expressed frustration with Western medicine's lack of a holistic perspective and sought other healing modalities, including FN traditional medicines and practices, as well as modalities from other cultures. Prescription medications for arthritis were considered universally undesirable. There was a strong desire to avoid medications due to fear of side effects.

Conclusion: Primary coping strategies used by FN people living with IA involved persevering through pain, listening to one's body and its limitations, humour, and a holistic approach to healing, including use of traditional modalities. These results will inform program development of a culturally relevant arthritis program for FN communities.

33

Biologics and Mortality Risk in Rheumatoid Arthritis - Results of a Population-based Study

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Objective: Biologic agents, due to their disease-modifying effect, may reduce the risk of premature mortality in RA. We evaluated the association between exposure to biologics and risk of mortality in RA.

Methods: Using administrative data, we assembled a population-based cohort of RA cases in British Columbia who received care between 01/1996 and 03/2006, with follow-up until 03/2010. Data was obtained on all medications, MD visits, hospitalizations, and tests. For this study we identified all RA cases who used a biologic agent (anti-TNF, rituximab, anakinra or abatacept) during follow-up. Each biologic user was matched with one RA control who never used a biologic but used at least 3 disease-modifying antirheumatic drugs (DMARD; to mimic coverage requirements) and with recent (within 6 months) change in DMARD. Controls were also matched on age, sex, calendar year of inclusion and closest propensity score, using a greedy matching technique. Controls were given the date of initiation of first biologic of their matched user. A propensity score (PS) was calculated at time of initiation using markers of RA severity and co-morbidities increasing risk of death. Cox proportional hazard model (PHM), starting from time of biologic initiation, was used to estimate risk of death, associated with biologic exposure, evaluated as a time dependent variable representing current exposure with cases considered exposed for up to 3 months after discontinuation. PHM analysis was also adjusted for age, sex, RA duration, Charlson co-morbidity score, PS quintiles (because matching on PS was imperfect) and imbalanced variables from the PS model.

Results: Our sample includes 2156 biologic users and 2156 matched controls (mean(SD) age: 56.3(14.6), 74.7% females). We observed 573 deaths (326 in controls; 247 in biologic users). Exposure to biologics was associated with a reduced risk of death (aHR, 95%CI: 0.25, 0.18;0.36, $p < 0.0001$). Sensitivity analysis not requiring controls to have used 3 prior

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DMARD or recent DMARD change yielded almost identical results (aHR, 95%CI: 0.26, 0.18;0.36, p < 0.0001). Another sensitivity analysis, without use of PS, but where PS variables entered the PHM, yielded similar results (aH, 95%CI: 0.31, 0.22;0.45, p < 0.0001). Limitations of our study are those inherent to observational study, including possible effect of residual or unmeasured confounding, and selection bias from non-random allocation of treatment.

Conclusion: In a population-based cohort, exposure to biologics was associated with a significant reduction in mortality. Given the increased mortality risk of RA, this has important implications for health policy makers, health care providers and people with arthritis.

34

Association of Axial Spondyloarthritis and Primary Sclerosing Cholangitis

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Case Report: Primary sclerosing cholangitis (PSC) is a chronic liver disease characterized by inflammation and fibrosis of bile ducts. Approximately 70% of patients have concomitant inflammatory bowel disease (IBD). Approximately 10% of patients with ankylosing spondylitis (AS) have IBD but PSC is not a well-recognized complication of AS. We report three cases of PSC in patients with axial spondyloarthritis and speculate that a common mechanism underlies the pathogenesis of both diseases. Patient 1, an HLA-B27 positive male, developed inflammatory back pain in 1990 at the age of 23 years. AS was diagnosed in 1999. Previously endoscopy had found no evidence of IBD. A diagnosis of PSC was made on the basis of cholestatic liver enzymes, ultrasound showing thickened extra-hepatic bile ducts and liver biopsy demonstrating portal inflammation. Ursodeoxycholic acid was started in August 2000 with no change in liver enzymes. For refractory AS the patient was treated with infliximab 5mg/kg in January 2001 with good symptomatic response. By May 2001 the liver enzymes had improved (ALP 128 U/L, ALT 65 U/L). He still takes infliximab with stable liver enzymes. Patient 2, a male, developed pruritus and colitis in 2006 at the age of 21 years. Ulcerative colitis was diagnosed with coexisting PSC, based on elevated liver enzymes and MRI demonstrating multiple intrahepatic bile duct strictures. Treatment with ursodeoxycholic acid was initiated. IgG4 titre was found to be elevated in February 2012 and a one month tapering course of prednisone 40mg was initiated for the symptoms of pruritis and fatigue. Two weeks after completing the last dose of prednisone, the patient reported severe inflammatory low back pain. HLA-B27 was negative and plain radiography of the sacroiliac joints nondiagnostic, but MRI demonstrated bone marrow oedema in both sacroiliac joints consistent with a non-radiographic axial spondyloarthritis. Patient 3, an HLA-B27 positive female, presented in 2011 at the age of 27 years with inflammatory back pain. MRI was consistent with non-radiographic axial spondyloarthritis. Elevated liver enzymes were noted. MRI of the liver showed scattered intrahepatic bile duct dilatation peripherally with central bile duct narrowing consistent with PSC and liver biopsy demonstrated portal inflammation. The pathogenesis of PSC is not well understood. It is conceivable that a common mechanism underlies the pathophysiology in AS and PSC and that in AS / PSC overlap without IBD, microbial antigens deriving from the inflamed biliary tree may trigger an immune response leading to spinal inflammation.

35

Infection Risk in Ankylosing Spondylitis – an Observational Study

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Objective: Longterm data on infection risk in ankylosing spondylitis (AS) are sparse. Anti-TNF therapy is increasingly used in AS, with infection being the most important adverse event. We aimed to investigate the frequency of infections in AS and to identify factors predisposing to infection.

Methods: The Toronto spondyloarthritis (SpA) database comprises clinical, laboratory and radiological data, which are collected annually during clinic visits according to a standard protocol. Data were extracted for patients meeting Assessment of SpondyloArthritis international Society (ASAS) criteria for axial SpA. Chi-squared and Fisher's exact test were used to compare categorical variables. T-tests were used to compare continuous variables.

Results: 695 patients (74% male) were included in the analysis with a total follow-up of 1716 patient-years. 211 infections were recorded. Details of the type of infection were available for 169 episodes (114 bacterial, 20 viral, 35 other). 176 infections required treatment with antibiotics, of which 12 required intravenous antibiotics. The most common sites of infection were lung, genitourinary tract, and sinus. Patients who reported infections did not differ significantly from those who did not report infections with regard to age, gender, disease duration, smoking history, alcohol consumption, or disease severity as reflected by the Bath Ankylosing Spondylitis Disease Activity Index and the Bath Ankylosing Spondylitis Functional Index. 11.8% of patients reporting infections had used glucocorticoids, compared to 6.2% of patients without infection (p=0.01). There was no significant difference between the two groups in the proportion of patients using biologic drugs although there was a trend for a higher rate of biologic use in patients who reported infections (34.3%) than in those without infections (28.4%; p=0.27). Patients who reported infections had a higher rate of non-infective comorbidities than those without infections, including constitutional illness (46% vs 37%, p=0.04), mucous membrane lesions (8.4% vs. 1.5%, p< 0.0001), respiratory disease (22.2% vs 10.8%, p=0.0002), chest pain (8.1% vs 2.5%, p=0.0008), gastrointestinal disease (32.8% vs 19.9%, p=0.0007), neurological disease (22.2% vs 9.8%, p< 0.0001) and other illness (21.0% vs 13.2%).

Conclusion: The incidence of infection in this prospective AS cohort is 0.69 per 100 patient-years. As expected, the risk of infection appears to be higher in patients with comorbidities and in those taking glucocorticoids. There does not seem to be a significant association of infection with use of biologic drugs.

36

Longterm Use of Adalimumab as Monotherapy Following Attainment of Low Disease Activity with Adalimumab plus Methotrexate

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Objective: It is unclear whether patients may withdraw methotrexate (MTX) following achievement of a clinical target with combination biologic+MTX. This analysis evaluated long-term clinical, functional, and radiographic outcomes with open-label (OL) adalimumab (ADA) monotherapy following attainment of low disease activity (LDA) with ADA+MTX.

Methods: PREMIER was a 2-year, randomized, controlled trial (RCT) in MTX-naive patients with early RA randomized to MTX, ADA, or ADA+MTX. Patients completing the RCT were eligible to receive OL ADA for an additional 8 years; MTX could be added at the investigator's discretion. This post hoc analysis included data from patients randomized to ADA+MTX, who achieved LDA [DAS28(CRP) < 3.2] at Year 2, and received OL ADA monotherapy up to Year 5. The percentages of patients remaining in LDA or with normal function (HAQ-DI < 0.5) at Year 5 were summarized using non-responder imputation based on the population entering the OL period and as observed for patients with available Year 5 data. Mean ΔmTSS and the proportion without radiographic progression (ΔmTSS ≤0.5) from Years 2-5 were summarized as observed. Conditional logistic regression analysis based on propensity score matching was used to identify variables significantly associated with MTX use.

Results: Of the 183 ADA+MTX-treated patients who enrolled in the OL

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extension, 140 (83%) achieved LDA at Year 2. Among the LDA responders, 84 (60%) received ADA monotherapy and 56 (40%) reinitiated MTX during the OL extension (time to 1st MTX use: mean/median=28/5 weeks). Higher physician's global assessment predicted MTX use during the OL extension ($P < 0.01$). In total, 60 of 84 patients (75%) completed 3 years of OL ADA monotherapy. Adverse events were the most frequently cited reason for study discontinuation (n=9); no patient withdrew citing loss of efficacy. Of the 84 ADA monotherapy patients, 63% retained LDA, 50% were in DAS28(CRP) remission, and 58% had normal function at Year 5. Among patients with Year 5 data available (n=60), 88% were in LDA and 78% had normal function. Clinically insignificant radiographic progression was observed for patients completing Year 5 of OL ADA (mean annual mTSS progression rate from Years 2-5 =0.5 units/year).

Conclusion: Following achievement of LDA with ADA+MTX at Year 2, OL ADA monotherapy was sufficient for most patients to retain LDA with minimal radiographic progression for an additional 3 years. Thus, MTX withdrawal appears to be an option for some patients whose disease activity is responsive to ADA monotherapy.

37

Analysis of Integrated Radiographic Data for Two Longterm, Open-Label Extension Studies of Adalimumab

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Objective: Longterm radiographic studies usually rely on multiple readers evaluating subsets of films from different time points, often re-scoring previously read images. This study describes an integration approach to evaluate the complete set of radiographic scores assessed over several years from longterm studies of adalimumab (ADA).

Methods: Data from 2 large, multicenter, randomized, placebo (PBO)-controlled trials of ADA were analyzed: PREMIER (MTX-naive patients, early RA) had a 2-year double-blind period followed by an 8-year open-label extension (OLE); DE019 (MTX-inadequate responders, long-standing RA) had a 1-year double-blind period followed by a 9-year OLE. Patients received OL ADA±MTX in both OLE. This post hoc analysis evaluated radiographic data based on randomization to the original PBO+MTX and standard dose ADA+MTX arms through 8 years in PREMIER and 10 years in DE019. Radiographic progression was assessed using the change in modified total Sharp score (ΔmTSS) from baseline. Radiographs were assessed at Years 2, 3, 5, and 8 (PREMIER) and Years 1, 2, 3, 5, 6, 8, and 10 (DE019). At each assessment year, radiographs from baseline and selected prior years were re-read. A mixed effect model was used to evaluate the repeated measurements at different time points within different assessment years in the integrated analysis. ΔmTSS was estimated by least square mean and summarized alongside the most recent assessment year of PREMIER (Year 8, including repeat reads for baseline and Years 2 and 6) and DE019 (Year 10, including repeat reads for baseline and Years 1 and 8).

Results: Radiographic data from 452 patients in PREMIER (215 PBO+MTX; 237 ADA+MTX) and 327 patients in DE019 (162 PBO+MTX; 165 ADA+MTX) with baseline and ≥1 post-baseline radiograph were identified. Radiographic progression was most pronounced in patients receiving PBO+MTX during the double-blind periods, but progression slowed dramatically upon switch to OL ADA±MTX therapy in both trials. Following up to 8 years of treatment, patients in PREMIER experienced ΔmTSS estimates of 11.1 (PBO+MTX) and 3.9 (ADA+MTX); patients in DE019 experienced estimates of 6.6 (PBO+MTX) and 0.9 (ADA+MTX) through 10 years of treatment. The estimated curves in each of the studies revealed subtle changes in progression rates not seen in their respective most recent assessment year.

Conclusion: Longitudinal data integration analyses factoring in mTSS from all available assessments enabled a robust estimate of total radiographic progression in 2 long-term studies of ADA±MTX. Moreover, the present analysis confirmed the radiographic efficacy of long-term therapy with ADA±MTX.

38

Longterm Remission with Golimumab in Active Rheumatoid Arthritis Patients Despite Methotrexate Through 2 Years

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Objective: To assess longterm remission through 2 years from the GO-FORWARD trial.

Methods: This is a retrospective analysis of data from GO-FORWARD (RA pts with inadequate response to MTX) through Wk104. Active RA (N=444) pts despite MTX were randomized to PBO+MTX, GLM100mg+PBO, GLM50mg +MTX, or GLM100mg+MTX, Pts with < 20% improvement in SJC/TJC at wk16 entered early escape: PBO+MTX→GLM50mg+MTX, GLM 100mg+PBO→ GLM100mg+MTX, GLM 50mg+MTX→GLM100mg+ MTX. At Wk 24, pts receiving PBO+MTX, crossed over to receive GLM 50mg+MTX. GLM/PBO was injected q4wks. Remission rates at Wk 24, and the proportions of pts who remained in remission at Wks 52 and 104 were assessed using the following 4 definitions: DAS28 (weighted sum of SJC/TJC, 28 joints, CRP, and pt global assessment); EULAR Boolean (Def A) TJC/SJC, 28 joints, CRP mg/dL, and pt global assessment, each score ≤1; EULAR SDAI (Def B)-SDAI score is sum of TJC/SJC, 28 joints, pt global assessment, physician global assessment, and CRP mg/dL with scoring ≤3.3; and CDAI (sum of SJC/TJC, 28 joints, pt global assessment, physician global assessment ≤2.8). In addition, among those who did not achieve remission at Wk 24, the proportions of pts who later achieved remission at Wks 52 and 104 using each definition are presented (Table). Observed data was used to conduct this analysis.

Results: At Wk 24, significantly greater proportions of pts achieved remission in the GLM +MTX groups vs PBO+MTX; about 30% vs 8%, respectively, using DAS28 and about 12% vs 2% using the Boolean, SDAI, and CDAI remission definitions. At Wk 52, about 80% of pts in the GLM +MTX group remained in remission using DAS28, SDAI, and CDAI; about 70% remained in remission using Boolean definition. At Wk 104, among those GLM+MTX pts who achieved remission at Wk 24, the proportions of pts with sustained remission were DAS28 ~90%, Boolean~55%, and SDAI and CDAI~65% each. About 20% of pts who did not achieve remission at Wk 24, did achieve remission at Wks 52 and 104, with higher rates using DAS28~30%, and slightly lower rates using Boolean definition~15%.

Conclusion: Using any of the 4 remission criteria, GLM+MTX induced remission in a greater proportion of pts than PBO+MTX and remission was sustained in the majority of those pts through years 1 and 2.

39

Validation of Remission of Rheumatoid Arthritis by Traditional Disease Activity Score and Provisional Criteria by American College of Rheumatology and European League Against Rheumatism: Analysis Based on Patient Reported Outcomes Analyzed from 3 Phase III Golimumab Clinical Trials of Golimumab

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Objective: Remission by Boolean-based definition (all scores on the tender

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joint and swollen joint count, CRP (mg/dL), and patient global assessment ≤1) and by SDAI-based definition (< 3.3) were proposed by ACR/EULAR. Using patient reported outcomes as anchors, this analysis validated these remission criteria against traditional DAS28 using CRP remission (< 2.6) in 3 RA patient populations.

Methods: Efficacy of golimumab (GLM) was assessed in MTX-naive RA patients (GO-BEFORE, N=637), RA patients with inadequate response to MTX (GO-FORWARD, N=444) and RA patients previously treated with biologic anti-TNFα agent(s) with baseline MTX use (GO-AFTER, N=305). Pooled data from patients who received PBO + MTX, or GLM (50 or 100mg)+MTX, q4 wks were used for this analysis. Patient-reported outcomes were measured with the following: HAQ, Physical and Mental Component Summary Scores of 36-item short-form health survey (SF36 PCS and MCS), Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue), and a Visual Analog Scale (VAS, 0-10) of impact of RA on daily work productivity. Descriptive statistics were provided for patient-reported outcomes among patients in remission as defined by the 3 remission definitions.

Results: Greater proportions of patients treated with GLM + MTX vs patients treated with PBO+MTX achieved remission by each remission definition. In pooled analysis, the remission rate at wk24 was the highest (20.2%) by DAS28, compared to remission by SDAI (10.6%,p< 0.001) and remission by Boolean-based definition (8.6%,p< 0.001). Patients with remission by DAS28 achieved normal physical function (HAQ≤0.5), normal SF-36 PCS, and MCS(≥50) by 67.8%, 38.4%, 62.2%, respectively; these parameters were numerically lower when compared to patients with remission by SDAI (81.3%,62.8%,72.1%, respectively) or by Boolean-based definition (82.0%,63.5%, 74.3%, respectively). Patients in remission by DAS28 had higher HAQ scores (0.43 ±0.49) compared to patients in remission by SDAI (0.26±0.41) or Boolean-based criteria (0.28±0.44). Similar results were observed in measures of FACIT-fatigue and productivity VAS scores. Among MTX-naive patients in the GO-BEFORE study who achieved remission by DAS28, 71.3% achieved normal physical function compared to 86.9% of those in remission by SDAI and 86.5% of patients in remission by Boolean-based definition. Among anti-TNFα experienced patients in the GO-AFTER study, 62.1% of those in remission by DAS28 achieved normal physical function compared to 65.0% of those in remission by SDAI, and 66.7% of patients in remission by Boolean-based definition.

Conclusion: While disease remission has been adapted as a target in the management of RA, more stringent remission criteria proposed by ACR/EULAR can provide optimal patient-reported outcomes.

40

Follow-Up Project : Study on the Impact of Physical Therapy in Etanercept-treated Patients

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Objective: Rheumatoid arthritis (RA) and psoriatic arthritis (PsA) are chronic autoimmune diseases characterized by inflammation, pain, stiffness and joint destruction. RA and PsA can lead to functional impairment, disability and poor quality of life in addition to higher rates of morbidity and mortality. Major advance has been made in the treatment of these diseases with biologic agents but still there are unmet needs. Remission is attained for a minority of patient and the employability is not maintained for all patients. Physiotherapy has an important role in the care of patients and maybe the care gap is in part in non-pharmacological treatment. The purpose of this study was to assess the effectiveness of physiotherapy in the management of RA and PsA diseases.

Methods: Forty-one patients were enrolled in this study and randomly assigned into two groups, a control group and a physiotherapy group. Each patient has begun a pharmacological treatment with etanercept. For physiotherapy group, physiotherapist have seen patient at baseline, after 1 month and every 3 months for a period of 12 months. Patients have a home-based exercise program between physiotherapy sessions. The control group was seen every 6 months by the rheumatologist alone as well as the physiotherapy group.

Results: After 12 months of pharmacological treatment and physiotherapy (if randomized in the physiotherapy group), the DAS28 and the HAQ significantly decrease in both groups. The decrease in DAS28 was more important in the physiotherapy group (Δ=1.052) than in the control group (Δ=0.627). However, the decrease in HAQ was more important in the physiotherapy group (Δ=0.592) than in the control group (Δ=0.509). However, differences were not statistically significant (X^2 test, p>0.05).

Conclusion: The present study shows the effectiveness of physiotherapy in the management of RA and PsA with the pharmacological treatment. It also highlights the need to do multicenter study on the impact of physical therapy in order to have results that reach statistical significance.

41

The Rituximab Registry at the Centre de Rhumatologie de l'Est du Québec: Description of the Real-world, Canadian Rural Patient Cohort

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Objective: Rheumatoid arthritis (RA) is a chronic autoimmune disease characterized by inflammation, pain, stiffness and joint destruction. RA can lead to functional impairment, disability and poor quality of life in addition to higher rates of morbidity and mortality. Major advance has been made in the treatment of these diseases with tumor necrosis factor-α (TNF-α) inhibitors. However, some patients have inadequate response to TNF-α inhibitors and may switch to an alternative treatment from a different class of drugs, such as rituximab (RTX). RTX, which is a chimeric monoclonal antibody, is indicated for use after the failure of a TNF-α inhibitors and approved in 2006 for the treatment of RA. The objective of this study was to assess in Canadian clinical practice the 30-month outcome in patients with RA treated with rituximab.

Methods: Charts of fifty RA patients taking RTX were reviewed and detailed data including demographic information, disease characteristics, rheumatoid factor (RF) and anti-cyclic citrullinated peptide status (ACCP), co-morbid medical condition, 28-joint disease activity score (DAS28), C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), Health Assessment Questionnaire-Disease Index (HAQ-DI) and adverse events were collected. Descriptive statistics were used to describe patients initiating RTX in this real-world setting. Predicted factors for response were studied with the X^2 test such as RF, ACCP, gender and smoking status.

Results: Overall, DAS28-ESR decreased from 4.67 at baseline to 3.02 at month 30. More than 59% of patients (30/50) obtained a EULAR good response at week 16. Fifty percent of patients are RF positive. No predicting factor for response was found in this cohort regarding RF, ACCP, and smoking status. The data from the present study suggest that RTX is as effective in active seropositive RA as in seronegative RA patients. After 30 months, 78% of patients are still on RTX. The safety profile was comparable and consistent with published data on patients with RA. The overall serious infection rate was 3.2/100 patient-years.

Conclusion: The present study suggests that RTX offers clinical benefits in RA patients and is well tolerated. Results are consistent with other registries such as the Belgian MIRA, AIR, and ORA French Registries as well as published data based on clinical trials except for the effectiveness in seronegative RA (van Vollenhoven, et al., 2010, Vander Cruyssen et al., 2012). This is an explorative question as if RA patients in eastern Quebec may be different.

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42

The Survival Rates of Biologics-treated Patients at the Centre de Rhumatologie de l'Est du Québec: Description of the Real-world, Canadian Patient Cohort

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Objective: In recent years, major advance has been made in the treatment of rheumatoid arthritis (RA). The efficacy of tumor necrosis factor-α (TNF-α) inhibitor has been demonstrated in different controlled clinical trials. However, some patients have inadequate response to TNF-α inhibitors and may switch to an alternative treatment from a different class of drugs, such as rituximab (RTX) and abatacept (ABA). RTX and ABA are indicated for use after inadequate response to traditional disease-modifying antirheumatic drugs (DMARD) or TNF-α inhibitors for the treatment of RA. The objective of this study was to assess in Canadian clinical practice the survival rate in patients with RA treated with a TNF-α inhibitor such as etanercept (ETN) and alternative treatments such as RTX and ABA.

Methods: Charts of all RA patients taking ETN, RTX and ABA at the Centre de Rhumatologie de l'Est du Québec were reviewed and detailed data including demographic information, disease characteristics, rheumatoid factor and anti-cyclic citrullinated peptide status, co-morbid medical condition, 28-joint disease activity score (DAS28), C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) and Health Assessment Questionnaire-Disease Index (HAQ-DI) were collected. Descriptive statistics were used to describe patients initiating biologic treatment in this real-world setting.

Results: A total of 261 RA patients starting treatment with ETN, ABA or RTX were enrolled in this study. 147 patients were on ETN, 64 patients were on ABA and 50 patients were on RTX therapies. Overall, DAS28-ESR decreased from 4.40 at baseline to 2.86 at month 30 for ETN, from 4.57 at baseline to 2.94 for ABA and from 4.67 at baseline to 3.02 for RTX. After 30 months, for all patients, 60% of patients are still on ETN, 55% of patients are still on ABA and 78% of patients are still on RTX. However, for biologic-naive patients, 62% of patients are still on ETN (n=117), 67% of patients are still on ABA (n=15), and 100% of patients are still on RTX (n=3) at month 30.

Conclusion: The present study suggests that the survival rate of treatment for biologic-naïve patients is higher than on patients who failed to respond to their previous biologic. It also suggests that RTX has a better survival rate than ETN and ABA in second-line treatment. Also, ABA has better profile when used as a first-line agent.

43

Incidence and Management of Infusion Reactions to Infliximab in a Prospective Real-life Community Registry

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Objective: Infliximab (IFX) is a therapeutic monoclonal antibody targeting tumor necrosis factor (TNF-)a indicated in the treatment of a number of chronic inflammatory diseases. IFX is administered by intravenous infusion and may be associated with infusion reactions (IR).

Methods: RemiTRAC Infusion is a prospective Canadian observational registry in which IFX infusions are followed to document IR and their management, pre-medication use and adverse events. An IR was defined as any adverse event occurring during the infusion or within 1 hour post-infusion.

Results: Since its inception in 2005, 1398 patients have been enrolled and 18,121 infusions were recorded. The majority (64%) of patients in this cohort are treated with IFX for rheumatologic conditions such as rheumatoid arthritis (42%), ankylosing spondylitis (16%), and psoriatic arthritis (6%). 181/1398 (13%) patients reported at least one IR. Only 292/18,121 infusions resulted in an IR (1.6%) and almost all IRs were mild to moderate in severity (94%). The most common IR was pruritus, occurring in 14.2% of infusion reactions. Flushing (9.9%), urticaria (9.2%), nausea (6.3%) dyspnea (6.0%), and chest discomfort (5.0%) are the only other infusion AE occurring in ≥5% of IR. There has been no serious anaphylactic reaction recorded to date. A total of 42% of infusions were carried out following pre-medication of patients which included oral anti-histamines, intravenous steroids, and/or acetaminophen. Pre-medication were administered at the physician's discretion both as a precautionary measure and in patients who had previously experienced an IR in the past. Infusions without any pre-medication were associated with a 1.4% incidence of IRs. In contrast, infusions pre-medicated with either anti-histamines or steroids were associated with a statistically significant increase in the incidence of IRs, up to 2.8% in the presence of anti-histamines ($p< 0.0001$) and up to 2.3% in the presence of steroids ($p< 0.0001$). In contrast, the presence of acetaminophen pre-medication was associated with a 1.4% incidence of IRs, an incidence rate comparable to infusions without any pre-medication ($p=0.0603$).

Conclusion: This registry shows that, in community-based infusion clinics, IR to IFX are rare in incidence, largely mild to moderate in nature and successfully managed by the health care professionals in place using a standardized infusion protocol.

44

Preliminary Validation of the OA GO AWAY, a Self-Management Intervention for Patients with OA of the Hip or Knee to Promote Exercise Adherence

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Objective: The objective of this study was to determine the face and content validity of the OA GO AWAY, a self-management intervention and assessment tool that combines a monthly personalized self evaluation journal with goal setting and a weekly exercise log. It was created to promote long term adherence to exercise recommendations for people with hip or knee osteoarthritis.

Methods: A sample of ten patients with OA of the hip and/or knee, with a mean age of 59.5 years, mean disease duration of 15.2 years, and 60% female, were recruited at The Arthritis Society office in Ottawa. Ten health care experts (researchers and clinicians with expertise in osteoarthritis and self-management) were recruited by invitation to selected Canadian Arthritis Network researchers and by "snowball sampling" recommendations from Ontario rheumatology professionals. Patients and experts reviewed the OA GO AWAY Journal and Exercise Log, and rated the relevance of each item as essential, useful but not essential, or not necessary, and commented on comprehensiveness and clarity. Their answers and comments were recorded on the Face and Content Validity Rating form and the content validity ratio (CVR) was determined for each item.

Results: The CVR was adequate (ranging from 0.5 to 0.99) for 18 out of 30 items rated. Overall, the OA GO AWAY was found to be clear. However, ten items (6 from the Journal and 4 from the Exercise log) were removed due to low CVR ratings, while 2 low-rated Journal items were replaced by new items; and eight items were reworded and descriptors added to improve clarity and simplicity. Items of the improved OA GO AWAY Journal were categorized into 4 domains: (1) 'Top 3 activities that are difficult due to my OA that I would like to improve'; (2) 'Other possible impacts of my OA'; (3) 'My fitness and weight measures'; and (4) 'Treatment for my OA pain'. Participants felt that goals should be removed from the Journal and a separate "Goals and Action plan" page was created to act as a bridge' between the Journal and Exercise log.

Conclusion: Modifications to the OA GO AWAY based on patient and expert feedback have led to an improved OA GO AWAY with adequate face

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and content validity. Next steps will assess construct validity and test-retest reliability to ensure that the journal and exercise log helps motivate patients to monitor their disease and exercise behaviours.

45

The Comparative Effectiveness of Oral Methotrexate versus Subcutaneous Methotrexate for the Treatment of Early Rheumatoid Arthritis

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Objective: To determine the comparative effectiveness of subcutaneous (sc) versus oral methotrexate (MTX) as initial therapy for patients with early rheumatoid arthritis (ERA) in routine clinical care.

Methods: Patients with early inflammatory arthritis initiating methotrexate therapy were included from the Canadian Early Arthritis Cohort (CATCH), a multicenter, prospective cohort study of patients with ERA. In CATCH, patients are treated at the discretion of the rheumatologist and followed every 3 months over the first year according to a standardized protocol. For this study, all patients had an age >16 years, a diagnosis of RA by 2010 criteria, symptom duration < 1 year, used MTX within 3 months of study entry and were MTX-naive or minimally exposed to MTX. The exposure was route of MTX (oral vs. sc) and the outcome was DAS-28 over the first year (3, 6, 9, 12 months). A generalized estimating equation (GEE) model was used to account for repeated measures within patients while adjusting for potential confounders: age, gender, comorbidities, smoking, education, symptom duration, serological status, erosions, baseline DAS-28, functional status (HAQ-DI), and other concurrent disease-modifying antirheumatic drugs (DMARD) or corticosteroids. The analysis was performed with and without adjusting for the starting dose of MTX.

Results: 653 patients were included (442 oral MTX, 211 sc MTX); mean age 54 (SD 14), 72% female, mean symptom duration 5.3 (SD 2.7) months, mean baseline DAS-28 4.6 (SD 1.2). Patients treated with sc MTX were more likely to have erosions at baseline (35% vs. 25%, p=0.01), were less likely to receive other DMARD (38% vs. 58%, p< 0.01), and had a higher median starting dose of MTX (25 mg vs. 15 mg, p< 0.01). Other characteristics were similar between groups. In the GEE model, after adjusting for all potential confounders except starting dose of MTX, sc MTX was associated with a reduction in the average DAS-28 score over the first year of 0.23 [(95%CI:0.08, 0.38), p< 0.01]. After adjusting for starting dose, the route of MTX (oral/sc) was no longer significant (p=0.22), but for each additional mg of MTX, the average DAS-28 decreased by 0.02 [(95%CI:0.004, 0.03), p=0.02].

Conclusion: Sc MTX was associated with lower DAS28 scores over the first year of treatment, which may be mediated through the higher starting dose used in clinical practice.

46

Family Physician's Perceptions of Academic Detailing for Rheumatoid Arthritis

Harpreet Chhina (Arthritis Research Center Of Canada, Richmond); Wendy Hall (UBC School of Nursing, Vancouver); Janusz Kaczorowski (University of Montreal, Montreal); Diane Lacaille (Arthritis Research Centre, University of British Columbia, Vancouver)

Objective: To understand family physicians'(FP) perceptions toward the use of Academic Detailing (AD) for the management of rheumatoid arthritis (RA); specifically, its usefulness, acceptability and feasibility. AD involves trained healthcare professionals, such as pharmacists, or visiting physicians in their offices, to provide evidence-based information on a selected topic. We used AD to update FP about recent changes in the management of RA.

Methods: A mixed methods design incorporating a survey and a qualitative descriptive component was used. All FPs who received AD about RA, as part of an AD intervention study, were invited to participate. The survey, sent two weeks after AD visits, asked FPs to rate various aspects of the AD visit using a 10 point scale from 1 (not at all) to 10 (extremely). All FPs who completed the survey were invited to participate in a semi-structured telephone interview. Interviews were conducted until analysis indicated data saturation and were analyzed independently by two researchers using inductive content analysis.

Results: Of the 28 FPs who received AD, 23 completed the survey. AD for RA was generally well accepted by participating FPs. It was perceived as useful [mean (SD): 8.3(1.6)], providing high educational value [mean (SD): 8.2(1.3)], and convenient [median (IQR): 9.0(1.5)]. The topic (management of RA) was rated as relevant to their practice [mean (SD): 8.3(1.7)]. FPs described improved confidence [median (IQR): 8.0(1)], willingness to participate in AD again [Median (IQR): 9(1.5)], and 87% expected to make practice changes. Twelve FPs participated in the qualitative component. The qualitative analysis indicated that FPs highly appreciated AD for its educational value, convenience, short duration, and one-on-one interaction. They valued being provided with a focused, evidence-based review of the topic, with input from subject experts, as well as practical information about managing RA. Having a pharmacist as the academic detailer was acceptable to all FPs in our study, especially because the topic focused on medication use. Disadvantages revealed included difficulty incorporating AD during FP work days, lack of dedicated CME time and time for detailed discussion, the standardised nature of the message delivered, and difficulty finding time to consult information left by the detailer.

Conclusion: AD was perceived by the participating FP as a useful, acceptable, and feasible CME technique to receive information about the management of RA. Whether AD will translate into actual practice changes and will lead to optimized care remains to be evaluated in an effectiveness study.

47

Adalimumab-associated Antiphospholipid Syndrome: A Case Report and Review of the Literature

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Objective: Presentation of the first reported case of adalimumab-associated antiphospholipid syndrome (APS). Review of the literature on adalimumab-induced vasculitis and APS.

Methods: A case of APS associated with adalimumab use in a 67-year-old woman is reported. The English medical literature was reviewed for anti-tumor necrosis factor (TNF) agents and their association with APS and vasculitis.

Results: Adalimumab is a fully humanized monoclonal antibody targeted against TNF-α that is widely used in the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, and Crohn's disease (CD). Literature review reveals several cases of anti-TNF-induced vasculitis including cases associated with adalimumab. We report the first case of adalimumab-induced APS in a 67-year-old woman who developed APS and vasculitis associated with de novo positive anti-cardiolipin (aCL) antibody following the third dose of adalimumab therapy for the treatment of spondyloarthropathy.

Conclusion: This is the first case demonstrating that a short course of adalimumab therapy may induce immunoglobulin M (IgM) aCL autoantibodies leading to APS. With the growing use of anti-TNF medications in immune-mediated and inflammatory diseases, adalimumab and other anti-TNF medications should be considered as a possible explanation for APS.

48

Comparison of Anatomic Knee Alignment on Physical Examination and Radiographs.

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Objective: The aim of this study was to evaluate: 1) the correlation of knee alignment angle measured by goniometer on physical examination with the anatomic angle measured on knee radiographs and 2) whether the relationship is confounded by clinical variables that may affect goniometric measurements.

Methods: A simple random sample was selected from the MoDEKO (Model for the Diagnosis of Early Knee Osteoarthritis) cohort, cohort of people with knee pain, age 40-79. Knee alignment was measured to the nearest degree by: 1) anatomic-axis on fixed-flexion PA knee radiographs and 2) standardized goniometer assessment on physical examination. Varus was defined as angle < 0, valgus > 0 and 0º as neutral. Anatomic axis was defined by the intersection of two lines originating from points bisecting the femur and tibia and converging at the centre of tibial spine tips. Inter- and intra-rater reliability of anatomic angle measurements from radiographs were determined by intraclass correlation coefficient (ICC) of two independent assessors. The correlation of radiographic anatomic angle with goniometer measurements was analyzed by linear regression. Western Ontario and McMaster Universities (WOMAC) pain score, body mass index (BMI), and flexion contracture were assessed as potential confounders. Analysis was weighted by stratum sampling weights.

Results: Of 120 subjects, 52% were male, with mean (SD) age of 58 (11) years and BMI of 27 (5). The mean (SD) angle measured on PA radiographs and goniometer were 2 (3.6) and 3 (2.3) degrees respectively. Intra- and inter-rater ICC for radiographic measurements were 0.93 and 0.83 respectively. A significant correlation was found between radiographic and goniometer measurements ($r = 0.48$; $P < 0.0001$). A model was developed to predict anatomic angle based on goniometer angle: anatomic angle on PA radiographs = 0.410 + 0.749*goniometer angle. WOMAC pain score, BMI and flexion contracture were not significantly associated with PA radiographic angle and did not significantly change the correlation of radiographic and goniometric measurements, and were dropped from the model.

Conclusion: In this study, knee alignment assessed by goniometer was significantly correlated with the anatomic axis angle on PA knee radiographs. Factors such as pain, BMI, and flexion contracture did not confound the relationship of goniometric with radiographic angle measurements. Given the ease of application, goniometric measurements may be preferable to radiography, although the predictive utility of goniometric alignment measurement will require further assessment in longitudinal studies of knee OA.

49

IgG4-related Hypertrophic Pachymeningitis: A Case Report

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Objective: We present a case of IgG-4 related disease presenting as spinal hypertrophic pachymeningitis that was successfully treated with prednisone and methotrexate.

Methods: A 58-year old woman presented with interscapular pain and diffuse numbness from the breast region distally developing over two months. Her history was significant for hypertension, dyslipidemia, and hypothyroidism.

Results: Physical examination revealed increased knee jerks, upgoing plantar responses, and clonus bilaterally. Proprioception and vibration were reduced at the right first toe. Pinprick sensation and motor testing were normal. MRI of the spine with gadolinium showed an enhancing circumferential dural thickening from C7 to T7. A month later, she developed progressive leg weakness. She underwent a laminectomy from T2 to T4 with excision of a hypertrophic dural lesion which resulted in resolution of symptoms. Initial pathology was consistent with idiopathic hypertrophic pachymeningitis. Malignancy and infectious workup was negative. Ten months post operatively, she developed recurrence of symptoms including back pain, numbness and lower extremity weakness. MRI at that time showed progression of the dural based mass with cord compression and spinal canal stenosis. She was referred to us for assessment of a possible rheumatologic condition. Rheumatologic review was unremarkable. The examination demonstrated some residual neurologic deficits. Laboratory investigations showed increased ESR (22 mm/h), and positive RF (60 KIU/L), c-ANCA with anti-MPO antibodies (100 AU/mL). Anti-CCP, anti-PR3 antibodies, p-ANCA, and ANA were negative. CRP, complement levels, CBC, creatinine, LFTs, CK, TSH, immunoglobulins (IgG, IgA and IgM), and serum IgG4 level were normal. ACE level was not elevated. Despite positive serology, she had no clinical evidence of an autoimmune or vasculitic process. Further immunohistochemical staining of the initial pathology specimen revealed a moderate number of IgG4+ plasma cells predominantly in foci of active inflammation. Prednisone was started at 40 mg b.i.d and methotrexate was subsequently added. Three months later, she was symptom-free with significant radiologic improvement.

Conclusion: IgG4-related disease is a new clinicopathologic entity frequently affecting pancreas, salivary glands, and lacrimal glands. Hypertrophic pachymeningitis is an uncommon disorder which has been associated with infections, malignancies, and several rheumatologic disorders including granulomatosis with polyangiitis, rheumatoid arthritis, and sarcoidosis. We report a rare manifestation of IgG4-associated disease, namely hypertrophic pachymeningitis. Only a few cases of spinal involvement have been reported in the literature. Response to steroids and other immunosuppressants is variable but generally favorable. The recognition of this rare manifestation is therefore of great clinical significance.

50

Is there a Scleroderma Care Gap?

Jason Reed (London); Janet Pope (University of Western Ontario, London)

Objective: To determine if there is a care gap in systemic sclerosis (SSc, scleroderma) in Canada.

Methods: Information relating to demographics, complications, investigations, and treatment of SSc patients was obtained from online survey responses, and chart audits of members of the Canadian Rheumatology Association (CRA). Results were compared to data from a SSc database (Canadian Scleroderma Research Group; CSRG).

Results: Overall, the online survey (61 respondents of about 300 members) revealed high positive response rates of >60% for most SSc guidelines regarding screening and treatment. Some exceptions to this were that only 47% of respondents order annual echocardiograms, and 45% order annual pulmonary function tests. Chart audits of 70 SSc patients from 7 practices revealed that there were no significant differences in the treatment practices of physicians in the CRA or CSRG groups. There was a high degree of site variability among the CRA centres relating to investigations, SSc-related complications, and treatment practices. Patients receiving an annual echocardiogram varied from 10-90% depending on the site, and PA pressure was recorded in the echocardiogram report in 30-100% of cases. Overall, 91% of SSc patients seen by CRA had ever received an echocardiogram, but in 30% of cases there was no PA pressure recorded.

Conclusion: Members of the CRA generally provide a good standard of care despite the fact that they do not see many SSc patients when compared to the CSRG experts. However, one major care gap that was discovered is that although echocardiograms are being ordered, PAH is not being effectively detected.

51

Physician Global Assessment at Three Months is Strongly Predictive of Disease Activity at 12 Months in Early Rheumatoid Arthritis. Results from the CATCH Cohort

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(University of Montreal, Montreal); Carol Hitchon (University of Manitoba, Winnipeg); Carter Thorne (Southlake Regional Health Care, The Arthritis Program, Newmarket); Edward Keystone (University of Toronto, Toronto); Janet Pope (University of Western Ontario, London)

Objective: To determine predictors of remission at 12 months in patients with early rheumatoid arthritis (ERA) at baseline and 3 months to predict as early as possible who will be in remission.

Methods: Data from the Canadian Early Arthritis Cohort (CATCH) were included if the patient had baseline, 3 and 12 months data. Regression analyses for different definitions of remission were done to determine factors associated with remission at one year and included in the analyses if P< 0.1 in univariate analyses.

Results: Of 1842 patients with ERA, full dataset ranged from 522 to 579 patients for the different remission outcomes [Boolean based ACR/EULAR definition, DAS28< 2.6, Clinical Disease Activity Index (CDAI)< 2.8, Simplified Disease Activity Index (SDAI)< 3.3]. The mean age was 52.6 years (SD 15.5), disease duration 6.2 months (SD 4.1), 73% were female. The factors at baseline associated with all four remission outcomes at 12 months were age, gender, tender joint count (TJC), physician global assessment (MDGA), patient global assessment (PTGA), health assessment questionnaire (HAQ) and pain. Erythrocyte sedimentation rate (ESR) at baseline was associated with DAS28 remission only and swollen joint count (SJC) was associated with CDAI and SDAI remission. The factors at 3 months associated with all four remission outcomes were age, gender, TJC, SJC, MDGA, PTGA, HAQ, pain, ESR and C-reactive protein (CRP) in univariate analyses. In the regression model, the variables independently associated with SDAI remission were MDGA (OR 0.76, p< 0.001), pain (OR 0.86, p=0.008), HAQ (OR 0.49, p=0.010), and age (OR 0.98, p=0.043). The variables associated with CDAI remission status were MDGA (OR 0.73, p< 0.001), pain (OR 0.87, p=0.009), and HAQ (OR 0.52, p=0.013). DAS28 remission at 12 months was associated with ESR (OR 0.95, p< 0.001), MDGA (OR 0.78, p< 0.001), age (OR 0.97, p=0.001), HAQ (OR 0.54, p=0.002), and male gender (OR 1.99, p=0.007), whereas Boolean remission status were associated with PTGA (OR 0.75, p< 0.001), MDGA (OR 0.83, p=0.007), and HAQ (OR 0.49, p=0.015).

Conclusion: A low MDGA measured at 3 months was consistently associated with remission at 12 months in early RA using all remission criteria. It appears that rheumatologists can predict remission at 12 months by the 3 months assessment. This has implications for treatment in early RA, as conversely a high MDGA will be predictive of lack of remission and thus at 3 months therapy should be altered to improve the chance of remission.

52

Treatment on Healing and Prevention of Digital Ulcers in Systemic Sclerosis: Results from a Metaanalysis

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Objective: To assess the efficacy of therapies in healing and preventing digital ulcers (DU) in systemic sclerosis (SSc).

Methods: MEDLINE and EMBASE databases and ACR and EULAR abstracts were searched. Randomized controlled trials (RCT) with 1) outcomes investigating healing or prevention of DU in SSc and 2) comparing a pharmacological therapy with placebo or an active agent were included. The pooled risk ratios (RR) using the fixed-effects model was calculated and heterogeneity was tested using the I^2 statistic.

Results: Sixty studies were found; 19 were not randomized, 10 did not give DU quantitative data or no comparison of a different drug, leaving 31 RCT with 1989 patients. Quality was 3/5 or less for 11 trials. DU were not the primary outcome in many RCT. Phosphodiesterase type 5 (PDE5) inhibitors were significant for DU healing (RR 3.28 [95% CI 1.32,8.13]; p=0.01). Two large bosentan trials were significant for mean number of new DU (standard mean difference [SMD] -0.34 [-0.57, -0.11]; p=0.004). Prostacyclins were not statistically different from placebo, but IV iloprost prevented new DU (SMD-0.77 [-1.46, -0.08]; p=0.03). Single trials for atorvastatin and vitamin E were positive in the prevention and healing of DU, respectively. There were many negative trials: antiplatelet therapy, heparin, dimethyl sulfoxide (DMSO), ketanserin, prazosin, prostaglandin E1 (PGE1), cyclofenil, quinapril, oral N-acetylcysteine (NAC), and topical nitroglycerin formulation.

Conclusion: Small sample sizes, few comparative trials, and heterogeneity limits the conclusions. The results suggest a role for PDE5 inhibitors in the healing of DU; bosentan, IV iloprost, and atorvastatin may prevent new DU.

53

Patterns of Venous Thromboembolism Regimen Use for Patients Undergoing Knee or Hip Arthroplasty: A National Cohort Study

Jasvinder Singh (University of Alabama at Birmingham, Birmingham)

Objective: Due to differing recommendations from the American Academy of Chest Physicians and American Academy of Orthopedic Surgeons, there is a huge controversy regarding the choice of venous thromboembolism (VTE) prophylaxis regimen for patients undergoing total knee or total hip arthroplasty (TKA/THA). We investigated the variation in practice regarding the use of various VTE prophylaxis regimens among a national sample of veterans undergoing elective TKA/THA.

Methods: This retrospective study used the national Veterans Affairs (VA) administrative and clinical databases claims from fiscal years 2002 to 2010, to define the joint replacement cohort, using the presence of Common Procedure Terminology (CPT) codes for TKA/THA. The outcome of interest was the proportion receiving various VTE prophylaxis regimens within 30 days of indexes elective TKA/THA. VTE prophylaxis were defined as (1) low molecular weight heparins (LMWH); (2) coumadin; (3) unfractionated heparin; (4) indirect inhibitors of factor Xa such as fondaparinux; or (5) aspirin.

Results: The elective primary TKA and THA cohorts consisted of 41,764 and 22,049 patients, respectively. Mean age (standard deviation) was 64.1 (9.8) and 62.7 (11.1) years, 94% and 96% were male; 83% and 78% were white, 14% and 20% were African American and 3% and 2% were other race category, respectively. Mean Charlson index score (standard deviation) was 0.54 (0.9) and 0.56 (1.0). The mean (standard deviation) length of hospital stay was 6.4 (10.8) days and 7.7 (29) days, respectively. The use of various VTE prophylaxis among patients who underwent elective TKA were as follows: LMWH, 40.6%; coumadin, 17%; unfractionated heparin, 10.1%; indirect inhibitors of factor Xa (fondaparinux etc.), 3.4%; and aspirin, 28.9%. Similarly, VTE prophylaxis among patients who underwent elective THA was LMWH, 40.4%; coumadin, 18%; unfractionated heparin, 10.7%; indirect inhibitors of factor Xa (fondaparinux etc.), 3.4%; and aspirin, 27.4%.

Conclusion: To our knowledge, this is the first study of describing the use of various VTE prophylaxis regimens in a national cohort of veterans undergoing elective joint replacement surgery. This wide variation in use of VTE prophylaxis regimens is troubling. Further studies need to examine the factors associated with this wide variation and to assess the comparative effectiveness and safety of these VTE regimens.

54

Prevalence and Factors Associated with Venous Thromboembolism in Patients Undergoing Knee or Hip Arthroplasty: A Study Using National Veterans Affairs Data

Jasvinder Singh (University of Alabama at Birmingham, Birmingham); Sandre McNeal (Birmingham)

Objective: Venous thromboembolism (VTE) is an uncommon but serious complication following total knee or total hip arthroplasty (TKA/THA). We studied the risk of 30-day VTE among a national sample of veterans undergoing elective primary TKA/THA.

Methods: This retrospective study used the national Veterans Affairs (VA) administrative and clinical databases claims from fiscal years 2002 to 2010

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to define the joint replacement cohort, using the presence of Common Procedure Terminology (CPT) codes for TKA/THA. The outcome of interest was the proportion with VTE within 30 days of index elective TKA/THA.

Results: The elective primary TKA and THA cohorts consisted of 41,764 and 22,049 patients, respectively. Mean age (standard deviation) was 64 (10) and 62.7 (11) years, 94% and 96% were male; 83% and 78% were white, 14% and 20% were African American, and 3% and 2% were other race category. Charlson index distribution was as follows: Zero, 62% and 64%; 1, 27% and 24%; 2, 8% and 8%; 3 or more, 3% and 4%. The mean (standard deviation) length of hospital stay was 6.4 (10.8) days and 7.7 (29) days. In the primary elective TKA cohort, there were 175 patients with pulmonary emboli (PE; 0.42%) and 1390 with deep venous thrombosis (DVT; 3.33%), leading to a total of 1548 (3.71%) with VTE (DVT and/or PE). Compared to elective TKA patients without VTE, patients with any VTE were older (66.6 vs. 64.0 years, p< 0.001), had a longer hospital length of stay (8.7 vs. 6.3 days, p< 0.001), and higher Charlson index (0.8 vs. 0.5, p< 0.0001). In the primary elective THA cohort, there were 65 patients with PE (0.29%) and 925 with DVT (4.2%), leading to a total of 962 patients (4.45%) with VTE (DVT and/or PE). Compared to elective THA patients without VTE, patients with any VTE were older (65.7 vs. 62.6 years, p< 0.001), had a longer hospital length of stay (11.1 vs. 7.6 days, p=0.002), and higher Charlson index (0.9 vs. 0.5, p< 0.0001).

Conclusion: This study provides the estimates of VTE in veterans undergoing elective TKA or elective THA. Studies need to define which pre-existing disease conditions are associated with higher VTE risk and whether optimal preoperative disease management can further reduce the risk of this rare complication.

55

Outcomes of Plasma Exchange for Antineutrophil Cytoplasm Antibody (ANCA) - Associated Vasculitis

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Objective: Microscopic polyangiitis (MPA), granulomatosis with polyangiitis (GPA), and Churg-Strauss Syndrome (CSS) are syndromes known as ANCA-associated vasculitis (AAV). In addition to immunosuppressive therapy, plasma exchange (PLEX) may be indicated in patients with pulmonary hemorrhage and/or renal insufficiency. However, PLEX may be associated with serious adverse effects such as infection. The objective of this study was to characterize and examine outcomes in patients with AAV treated with PLEX, in addition to corticosteroid and cytotoxic agents, at a major referral centre for PLEX in Ontario, Canada.

Methods: All patients with AAV treated with PLEX at St. Michael's Hospital (SMH), Toronto, Ontario, between January 1, 2002, to May 31, 2012, were studied. Patients with GPA, MPA, CSS, systemic p-ANCA vasculitis, and systemic c-ANCA vasculitis were included while those with incomplete charts were excluded. Demographic, clinical, laboratory, and radiographic data from electronic and paper medical records were collected. Acute kidney injury was defined as an increase in serum creatinine by ≥ 26.5 umol/l within 48 h, or a ≥ 1.5 times increase above baseline serum creatinine within 7 days. Disease activity was assessed by the Birmingham Vasculitis Activity Score (BVAS; v.3). Primary outcomes were survival at 1 year, endstage renal disease (ESRD) at 1 year, and ESRD at 3 months from initiation of PLEX. The study was approved by the SMH Research Ethics Board.

Results: Forty-nine patients with AAV were treated with PLEX at SMH during the study period. At the time of this submission, complete one year data were available on 27 patients. Twenty patients were transferred to the referring institution and 2 patients had incomplete records. 52% were female, and the median age was 55 years (range 25-83 years). GPA, MPA, CSS, systemic p-ANCA vasculitis, and systemic c-ANCA vasculitis was the primary diagnosis in 44.5%, 37.0%, 0%, 11.1%, and 7.4% of patients, respectively. This was the first presentation of AAV for 81.4%. Both pulmonary hemorrhage and acute kidney injury were present in 77.8%. The mean BVAS (v.3) score at presentation was 18.2. Triple therapy with systemic corticosteroid, cyclophosphamide, and PLEX occurred in 79.3%. Survival at 1 year, ESRD at 1 year, and ESRD at 3 months was 81.5%, 18.5%, and 18.5%, respectively.

Conclusion: This preliminary analysis indicates that the majority of patients with AAV who were treated with PLEX survived at least 1 year after the initiation of PLEX. Further, over 80% remained dialysis-independent after 1 year. Analyses are ongoing.

56

Incidence of Non-Melanoma Skin Cancers in Patients on Biologic Therapy

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Objective: The use of tumor necrosis factor α (TNF-α) antagonist therapy has been previously shown to be associated with an increased risk of non-melanoma skin cancer (NMSC) in a cohort of veterans with rheumatoid arthritis (RA). We hypothesized that this finding could be found in a broader range of patients of age and gender, and with other indications for anti-TNF-α therapy, including inflammatory bowel diseases (IBD).

Methods: A retrospective study reviewed 131 patient charts with inflammatory diseases in rheumatology and gastroenterology. A chart review was conducted with 68 patients in the control group (non-biologic) and 63 in the treatment group (taking TNF-α inhibitors) while data for a few patients were incomplete. The cohort for this study included 77 females and 52 males. Survival analyses were used to determine incidence rates for NMSC. Besides the combined analysis of rheumatologic and gastroenterology patients, individual analyses were also performed to explore associations between use of TNF-α inhibitors, other medications, and development of NMSC.

Results: Patients' data were analyzed for a maximum of 11 years with a mean follow up of 2.03 years for the treatment group. In all, 5 patients were identified with skin cancer. Data for the treatment group (biologics) was analyzed individually as well as with the control (non-biologics) group. No significant NMSC risk was found among individuals on TNF inhibitors (p>0.5).

Conclusion: No significant NMSC risk was found among individuals on TNF inhibitors (p>0.5) in this small Saskatchewan cohort.

57

Disease-modifying Agents Combined with Isoniazid for Latent Tuberculosis in Patients with Rheumatic Diseases

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Objective: Reactivation of latent tuberculosis (LTB) has been described with the use of anti-TNF for the treatment of rheumatic diseases. Combined treatment of isoniazid (INH) and disease-modifying antirheumatic drugs (DMARD) such as methotrexate (MTX) and sulfasalazine (SSZ) can potentially increase the risk of liver toxicity. The goal of this study was to investigate the risk of liver toxicity in rheumatic patients taking isoniazid (INH) and DMARD or biologics.

Methods: We reviewed the Institut de Rhumatologie de Montréal database (RhumaData) for rheumatic patients with positive tuberculin skin test who took INH and at least one concomitant DMARD or biologic between August 2001 and April 2011. Liver function tests (LFT) were tested at baseline and during therapy.

Results: Of 922 patients screened with tuberculin skin test, 87 patients tested positive and received INH. During INH treatment, 75.9% were taking concomitant DMARD (71.3% MTX, 19.5% hydroxychloroquine (HCQ), 5.7% SSZ, 3.4% leflunomide), 82.% were taking concomitant biologics, and 46.0% were using nonsteroidal antiinflammatory drugs on a regular basis. Twenty-four percent had abnormal liver enzymes during INH therapy. Most of them were mild or transient, but 8% (7 patients) had

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significant abnormalities leading to INH discontinuation. Among these patients, mean (min, max) was 241 (52, 617) for AST and 262 (92, 669) for ALT. Concomitant medications taken by patients who stopped INH were biologics (4 patients), MTX (1), biologic and MTX (1), biologic, leflunomide, and HCQ (1).

Conclusion: The use of INH for LTB was generally well tolerated in patients with rheumatic diseases on a background regimen of DMARD or biologics. However, the rate of significant abnormalities is our study is higher than the reported rates for INH hepatitis in the literature. Therefore, it is prudent to follow LFT closely in patients taking combination therapy.

58

Telephone Consultation Usage in a Pediatric Rheumatology Clinic: Considerations in Optimizing Nursing Resources

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Objective: Telephone consultation is essential to the delivery of patient care in the ambulatory care clinics at the Children's Hospital of Eastern Ontario (CHEO). Our objective was to quantify and analyze all telephone calls received by the pediatric rheumatology nurses at CHEO.

Methods: As per CHEO policy and procedure, all telephone calls nurses receive are documented on standard forms. Calls documented by the nursing staff in the Division of Pediatric Rheumatology over a six-month period from Jan 1, 2012, until June 30, 2012, were retrospectively analyzed for selected characteristics. An incoming call addressing a new concern relating to a specific patient was considered to be the index call. Index calls and all subsequent documented communications generated by the index call, both outgoing if initiated by the nurse and incoming if received by the nurse, were then examined. Calls that only confirmed appointments and calls confirming that a message was received were excluded from analysis.

Results: 321 index calls were received during the study period (0.6 calls per clinic hour), generating a total of 780 follow-up calls. The most frequent patient diagnosis was juvenile idiopathic arthritis (57%) and most patients were 12-18 years old (52%). 79% of calls were placed by the patient's mother, while only 1% of callers were the patient themselves. 44% of calls lasted 1-5 minutes, 29% lasted 5-10 minutes and 27% lasted more than 10 minutes. The most common reasons for calls were concerns relating to rheumatologic condition and medications taken (50%). Large number of calls was related to administrative issues such as requests for appointment change, prescription refills, etc (34%). Pain management was discussed in 29% of all calls. Nurses managed independently 40% of calls; when other healthcare providers were consulted, the physician was approached in 91% of cases. Only 8% of index calls resulted in an advanced clinic appointment.

Conclusion: This study provides a descriptive analysis of calls nurses receive in a tertiary care pediatric rheumatology clinic. While nursing telephone consultation is beneficial in providing interdisciplinary patient care and in minimizing clinic visits, the associated workload is significant and utilization of this service needs to be optimized, including redistribution of administrative calls. Teenage patients rarely call themselves and their independence needs to be encouraged.

59

Optimal Care of Rheumatoid Arthritis and Spondyloarthropathies: A Road Going Through Enhanced Collaboration and Communication for Canadian Rheumatologists

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Objective: To identify the clinical practice gaps and educational needs of Canadian healthcare providers (HCP) who care for patients with rheumatoid arthritis (RA) and spondyloarthropathies (SpA), to mitigate risk of bias in the development of evidence-based educational interventions.

Methods: An institutional review board-approved needs assessment study was designed and deployed nationally. A review of existing literature, combined with insights from faculty and field liaisons interfacing with HCP on a regular basis, informed the development of two 15-minute online surveys: one deployed to HCP involved in the care of RA/SpA patients, and the other deployed to RA/SpA patients and their caregivers. Source triangulation (i.e., patients and providers) was used to increase reliability and validity of the findings.

Results: A total of 115 HCP participated in the study (50 rheumatologists, 47 nurses, and 18 internists). Additionally, patient survey was completed by 52 patients and 2 caregivers. Six key gaps were identified. (1) 67% of rheumatologists reported a lack of confidence in having an informed discussion with radiologists about MRI results, and 50% of them acknowledge a challenge in ordering the proper MRI sequence. (2) Rheumatologists lack confidence in prescribing biologics to special populations (immunocompromised, high cardiovascular risk), and reported challenges in communicating risks and longterm safety to the patients, due in part to a lack of specific knowledge. (3) Rheumatologists struggle with the management of patients' psychosocial issues, and perceive limited community resources to support their patients in that regard. (4) 45% of Rheumatologists reported rarely discussing missed work time or reduced on-the-job effectiveness with their patients, and 50% of patients cited poor quality of discussion on these topics. (5) A lack of follow-up on the education provided to patients was identified by Rheumatologists, and confirmed by patients, as 64% reported rarely being asked if they read and understood the materials received. (6) Primary care providers experience challenges in recognizing early symptoms of RA/SpA, which translates to delayed referrals, and patients not benefiting from timely initiation of treatment.

Conclusion: This needs assessment highlighted gaps that will allow for the development of evidence-based educational interventions to help improve patient outcomes. These could include interprofessional educational programs aiming to improve 1) providers' knowledge of biologic safety and use in special populations, 2) communication with patients on treatment decisions, psychosocial issues, and effect on work, as well as 3) collaboration and the referral process with primary care.

60

A Decision-making Needs Assessment and Acceptability Evaluation of a Stepped Decision Aid for Patients Considering Osteoarthritis Management Options

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Objective: To conduct a survey of decision-making needs and evaluate the acceptability of a newly developed osteoarthritis (OA) patient decision aid, which uses a stepped approach to present a wide spectrum of evidence-based interventions.

Methods: A decision making needs assessment survey was conducted with patients with knee or hip OA who had been faced with a treatment decision in the past six months. A standardized needs assessment was adapted and used to gather patients' experiences and needs when making a treatment decision for their OA. Based on the International Patient Decision Aid Standards, the stepped approach decision aid was created to respond to those needs and subsequently was assessed by patients with OA. Acceptability outcomes measured included appropriateness and clarity of

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the information provided by the decision aid, helpfulness in clarifying patients' values, and helpfulness for making an informed decision.
Results: Seventeen patients aged 44 to 84 years, with a mean disease duration of 9 years, completed the needs assessment. Needs assessment participants were uncertain about a treatment decision made in the past six months (65%) and felt they were not able to take part in their health care in their preferred ways (59%). These participants also felt that they would need information about pharmacologic and non-pharmacologic therapies for OA, as well as assistance in determining their values, and guidance throughout the decision-making process in the form of a booklet and discussions with their doctor, to make a future treatment decision. Fifty patients aged 45 to 84 years, with a mean disease duration of 12 years, reviewed the decision aid. Participants exposed to the decision aid thought that it presented the appropriate amount of information in a clear manner (56%), helped them to clarify their values (85%) and make an informed decision (75%).
Conclusion: This stepped decision aid encompassing multiple interventions is a unique adaptation of conventional decision aids. Patients rated it as helpful for clarifying their values and making an informed decision. Feedback can be used to enhance clarity of the information presented on treatment options. We anticipate that more formal evaluations will indicate that it will assist patients and their providers in making a shared decision for OA management.

61

Preliminary Validation of the "Which Health Approaches and Treatments are you using?" (WHAT) Questionnaires: A Multi-dimensional Assessment of Complementary and Alternative Medicine use in Children with Juvenile Idiopathic Arthritis

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Objective: Complementary and alternative medicine (CAM) is commonly used by children with juvenile idiopathic arthritis (JIA), yet no validated questionnaires exist to assess that use. The objective of this study was to determine face and content validity of the newly developed child self- and parent proxy-report "Which Health Approaches and Treatments are you using?" (WHAT) questionnaires to provide an assessment of CAM use in pediatric rheumatology.
Methods: A purposive sample of 20 children with JIA (8 to 18 years, mean age=13.4 years, mean disease duration=7.5 years, 20% of children with active joint inflammation) and their parents was recruited at the Children's Hospital of Eastern Ontario and the Hospital for Sick Children to participate in cognitive interviews of the self- and proxy-report WHAT questionnaires, respectively. A sample of 20 Canadian pediatric rheumatology experts was also selected to review both questionnaires. Patients, parents and experts were independently asked about the goal, understandability and comprehensiveness of the WHAT questionnaires, as well as the relevance of each domain and item. Relevance of the items was rated on a three-point scale ("essential", "useful but not essential" or "not necessary") and the content validity ratio (CVR) was computed to decide which items to include. The CVR ranges from -1 to 1, higher scores indicating a higher percentage of raters who thought the item essential, the minimum acceptable score being of 0.29 with our sample size.
Results: All participants were able to understand the purpose of the questionnaires. A total of 12 out of 17 items showed adequate content validity in the parent proxy-report questionnaire, including items from each domain: types of CAM used by the child in the past two weeks (CVR=0.89), reasons for CAM use (CVR=0.63), CAM benefits and harms (CVR=0.69), conventional care adherence (CVR=1) and communication about CAM with conventional care providers (CVR=0.76). Items showing inadequate validity include difficulty in accessing CAM (CVR=-0.27) and modes of payment for CAM (CVR=-0.09). In the child report questionnaire, 7 out of the 11 items were agreed upon by children and experts, with children's ratings being lower than those of experts for items showing inadequate validity (family communication about CAM (CVR=-0.15) and the CAM decision-maker (CVR=0.19)).
Conclusion: Modifications to the WHAT questionnaires have helped ensure adequate face and content validity. Further rigorous validity and reliability testing across two Ontario clinical pediatric rheumatology settings will ultimately improve the quality of CAM research, as well as knowledge translation about CAM in clinical practice.

62

Celecoxib Induced Change in Atrial Electrophysiologic Substrate in Arthritis Patients

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Objective: Cyclooxygenase-2 inhibitors, the newest class of nonsteroidal antiinflammatory drugs (NSAID), have equivalent efficacy and improved side effect profile compared with non selective NSAID. However, they pose an increased risk of adverse cardiovascular events. A large Danish population based case-control study reported an association between NSAID and the development of atrial arrhythmias such as atrial fibrillation (AF) and flutter. Patients at highest risk of AF development were taking a selective COX-2 inhibitor. We hypothesized that the potent COX-2 inhibitor celecoxib alters atrial electrophysiology and thus promotes the development of atrial fibrillation.
Methods: Using a prospective design, three cohorts were created: Healthy patients (n=35), inflammatory arthritis patients with no celecoxib use (n=22), and inflammatory arthritis patients treated with celecoxib (n=20). Patients were included in the arthritis cohorts if they were over the age of 18 and had a diagnosis of inflammatory arthritis. Patients in the celecoxib group must be actively treated with celecoxib for more than 2 months. Patients were excluded if they were taking antiarrhythmic medication, had a diagnosis of atrial fibrillation, refractory hypertension or congestive heart failure. High resolution signal averaged electrocardiogram was recorded and through a previously validated algorithm, p wave duration (PWD) was derived.
Results: PWD was significantly increased in inflammatory arthritis patients treated with celecoxib, as compared to both healthy and inflammatory arthritis patients (p=0.025). There was no difference in the PWD of healthy patients as compared to inflammatory arthritis patients (p>0.05). Mean PWD (standard error of the mean) of the inflammatory arthritis patients treated with celecoxib was 133.1 (2.7) msec as compared to 125.5 (1.7) msec in the healthy patients and 124.0 (2.9) msec in the inflammatory arthritis patients.
Conclusion: This is the first study to demonstrate a significant change in cardiac markers directly associated with celecoxib use. Given that p wave duration is a well-accepted non-invasive marker of atrial electrophysiology, our results show that celecoxib produces a change in atrial substrate. The prolongation of PWD is correlated with slowed atrial conduction velocity and can be used to predict the development of atrial fibrillation. Thus, our observed changes in atrial electrophysiology correlates well with the increased risk of atrial arrhythmia in patients treated with celecoxib.

63

ANCA-associated Vasculitis Incidence and Time to Diagnosis in Northern Saskatchewan

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Objective: Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitides are rare diseases characterized by inflammation of small blood

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vessel walls. Recent studies have suggested that the incidence of ANCA-associated vasculitis (AAV) is increasing. The objectives of this study were to estimate incidence of AAV in northern Saskatchewan and quantify diagnostic delays.

Methods: A retrospective file review was performed. As histology is usually required to confirm the diagnosis of AAV and renal biopsy is the most common site from which a biopsy is acquired, we used a pathology database to select our cases. Renal biopsies done from January 1, 2007, to December 31, 2011, were examined for results consistent with AAV. Chart review was then done to confirm the diagnosis in accordance with the Chapel Hill Consensus Conference definitions (1994). The study was conducted in the city of Saskatoon, one of two tertiary centers in Saskatchewan. It is estimated that Saskatoon's tertiary referral center serves 600,000 patients.

Results: 51 patients were identified with renal biopsies performed in Saskatoon consistent with AAV within the study period. After chart review, 33 patients fulfilled study criteria. 13 cases (39.4%) were granulomatous polyangiitis (GPA), 20 (60.6%) were microscopic polyangiitis (MPA). We calculate an average annual incidence of 4.4/million for GPA and 6.8/million for MPA. The incidence of GPA was not significantly different between genders and age group. MPA was significantly more common in older women. Men and younger patients (50 years of age and under) presented with significantly higher Birmingham Vasculitis Activity Score totals. The average time from symptom onset to diagnosis from the chart review was 2.85 months.

Conclusion: We evaluated renal biopsy proven vasculitis in northern Saskatchewan. Initial calculations put Saskatchewan's incidence of AAV significantly below the incidence reported for other regions. However, as cases not evaluated by renal biopsy were not captured in this review, these incidence figures are almost certainly underestimates. The demographic variations between AAV categories observed in this study are consistent with previous reports in other populations. Our reported time to diagnosis was also comparable to other centres.

64

The Use of Antiplatelet Agents in the Prevention of Large Vessel Vasculitis-associated Ischemic Complications: A Metaanalysis

James Jeong (University of Western Ontario, London); Lillian Barra (London)

Objective: To determine the effectiveness of antiplatelet therapy at reducing ischemic events in patients with large vessel vasculitis.

Methods: We performed a random effects metaanalysis of studies examining antiplatelet and/or anticoagulant therapy (AP/AC) and ischemic events in large vessel vasculitis. Severe ischemic events were defined as stroke, ischemic ocular manifestations, and claudication symptoms. Any ischemic event included jaw claudication in addition to above manifestations. Quality of studies was assessed using the Newcastle Ottawa Scale.

Results: Seven studies met the criteria: 6 studies included data on giant cell arteritis (GCA), while 1 study included patients with Takayasu arteritis. Four of the studies were retrospective cohorts and three of the studies were cross-sectional studies. Four of the studies were of moderate to high quality, three were of low quality. Sample sizes ranged from 48 to 210 participants with a total of 265 patients receiving AP/AC therapy and 694 controls. The majority of patients (>90%) were treated with aspirin and in most cases of GCA (>75%) the AP/AC therapy was initiated prior to the diagnosis of vasculitis. The pooled OR for any ischemic event at the time of diagnosis in patients treated with AP/AC agents compared to no treatment was 1.06 (95% CI 0.58-1.95). For severe ischemic events the OR was 0.87 (95% CI 0.40-1.92). When accounting for baseline atherosclerotic risk factors, AP/AC was protective for any ischemic events: OR 0.34 (95% CI 0.13-0.92); as well as for severe ischemic events: OR 0.2 (95% CI 0.12-0.31). Followup data (2-7 years) was available in 3 of the studies. At followup, AP/AC treatment was protective for severe ischemic events: OR 0.08 (95% CI 0.02-0.41).

Conclusion: Antiplatelet agents appear to decrease ischemic events in patients with large vessel vasculitis. However, in most cases of GCA the treatment was initiated prior to the diagnosis of vasculitis. Available studies do not address whether initiating antiplatelet therapy at the time of GCA diagnosis is beneficial.

65

Antibodies to Homocitrullinated Peptides are Specific for Rheumatoid Arthritis and Cross-react with Anticitrullinated Peptide Antibodies

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Objective: Antibodies to citrullinated proteins/peptides (ACPA) are specific for rheumatoid arthritis (RA). Recently, it has been reported that antibodies to homocitrullinated proteins/peptides (AHPA) also occur in RA. Citrulline and homocitrulline are structurally similar. Both can be generated during inflammation, but by different processes. The purpose of this study was to determine whether RA patients have antibodies to different AHPA and whether ACPA and AHPA are cross-reactive.

Methods: Serum was obtained from patients who met ACR criteria for RA, psoriatic arthritis (PsA) or systemic lupus erythematosus (SLE) and were compared to healthy controls. It was tested against the following antigens: fibrinogen (fib), citrullinated fibrinogen (citfib), homocitrullinated fibrinogen (homocitfib), JED (a proprietary synthetic citrullinated peptide) and homocitrullinated JED (homoJED). Citrullination was done *in vitro* using peptidyl arginine deiminase enzyme (PAD2). Homocitrullination was done using potassium isocyanate. Both modifications were confirmed by mass spectrometry using ESI-MSMS and MASCOT server analysis. ACPA was purified by affinity chromatography using JED. Antibodies to the above antigens and cyclic citrullinated peptide 2 (CCP2) were detected by ELISA. Inhibition assays using fib and homocitfib were conducted by ELISA.

Results: The majority of RA patients (n=87) were anti-CCP2 positive (87%). 1/37 PsA patients and 2/37 SLE patients and none of the normal controls were anti-CCP2 positive. Of the RA patients, 50% expressed AHFA and 68% expressed anti-homoJED. AHPA were not detected in anti-CCP2 negative RA patients. None of the normal controls and < 5% of PsA and SLE were AHFA or anti-homoJED positive. All AHFA positive patients were also anti-CCP2 positive. Reactivity to homocitrullinated sites on fibrinogen was confirmed by inhibition assays: there was an increase of inhibition from 25-38% with unmodified fibrinogen up to 71-89% with the equivalent concentrations of homocitrullinated fibrinogen. Affinity-purified ACPA using a citrullinated peptide (JED) had reactivity to JED, anti-CCP2, as well as the homocitrullinated peptides, homoJED, and homocitfib.

Conclusion: Antibodies to homocitrullinated peptides/proteins are specific for RA. These antibodies bind citrullinated and homocitrullinated antigens, suggesting cross-reactivity and possible pathogenicity.

66

An Emerging Role for Clarithromycin in Adult-onset Still's Disease

Lisa Nguyen (University of Saskatchewan, Saskatoon); Regina Taylor-Gjevre (University of Saskatchewan, Saskatoon)

Case Report: Adult-onset Still's disease (AOSD) is an infrequently diagnosed systemic inflammatory disorder. This disease can often be confused with other diagnoses. AOSD typically presents with daily fevers, arthritis, and a characteristic skin rash. Given that the etiology is still unknown, therapeutic interventions have been largely based on anecdotal experience. We present a case of a 22-year-old woman with a two-month history of generalized weakness, daily spiking temperatures, worsening rash and migratory arthralgias. Laboratory studies revealed elevated erythrocyte sedimentation rate, C-reactive protein, hepatic transaminases and serum ferritin. Anti-nuclear antibody and rheumatoid factor were negative. Microbiologic studies/cultures were repeatedly negative. A working diagnosis of AOSD was arrived at, and a trial of high dose

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nonsteroidal antiinflammatory drug therapy was initiated with minimal response. Midrange prednisone was subsequently added with excellent response, however, after a few weeks, despite ongoing prednisone use, her symptoms relapsed. The prednisone dose was increased and clarithromycin was added with immediate response. Over the next few months the prednisone was successfully tapered without relapse. After a six-month course of clarithromycin, the patient has been maintained off therapy without sequelae. Currently, there are no set treatment guidelines for AOSD. This case is an example of the successful use of clarithromycin in treatment of AOSD. There have been several other case reports and a small series highlighting the potential effectiveness of this agent in AOSD. Clarithromycin should be considered for potential use as a first line therapy in AOSD.

67

Muscle Function Assessment: Reproducibility of Jumping Mechanography

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Objective: To assess the interrater and intrasession reproducibility of mechanography tests in a healthy population.

Methods: Ten adults underwent two separate sessions, one week apart. Participants performed 2 different tests in both sessions: multiple one-legged hopping and single two-legged jump with arm swing. Muscle force and power were measured by mechanography using the "Leonardo" force platform. The coefficient of variation (CV) was calculated as a measure of reproducibility. Precision and accuracy of the instrument were also assessed.

Results: The main outcome measures of each test showed no systematic differences between session 1 and 2 for any of the test results. CV for peak force relative to body weight ranged between 6.7% and 8.1% inter-day for the multiple one-legged hopping (dependent on the rater) and were 4.7% and 3.9% for session 1 and 2 respectively when looking at the variability between raters. CV for total power per body weight for the single two-legged jump ranged between 5.6 and 5.9% inter-day and were 6.6% inter rater for session 1 and 4.4% inter rater for session 2. The device used in this study systematically underestimated the reference weights by < 1%. The maximal deviation from the reference weight in any of the 84 static measurements performed in this study was 1.1% (accuracy). The CV for 12 repeated measurements was 0.34% (10 kg weight) and below 0.25% for the largest weights (precision).

Conclusion: The mechanographic tests assessed in this study yield reproducible results in healthy subjects. The Leonardo ground reaction force plate system is an easy, safe and reliable method for the assessment of muscle function.

68

Exploring the Importance of the Theme of Hope in Patient Education Programs Across the Arthritis Spectrum

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Objective: There is limited literature exploring the theme of hope within chronic disease patient education programs. In 2009, The Arthritis Program (TAP) began collecting information on patients' learning goals from attending an Inflammatory Arthritis (IA) Education Program. These qualitative findings revealed an emerging theme of "hope" as participants identified wanting to gain the "feeling of hope". The aim of this study is to determine if this theme of hope is important across other education programs within TAP: osteoarthritis (OA), osteoporosis (OP) and fibromyalgia (FM).

Methods: Data were obtained from a convenience sample of patients participating in one of 11 of TAP's IA, OA, OP, and FM Education Programs between February and June 2012. In a focus group, patients were asked questions about program goals by a TAP staff member. On the first day of the program, patients were asked: (1) "What do you hope to learn from this program?", and (2) "At the end of the program, how are you going to know you got what you came for?" On the last day of the program they were asked: (1) "What do you feel you've learned from the program?" and (2) "Did you get what you came for?" Data was qualitatively analyzed by two coders to identify recurring themes.

Results: Four consistent themes emerged: 1) Self-management. Desire to improve in self-management was frequently noted. As it relates to our data, self-management can be explained as growth in patients' confidence in, and ability to cope with their condition, self-direct care, identify problems and make appropriate decisions as a result of feeling empowered and self-efficacious. 2) Hope. Participants consistently described feelings of decreased isolation; the establishment of clear and attainable goals; the ability to plan toward a bright future, and a sense of optimism as a result of partaking in the program. 3) Navigating the healthcare system. Many participants described the desire to access additional health and social resources, more reliable healthcare information, and more physician and specialist care. 4) Disease Specific Education. Participants wanted comprehensive, proven information regarding medication, nutrition, natural alternatives, exercise, and pain management strategies.

Conclusion: Our data suggest hope and self-management are interconnected. In order for patients to effectively self-manage, they must first have hope — hope that their current situation can be altered. These results may lead to a better understanding of how patients go through this trajectory toward the desired goal of self-management.

69

The Arthritis Program Interprofessional Training Program (TAP-ITP); Setting Teams on a Trajectory of Success

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Objective: To evaluate the effectiveness and sustainability of TAP-ITP in improving interprofessional care (IPC) within clinical teams through a facilitated change process that fosters positive collaborative change within the clinical environment.

Methods: A national needs survey on models of care and interprofessional team practice guided program development. The curriculum was developed in a blended, episodic manner using technology, classroom instruction and asynchronous learning. Successful elements of TAP, a patient-centred interprofessional model of care, were used to model and inform curriculum development. Eligible learner(s) included two cohorts: 1) Healthcare professionals working within hospital and community-based arthritis programs; 2) Trainees enrolled in the Advanced Clinician Practitioner in Arthritis Care (ACPAC) program 2010/2011 cohort. The design was pre-post single group. Data were collected at the beginning of program (T1), immediate post-program (T2), and one year (T3). Outcomes were assessed using reliable and valid measures: Demographics; Readiness for IPC; W(e)Learn Program Assessment; Interprofessional (IP) Learner and Team Contracts; Interprofessional Collaborative Competencies Attainment Survey (ICCAS); Bruyère Clinical Team Self Assessment Scale; and Attitudes Toward Health Care Teams (ATHCT). Analyses included descriptive and paired t-tests.

Results: 22 learners participated (n=15 professionals representing 4 clinical teams across Canada; n=7 ACPAC trainees). At T1, only 40% of learners felt that their team was in the prepared for action/action stage of

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readiness for IPC. At T2, there was a shift to 80%, and this reduced slightly to 60% at T3. The W(e)Learn indicated that participants were very satisfied with TAP-ITP (at T2). Mean scores ranged from 6.02 (program content) to 6.6 (program structure), where 7=positive learning experience. ICCAS scores revealed statistically significant differences from T1 to T2 in perceptions of IPC competencies (20 of 20 competencies, p< 0.05), indicating greater team function in areas of communication, collaboration, roles and responsibilities, collaborative patient/family-centred approach, conflict management/resolution, and team functioning. Paired t-tests for each T1 to post (T2 and T3) scores were all significant (p< 0.05) for each of the Bruyère subscale and overall scores. For ATHCT, paired t-tests for each T1 to T2 were significant for the Quality of Care/Process (p=0.04) and borderline significant for the Physician Centrality scale (p=0.06). At T3, improvement in both scales was maintained but was not statistically significant.

Conclusion: This study provides evidence that TAP-ITP improves knowledge, skills and attitudes in interprofessional care post-program and sustained at one year. Learners were very satisfied with the program that was provided and the method in which it was delivered.

70

Clinical Utility of the Hospital Anxiety and Depression Scale (HADS) for an Outpatient Fibromyalgia Education Program

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Objective: The Arthritis Program (TAP) recently added the Hospital Anxiety and Depression Scale (HADS) to measure patient outcomes from the outpatient Fibromyalgia (FM) Education Program, in addition to Fibromyalgia Impact Questionnaire (FIQ) and Arthritis Self-Efficacy (ASE) Scale. The objective of this study was to examine the clinical utility of HADS in measuring effectiveness of the program in helping patients to manage anxiety and depression.

Methods: A retrospective chart review was performed on 232 outpatients who attended the program between November 2011 and March 2012. These patients completed HADS, FIQ and ASE just prior to attending the first class. Post-program questionnaires were completed during the final class. Paired t-tests were performed on the 59 cases with complete pre- and post-program data. Results for the ASE and HADS scales are presented. Large sections of the FIQ were not applicable for this population.

Results: There was significant improvement in the ASE Pain subscale (mean±SD; N=59) (35.14±15.52 vs. 45.04±17.65, p=0.00) and the ASE Other Symptoms subscale (N=57; 40.02±18.10 vs. 49.44±17.61, p=0.00). ASE Daily Activity subscale did not see significant change (N=59; 63.05±22.47 vs. 61.75±21.20, p=0.521). There was no significant difference between the overall pre and post HADS score, HADS-A (N=61; 11.97±4.04 vs. 11.90±4.16, p=0.866) and HADS-D (N=60; 9.98±3.76 vs. 9.33±3.87, p=0.074). In order to further explore our HADS data, HADS paired pretest and posttest scores were examined for two subsets of patients: (1) those taking one or more neuropathic pain reliever (SNRI, antiepileptics, TCA) and/ or mood stabilizer (SSRI, Bupropion) at the beginning of program and (2) those who were not taking any of these drugs at the beginning of the program. There was a significant improvement in their HADS depression scale score and HADS anxiety scale score in the pre-post period for the group not taking any neuropathic pain reliever or mood stabilizer at baseline (HADS-A (N=19; 10.99±4.29 vs. 9.79±4.17, p=0.043) and HADS-D (N=19; 9.53±4.03 vs. 8.16±3.53, p=0.008).

Conclusion: HADS is sensitive for detecting changes in level of anxiety and depression for certain subsets of fibromyalgia patients. Those who are not taking any neuropathic pain relievers or mood stabilizers at baseline show improvement in level of anxiety and depression measured by HADS upon completion of a seven-week Education Program. Further, improvement in the pain and other symptoms subscales of the ASE were demonstrated in the full sample of patients who completed the program.

71

Physical Activity in an Inception Cohort of Children with New-onset Juvenile Idiopathic Arthritis

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Objective: Children with juvenile idiopathic arthritis (JIA) are reported to be less active than healthy children. This may be due to disease activity. We studied physical activity (PA) levels in an inception cohort of children with new-onset JIA.

Methods: Children aged 8 to 16 years with new diagnosis of JIA were enrolled at 11 Canadian pediatric rheumatology centers as part of the "Biologically-based Outcome Predictors in JIA (BBOP)" study. PA was measured using the Physical Activity Questionnaires for Children and Adolescents (PAQ-C, PAQ-A), a validated measure with scores ranging from 1 (low) to 5 (high). Age- and sex-specific z-scores were generated using normative data from the Healthy Bones Study (University of British Columbia). Clinical measures included body composition (BMI percentile), pain (visual analog scale), function (Child Health Assessment Questionnaire, CHAQ), disease activity (active joint count, physician global assessment) and health-related quality of life (Juvenile Arthritis Quality of Life Questionnaire, JAQQ). All measures were done within 6 months of diagnosis. Descriptive statistics were calculated.

Results: 87 children (69 girls, 79%; mean age 12.6 years, SD 2.3) completed the PAQ C/A. PA levels were low (score < = 2.0) in 44%, and average to high (score 2.0-5) in 56%. Median PAQ age- and sex-specific z-scores were -0.30 [range -3.7 to 4.8, 1st to 3rd quartile interquartile range (IQR) -1.60, 1.30]. Disease activity was variable with median active joint count 6 (range 0-35, IQR 2, 13). There were 6 outliers with 30-35 active joints. Median physician global assessment was 3.6 (range 0.0-9.1, IQR 0, 9.1). Children reported moderate impairments in health related quality of life (mean JAQQ score 3.33, 95% CI 3.00-3.66, SD 1.55), mild to moderate functional disability (median CHAQ score 0.6250, range 0-2.875, IQR 0.250, 1.25) and moderate pain (VAS median 4.0, range 0.0-10.0, IQR 2.0, 6.0). None of the individual clinical measures had significant correlation with PAQ scores.

Conclusion: Children with new-onset JIA and moderate disease activity, pain and functional impairments have variable levels of PA which are comparable to the normative population. Our results are unexpected, as previous studies report low levels of PA in children with JIA, during active disease and remission. We found no significant correlation between clinical variables and PA. However, PA is a complex behavior influenced by both personal and environmental factors. The relationship between PA, disease activity, and other potential influences will be further explored in prospective study of this cohort.

72

Effect of Biologic Disease Modifiers on Atherogenic Lipid Profile in Patients with Rheumatoid Arthritis

Majed Khraishi (St. John's); Rana Aslanov (Memorial University of Newfoundland, St. John's)

Objective: To evaluate the effects of individual biologic disease-modifying antirheumatic drugs (DMARD) on the serum levels of total cholesterol (TC), high density lipids-cholesterol (HDL-C) and 10-year cardiovascular risk in patients with rheumatoid arthritis (RA).

Methods: Over 300 patients with RA treated by biologics in a rheumatology clinic were assessed prior to the study. Biologic DMARD that were administered to < 25 patients and for a period longer than 1 year were excluded from the study. A total of 156 patients treated by etanercept, adali-

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mumab, rituximab, and tocilizumab were included in this analysis. TC and HDL-C serum concentrations were evaluated, the atherogenic index (AI) was calculated. The Framingham Risk Score was used in the assessment of 10-year CVD risk. A comparison between measurements over the indicated time was made using paired sample t-test. Regression models were used to estimate predictive values (SPSS V.19.0).

Results: The median age of 156 patients (69.2% females) was 55.0 years. The mean (SD) age at RA diagnosis was 41.7 (13.3) years with the mean (SD) duration of RA 13.9 (8.8) years. Inflammation indices C-reactive protein (13.0±19.0 vs. 8.6±14.7; p=0.015) and 28-joint Disease Activity Score (3.9±1.3 vs. 3.2±1.2; p< 0.001) significantly improved over the year. Mean TC and HDL serum levels were significantly higher at 12-month compared to the baseline (3.5±2.5 vs. 3.2±2.7; p=0.041 and 0.9±0.7 vs. 0.8±0.7; p=0.003, respectively). The AI was significantly reduced from baseline levels (3.9±1.1 vs. 4.6±1.8; p< 0.001). The 10-year CVD risk for all patients was non-significantly decreased from 11.1±9.3 to 10.8±9.6 with p=0.524. The analysis of the effect of each biologic DMARD on 10-year CV event risk showed non-significant changes except of tocilizumab, which significantly increased patients' risk for CVD from 12.9 (9.8) to 11.1 (8.8) with p=0.011.

Conclusion: The short- and long-term effects of biologic DMARD on a person's atherogenic lipid profile are still controversial. The study results demonstrated a favorable effect of biologic DMARD on the serum levels of atheroprotective HDL-C of RA patients. All of them significantly reduced the atherogenic index. No significant change was observed in the predicted 10-year risk for cardiovascular event with the possible exception of tocilizumab.

73

Effect of Psoriatic Arthritis on Healthcare Utilization

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Objective: To analyze and compare the use of healthcare services by patients with early (EPsA) and established (EstPsA) psoriatic arthritis over 12 months of follow-up.

Methods: Total 151 patients with PsA were recruited from a rheumatology clinic and followed prospectively for at least a 12-month period. Fifty-eight (38.4%) patients had EPsA and 93 (61.6%) patients had EstPsA (defined as < 2 and ≥2 years from diagnosis, respectively). The association of disease severity measured by 28-joint Disease Activity Score (DAS28) with the patients' utilization of healthcare services and their comparison between two cohorts were analyzed. Healthcare use was examined with the "Health Care Utilization Resource Use" form.

Results: Mean age of patients with EPsA and EstPsA at the onset of psoriasis and PSA was [39.4 (14.1) vs. 34.0 (15.4), p=0.031 & 48.6 (10.0) vs. 43.5 (12.7), p=0.011, respectively]. Duration of PsA symptoms in cohorts was 1.0 (0.8) & 6.3 (8.2), p< 0.001). Patients with EPsA had more acute disease presentation measured by DAS28 [3.3 (1.2), p=0.011]. At baseline, patients with EPsA generally utilized healthcare services for PsA and co-morbidities such as CHD (hypertension), diabetes, and infections more frequently compared to patients with EstPsA (0.41 vs. 035). These services included "ER" (0.12 vs. 0.09), "Doctor's Office Visit" (0.91 vs. 0.72; p=0.004), "Specialist Visit" (0.86 vs. 0.73), Psychologist/Counsellor (0.07 vs. 0.05), and "Physiotherapy/Rehabilitation" (0.26 vs. 0.19). Patients with EstPsA used more "Walk-in Clinic" (0.12 vs. 0.09) and "Hospital Admittance" (0.05 vs. 0.02) services. HCU significantly correlated with DAS28 in both cohorts (EPsA: r=0.17, p=0.045; EstPsA: r=0.24, p=0.001) and did not associated with Health Assessment Questionnaire. Mean (SD) DAS28 score significantly improved in both cohorts [EPsA: from 3.9 (1.3) to 2.1 (1.5), p< 0.001]; EstPsA: from 3.3 (1.2) to 2.6 (1.3; p< 0.001) and was strongly associated with patients' utilization of HCU services (EPsA: OR=1.3, p=0.049, 95% CI 1.0-1.7; EstPsA: OR=1.7, p=0.004, 95% CI 1.2-2.3). HCU significantly reduced in 12-month for EPsA from 0.41 to 0.22 (p=0.042), for EstPsA from 0.35 to 0.16 (p=0.004).

Conclusion: PsA causes considerable disability and affects the quality of life of those with the disease. Besides, PsA may lead to heart disease, cancer, infections, and even premature death, and the longer the disease duration the higher burden of illness on healthcare system. Early initiation of the treatment with disease-modifying antirheumatic drugs may reduce the burden of disease and significantly reduce the use of healthcare services.

74

The Concordance of Assessments of the Clinical Disease Activity Index (CDAI) Performed by a Rheumatologist and Rheumatology Nurses Using an Electronic Version in Patients with Rheumatoid Arthritis (RA)

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Objective: To validate the accuracy of the assessment of RA disease activity by a health care professional trained in joint examination using electronic version (iPad) of the CDAI.

Methods: Twenty-three consecutive patients (74% females) with RA attending a biologic therapy infusion centre were included in this analysis. The CDAI scores were obtained on the same patients by rheumatology nurses and by rheumatologist (MK). The order of the assessments was changed every second patient. The total score, swollen and tender joint counts (SJC & TJC) and the global assessment (GA) of disease activity were compared between evaluators using student t-test. All scores were assessed based on CDAI Disease Activity State levels: remission (< 2.8); low (2.8-9.9); moderate (10-22); and high (>22). The correlation coefficient (r) and the level of agreement between evaluators were also investigated using kappa (Chi-square) statistics. The HAQdas iPad app V4.0 (NLRT) was used in all cases.

Results: All measurements taken by nurses were strongly correlated with measurements provided by physician: SJC (r=0.92, p< 0.001); TJC (r=0.98, p< 0.001); GA of disease activity (r=0.98, p< 0.001); CDAI scores (r=0.99, p< 0.001); and Disease Activity State (r=0.94, p< 0.001). Nurses counted non-significantly less swollen joints [(5.0; 5.6) vs. 5.7 (5.8), p=0.20)] and more tender joints [(11.9; 10.4) vs. 11.7 (9.8), p=0.65)] compared to physician. The mean CDAI score by nurses was non-significantly lower than physician's [(24.9; 19.8) vs. 25.6 (18.9), p=0.29)]. The Disease Activity State measured by nurses was moderate and significantly differ from moderate to high level obtained by physician [(2.0; 1.1) vs. 2.2 (1.1), p=0.04; 95%CI -0.34- (-0.01)]. The agreement between evaluators was high with about 74% (p< 0.001) of patients concordantly classified by Disease Activity State.

Conclusion: There was strong agreement between evaluators of different backgrounds in their assessment of RA patients' disease activity (CDAI). The study results suggest that the electronic version of the CDAI can be employed by a trained health care professional (HCP) independently in different locations and settings to assess and follow disease activity. This innovative approach may contribute to treating RA patients to target (to obtain remission or low disease activity). The involvement of patients and HCP could eventually lead to improved outcomes. The electronic version of the CDAI seems to be useful for both purposes the evaluation of Disease Activity State and improved outcomes.

75

The Validation of a New Simple Disease Activity Tool in Systemic Lupus Erythematosus (SLE): The Lupus Activity Scoring Tool (LAST) as Compared to the SELENA SLEDAI (SS) Modification

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Objective: Primary: To validate a SLE activity tool with it correlation to the SELENA SLEDAI modification. Secondary: To test the usability and the accuracy of electronic application of the same tool in clinical settings.

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Methods: The new disease activity tracking and evaluating tool included patient global assessment of disease activity, physician global assessment of disease activity, and a formula incorporating the current immunomodulating medication used as an indication of SLE activity. The LAST included C3, C4 and Anti-ds Anti-DNA titer abnormalities as an activity indicator. Patients were seen in a rheumatology clinic within the last 12 months and had the laboratory investigations done within 2 weeks of their visit. The SS was calculated for each visit. The patients met the SLE ACR 1997 criteria update. Five different systems (algorithms) of weighting the different variables of disease activity were calculated. Apple iPad and Windows web-based applications were developed for the LAST and a clinical only LAST (without incorporating serological values). Descriptive statistics and correlation bivariates (Pearson's & Spearman's) were conducted. Each algorithm result and the disease activity of patients with multiple assessments were compared to the SS scores.

Results: Twenty-three patients (91% females) with 43 assessments were included. Scores from 5 algorithms of the variables in addition to the SLEDAI scores were obtained at each visit. The mean (SD) age was 48.0 (14.6) years and the mean (SD) of disease duration was 12.3 (6.5) years. The mean (SD) SLEDAI score was 6.30 (4.01). The mean (SD) LAST (with C3, C4 and Anti-ds Anti-DNA) score was 39.85 (18.67). The correlation between the two new activity indices was very high: 0.920 with $p< 0.001$. The SLEDAI scores were consistent with the LAST scores at the baseline and follow-up visits: SS scores 0-4 corresponded to the LAST scores of 0-30 while SS scores of 8 or higher corresponded to 50 and higher, respectively. The electronic applications of the LAST were easy to use and no errors were found with their results as compared to the manually obtained scores.

Conclusion: LAST is a new disease activity index correlated well with the SELENA SLEDAI modification. The use of simple clinical variables as a measure of SLE activity seems to be valid. The development of easy to use electronic apps will make the use of these activity tracking tools easier to calculate and can be possibly be used in non-specialist settings.

76

Work-related Injuries Causing or Aggravating Fibromyalgia in the Medicolegal Arena: A Jurisprudential Analysis

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Objective: Up to 40% of persons report onset of fibromyalgia (FM) following a "triggering event". Injuries occurring in the workplace link FM to compensation. In Ontario, injuries without body changes, i.e. soft tissue, are compensated according to a chronic pain policy under which falls FM. The Workplace Safety and Insurance Appeals Tribunal (WSIAT) is the final level of appeal for workers who request compensation for a work-related injury as causation for FM.

Methods: Between June 2006 and December 2011, 150 tribunal decisions relevant to FM were examined by predetermined search protocol. Twelve did not meet inclusion criteria; FM was not the central issue in 4, and 8 were for increased awards. New-onset FM was appealed in 123, and aggravation of pre-existing FM in 15. Information in the aggravation cases was limited.

Results: Of the 15 cases pleading aggravation of FM (14 female, mean age 50 ± 8 years), 5 were manual, 3 clerical, 7 healthcare or education workers. Thirteen injuries were acute, 2 occurred gradually, with low back or neck identified in 13, and the tribunal accepted 10/15 (67%). In the 123 new-onset FM, (104 female, mean age 52 ± 9 years), 60 were manual, 29 clerical, 30 healthcare or education workers, 4 unknown, with 32% reporting repetitive work activity. Time from injury to diagnosis of FM (available for 117) was 4.3 ± 4.1 years, with 6.3 ± 2.8 physicians cited for each worker. Previous psychological illness, injuries, neck pain or back pain were recorded as present for 17%, 22%, 10%, and 13% respectively, whereas there was no statement of previous health status for 26%. Injuries were a single event in 68%, and gradual in 32%, with location of injury in low back for 44%, and shoulder/upper limb in 40%. The FM diagnosis was based on report by a rheumatologist in 74%, and family physician in 13%, with 73 (59%) appeals accepted by the tribunal.

Conclusion: Over half of appeals for aggravation or causation of FM following a work-related soft tissue injury were upheld by the tribunal. Claimants were demographically similar to other FM cohorts, although healthcare use was very high. Low back and upper limb injuries predominated as causation, with over two-thirds reporting FM following a single incident. The attribution of causation of FM to a single workplace traumatic event is contentious and requires further examination.

77

Weighting of Evidence in an Appeals Tribunal Adjudicating Work-related Injuries as a Causation of Fibromyalgia

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Objective: Workers in Ontario with denial of compensation claims for a work-related injury causing fibromyalgia (FM) may appeal to the Workplace Safety and Insurance Appeals Tribunal (WSIAT). The adjudication process is reliant on available medical information, guided by input from board "expert advisors" as well as a "medical discussion paper" prepared by a rheumatologist. The objective of this study was to examine the tribunal weighting of evidence in reaching a decision.

Methods: Between June 2006 and December 2011, the WSIAT heard 123 appeals for new onset FM following a work-related soft tissue injury.

Results: Demographic information for 123 claimants: 104 female, mean age 52 years, manual worker 60, clerical 29, healthcare or education 30, unknown 4, and time from injury to FM diagnosis 4.3 ± 4.1 years, with 6.3 ± 2.8 MDs cited. Previous health status was mentioned in 91 (74%) decisions, and the "discussion paper" in 49 (40%) cases. The reliability of testimony/medical report was doubted for 15 (12%) claimants, 19 (15%) board experts, 19 (23%) specialists, 6 (5%) family physicians (FP). When allowed (N = 73) vs. rejected (N = 50) appeals were analyzed separately, there were no differences for demographics, specific injury, time to diagnose FM, comment on previous medical status and numbers of MD cited. In allowed appeals, the weight of evidence was based on a rheumatologist report in 73%, GP report 36%, tender point count (TPC) 36%, and temporality 23% whereas for rejected appeals, weight was respectively 36%, 20%, 14%, and 30%. For appeals allowed, the tribunal was more likely to rely on rheumatologist report 73% vs. a FP report 36 % ($p< 0.0001$).

Conclusion: Legal decisions are reliant on evidence brought forward, especially in examination of a workplace soft tissue injury resulting in prolonged chronic diffuse pain. Concerns regarding the process examined include neglect of attention to prior health status, weight given to a specialist diagnosis, often with consultation many years after the injury, and importance of the TPC, a subjective controversial test open to faking. Considerably less importance was attributed to the opinion of the FP, who likely has a better knowledge of the worker. Additionally, the "medical discussion paper", authored by a rheumatologist in 2003, without initial peer review, was reviewed in 2010 without any update. Medicolegal decisions regarding FM must be based on current knowledge and sound applicable evidence for this condition.

78

A Descriptive Analysis of the Art of the Body Map in Patients with Fibromyalgia

Mary-Ann Fitzcharles (McGill University Health Centre, Montreal); Marta Ceko (McGill University Health Centre, Montreal); Peter Ste-Marie (Université de Montréal, Montreal)

Objective: The body map, a manikin drawing facing forward and backward, is a commonly used tool that is quantitatively scored and can also provide a visual impression of location of pain. We have assessed body map drawings in fibromyalgia (FM) patients to determine whether the

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"artistic component" associated with other measurable disease parameters.
Methods: Patients with FM currently enrolled in a prospective cohort study at a multidisciplinary pain center completed the body map with the instruction to shade areas where pain is felt. We have observed the use of various other drawing techniques including symbols, additional writing, and drawing outside the body. All maps were independently scored by 2 examiners according to the presence or absence of the following criteria: 1. Shading, 2. Areas circled, 3. Other drawings such as crosses, lines, arrows, 4. Drawing outside the body, 5. Written script. Discrepancies were resolved by consensus. Demographic and disease related parameters including fibromyalgia impact questionnaire (FIQ), body map quantitative score (0-50), pain VAS, mood by arthritis impact measurement scale (AIMS), and pain catastrophizing scale (PCS) were recorded for all patients. Univariate comparisons of continuous variables were made using Student's t-tests, and for categorical variables using chi-squared tests.
Results: 182 FM patients completed a body map at the baseline visit. 172 (94%) were female, with mean age 48 (±10) years and disease duration 11(±9) years. The body map scores were as follows: quantitative score 28 (±11), shading vs. no shading 128 (70%) vs. 55 (30%) respectively, circles 92 (50%), other drawings 75 (41%), outside map drawing 108 (59%), written script 15 (8%), and high intensity drawing 69 (38%). The numbers of different drawing techniques per patient were: 1 only - 30%, 2 - 24%, 3 - 35% and >3 techniques - 11%. There were no significant associations with any disease or psychosocial parameters and the descriptive assessment of the body map.
Conclusion: Most patients with FM used additional drawing techniques, in addition to shading, when completing the body map. Descriptive assessment of the body map drawings did not associate with any standard disease or psychological measures in FM patients. The "artistic component" of the body map likely reflects factors other than specific disease related variables.

79

Randomized Controlled Trial of Adalimumab in Patients with Peripheral Spondyloarthritis

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Objective: Adalimumab (ADA), indicated for the treatment of psoriatic arthritis (PsA) and ankylosing spondylitis (AS), may also benefit patients with peripheral spondyloarthritis (SpA) not previously diagnosed with psoriasis or PsA (non-PsA), who present primarily with arthritis, enthesitis and/or dactylitis. ABILITY-2, the first randomized controlled trial to use the ASAS peripheral SpA criteria[1] to classify patients, evaluated the efficacy and safety of ADA in patients with active non-PsA peripheral SpA.
Methods: ABILITY-2 is an ongoing, multicenter, phase 3 study. Eligible patients were age ≥18 yrs, fulfilled ASAS peripheral SpA criteria, did not have a diagnosis of psoriasis, PsA, or AS, and had inadequate response or intolerance to nonsteroidal antiiflammatory drugs (NSAID). Patients were randomized 1:1 to ADA 40 mg every other week or placebo (PBO) for 12 weeks followed by a 144-week open-label extension. Primary endpoint was the proportion of patients achieving peripheral SpA response criteria (PSpARC40) at week 12: ≥40% improvement (≥20 mm absolute improvement in VAS) from baseline in Patient's Global Assessment of Disease Activity (PGA) and of pain (PGA-pain) and ≥40% improvement in ≥1 of the following: SJC and TJC, enthesitis count, or dactylitis count. Other outcomes included Physician's Global Assessment, BASDAI, enthesitis indices, PSpARC 20/50/70, HAQ-S, and SF-36v2. Adverse events (AE) were collected throughout the study.
Results: 165 patients (ADA 84/PBO 81) were randomized. Baseline demographics/disease characteristics were similar between groups, except for mean age and percent patients with dactylitis count >0 (ADA/PBO): 57/52% female, 67/56% HLA-B27+, mean TJC 13.0/13.6, SJC 6.1/7.3, enthesitis count 6.7/7.3, and dactylitis count 0.4/0.7. At Week 12, the percent of ADA patients achieving PSpARC40 was higher vs. PBO (39.3% vs. 19.8%, P=0.006), primarily due to the PGA, PGA-pain, and TJC/SJC components. Overall, improvement based on other outcomes was greater with ADA vs. PBO. AE were similar (ADA/PBO, %): any AE (54.8/54.3), serious AE (1.2/1.2), and infectious AE (21.4/28.4); there were no serious infections, TB, or malignancies during the double-blind period.
Conclusion: Adalimumab was well tolerated and significantly improved signs, symptoms, and physical function of patients with active non-PsA peripheral SpA, suggesting that ADA may be an effective treatment option for non-PsA peripheral SpA patients with inadequate response or intolerance to NSAID. Further, these results suggest that the PSpARC assessment instrument, pioneered in this study to evaluate this patient population, is a responsive and discriminative outcome measure.
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80

Patient's Insights and Attitudes Regarding the Role of Nurse Practitioners in the Management of Inflammatory Arthritis

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Objective: There is a general shortage of rheumatologists in Canada, particularly in the province of Newfoundland. Nurse practitioner (NP) is the fastest-growing advanced nursing role in Canada, and NP are increasingly being used in rheumatology clinics. Our objective was to better understand patients' perspectives on the role of the NP in managing inflammatory arthritis in order to enhance the integration and long-term viability of NPs into our healthcare system.
Methods: A qualitative study was performed by evaluating the attitudes of consecutive patients regarding their perspective on the role of NP in inflammatory arthritis. All patients were required to have at least one assessment by the NP. Limited demographic information was collected on each patient including age group, sex and diagnosis. Patients were asked the following open ended question "What do you see as the role of a Nurse Practitioner in the management of rheumatology patients?" This questionnaire was filled out in a blinded fashion with no identifying information documented.
Results: In total there were 72 patients that filled out questionnaires, of which 69% were females. Overall the female patients were very positive regarding medical assessments solely by NPs, while some of the male patients were more guarded regarding the role of the NP. The five most common suggested roles for a NP in rheumatology clinic include 1) Monitoring "stable" patients (e.g. blood work, response to medications including biologics); 2) Direct link to rheumatologist (e.g. to inform rheumatologists regarding response to therapy, side effects and flares); 3) Provide teaching and counseling (e.g. disease and drug information, access to allied health), 4) Reduce work load for the rheumatologist (e.g. by doing history, physical examination, joint examination and anthropometric measurements prior to the rheumatologist's assessment), 5) screening referrals so rheumatologist can see more severe patients. Some concerns were expressed with regards to seeing a nurse practitioner when 1) an initial diagnosis was required; 2) for complicated clinical cases; 3) or when patients had recurrent flares that were difficult to treat. Under such circumstances those patients felt that there should be a seamless communication with the rheumatologist and they should also be reviewed by the rheumatologist.
Conclusion: There is overwhelming acceptance of NP in rheumatology clinics, particularly among females. Obtaining a more thorough understanding of patients' perspectives on the role of NP will guide the development of interventions that better meet our patients' needs.

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81

Ustekinumab in Patients with Active Psoriatic Arthritis: Results of the Phase 3, Multicenter, Double-blind, Placebo-Controlled PSUMMIT I Study

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Objective: To assess the efficacy and safety of ustekinumab in patients with psoriatic arthritis.

Methods: Adult psoriatic arthritis patients (n=615) with active disease (≥5 SJC&≥5 TJC; CRP≥0.3mg/dL) despite disease-modifying antirheumatic drugs and/or nonsteroidal antiinflammatory drugs were randomized to ustekinumab 45mg, 90mg, or PBO at wks 0,4, and q12wks. At wk16, patients with < 5% improvement in TJC and SJC entered blinded early escape (PBO→ustekinumab 45mg; ustekinumab 45mg→90mg; 90mg→90mg). Stable concomitant methotrexate was permitted but not mandated. Patients treated with prior anti-TNF agents were excluded. Primary endpoint was ACR20 response at wk24; secondary endpoints: ACR 50/70, DAS28-CRP response, change from baseline in HAQ-DI, PASI75 response (in patients with≥3% BSA), and percent change from baseline in enthesitis and dactylitis scores (in patients affected at baseline).

Results: At wk24, ACR20 responses were 42.4%,49.5%, and 22.8% for the ustekinumab 45mg, ustekinumab 90mg, and PBO groups, respectively (p< 0.001). Significant improvements were also observed with ustekinumab 45mg and 90mg versus PBO for ACR50/70 responses and DAS28-CRP responses. Changes from baseline in HAQ-DI at wk24 were significantly greater in the ustekinumab versus PBO, and significantly greater proportions of ustekinumab-treated patients had a clinically meaningful change from baseline in HAQ-DI (≥0.3). Nearly half used concomitant methotrexate at baseline; this did not alter the likelihood of benefit of ustekinumab versus PBO. While ACR responses were greater with ustekinumab than PBO regardless of methotrexate use, differences were numerically larger among patients not taking methotrexate. Of 440 patients with ≥3% BSA involvement at baseline, PASI75 was achieved in 57.2%,62.4%, and 11.0% of ustekinumab 45mg, ustekinumab 90mg, and PBO, respectively (p< 0.001). Among patients with enthesitis (n=425) or dactylitis (n=286) at baseline, greater improvements in enthesitis and dactylitis were observed at wk24 in the ustekinumab groups vs PBO (p< 0.001,each). Through wk16 (PBO-controlled period), proportion of patients with ≥1 AE was similar between patients receiving ustekinumab (41.8%) and PBO (42.0%), with infections being the most common adverse event;1.7% (ustekinumab) and 2.0% (PBO) had ≥1 serious adverse event. No malignancies, serious infections, tuberculosis, opportunistic infections, or deaths occurred through wk24.

Conclusion: Ustekinumab significantly reduced signs and symptoms of arthritis, improved physical function, enthesitis and dactylitis, and plaque psoriasis versus PBO-treated patients at wk24. Safety profiles were similar between ustekinumab and PBO.

82

Measuring Partial and Complete Recovery in Active Organ Systems of Lupus Patients on Standard of Care Treatment

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Objective: Systemic Lupus Erythematosus Disease 2000 (SLEDAI-2K) measures only complete recovery (CR) in active descriptors. SLEDAI-2K Responder Index-50 (S2K RI-50) is a novel index that measures partial recovery (PR), ≥50% improvement in active descriptors. To determine: 1) PR and CR in active systems on standard of care (SOC) treatment and 2) the benefit of measuring ≥50% improvement in active descriptors with S2K RI-50.

Methods: All consecutive lupus patients seen at the Lupus Clinic from February 2009 to May 2012 were analyzed. Patients included had at least one active system. We excluded patients with CNS or with nephrotic range proteinuria lupus nephritis to reflect inclusion criteria of current lupus clinical trials. CR was measured with SLEDAI-2K and PR with S2K RI-50.

Results: 548 (63% white, 16% black, 10% Asian and 11% others) patients (90% F) with at least one active SLEDAI-2K system were analyzed. Age at lupus diagnosis was 29.2 ± 12.3 years and disease duration at study inclusion was 15.2 ± 11.0 years. Among the 8 systems studied at baseline, the most commonly represented systems were: immunology (n=373), renal (n=205), mucocutaneous (n=117) and musculoskeletal (n=90). For example, in 117 patients with mucocutaneous involvement, CR by SLEDAI-2K was achieved by 68 patients at 6 months, by 95 patients at 12 months and 106 patients at 2 years. PR and CR by S2K RI-50 were identified in 83 patients at 6 months, 105 patients at 12 months and 113 patients at 2 years. The number of patients who achieved PR and CR by S2K RI-50 was greater to the number of patients who achieved CR by SLEDAI-2K in all studied systems. The total possible score for the mucocutaneous system by SLEDAI-2K is 6. At baseline visit the total score for the mucocutaneous system was 2.56±1.01. At 6 months the score decreased to 1.02±1.51, at 12 months to 0.47±1.07 and to 0.27±0.91 at 2 years by SLEDAI-2K. At 6 months the score decreased to 0.87±1.35, 12 months to 0.40±0.95 and at 2 years to 0.20±0.67. The decrease of S2K RI-50 scores was greater than the decrease of SLEDAI-2K scores in all active systems.

Conclusion: With SOC treatment, patients improve progressively over a 2 year period. The use of S2K RI-50 allows the capture of an additional number of patients with ≥50% improvement in active systems not discerned by SLEDAI-2K. S2K RI-50 will allow for an earlier signal of efficacy with new agents in therapeutic trials.

83

Outcome of Renal Transplantation in Lupus Patients with Positive and Negative Serology: Survival of the Graft and Patients After Transplant

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Objective: Up to 20% of LN patients may advance to endstage renal disease over a 10-year period. To provide an overview of the characteristics of lupus patients with renal transplantation (RT) followed in the Lupus Clinic (1970-2012) and to determine the survival of the graft and patients after RT.

Methods: Patients who underwent RT were identified from the database. RT outcomes included: a) nonfunctional graft requiring dialysis within ≤3 weeks, b) graft failure requiring permanent dialysis after 3 weeks, c) graft survival not requiring dialysis and d) death. We grouped the patients into graft failure and graft survival. The duration of graft failure was defined as the time between RT and subsequent permanent dialysis. The duration of graft survival was defined as the time between RT and recipient death or the end of the study with functioning graft.

Results: 25 (20 F) of 1645 patients followed in the lupus cohort and of 780 with renal involvement were identified with RT. 10 (40%) were white, 7 (28%) black, 4 (16%) Asian and 4 (16%) others. The age at diagnosis of lupus and at transplant was 30.7±13.8 and 38.1±9.6 years respectively. Lupus duration at RT was 13.3±7.6 years. 2 (8%) patients had a nonfunctional graft, 4 (16%) patients had graft failure (1 patient had failure < 5 years and 3 ≥5 years) and 19 (76%) patients had graft survival (8 had S ≥5 years) (Table 1). Patients with graft survival were older and had longer lupus duration compared to patients with failure at the time of RT. 25% of the graft failures had positive lupus serology (positive anti-dsDNA and/or low complements) compared to 47% in the graft survival 1 year prior to RT. 67% of the graft failures had positive lupus serology compared to 42% in the graft survival 1 year after the transplant. The time to graft failure (n=4)

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was 5.75±4.99 years. In the failure group 3 patients died by 6±5.19 years and one patient is still alive. In the graft survival group 3 patients died by 5.6±4.6 years and one patient was lost of follow-up. Cause of death was not related to renal disease in 2 patients and unknown in one patient.
Conclusion: 25 of 780 lupus nephritis patients followed at the Lupus Clinic underwent RT. The persistence of serological abnormalities at the time of RT was not associated with graft failure.

84

Partial and Complete Recovery from Proteinuria in Lupus Nephritis Patients Receiving Standard of Care Treatment

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Objective: In lupus trials, partial proteinuria recovery (PPR) is a component of the composite outcome of partial renal remission. To determine: 1) the percentage of patients who achieve complete proteinuria recovery (CPR), PPR and CPR and/or PPR in lupus nephritis (LN) patients receiving standard treatment (SOC) at 6 months, 1 year and 2 years, and 2) determine if the initial level of proteinuria predicts recovery from proteinuria.
Methods: We studied all active LN patients at the Lupus Clinic (1970-2011). Proteinuria was defined as >0.5g/24 hours. Patients with proteinuria and at least one of the urinary sediments (hematuria, pyuria or casts) present at the entry of the study and persistent on 2 consecutive visits were enrolled. Patients were grouped: group 1 as 0.5-0.9g/day, group 2 as 1-2g/day and group 3 as ≥2g/day. Endpoints: CPR < 0.5g/day based on SLEDAI-2K and PPR a decrease of ≥ 50% in the level of proteinuria from baseline as defined by SLEDAI-2K Responder Index-50 (S2K RI-50). We determined: 1) The percentage of PPR, CPR and PPR and/or CPR: a) on 1 visit at 6 months, 1 year and 2 years b) persistent on 2 consecutive visits at 6 months, 1 year and 2 years. 2) The percentage of patients who recovered from proteinuria was evaluated based on initial proteinuria levels with the Kaplan-Meier estimator.
Results: 217 patients (81.8% F) were identified (age and duration of lupus at the start of the study was 34.2 ± 12.4 and 5.7 ±6.3 years). PPR was achieved by 27% of patients at 6 months, 48.3% at 1 year and 69.4% at 2 years. PPR and/ or CPR was achieved by 31.8% of patients at 6 months, 57.6% at 1 year and 79.3% at 2 years. CPR was achieved by 8.8% of patients at 6 months, 35.2% at 1 year and 60.2% at 2 years. The percentage of PPR, CPR and PPR and/or CPR decreased when proteinuria recovery was required on 2 consecutive visits. Based on the level of proteinuria, in group 1, 2 and 3 more patients achieved at least PPR compared to CPR at 6 months ($p=0.81$), 1 and 2 years ($p< 0.05$).
Conclusion: The identification of partial proteinuria recovery allowed the detection of additional patients who improved their proteinuria on SOC treatment. 58% of patients achieved at least partial while only 35% achieved CPR at year 1. PPR can serve as an important primary endpoint in research studies and trials.

85

A Retrospective Study to Evaluate the Effectiveness, Drug Survival, and Safety of Golimumab in Rheumatoid Arthritis Patients in Canadian Rheumatology Practice

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Objective: The efficacy, tolerability and safety of golimumab have been demonstrated in a number of randomized controlled trials for patients with rheumatoid arthritis (RA). However, little is known regarding golimumab's effectiveness in clinical practice. The objective of this study was to assess the effectiveness of golimumab for RA patients in a Canadian rheumatology practice.
Methods: A retrospective cohort study was conducted using the charts of the Rheumatology Health Team in Hamilton from July 2009 to April 2012. All patients with RA treated with golimumab at any dose, for a minimum of 3 months were included. Baseline data, adverse events, time on treatment and reason for stopping treatment were recorded. Effectiveness was assessed with mean absolute changes in swollen joint counts (SJC) and tender joint counts (TJC) between baseline, and over a period of time. We assessed drug survival by auditing the reasons for drug discontinuation. Drug survival was estimated by Kaplan-Meier plot.
Results: A total of 66 patients had SJC and TJC data up to 19 months were included in the analysis. In addition, 35 of those patients with DAS28-CRP values at baseline, 3 and 6 months follow-up were analyzed. The majority of the patients were female (75.7%), with mean age of 60.4 years (SD 14.1). Most patients had a disease duration less than 10 years (65.7%) and RF positive (62.3%). At baseline, most patients had at least moderate disease activity with a DAS28 >5.1 in 11.4%, and a DAS28 between 3.2 to 5.1 in 65.7%. Of the 66 patients who started on golimumab, 3 patients (4.5%) discontinued due to primary failure, 10 (15.2%) due to secondary failure, 5 (7.6%) due to lack of funds, 2 (3%) due to adverse effects. At the end of the 19 month period, 42 patients (63.6%) remained on golimumab. At baseline, there were 9.28±5.34 SJC and 8.18±7.08 TJC. By 3 months, the SJC fell to 4.92±3.66 and TJC to 4.72±5.86. At the end of the study, the mean SJC was 1.17±2.03 and mean TJC was 3.33±3.86. Treatment was discontinued in 2 patients due to adverse events. Regarding drug safety, 3 patients developed pneumonia, 3 developed URTI, and 1 developed non-Hodgkin's lymphoma.
Conclusion: Our results show that golimumab is an effective agent in reducing clinical synovitis and symptoms which are evident even after 3 months of treatment. Overall, the drug was well tolerated, and the durability of the drug was quite acceptable.

86

Golimumab Start-Stop: Drug Discontinuation due to Financial Constraints; Experience from a Single Hamilton Center

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Objective: The efficacy, tolerability and safety of golimumab have been demonstrated in a number of randomized controlled trials for patients with rheumatoid arthritis (RA). However, in real-life practice, patients often face financial constraints, and treatment may need to be interrupted or even discontinued. The objective of this study was to document the effect that golimumab discontinuation had on RA disease activity of patients in a Canadian rheumatology practice.
Methods: A retrospective cohort study was conducted using the charts of the Rheumatology Health Team in Hamilton from July 2009 to June 2012. All patients with RA treated with golimumab at any dose, for a minimum of 3 months and had to discontinue treatment due to financial/coverage reasons were included. After discontinuation, these patients were treated with maximal doses of methotrexate and leflunomide. SJC and TJC were recorded at baseline and every 3 months.
Results: From our database, 15 patients had to discontinue golimumab due to financial reasons. All patients were treated for 14 months before losing

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drug coverage. An increase in SJC and TJC evident even after 2 months of discontinuing golimumab and continued to increase with subsequent assessments at 16, 19 and 22 months. After discontinuation, 13 patients had significant flare, and 7 of the 13 patients required frequent glucocorticoids. After flaring, 10 patients received financial approval and were restarted on golimumab. There was a significant clinical improvement which was evident within 3 months of restarting golimumab. All 10 patients were subsequently able to achieve remission or minimal disease activity (MDA). The other 3 patients who flared developed other health issues and did not want to be restarted on golimumab. The 2 patients who did not flare have continued to maintain low disease activity on combination disease-modifying antirheumatic drugs (DMARD).

Conclusion: In patients with well-established disease, combination DMARD was not sufficient to maintain MDA after golimumab was discontinued. However, 2 patients with early sero-negative disease were able to maintain MDA after golimumab was discontinued. This suggest that patients with longstanding moderate or severe RA may require continued biological therapy, which can be possibly avoided in patients with early RA which has not become embedded. Stopping golimumab treatment only delays the inevitable of requiring the drug to be restarted at a later date, but at the cost of recurrent flares and likely damage incurred.

87

Care Gap in the Treatment of Patients with High Risk for Fractures in a Single Canadian Academic Center

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Objective: A number of clinical prediction tools are available to stratify patients from low to high risk for future fractures and identifies patients requiring anti-osteoporotic therapies. Bone Destiny is a validated tool which accurately predicts 10-year fracture risk. Patients are stratified into colours (green, yellow, orange, red and purple) which range from low to high 10-year risk. Purple and red range are at very high and high risk respectively (10-year risk>20%). The goal of this study was to assess if a care gap exists in patients deemed at high risk of fractures using the Bone Destiny tool, and based on bone mineral density (BMD) T-scores in the osteoporotic range.

Methods: At a large single academic center in Hamilton, Canada, all patients who received a BMD from May 1, 2011, to April 30, 2012, were assessed using the Bone Destiny tool. All prevalent fragility fractures were recorded. The percentage of patients on appropriate anti-osteoporotic treatment was recorded.

Results: At our center, 26,213 patients received a DXA scan and Bone Destiny assessment. 3,643 patients were in the purple group, 4,501 patients in the red group. Overall, 1805/3643 (49.5%) and 1817/4501 (40.4%) patients in the purple and red groups respectively were on treatment. The younger patients (age< 60 years) in the purple group were less likely to be started on treatment compared to older patients (32.5% in age< 60, 46.1% in age 60-69, 53.9% in age 70-79, and 51.7% in age>80 years). The same trend was seen in the patients in the red group (32.9% in age < 60, 41.4% in age 60-69, 44.3% in age 70-79, and 41.4% in age>80 years). We found 3,367 patients with a T-score less than -2.5. Only 1579/3367 (46.9%) patients were on treatment. A similar trend was noticed, as younger patients were less likely to be treated (33.8% in age< 60, 46.5% in age 60-69, 53.6% in age 70-79, and 53.7% in age>80 years).

Conclusion: Risk assessment tools are important to predict those at high risk for fractures and start them on appropriate treatment. We found a sub-optimal percentage of high risk patients on treatment. This is alarming, as 67% (2443/3643) of patients in the purple group, and 33.4% (1502/4501) in the red group have a prevalent fragility fracture. This study suggests a care gap indeed exists in patients at high risk for fractures and more education is required to educate physicians and other healthcare providers about the availability and usefulness of such tools.

88

Real-world Efficacy and Safety of Abatacept Treatment for Rheumatoid Arthritis: 12-Month Interim Analysis of the ACTION Study

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Objective: To evaluate 1-year retention, efficacy, and safety of abatacept in RA patients treated in routine clinical practice (according to label at enrollment).

Methods: AbataCepT In rOutiNe clinical practice (ACTION) is an ongoing, non-interventional, prospective cohort of abatacept-treated RA patients with inadequate response to methotrexate (MTX) or anti-tumor necrosis factor (TNF) therapy in Europe and Canada, initiated March 2008.[1] At data cut-off (February 2012) all patients had 1-year follow-up. Retention rate (Kaplan-Meier estimate) and disease activity are reported at Month 12 for patients on treatment, according to whether patients received abatacept as a first biologic, or after failure of 1 or ≥2 anti-TNFs. Safety is reported for all patients enrolled, up to data cut-off.

Results: 1120/1138 patients enrolled were evaluable; 1000 (89.3%) had previously failed biologic treatment, 982/1000 (98.2%) had failed ≥1 anti-TNF agent, 120 (10.7%) had not received biologic treatment prior to abatacept initiation. For abatacept at Month 12, when used as the first biologic, first switch agent, and after ≥2 anti-TNFs, retention rates (95%CI) were 83.6% (74.9, 89.5), 73.2% (68.8, 77.2), and 64.1% (59.5, 68.4); discontinuations for lack of efficacy were 9.2%, 15.6%, and 20.2%; discontinuations for intolerance were 2.5%, 2.3%, and 3.0%; good EULAR responses were 34.5%, 34.5%, and 27.3%; moderate EULAR responses were 37.9%, 41.8%, and 45.5%, respectively. 106 serious adverse events occurred in 60/1138 (5.3%) patients (21 discontinuations). 11 deaths occurred including 3 due to serious infections (sepsis [4 months after last abatacept infusion; patient was receiving tocilizumab]; *Pneumocystis jiroveci* [4 months after last abatacept infusion, patient had deep vein thrombosis]; and urosepsis) unrelated to abatacept. 23 patients experienced serious infections; 9 malignancies; 5 serious cardiac disorders; and 3 serious vascular disorders. No TB occurred, two opportunistic infections occurred (cytomegalovirus and *P. jiroveci*).

Conclusion: This large-scale, international, observational real-life study showed that the use of abatacept as the first biologic in MTX-inadequate responders, or after switching from anti-TNFs, was associated with good patient retention over 12 months, particularly when used earlier in the treatment course. Abatacept was clinically effective and well tolerated. These data are consistent with previous findings.[2-6] 1. Nüßlein H, et al. Ann Rheum Dis 2011;70(Suppl 3):464 2. Genovese M, et al. N Engl J Med 2005;353:1114-23 3. Kremer JM, et al. Annals Internal Med 2006;144:865-76 4. Leffers HC, et al. Ann Rheum Dis 2011;70:1216-22 5. Gomez-Reino J, et al. Arthr Res Ther 2006;8:R29 6. Lindblad S, et al. Ann Rheum Dis 2012;71(Suppl3):383

89

Certolizumab Pegol Improves Productivity at Paid Work and within the Household in Adult Rheumatoid Arthritis Patients in Daily

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Practice in Canada: Interim Analysis of the Observational Noninterventional FasT CAN Study

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Objective: The ongoing FasT CAN trial is a two year prospective, observational, noninterventional, noncomparative, postmarketing study designed to assess the efficacy and tolerability of certolizumab pegol (CZP), a PEGylated Fc-free anti-TNF, in routine daily clinical practice for the treatment of rheumatoid arthritis (RA) in Canada. The primary objective is achievement of 28-joint count Disease Activity Score (DAS28) remission after 2 years in adult RA patients. The purpose of this analysis was to assess the effect of CZP on productivity at paid work and within the household, and participation in daily activities.

Methods: This interim analysis includes data from all visits up to either week (wk) 20 or wk24. At the cut-off date for this analysis (17 January 2012), 150 patients were enrolled, 113 of which were included in the Full Analysis Set (FAS), defined as all patients who took at least one dose of CZP and had at least one valid post-baseline DAS28 value. This analysis reports the productivity results on the FAS at the wk20 or wk24 visit. The impact of RA on productivity at work and within the household was assessed using the validated arthritis-specific Work Productivity Survey.

Results: Of the 113 patients in the FAS, 37.2% (42/113) were employed at baseline (BL), 19.5% (22/113) were unable to work due to arthritis, 12.4% (14/113) were homemakers, and 25.7% (29/113) were retired. At wk24 employed subjects reported reduced absenteeism (mean 1.0 workdays missed/month due to arthritis at wk24 vs. 1.7 workdays missed/month at BL) and reduced presenteeism (mean 1.1 days/month with work productivity reduced by at least half due to arthritis at wk24 vs. 7.0 days/month at BL). At wk24 most patients reported a reduction in days missed of household work (mean 6.7 days missed/month due to arthritis at wk24 vs. 10.6 days/month at BL) and in days missed of family/social/leisure activities (mean 2.6 days missed/month at wk24 vs. 4.6 days/month at BL). At wk24, patients reported a decrease both in days with reduced household work productivity (mean 6.4 days/month at wk24 vs. 12.5 days/month at BL) and in arthritis interference with household productivity (0-10 scale, mean rate 4.2 at wk24 vs. 6.3 at BL).

Conclusion: In daily practice in Canada, CZP for the treatment of RA improved productivity at the workplace and in the household, and also increased participation in social and daily activities.

90

Effect of Infliximab on Employment Status in Patients with Rheumatoid Arthritis or Ankylosing Spondylitis

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Objective: Rheumatoid arthritis (RA) and ankylosing spondylitis (AS) are associated with significant functional impairment and work disability. Without treatment, about 80% of RA patients show evidence of joint abnormalities or disability, while 50% have work disability after 10 years (1). Similarly, prevalence of work disability in AS ranges from 13% to 45% based on the patient population (2-4). The purpose of this analysis was to evaluate the prevalence of unemployment due to work disability and determine the effect of treatment with infliximab (IFX) in patients with RA and AS in a real-world, Canadian, routine clinical practice setting.

Methods: BioTRAC is an ongoing, prospective registry of patients initiated on treatment with IFX or golimumab as first biologics or after having been treated with a biologic for less than six months. A total of 798 RA and 290 AS patients initiated IFX between 2002 and 2012 and were included in this analysis.

Results: Among the total number of RA and AS patients, 179 (22.4%) and 57 (19.7%), respectively, reported being unemployed due to their disability, while 335 (42.0%) and 77 (26.6%) were unemployed due to other reasons. Patients reporting being unemployed due to disability had significantly higher disease severity. Furthermore, patients unemployed due to disability had RA for a longer period, while disease duration was comparable in AS patients across employment statuses. By 6 months on IFX treatment, clinically meaningful and statistically significant ($P< 0.05$) improvements in all parameters studied were observed in all three employment status groups in both RA and AS patients. No significant between-group differences in absolute change of these disease parameters were observed upon adjustment for baseline values with the exception of BASDAI and ASDAS which showed greater improvement in employed AS patients. Among RA and AS patients unemployed due to disability, 10.6% and 14.0%, respectively, returned to full-time or part-time employment post-baseline, the majority of whom (63.0%) within 6-months of treatment. The mean (SD) time to employment for this patient subpopulation was 10.8(13.6) months in RA patients and 12.1(6.6) months in AS patients.

Conclusion: At IFX initiation, patients with work disability had more severe disease compared to patients unemployed due to other reasons or employed patients. Further, RA patients had longer disease duration before being treated with IFX. However, treatment with IFX was effective in reducing disease severity and symptoms regardless of employment status and also enabled a portion of patients to return to employment.

91

Adrenal Suppression Following Systemic Glucocorticoid Therapy in Children with Rheumatic Diseases

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Objective: To determine the frequency, duration and predictors of adrenal suppression (AS) following discontinuation of chronic glucocorticoid (GC) therapy in children with rheumatic diseases.

Methods: All patients treated with GC in our pediatric rheumatology clinic who discontinued GC after Jan 1st 2011 were enrolled in a prospective observational cohort study. Morning cortisol level was drawn once GC were tapered to physiologic dose and re-checked monthly until normalization (>171 nmol/L). Thereafter, each patient underwent a low dose ACTH stimulation test; AS was defined as peak cortisol level below 500nmol/L. Duration of AS was defined as time from first morning cortisol test to normalization of low dose ACTH stimulation test.

Results: 26/30 eligible patients were included in the study (4 patients were excluded for study protocol violation). The most frequent diagnosis was Juvenile Idiopathic Arthritis (58% of patients). The most frequently prescribed GC was prednisone. AS was found in 12/26 patients (46%), median AS duration was 135 days. Patients who developed AS were significantly older (mean 12.9yrs vs 8.2yrs, p=0.01) and tended to receive higher cumulative dose of GC (median 2882mg/m2 vs 1488mg/m2, p=0.11) with longer GC therapy duration (median 326days vs 188days, p=0.14) than patients without AS. Use of concurrent GC for non-rheumatologic conditions was not significantly different between groups (25% vs 14.3% of patients, p=0.64).

Conclusion: AS was found in almost half of our patients following discon-

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tinuation of chronic GC therapy. An awareness of this entity is needed and routine assessment of the adrenal axis should be considered at GC discontinuation.

92

***RFC-1 80G>A* is a Genetic Determinant of Efficacy but not of Toxicity in the Treatment of Rheumatoid Arthritis with Methotrexate: Evidence from a Huge Review and Metaanalysis**

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Objective: Associations have been reported between candidate genes and response to methotrexate (MTX) in rheumatoid arthritis (RA) patients, but most of the studies have been small and yielded conflicting results. Systematic reviews of all variants are lacking, and metaanalyses have been reported for only the two most commonly studied variants. We undertook a systematic review of genetic variant associations with MTX efficacy and toxicity and performed metaanalysis of the most commonly studied single nucleotide polymorphism lacking prior cumulative analysis.

Methods: Studies were identified from the Medline/EMBASE/HuGENET Navigator and the Cochrane Library through July 2011, and the 2009-2010 ACR and EULAR proceedings' abstracts. Additional unpublished genotype data from a Canadian early rheumatoid arthritis cohort were also included. To address data heterogeneity, sensitivity analyses were performed including a restricted analysis of studies involving white-subjects to limit population stratification, and an established RA only analysis to explore variability in duration of MTX treatment. Lastly, a 'similar outcome' analysis was applied to explore heterogeneity in the definition of efficacy, restricting to only those studies using ACR or DAS28 EULAR responses for efficacy.

Results: From 67 studies examining genetic association with MTX efficacy and toxicity, Reduced Folate Carrier-1 (RFC-1) 80G>A (Arg27His) was selected for random-effects metaanalysis, including 1210 patients (795 responders and 415 non-responders). RFC-1 80G>A was associated with MTX efficacy using either recessive (OR 1.40, 95%CI: 1.01, 1.95) or additive models (OR 1.34, 95%CI: 1.12, 1.60). Restricting sensitivity analyses to white subjects, established RA subjects, or only those studies with similar outcome improved the associations for both models. No significant association was detected between RFC-1 80G>A and MTX toxicity.

Conclusion: The RFC-1 80G>A variant is associated with efficacy, but not toxicity to MTX in RA patients and merits further prospective analysis as a potential predictor of MTX efficacy. Although the effects identified may be relatively small, these association data may illuminate new mechanistic pathways underpinning MTX response as well as novel gene-gene interactions that may have larger effect sizes.

93

A New Role for Methotrexate: Functional Modulation of the Hematopoietic Stem and Progenitor Cells (HSPC) in Rheumatoid Arthritis (RA).

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Objective: Cellular changes of normal aging occur prematurely in rheumatoid arthritis (RA) affecting terminally differentiated effector immune cells and their precursors, CD34+ HSPC. Indeed, HSPC from young RA patients accumulate DNA damage and fail to progress through the cell cycle thus setting the stage for reduced maintenance of the immune system. Methotrexate (MTX), the most frequently used anti-rheumatic drug, is known to cause oxidative damage and to induce cell cycle arrest. This study evaluates the effect of low-dose MTX, such as those used in rheumatology, on HSPC biology.

Methods: Peripheral blood CD34+ HSPC were magnetically sorted from 6 RA patients and 6 age-matched healthy controls (HC). HSPC were stimulated with hematopoietins for 48 hours in graded concentrations of MTX (0-100 nM) ± folinic acid. We determined by FACS in CD34+ cells the: 1) expression of the reduced folate carrier 1 (RFC1); 2) apoptosis by 7-AAD & Annexin V; 3) proliferation by CFSE; 4) cell cycle by Pyronin Y/Vibrant DyeCycle; and 5) intracellular reactive oxygen species (ROS) by DCF-DA. The clonogenic capacity of HSPC was assessed by colony-forming cell (CFC) assays.

Results: 1- RFC1, the primary MTX transporter, is expressed in HSPC and is upregulated following HSPC activation ($p< 0.01$). 2- MTX leads to a. Increase of apoptotic rates (4.4± 0.8 [no-MTX] vs. 8.6± 1.4 [MTX], $p< 0.05$); b. Inhibition of proliferation (1.64± 0.15 [no-MTX] vs. 1.02± 0.01 [MTX], $p< 0.01$); c. Cell cycle arrest (% HSPC in S phase: 43% [no-MTX] vs. 71% [MTX]); 3- MTX increases intracellular ROS levels (by 40%); 4-MTX increases immature colonies (43.75± 10.3 [MTX] vs. 22.3± 3.0 [no-MTX]). 5- Folinic acid prevents the effect on proliferation, apoptosis, and ROS production while N-acetyl-L-cysteine rescues HSPC from apoptosis. 6- Baseline and post-MTX apoptosis rates of RA-HSPC are higher than in controls (RA vs. HC [no-MTX]: 13.9± 5.6 vs. 4.4± 0.8 and RA vs. HC [MTX]: 18.6± 7.0 vs. 8.6± 1.4).

Conclusion: Human HSPC express RFC1 and are thus susceptible to the effects of MTX. At therapeutic in vitro low-doses, MTX leads to G1/S cell cycle arrest and inhibition of HSPC proliferation, effects that are folic acid dependent. In addition, MTX induces HSPC apoptosis, an effect partly mediated by ROS production. Finally and paradoxically, although MTX increases the already higher apoptotic rates of RA HSPC, during that process, it selects HSPC with a higher clonogenic potential and thus, its net effect on immune regeneration could be beneficial.

94

Predictors of Sustained Clinical Remission in Early Rheumatoid Arthritis- Results from the CATCH Cohort

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Objective: Rapid time-to-remission has been associated with sustained remission in established rheumatoid arthritis (RA). However, the prevalence and predictive factors of sustained remission in early RA is poorly understood, especially in the context of stringent remission definitions.

Methods: We used data from the Canadian early ArThritis CoHort (CATCH) and included patients with probable or confirmed RA. Remission was defined according to the Boolean-based ACR/EULAR definition (TJC ≤1, SJC ≤1, patient global ≤ 1 and CRP ≤ 1) and SDAI ≤ 3.3. Sustained remission was defined as remission for ≥ 6 months or 2 consecutive visits. Logistic regression analysis, adjusted for clinical confounders, was used to identify predictors of sustained remission.

Results: 1244 patients were eligible. 83% were white and 73% female, with a mean age (SD) of 53.6 (14.6) years, and mean symptom duration (SD) of 6.0 (3.1) months. Initial treatment within the first 3 months included: methotrexate monotherapy in 392 (32%), combination disease-modifying antirheumatic drugs (DMARD) in 548 (44%), and biologics in 27 (2%). 432 (35%) achieved ACR/EULAR and 484/1205 (40%) achieved a SDAI remission, with a median time-to-remission of 9.4 months for each. In those ever achieving sustained remission, 234 (54%) and 273 (56%) did so for sustained ACR/EULAR and SDAI remission.

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Factors associated with increased probability of sustained remission were younger age and an earlier time-to-first remission. Lower baseline pain score was associated with sustained SDAI remission only. Baseline variables having no association with sustained remission included: symptom duration, smoking status, fatigue, patient global, DAS28, HAQ, RF, anti-CCP and erosive disease. Initial treatment with methotrexate alone was negatively associated with both types of remission, while combination DMARD therapy or biologic use, were not predictive.

Conclusion: Even when stringent definitions of remission are considered, sustained remission is possible within the first year for ERA patients initially treated with DMARD. Age and baseline pain influence remission. Shorter time-to-remission is related to sustainability and supports striving for early remission. However, the time to reach sustained remission may be falsely long in this cohort because data are only collected every 6 months after the first year. The optimal initial treatment approach could not be determined as the association between DMARD therapy and sustained remission likely suffers from confounding by indication.

95

Cost-effectiveness Analysis of Early Biologic Treatment in Polyarticular Juvenile Idiopathic Arthritis

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Objective: The optimal timing of high-cost biologic therapies in the treatment of polyarticular juvenile idiopathic arthritis (JIA) is uncertain. We evaluated the economic and health outcomes of initial compared with step-wise use of anti-tumor necrosis factor (TNF) agent, etanercept (ETN), in this setting.

Methods: We conducted a cost-utility analysis of two strategies from a Canadian healthcare payer perspective. In one strategy, initial therapy was with methotrexate (MTX) alone. ETN was added in a step-wise fashion for patients who did not respond to MTX. In the other strategy, initial therapy was with MTX in combination with ETN; patients who did not respond switched to another anti-TNF agent. In both strategies, third and fourth line therapies were modeled with additional biological agents. Our base case was a 12-year-old child (weight 40 kg) with newly diagnosed polyarticular JIA naïve to disease-modifying and biological agents. We simulated the course of the disease over 2 and 5 years using a Markov model with a cycle length of 1 month. Treatment response was defined as achieving an ACR Ped 70 response or better after 4 months of therapy. If this response was sustained over 12 months, without flare, patients entered a remission state. We derived model parameters, including treatment efficacy, disease flares, adverse events, costs, and quality of life weights from the medical literature. Effects were calculated as quality-adjusted life years (QALYs); costs and QALYs were discounted at a rate of 3% per year. We conducted sensitivity analyses on all model parameters to assess the robustness of our results and used a $50,000/QALY threshold for cost-effectiveness.

Results: Over a 2-year horizon, the combination of initial MTX and ETN, compared to MTX alone, resulted in a discounted incremental cost of $14,469 per patient, a discounted incremental effect of 0.10 QALYs, for an incremental cost-effectiveness ratio (ICER) of $144,471 per QALY. After 5 years, the incremental cost per patient was $18,320 with an incremental effect of 0.22 QALYs, for an ICER of $82,608 per QALY. The results were sensitive to the cost of ETN and estimates of the efficacy of initial combination therapy.

Conclusion: Our model suggests that initial combination therapy of MTX and ETN is unlikely to be cost-effective compared to using MTX alone, but more research is needed on key model parameters, including efficacy of initial anti-TNF agents and their impact on quality of life. A reduction in the cost of ETN by about 36% would make initial use of this drug cost-effective.

96

Is a Single Variable, the Swollen Joint Count, Valid as an Outcome Measure Separate from being in an Index Measure? An Analysis from the Prospective, Observational Registry, BioTRAC

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Objective: The importance of joint counts as measures of synovitis is reflected in their prominence in all major clinical composite indices, the Disease Activity Score (DAS), the Clinical Disease Activity Index (CDAI), and the Simplified Disease Activity Index (SDAI). The twenty-eight swollen joint count (SJC28) contributes numerically to about 16% of DAS28, 37% of CDAI and 33% of SDAI. The aim of this analysis was to examine whether SJC28 could be used as a stand-alone measure of disease remission.

Methods: BioTRAC is an ongoing, prospective registry of patients initiating treatment for RA, AS, or PsA with infliximab or golimumab as first biologics or after having been treated with a biologic for less than six months. In this analysis, data from RA patients treated with infliximab who were enrolled between January 2002 and June 2011 were used. Agreement between SJC28≤1 and remission or low disease activity as defined by the DAS28, CDAI, and SDAI criteria was assessed with the sensitivity, specificity, as well as the positive (PPV) and negative (NPV) predictive value.

Results: A total of 838 RA patients with mean (SD) age of 55.6 (13.5) years and mean (SD) duration since diagnosis of 10.5 (19.8) years were included in this analysis, providing information from 4,582 assessments. Using DAS28, CDAI, SDAI, and Boolean remission as reference standards, SJC28 sensitivity for predicting remission was 91.0%, 99.1%, 98.3%, and 100.0%, respectively. In addition, SJC28 correctly classified non-remission (NPV of 94.9%, 99.8%, 99.5%, and 100.0% for DAS28, CDAI, SDAI, and Boolean definition, respectively). However, specificity was only moderate (DAS28: 72.6%, CDAI: 64.0%, SDAI: 63.0%, Boolean: 61.8%), and SJC28 yielded a considerable proportion of false positives as indicated by the low PPV observed (DAS28: 58.9%, CDAI: 32.1%, SDAI: 33.0%, Boolean: 29.3%). When looking at low disease activity, SJC28≤1 showed lower sensitivity (DAS28: 83.2%, CDAI: 83.8%, SDAI: 85.0%) and NPV (DAS28: 85.8%, CDAI: 86.9%, SDAI: 87.5%) but higher specificity (DAS28: 83.2%, CDAI: 85.2%, SDAI: 84.2%) and PPV (DAS28: 80.1%, CDAI: 82.2%, SDAI: 81.1%).

Conclusion: The results of this analysis have shown that SJC28≤1 has high discriminatory power for low disease activity and moderate discriminatory power for remission as defined by the DAS28, CDAI and SDAI criteria. The more rigorous ACR/EULAR Boolean remission criteria were associated with increased sensitivity and NPV but decreased specificity and PPV.

97

Effect of Partial and Complete Proteinuria Recovery in Lupus Nephritis on Longterm Outcomes

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Objective: The identification of partial proteinuria recovery (PPR) of ≥ 50% allows for the detection of an additional number of patients with lupus nephritis (LN) who improve their proteinuria on standard of care (SOC) treatment. To determine the prognostic value of PPR and complete proteinuria recovery (CPR) at 1 year on longterm outcomes compared to patients who did not recover proteinuria ≥ 50% on SOC.

Methods: We studied all active LN patients registered at lupus clinic (1970-2011). Proteinuria was defined as> 0.5g/24 hours. Patients with proteinuria and at least one of the urinary sediments (hematuria, pyuria or casts) present at entry into the study and persistent on 2 consecutive visits were enrolled. CPR was defined as proteinuria < 0.5g/24 hours based on SLEDAI-2K. PPR was a decrease of ≥ 50% in the level of proteinuria from baseline as defined by SLEDAI-2K Responder Index-50 (S2K RI-50). Proteinuria recovery was identified if present on 2 consecutive visits within 1 year. The longterm outcomes (death, eGFR< 15, dialysis or kidney transplant, SLICC Damage Index (SDI)>0, SDI>3) occurring after the identification of proteinuria related to LN at entry into the study were studied. The mean time to longterm outcome was determined. Proportional hazard models were used to determine the hazard ratio (HR) for long termoutcomes for the different recovery definitions.

Results: 217 patients (81.8% F) were identified. At 1 year: 45 patients achieved PPR, 48 CPR, and 124 not recovered. Longterm outcomes: eGFR< 15 was identified in 14.3% of the patients, dialysis or kidney transplant in 12.8%, 18% of the patient died, and 56% developed damage (SDI>0); SDI >3: 30.7%. The mean time to event from 1st visit: 7.0 ± 8.3 years for death (n=39), 3.7 ± 3.7 years for eGFR< 15 (n=30), 5.5 ± 6.0 for dialysis or kidney transplant (n=20), 3.6 ±5.6 years for SDI>0 (n=75) and 6.1 ± 7.3 years for SDI>3 (n=57). Achieving a PPR at 1 year protects from the development of eGFR< 15; HR=0.29. Achieving a CPR at 1 year protects from the development of eGFR< 15 (HR=0.25), accrual of damage with SDI>3 (HR=0.23) and none with CPR at 1 year subsequently went on to dialysis or transplant.

Conclusion: Achieving complete recovery from proteinuria in patients with active LN at 1 year from the onset of LN protects against endstage kidney disease, dialysis and transplant, organ damage and death. Nonetheless, achieving at least partial recovery in proteinuria, ≥ 50%, at year 1 against the development of eGFR< 15.

98

Spinal Inflammation in the Absence of SI Joint Inflammation on MRI in Patients with Active Non-radiographic Axial Spondyloarthritis

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Objective: The imaging arm of the ASAS axial spondyloarthritis (SpA) criteria requires the presence of sacroiliitis on magnetic resonance imaging (MRI) or radiographs. In patients (pts) with non-radiographic axial SpA (nr-axSpA), there may be inflammation along the spine in the absence of sacroiliac joint (SIJ) inflammation on MRI. This analysis evaluated the existence of spinal inflammation on MRI at baseline (BL) in nr-axSpA pts with and without inflammation in the SIJ on MRI.

Methods: ABILITY-1 is an ongoing multicenter, randomized, controlled trial of adalimumab vs placebo in pts with nr-axSpA classified using the ASAS axial SpA criteria, who had an inadequate response, intolerance to, or contraindication for nonsteroidal antiinflammatory drugs. MRI of the SIJ and spine performed at BL were centrally scored using the SPARCC method (6-DVU method for the spine) by 2 independent readers blinded to the treatment codes. Mean scores of the readers were used. SPARCC score ≥2 for either the SIJ or spine was used as the operational definition of positive MRI evidence of inflammation. For these analyses, all pts were combined, independent of randomization.

Results: Mean symptom duration of the study population (N=185) was 10 yrs. At BL, 48% of pts were reported by the local investigator to have past or present MRI evidence of sacroiliitis as required by the ASAS axial SpA criteria. Of pts with available BL SPARCC scores, 40% had a BL SIJ score ≥2 and 52% had a BL spine score ≥2. Of the pts with BL SPARCC SIJ score < 2, 49% had evidence of spinal inflammation (BL SPARCC spine score ≥2). Comparison of BL disease characteristics based on BL spine and SIJ scores < 2 vs. ≥2 were generally comparable except for a greater proportion of males among those with spine and SIJ scores ≥2, and younger age and shorter symptom duration among those with spine and SIJ scores < 2. Similar distribution of SPARCC spine scores were observed regardless of presence or absence of SIJ inflammation on MRI. The most frequently involved DVUs with bone marrow edema were in the lower thoracic and lumbar spine.

Conclusion: Assessment by experienced readers shows that spinal inflammation on MRI may be observed in half of nr-axSpA pts without SIJ inflammation on MRI. MRI of both sites might be of value when evaluating pts with nr-axSpA. These data in pts with long-standing disease need to be confirmed in pts with shorter disease duration.

99

Epoprostenol Rescue Therapy in SSc-PAH and IPAH

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Objective: Epoprostenol has been demonstrated to improve hemodynamics, functional class, and six-minute walk distance (6MWD) in systemic sclerosis-associated pulmonary arterial hypertension (SSc-PAH) and idiopathic PAH (IPAH) patients. In contemporary practice, it is usually reserved for patients who have failed treatment with endothelin receptor antagonists and/or phosphodiesterase-5 inhibitors. The effect of epoprostenol rescue therapy on survival has not been evaluated. The objective of this study was to evaluate the role of intravenous epoprostenol as rescue therapy in the SSc-PAH and IPAH patients.

Methods: Patients attending the University Health Network Pulmonary Hypertension Programme between 1998 and 2012 were included if they had a diagnosis of SSc-PAH and IPAH based on a mean pulmonary artery pressure (mPAP) of ≥ 25 mmHg and a pulmonary capillary wedge pressure of < 15 mmHg on cardiac catheterization, and had been treated with intravenous epoprostenol after treatment with endothelin receptor antagonists and/or phosphodiesterase-5 inhibitors for PAH. The primary outcome was survival. Survival was defined as the time from initiation of epoprostenol to death from any cause. Patients were censored as of May 1, 2012. Survival was evaluated using Kaplan Meier curves.

Results: 1140 patients were reviewed to identify 36 patients with SSc-PAH and 24 patients with IPAH treated with epoprostenol after failure with oral pulmonary hypertension specific therapies. 83% of SScPAH and 75% of IPAH patients were female. The mean (standard deviation) PAH duration prior to initiation of epoprostenol was 3.3 ± 5.7 years for SScPAH, and 2.1 ± 2.1 years for IPAH patients. Median 1-, 2-, 3-, 4-, 5-year survival for SSc patients was 85.7%, 60.7%, 53.6%, 46.1%, 42.3%; and for IPAH patients was 83.3%, 70.8%, 65.8%, 59.2%, 59.2%. There was no significant difference in survival between the SScPAH and IPAH patients treated with epoprostenol (p=0.13).

Conclusion: Our findings demonstrate desirable long-term survival and support the use of epoprostenol as rescue therapy for SSc-PAH and IPAH patients.

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100

Comparison of Subsets of IgG4-Related Disease

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Objective: IgG4-related disease (IgG4-RD) is a novel clinicopathological entity of unknown etiology characterized by elevated serum IgG4 subset, multiorgan IgG4-secreting plasma cell (IgG4-PC) infiltration and marked response to corticosteroids. Although IgG4-related autoimmune pancreatitis (IgG4-AIP) is well-recognized, criteria for multi-organ IgG4-RD were only recently proposed and classified patients as: A. Definite IgG4-RD: positive serology (IgG4≥135mg/dl) and pathology (>10 IgG4-PC/high-powered field[IgG4-PC/HPF], IgG4:IgG-plasma cell ratio≥40%); B. Probable IgG4-RD: pathology alone; C. Possible IgG4-RD: serology alone; the relationship of IgG4-AIP to extra-pancreatic IgG4-RD and between these categories has not been explored. Our objectives were to compare: (I) IgG4-AIP(A1) to extra-pancreatic IgG4-RD(A2); (II) definite(A) to probable(B) and possible(C) IgG4-RD; with respect to epidemiology, organ involvement, histopathology, serology, and treatment.

Methods: Medline was used to identify detailed case reports of IgG4-RD published in English-language peer-reviewed journals during the last decade. Patients satisfying the proposed diagnostic criteria were divided into four groups (A1,A2,B,C) as described above and examined for significant differences in age, gender, organ involvement, serum IgG4, biopsy IgG4-PC/HPF and IgG4:IgG ratio in serum and tissue, autoantibodies and steroid-responsiveness. Unpaired t-tests with Welch modification, Chi-squared, Fisher's exact, and Pearson correlations were used for group comparisons using R-project.

Results: We identified 122 articles with 220 case reports; 169 met inclusion criteria. I. When comparing group A1 vs A2: i. M:F ratios were 8.6:1 vs 2.1:1 (OR 4.04,p=0.010); ii. Hepatobiliary involvement occurred in 65% vs 13%(p< 0.001) and retroperitoneal fibrosis in 27% vs 11% (p=0.041). iii. Serum IgG4 was marginally higher (1075±904 vs 786±603, p=0.074); iv. Tissue IgG4-PC/HPF was lower (73.7±61.1 vs 176.1±149.1, p=0.037); v. Likelihood of steroid treatment was 85% vs 62% and remission was seen in 98% vs 97%. II. When comparing group A vs B and C: i. Lymphadenopathy occurred in 51% of A vs74% of C (p=0.03); ii. Serum IgG4 was higher in A vs C (933.5±781 vs 617±390, p=0.005); iii. Likelihood of steroid treatment was 75% in A vs 32% in B (p< 0.001) with remission in 97% vs 80% (p=0.010). III. The number of organs affected correlated with serum IgG4 level in all groups (R=0.31-0.85)

Conclusion: I. In comparison to extra-pancreatic IgG4-RD(A2), IgG4-AIP(A1) was associated with increased male bias, hepatobiliary disease, retroperitoneal fibrosis, higher IgG4 in serum and lower IgG4-PC/HPF in tissue (but similar IgG4:IgG ratios), and higher steroid treatment likelihood. II. In comparison to definite IgG4-RD(A), possible IgG4-RD(B) was associated with lymphadenopathy and lower serum IgG4, while probable IgG4-RD(C) was associated with lower steroid treatment likelihood and lower remission rates. III. Serum IgG4 level was associated with the number of organs affected.

101

Male Gender is Associated with Accelerated Radiographic Progression in Axial Damage but not with Progression of Peripheral Damage in Psoriatic Arthritis

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Objective: Gender-related differences have not been thoroughly explored in psoriatic arthritis (PsA). Our group recently reported that men have more severe radiographic damage in their peripheral and axial joints in a cross-sectional analysis. We aimed to further investigate whether male gender is associated with increased radiographic progression of joint damage compared to females.

Methods: A retrospective cohort analysis was performed among patients who have been followed in a large PsA clinic from 1978 to 2012. Patients were followed according to a standard protocol. Radiographs of the hands, feet and spine were performed at 2 year intervals. Radiographic damage based on 42 joints in the hands and feet was assessed according to a modification of the Steinbrocker method. Radiographic damage to the lumbar and cervical spine was scored using the modified Stoke Ankylosing Spondylitis Spinal Score (mSASSS). For each patient, all available radiographic data were included. Patients who initiated treatment with anti- tumor necrosis factor-α (TNF-α) agents were censored. The outcome of interest was the difference in the modified Steinbrocker score and mSASSS compared to the first visit. Multivariate regression analysis using Generalized Estimating Equations (GEE) for repeated measures was used to compare progression in radiographic damage across the genders incorporating available information from all time points.

Results: 1067 PsA patients were included in the study (females: 43.5%, males: 56.5%). Females had higher duration of psoriasis (16.8±13.3 vs. 14.1±11.5 years, p< 0.001) and PsA (7.6±9.3 vs. 6.2±7.3 years, p=0.007). At first visit, mSASSS was higher in males (2.4±7.7 vs. 0.03±0.24, p=0.002); however no difference was found in the mean modified Steinbrocker scores across the genders (p=0.24). Gender was not associated with progression in radiographic damage in the peripheral joints in both univariate and multivariate analyses. In a multivariate regression analysis tender joint count (p=0.01), ever use of disease-modifying antirheumatic drugs (p=0.004) and radiographic damage at first visit (p=0.0006) predicted progression in modified Steinbrocker score. In contrast, male gender predicted progression in mSASSS (β=0.25, p=0.04) in multivariate analysis, while the use of nonsteroidal antiinflammatory drugs was found to have a protective effect (p< 0.0001).

Conclusion: Among patients with PsA, men tend to accumulate more radiographic axial damage compared to women. No effect of gender on progression in radiographic joint damage was observed. It is unclear whether these findings are secondary to differences in occupational physical activity, hormonal changes, or other factors.

102

Clinically Apparent Arterial Thrombosis in Persons with Systemic Vasculitis

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Objective: Systemic vasculitides are a group of heterogeneous, autoimmune disorders characterized by inflammation and necrosis of blood vessels. As with other autoimmune disorders, inflammation leads to accelerated atherosclerosis, with subsequent arterial thrombosis being a significant adverse outcome. Our first goal is to compare the rate of arterial thrombotic events in patients with polyarteritis nodosa (PAN) and granulomatosis with polyangiitis (GPA), with that in the general population. Our second goal is to determine if clinical factors within the vasculitis group were associated with an increased incidence of arterial events.

Methods: Data were collected from the provincial administrative data (Quebec population) from the years 1996-2006. Incident cases of PAN (ICD 446.0) and GPA (ICD 446.4) were included in the cohort, and age (under 65, over/= 65) and sex-matched controls were taken from general population. Outcomes included acute myocardial infarction (MI; ICD 410.x) and cerebrovascular accident (CVA - ICD 433.x, 434.x) were assessed longitudinally via hospitalization records within the same administrative data. Outcomes in vasculitis cases were compared to those in the general population. Further, Cox regression analysis was conducted to elucidate any differences in baseline clinical characteristics (sex, diagnosis of hypertension, dyslipidemia, diabetes, congestive heart failure) between the group diagnosed with vasculitis compared to the group without vasculitis.

Results: Mean incidence was 6.2% in the PAN and GPA group compared to 2.6% in the general population from 1996-2006 (1412 subjects with

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vasculitis). A statistically significant difference in acute myocardial infarction was observed in both male and female individuals under 65 years old. Younger males with vasculitis had an 8.26% (CI 95% 3.02-13.51) difference in incidence of myocardial infarction (9.32% vs. 1.06% in the general population). Similarly, females under 65 years old had a 2.55% (CI 95% 0.34%-4.76%) difference in myocardial infarction (2.80% vs. 0.25% in the general population). Among subjects with GPA, there was an overall mean incidence of 3.31% (N=242) compared to 2.62% in the general population, however this did not achieve statistical significance.
Conclusion: Patients with PAN and GPA have a higher incidence of arterial thrombotic events, with the most significant difference seen in males and females under the age of 65 within the PAN subgroup. As such, if there is increased risk of arterial thrombotic events in these patients more intense cardiovascular risk factor modification may be undertaken, which will hopefully lead to improved outcomes.

103

Literacy Rates of Patients with Rheumatoid Arthritis in Southwestern Ontario

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Objective: To determine the low health literacy rate in the rheumatoid arthritis (RA) patient population in Southwestern Ontario by using four common healthy literacy assessment tools.
Methods: A total of 432 RA patients were contacted, and 311 completed the assessment. The health literacy levels of the participants were estimated by using four assessment tools: the Shortened Test of Functional Health Literacy in Adults (STOFHLA), the Rapid Estimate of Adult Literacy in Medicine (REALM), the Medical Term Recognition Test (METER), and the Single-Item Literacy Screener (SILS).
Results: The study included 235 women (75.6%), with a mean age (SD) of 62.8 (12.7) yrs. The rates of low literacy as estimated by STOFHLA, REALM, METER, and SILS were 14.5%, 14.8%, 14.1%, and 18.6%, respectively. All four assessment tools were statistically significantly correlated. STOFHLA, REALM, and METER were strongly correlated with each other (r = 0.59-0.79), while SILS only demonstrated moderate correlations with the other assessment tools (r = 0.33-0.45). Multiple linear regression and binary logistic regression analyses revealed that low levels of education and a lack of daily reading activity were common predictors of low health literacy shared by all four instruments. Some similarities and differences were noted between STOFHLA, REALM, and METER. Using a non-English primary language at home was found to be a strong predictor of low health literacy in STOFHLA, REALM, and METER. Male sex was found to be a significant predictor of poor performance in REALM and METER, but not STOFHLA.
Conclusion: Low healthy literacy is an important issue in the Southwestern Ontario RA patient population. Approximately 1 in 7 RA patients may not have the necessary skills to become involved in making decisions regarding their personal health. Rheumatologists should consider assessing health literacy clinically and identify those who are at risk. Supported by a CIORA grant.

104

Real-world Effectiveness of Infliximab in Improving Routine Assessment of Patient Index Data 3 Outcomes: The Canadian Experience

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Objective: The routine assessment of patient index data 3 (RAPID3) was designed as a pooled index of 3 patient-reported outcomes (PRO): physical function, pain, and patient global. Compared to other simplified disease activity scores, RAPID3 may be more desirable in a clinical setting due to the shorter scoring time required. The objective of this study was to assess, in a Canadian real-world setting, RAPID3 outcomes in rheumatoid arthritis (RA) patients treated with infliximab (IFX).
Methods: BioTRAC is an ongoing Canadian registry of RA, ankylosing spondylitis, or psoriatic arthritis patients initiating treatment with infliximab (IFX) or golimumab (GOL) as first biologics or after having been treated with a biologic for less than six months. A total of 806 RA patients initiated IFX between 2002 and 2012 and were included in this analysis. RAPID3 was assessed both in a continuous scale and a categorical scale defining high activity (>12), moderate activity (6.1-12), low activity (3.1-6), and remission (≤3).
Results: Mean (SD) age of patient cohort was 55.3 (13.5) years, and mean (SD) duration since diagnosis was 8.9 (9.3) years. Mean (SD) patient characteristics at baseline were: ESR= 32.5 (24.2) mm/hr; CRP= 19.0 (24.0) mg/L; SJC-28= 10.8 (7.0); TJC-28= 12.7 (8.0); HAQ-DI= 1.7 (0.7); DAS28-CRP= 5.4 (1.3); Pain-VAS= 5.8 (2.4); PGA-VAS= 6.6 (2.1); SGA-VAS= 6.1 (2.4) and CDAI= 36.4 (16.2). By 6 months of treatment, clinically meaningful and statistically significant (P< 0.05) improvements were observed in all measurements, which were sustained over 24 months. Similarly, the mean (SD) RAPID3 score significantly decreased from 17.3 (6.2) at baseline to 11.4 (6.9), 10.5 (7.0), and 9.3 (6.9) at 6, 12, and 24 months, respectively. RAPID3 disease categories changed over time upon IFX treatment. The proportion of patients with high disease activity decreased from 80.6% at baseline to 34.2% at month 24. Further, the proportion of patients with low activity or remission increased from 6.0% at baseline to 41.6% at month 24. The positive correlation over time between DAS28-CRP and RAPID3 (rho=0.748; P< 0.001) and between SDAI and RAPID3 (rho=0.743; P< 0.001) further confirms the validity of the RAPID3 as disease activity score in real-life RA patients.
Conclusion: The results of this Canadian real-world observational study demonstrate that, over two years of treatment, IFX is effective in reducing symptom severity and improving patient-reported outcomes in RA patients. Further, the data from this registry confirmed the validity of the RAPID3 index as disease activity measure in a real-world RA cohort.

105

What Proportion of Patients with Rheumatoid Arthritis Fail to Achieve Remission Based on the Patient Global? An Analysis from the Prospective, Observational Registry, BioTRAC

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Objective: According to the latest ACR/EULAR guidelines, Boolean remission in rheumatoid arthritis (RA) is defined as achievement of patient global assessment (PtGA) ≤1, 28-swollen joint count (SJC) ≤1, 28-tender joint count (TJC) ≤1, and C-reactive protein (CRP) ≤1 mg/dL. Recently, PtGA has been criticized for not accurately assessing RA disease activity, as it may reflect aspects not directly related to RA disease activity such as fibromyalgia, low back pain, depression, or other conditions. The aim of this analysis was to assess the proportion of patients failing to achieve remission based on PtGA in a real-world, routine clinical care setting in Canada.
Methods: BioTRAC is an ongoing, prospective registry of patients initiating treatment for RA, ankylosing spondylitis, or psoriatic arthritis with infliximab or golimumab as first biologics or after having been treated with a biologic for less than six months. In this analysis, data from RA patients

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who were treated with infliximab between January 2002 and June 2011 were used. Correlation of PtGA with other clinical outcome measures was assessed with general linear models.

Results: Eight hundred and thirty-eight RA patients who had 4,582 assessments were included in the analysis. Mean (SD) age was 55.6 (13.5) years and mean (SD) duration since diagnosis was 10.5 (19.8) years. A total of 2,015 instances of non-remission were identified, of which 620 (30.8%) were near-remission cases. Near-remission is defined as attainment of three of the four Boolean criteria (CRP, SJC, TJC and PtGA). Among these, PtGA was the most common reason of non-remission (54.0%), followed by 28-tender joint count (TJC28; 27.7%), C-reactive protein (CRP; 10.0%), and 28-swollen joint count (SJC28; 8.2%). General linear models using PtGA as the dependent variable showed a statistically significant (P< 0.001) positive association with HAQ-DI [mean (95%CI) estimate = 2.57 (2.47, 2.67), TJC28 0.21 (0.20, 0.22), SJC28 0.24 (0.23, 0.26)], physician global assessment [0.67 (0.64, 0.70)], and pain [0.940 (0.93, 0.95)].

Conclusion: The results of this analysis have shown that PtGA is the most common limiting factor in achieving Boolean ACR/EULAR remission, accounting for as many as 54% of the near-remission cases. However, a positive association was observed between PtGA and clinical outcomes, functional activity, and pain. Further analyses are required to identify the determinants of patient global assessment.

106

A New Approach to Measure Treatment Efficacy in Early Inflammatory Arthritis by High-resolution 3D Quantitative Measures of Bone Density, Joint Space Width, and Erosions

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Objective: Quantify measures of bone damage in the first year of rheumatoid arthritis (RA) and undifferentiated arthritis (UA) by high-resolution peripheral quantitative computed tomography (HR-pQCT, Scanco Medical AG), which provides bone microarchitecture resolution at 82 μm.

Methods: HR-pQCT images of the 2nd and 3rd MCP joints of subjects at diagnosis and controls were obtained, with repeat scans at 1 year. The manufacturer's standard evaluation protocol was applied to quantify measures of bone density and microarchitecture. Joint space width was measured using a custom analysis implemented for the HR-pQCT based on direct measurements from the high resolution image data. Erosions were quantified based on identification of non-physiological cortical breaks in 3D.

Results: Eight subjects have completed the study (RA=3, UA=3, 50% female, 53 years of age, symptoms 7.4 months, BMI 28.5, 2 RF positive and 4 anti-CCP positive). The mean reduction in DAS28 at 1 year was 3.82 (SD 1.33), with subjects exposed to steroids (n=3), DMARD monotherapy (n=3), combination DMARD therapy (n=5) and 1 requiring anti-TNF treatment to achieve low disease activity. Joint space width was unchanged after 1 year in all subjects. The mean 2nd MCP width at baseline was 2.16 (SD 0.46) mm vs 2.18 (SD 0.40) mm at 1 year in RA and UA, and 2.23 (SD 0.55) mm vs 2.24 (SD 0.49) mm in controls. Total bone density improved in RA and UA subjects over 1 year [302.5 (SD 49.3) to 347.0 (SD 135.8) mgHA/cm3)] and was unchanged in controls [378.0 (SD 38.2) to 377.1 (SD 34.6) mgHA/cm3]. Trabecular density also improved over 1 year in RA and UA subjects [230.5 (SD 37.9) to 257.5 (SD 89.7) mgHA/cm3)] and was stable in controls [301.0 (SD 41.0) to 300.1 (SD 36.8) mgHA/cm3]. HR-pQCT imaging was more sensitive in detecting erosive changes, with only 1 subject determined to have erosions on plain radiograph at baseline and another at 1 year, compared to 2 subjects with erosions by HR-pQCT at baseline and 4 at 1 year.

Conclusion: Bone density improved in the first year of treated RA and UA. Precise measurements of joint space width were obtained, with no apparent changes occurring in any subject group over 1 year. HR-pQCT provides 3D assessment of erosions, rather than relying on projection data from radiograph. HR-pQCT technology is a novel and exciting addition to the assessment of treatment efficacy in RA.

107

Results of a Screening Program to Detect Inflammatory Arthritis in a First Nations Community

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Objective: 1) Institute an arthritis screening program in a First Nations community with a large suspected burden of inflammatory arthritis, to enable diagnosis and treatment at an earlier stage of disease. 2) Determine the prevalence of inflammatory arthritis, musculoskeletal symptoms, and resulting functional status, and autoantibodies in an Alberta First Nations community.

Methods: Consenting participants were recruited from a variety of community settings. A standardized musculoskeletal history and examination by a rheumatologist and the Health Assessment Questionnaire (HAQ) were completed. Serologic testing (RF, ANA, ENA, anti-CCP) was performed using conventional diagnostic technologies and protocols.

Results: 162 participants were screened (76% female, mean age 51 years). A family history of rheumatoid arthritis (RA) or systemic lupus erythematosus (SLE) was documented in 49% and 15%, respectively. All individuals reported at least 1 musculoskeletal symptom with the most frequent being pain localized to the hands (85%), knees (74%), and lumbar spine (63%). The most frequent noninflammatory arthritis conditions were osteoarthritis (55%), tendonitis/bursitis (22%), and degenerative disc disease or mechanical back pain (19%). Twenty-seven new cases of inflammatory arthritis were diagnosed (RA=12, SLE=2, PsA=4, UA=7, crystal=1, JIA=1; median symptom duration 6 months) and 19 patients with previously diagnosed inflammatory arthritis were returned to active care (RA=7, SLE=6, PsA=2, SpA=1, JIA=1, crystal=1, median disease duration 13 years). The mean DAS28 at enrollment was 4.23 (SD 1.06) for new RA cases and 3.92 (SD 1.34) for established patients. RF and anti-CCP were positive in 54% and 64% of participants with RA respectively but only in 1% and 4% of participants with non-inflammatory arthritis conditions. ANA was positive in 48% of the non-inflammatory arthritis group, with 41% having titers >1:320, but positive ENA tests were rare. The mean HAQ score in patients with inflammatory arthritis conditions was 1.30 compared to 0.92 for non-inflammatory arthritis conditions (p=0.0018), with the mean pain (5.6/10), fatigue (5.4/10), sleep (5.4/10), and global evaluation (4.2/10) scores not being significantly different between inflammatory and non-inflammatory arthritis participants.

Conclusion: The screening program has been successful in detecting new cases of inflammatory arthritis in this First Nations community early in the disease course and returning established rheumatology patients to active care. We have identified frequent musculoskeletal symptoms attributable to osteoarthritis, and ANA positivity in the absence of a recognizable connective tissue disorders. These findings highlight the need for a multidisciplinary team incorporating primary care providers, allied health professionals, and specialists to maximize musculoskeletal care in the community. Supported by a CIORA grant.

108

Impact of Biologics on Healthcare Utilization in Patients with Rheumatoid Arthritis: An Instrumental Variable Approach

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Canada, Richmond); Aslam Anis (University of British Columbia, Vancouver)

Objective: Expenditure on biologic therapies for rheumatoid arthritis (RA) accounts for the highest pharmaceutical spending in many Western healthcare systems. These costs have been justified by improvements in quality of life and reductions in joint erosions. Despite over 10 years of use, there is currently no direct evidence supporting an association between biologics and subsequent reductions in healthcare use. The objective of this study was to estimate the impact of biologic treatment compared to disease-modifying antirheumatic drugs (DMARD) on other healthcare utilization, using instrumental variable (IV) techniques to control for confounding by indication.

Methods: From a population-based cohort of all BC patients with a rheumatologist diagnosis of RA identified from administrative data, we selected patients attaining eligibility for biologics between 2003-2007 based on DMARD use history and having 3-year followup under continuous care of rheumatologists since eligibility. Patients receiving biologics in the first followup year form the treatment group whereas others who never received biologics throughout the followup form the control group. The data contains patient-level information on hospitalizations, physician visits (investigations and procedures), and prescription medications. Since disease severity is known to be associated with treatment received and healthcare use, but is not adequately captured in administrative data, an IV based on the prescribing rheumatologist's preference for biologic use at the time of treatment assignment was used to address confounding by indication. Separate analyses were performed on physician visits and medications, but not on hospitalizations due to few inpatient encounters.

Results: The final analysis included 321 and 334 patients with a mean age 56.8 and 58.1 in the biologic and DMARD groups, respectively. As expected, conventional multivariable regression adjusting for observed confounders did not attribute biologic use with cost offsets. The IV analysis results suggest that RA-related costs in the biologic group, compared to the DMARD group, was 2.3% and 22.9% more for physician visits but 29.6% and 33.1% less for medications excluding biologics or DMARD in the 2- and 3-year followup periods, respectively. A similar pattern was observed for total resource use.

Conclusion: While RCT are the gold standard for determining causal relationships, such studies would be infeasible to investigate this important question. Through the use of established econometric methods and a population-based administrative dataset, this study showed that biologic use in the short-term offset medication costs but not physician visits costs. Incorporating future long-term data will enable us to estimate whether biologic use leads to reduced costs from joint surgeries and other hospitalizations. Supported by a CIORA grant.

109

Breast Cancer in Systemic Lupus Erythematosus

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Objective: Evidence points to a decreased breast cancer risk in systemic lupus erythematosus (SLE). We provide a brief report of the breast cancer cases from a very large international SLE cohort.

Methods: Data were obtained from a multi-site cohort study of 15,980 SLE patients from 28 centres. Cancer cases were ascertained through linkage with regional tumor registries. Information on date of birth, date of SLE diagnosis, and cancer date was available, as were the histology reports from the cancer registries where the breast cancer cases had been ascertained. Cancer cases were included if they had occurred any time after SLE diagnosis, and cancers of all stages, including non-invasive lesions, were assessed. We summarized demographic characteristics, and analyzed information on histology type. Within the cancer cases that had occurred in SLE, we also performed multivariate logistic regression analyses to determine whether there were independent effects on histology type of breast cancers in SLE, according to sex, age, race, calendar year, and SLE duration. Here, the outcome modelled was the odds ratio (OR) for lobular versus ductal cancer histologic type.

Results: We studied 183 breast cancer cases that had occurred in the SLE cohort. Average age of SLE patients at breast cancer diagnosis was 54 years (median 53, SD 11.5). The average SLE duration at the time of breast cancer diagnosis was 14 years (median 13, SD 9.5). In 25 cases, the histological type was not specified. In the remaining 157, the most common histological type was infiltrative ductal adenocarcinoma (N=87, 55%), followed by infiltrative lobular adenocarcinoma (N=19, 12%). The remaining 32% were a variety of "special types" including mixed ductal-lobular adenocarcinoma and other histologic types. In our multivariate regression analyses, the only independent risk factor, for lobular versus ductal breast cancer, was age, as a continuous variable (OR 1.07, 95% CI 1.01, 1.12).

Conclusion: In the general population, about 70% of breast cancers are ductal carcinomas. Lobular carcinoma makes up 10%-15% of the rest, and the remaining 15% are "special types". Based on our results, the distribution of histological breast cancer types in SLE seems similar to that of the general population, though there may be some increase in the frequency of 'special' histological types in SLE. Age, but not necessarily SLE duration, race, or calendar year, was an independent predictor of histological status. Further work is planned to assess other features of these cancers, including stage and hormone receptor status.

110

Medication Access for First Nations Patients with Inflammatory Arthritis

Christine Peschken (University of Manitoba, Winnipeg); Carol Hitchon (University of Manitoba, Winnipeg)

Objective: Prescription coverage for First Nations (FN) Manitobans is provided by a federal insurance program (FNIHB), while all other Manitobans (AOM) are covered by Manitoba Pharmacare (MBP). These two programs differ substantially with respect to formulary rules, logistics, and complexity. We investigated whether the program differences result in differences in access to biologic medications for FN versus AOM patients with inflammatory arthritis (IA).

Methods: New prescriptions for biologic medications for all IA patients followed at the Arthritis Centre were tracked for a 4-month period. All IA patients for whom a new biologic prescription was initiated were recorded at the time of their clinic visits. The time from the date of the request to medication approval, time to first dose administration, and timelines between steps of the approval process were recorded (e.g. receipt of forms from FNIHB), along with reasons for delay or denial, if applicable. The number of prior disease-modifying antirheumatic drugs (DMARD), including prior biologics failed as well as concurrent prednisone use, was abstracted from the Arthritis Centre database for each patient and compared for FN and AOM.

Results: Twenty-five percent of IA patients seen at our centre are FN. From February - May 2012, 38 new applications were made for biologics for FN patients, and 129 applications for AOM. The mean time to approval was 14.2 days for FN, compared to 1.5 days for AOM, $p < 0.001$. This difference related primarily to more "outliers" in the FN group. Fifty percent of AOM received approval on the same day, while 50% of FN received approval within 7 days, but 25% of FN received approval in ≥ 30 days, and 5% in ≥ 58 days, while for 95% of AOM patients, approval was received within 3 days. Findings were similar for time to first dose of medications. FN patients had failed a mean of 4.5 DMARD compared to 3.4 in AOM; p=0.012, and 58% of FN were taking prednisone, compared to 35% of AOM; p=0.015.

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Conclusion: Time to approval and initiation of biologic medications for IA was longer in FN compared to AOM patients. This difference alone, while statistically significant, is unlikely to be a clinically significant contributor to IA outcomes for FN. However, taken together with increased DMARD failures and prednisone use in FN, along with known increased disease severity, these results suggest that difficult medication access contributes to delayed care and worse outcomes for FN with IA. Supported by a CIORA grant.

111

Shared High Risk of Intensive Care Unit Admission in Three Autoimmune Inflammatory Diseases

Christine Peschken (University of Manitoba, Winnipeg); Carol Hitchon (University of Manitoba, Winnipeg); Alan Garland (Winnipeg); Charles Bernstein (University of Manitoba, Winnipeg); Randy Fransoo (Winnipeg); Ruth Ann Marrie (Winnipeg)

Objective: Little is known about the influence of autoimmune inflammatory diseases on the risk of critical illness, as defined by intensive care unit admissions (ICU). Using a large, population-based dataset, we determined the incidence of ICU admissions in rheumatoid arthritis (RA), multiple sclerosis (MS), and inflammatory bowel disease (IBD). These conditions are highly prevalent in Western countries and often managed with immunomodulatory therapies.

Methods: In a stable population of over 900,000 adults, hospital claims from an administrative database were linked to a population based ICU database to determine the incidence of ICU admissions from 2000-2010. RA, MS, and IBD patients were compared to cohorts from the general population, matched on sex, year of birth and region of residence, with up to 5 controls per case. Individuals with any autoimmune inflammatory disease were excluded from the control cohorts. We used previously validated definitions for RA, MS, and IBD. Annual incidence rates were estimated by age group, sex, and geographic region (number of persons in each cohort with ≥ 1ICU admission/ number of persons alive in that cohort at year-end). Results were age and sex standardized to the general Canadian population. The incidence of ICU admission between the disease specific cohorts and matched cohorts were compared using incidence rate ratios (IRR). The 10-year cumulative incidence of ICU admission for the period 2000-2010 was compared (number of persons with disease who had ≥ 1 episode of critical illness/ person-years at risk). Hazard ratios for the 10-year period were calculated after adjustment for age, sex, socioeconomic status, and comorbidity.

Results: The annual incidence rates of ICU admission over the 10-year period were RA 0.82-1.18%; MS 0.51-1.07%; and IBD 0.55-1.12%, compared to the matched cohorts, 0.32-0.60%. The IRR for the 10-year cumulative incidence rate was 1.62 (95% CI 1.46-1.80) for RA; 1.54 (95% CI 1.30-1.77) for MS; 1.52 (95% CI 1.36-1.68) for IBD. Hazard ratios over the 10-year period for the 3 diseases were RA HR=1.86 (95% CI 1.68-2.05); MS HR= 1.65 (95% CI 1.36-2.01); IBD HR= 2.02 (95% CI 1.78-2.28).

Conclusion: The risk of ICU admission is significantly increased in RA, MS, and IBD patients compared to the general population. Close to 1% of adults with these diseases develop critical illness each year; representing a substantial cost to the healthcare system. The risks between the 3 diseases are remarkably similar, suggesting shared risks from chronic inflammation and/or immunomodulatory therapy.

112

Determinants of Prognosis in Reactive Arthritis

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Objective: On initial presentation of reactive arthritis (ReA), little is known about how the disease will evolve in each individual patient. 4 to 9 percent of patients with ReA will go on to develop a chronic course. The goal of this study is to identify prognostic factors at initial presentation that will help to direct therapy and inform the patient.

Methods: Patients were identified via two methods. One group of patients was identified from a database of a large spondylitis clinic. The other group of patients was identified using billing codes from an urgent rheumatology clinic. Baseline data at presentation, including history, physical exam, radiographs, and serology were collected. Patients with self-limited ReA were compared to those with chronic ReA.

Results: A total of 39 patients with ReA were identified. Of these patients, 17 were classified as self-limited and 22 were deemed to have a chronic form of ReA. A difference was detected in presence of HLA-B27 in the self-limited vs. chronic group (43.8 percent vs. 90.9 percent, p 0.003). Both the presence of inflammatory back pain and a younger age at diagnosis trended towards an increased risk of developing chronic ReA (OR 3.89, 95% CI 0.865 to 17.482; OR 1.07, 95% CI 0.995 to 1.141, respectively). A subgroup analysis of chronic ReA patients revealed an increased incidence of both uveitis and SI joint involvement over time; only 4 (18.2%) patients presented with iritis; however over time, 10 patients (45.4%) developed it. Similarly, 45.4% of chronic ReA patients presented with sacroiliitis vs. 60% over time.

Conclusion: Only HLA-B27 was identified as a risk factor for chronicity. This study was limited by the sample size as well as its retrospective nature. Further research needs to be conducted in order to better delineate acute from chronic ReA. Further, prognostic factors will be difficult to determine unless a rigid definition as well as the culprit pathogens are firmly cemented.

113

Retention Rate of Adalimumab, Etanercept, and Infliximab at 5 Years in Patients with Ankylosing Spondylitis: Report from the Rhumadata Computerized Database

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Objective: The primary objective of this study is to evaluate the retention rate of patients suffering from ankylosing spondylitis after 5 years of exposure to either adalimumab (ADA), etanercept (ETA), or infliximab (INF). The secondary objective is to evaluate if all patients exposed to each biologic agent are similar or if there are characteritics that are different at entry between adalimumab, etanercept, and infliximab.

Methods: Using the Rhumadata software, we extracted all patients with ankylosing spondylitis as diagnosed by a rheumatologist.These patients had to be exposed to either adalimumab, etanercept, or infliximab as first exposure ever to a biologic agent. Data extraction period ranges from 2005 to 2011. All patients had to exposed to at least two different NSAIDS for a minimum of three months each to be eligible to received an anti-TNF agents. Their baseline BASDAI had to be equal or superior to 4 at entry. The different variables extracted from Rhumadata for each cohorts are: Number of patients, duration of disease, age at the time of anti-TNF introduction, gender, HLA-B27 status, morning stiffness duration, VAS pain evaluation, BASDAI and BASFI.

Results: 119 patients suffering from ankylosing spondylitis and exposed to either ADA, ETA or INF were found and extracted from the Database. 53 patients were prescribed ADA, 18 ETA and 48 INF. More than 75% of patients of each cohort were of male gender and the Mean age is 46 (SD 11). No significant differences in demographics and clinical variables were found between each group at baseline (T-test). Proportion of patients remaining on the same anti-TNF agent at 1 year is 80%, 2 years 70% and 5 years 55% (p=.988) (Kaplan-Meier analysis).

Conclusion: Adalimumab, etanercept, and infliximab retention rates at 1, 2 and 5 years for patients with ankylosing spondylitis are similar. Each of these agent is a adequate option in the treatment of ankylosing spondylitis.

114

Better Retention Rate at 5 Years of Anti-TNF Agents Used in Conjunction with Methotrexate Versus Anti-TNF Monotherapy in Patients with Rheumatoid Arthritis: Real-Life Data from the Rhumadata Computerized Database

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Objective: The primary objective of this study is to compare the survival rates of two different anti-TNF agents, adalimumab (ADA) and etanercept (ETA) used as first biologic agent with and without associated DMARDS in the treatment of rheumatoid arthritis (RA) using the data coming from the Rhumadata computerized database at the Institute of Rheumatology of Montreal. The secondary objective is to evaluate the influence of baseline demographic and clinical data on the primary outcome.

Methods: Data for all patients with rheumatoid arthritis according to the ACR criteria included in the database since 2005 and exposed for the first time only to an anti-TNF agents were extracted. Only patients exposed to adalimumab and etanercept were included in this analysis to standardize route of administration. Demographics and baseline clinical data are: age, gender, disease duration, tender joint count (TJC), swollen joint count (SJC), disease activity score including DAS 28 ESR and CRP 3-4 variables, CDAI, SDAI, Rheumatoid Factor and Anti-CCP baseline status, ESR and CRP at baseline, HAQ score, VAS fatigue scale, VAS pain Scale, morning stiffness duration, DMARDs and glucocorticoid usage.

Results: Data from 249 patients with rheumatoid arthritis are used. 95 and 154 patients were respectively using adalimumab or etanercept. All baseline demographic and clinical variables were comparable for both group ($p \geq 0.05$). There was slightly more usage of Dmards with ADA than ETA (89% vs 78%, p=0.02). TJC slightly lower for ETA than ADA (7.3 vs 9.5, p=0.04). There were more female patients in the monotherapy group than in the combination group (75% vs 90%, p=0.01). The 4 year survival rates (Kaplan-Meier survival proportion) for ADA+DMARDS vs ADA mono are respectively 56% and 11% (p=0.03 Log-rank statistic), for ETA+DMARDS vs ETA mono, 67% vs 47% (p=0.007), for combined ETA-ADA+DMARDS vs ETA-ADA MONO, 62% vs 40% (p=0.001) and for ADA or ETA both on MTX, 67% vs 57% (p=0.12).

Conclusion: Combination of etanercept or adalimumab with a traditional DMARDS agent such as methotrexate exhibit a far better survival rate at 5 years than adalimumab or etanercept used in monotherapy.

115

Prolonged Exposure to Subcutaneous and Intravenous Abatacept in Patients with Rheumatoid Arthritis does not Affect Rates of Infection, Malignancy and Autoimmune Events: Results from Pooled Clinical Trial Data

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Objective: To investigate the long-term (LT) safety of subcutaneous (SC) and intravenous (IV) abatacept using the largest pool of integrated abatacept clinical trial data to date.[1,2]

Methods: Data were pooled from the cumulative periods ([CP]; double-blind and open-label short-term [ST] and open-label LT extension) of 13 clinical studies: one Phase II and four Phase III with SC abatacept,[1] two Phase II and six Phase III with IV abatacept.[2] Incidence rates (IR) for AEs, serious AEs (SAEs), infection, malignancy and autoimmune AEs were calculated as events per 100 patient-years (pt-yrs) of exposure (Poisson 95% CI). IRs for the CP were compared with IRs originally estimated from the pooled ST periods of the eight IV abatacept trials.[2]

Results: During the CP, 6028 patients received IV or SC abatacept, with abatacept exposure of 16,670.56 pt-yrs (ST period n=3173; 2330.82 pt-yrs); 1167 patients received abatacept for >5 yrs. IRs of AEs (213.95 [208.33, 219.68] vs 386.70 [372.31, 401.51]), SAEs (13.24 [12.63, 13.88] vs 18.10 [16.37, 19.97]), death (0.60 [0.49, 0.73] vs 0.51 [0.27, 0.90]), infections (66.33 [64.33, 68.37] vs 98.00 [93.20, 102.99]), or serious infections (2.57 [2.32, 2.83] vs 3.68 [2.94, 4.55]) did not increase in the CP relative to the ST, respectively. The most frequently reported serious infections in the CP were pneumonia (IR: 0.43 [0.34, 0.54]), upper respiratory tract infection (0.18 [0.12, 0.26]), and cellulitis (0.15 [0.10, 0.23]). IRs of hospitalized, opportunistic, or tuberculosis infections did not increase between the ST and CP. IRs of overall malignancy (1.35 [1.18, 1.55] vs 1.55 [1.09, 2.15]), combined lymphomas, and lung cancers did not increase in the CP versus the ST; the most common malignancies in the CP were basal cell carcinoma (IR: 0.46 [0.36, 0.58]), squamous cell carcinoma (IR: 0.15 [0.09, 0.22]), breast cancer (IR: 0.12 [0.07, 0.19]), and squamous cell carcinoma of the skin (0.08 [0.04, 0.14]). The IR of autoimmune AEs during the CP was comparable with the ST (1.83 [1.62, 2.05] vs 2.07 [1.53, 2.75]), the most common event being psoriasis (IR: 0.51 [0.40, 0.63]).

Conclusion: Based on the cumulative short- and long-term exposure to IV or SC abatacept (16,670.56 pt-yrs), the IRs and events reported with long-term abatacept were similar to short-term results, with no increase in rate for any event with increasing exposure. Long-term IV and SC abatacept were both generally well tolerated. [1]Alten R, et al. Arthritis Rheum 2011;63(10 Suppl):S150. [2]Hochberg M, et al. Arthritis Rheum 2010;62(10 Suppl):S164.

116

Rituximab versus Abatacept in Rheumatoid Arthritis Patients with an Inadequate Response to Prior Biologic Therapy: A Retrospective Single-Center Study

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Objective: Patients with RA who experience an inadequate response to TNF inhibitor (TNFi) therapy (TNF-IR) may be successfully treated using an alternative TNFi or a biologic with a different mode of action such as rituximab (RTX) or abatacept (ABA). The relative effectiveness of these approaches has not been determined in head-to-head trials. Evidence from real-world experience would help to guide treatment decisions for TNF-IR patients.

Methods: This was a retrospective chart review of patients from a single site (Rebecca MacDonald Center) with ACR-defined RA who initiated RTX or ABA after failure of at least one TNFi. The relative effectiveness of RTX and ABA was evaluated by analyzing drug survival distribution. Kaplan-Meier survival curves were compared using the log rank test (p-values < 0.05 indicated statistical significance).

Results: The study cohort comprised 61 patients, of whom 37 and 24 were treated with RTX and ABA, respectively. In the RTX group, 10 patients received prior therapy with ABA. Demographics and disease characteristics were generally similar in the two groups, although RTX patients had higher disease activity compared with ABA patients (mean CDAI: RTX 32.5 vs ABA 26.9) and received more prior TNFis (1.8 vs 1.7) and/or ABA (2.1 vs 1.7). After excluding the RTX patients who received prior ABA, survival rates over time were generally better with RTX vs ABA. Estimated survival rates at time 0.5, 1.0, 1.5, 2.0, 3.0 and 4.0 years were 0.92, 0.79, 0.74, 0.68, 0.68, and 0.68 for RTX (n=27) and 0.83, 0.74, 0.54, 0.54, 0.54, and 0.41 for ABA (n=24). Overall, survival distribution was not significantly different between the RTX and ABA groups (p=0.658); however, RTX patients who also failed ABA had significantly reduced survival compared with those who had not received ABA (p=0.015). Stratification of survival data according to number of prior TNFi failures indicated that RTX (exluding patients with prior ABA) was superior to ABA among patients who failed 3 TNFis. Survival was also numerically greater with RTX vs ABA in patients who failed 1 prior TNFi. Finally, survival was better on both RTX

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and ABA when compared with that seen in a separate cohort of patients (n=88) who received a second TNFi after first TNFi failure.

Conclusion: These results from real-life practice suggest that in RA patients who failed one or more TNFi, RTX may have better long-term survival than either ABA or an alternative TNFi. Prior ABA appears to reduce RTX efficacy. Further data are needed.

117

Effective Disease Control Following Up to 10 Years of Treatment with Adalimumab in Patients with Long-Standing Rheumatoid Arthritis and an Inadequate Response to Methotrexate: Final 10-Year Results of the DE019 Trial

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Objective: This post hoc analysis evaluated data from patients completing up to 10 years of adalimumab (ADA)+ methotrexate (MTX) therapy to determine 1) long-term efficacy and safety, and 2) whether a 1-year delay in ADA initiation results in differences in clinical, functional, or radiographic efficacy.

Methods: DE019 was a phase 3, randomized, controlled trial (RCT) of patients with long-standing RA and an inadequate response to MTX, randomized to 1 year of ADA 40 mg every other week+MTX (ADA-40), ADA 20 mg weekly+MTX (ADA-20), or placebo (PBO)+MTX. Patients completing the RCT were eligible to receive open-label (OL) ADA-40+MTX for an additional 9 years. This post hoc analysis included data from patients completing 10 years of treatment who also had baseline and Year 10 radiographs available; results are summarized overall and by initial treatment arms. Clinical and functional outcomes were assessed by DAS28(CRP) and HAQ-DI, respectively. Radiographic damage was assessed using the modified total Sharp score (mTSS) at baseline and Years 1, 8, and 10. Adverse events were assessed for all patients exposed to ADA.

Results: Of the 619 patients initially randomized, 202 (32.6%; 80, 66, and 56 from the initial ADA-40+MTX, ADA-20+MTX, and PBO+MTX arms, respectively) continued on OL ADA+MTX through Year 10. Following up to 10 years of ADA+MTX treatment, patients continued to demonstrate effective disease control and inhibition of radiographic progression [mean DAS28(CRP)=2.6, DAS28(CRP) < 2.6=59.6%; mean HAQ-DI=0.7, HAQ-DI < 0.5=42.8%; mean ΔmTSS=2.8]. Significant differences in clinical and functional responses between ADA-40 or -20+MTX and PBO+MTX observed during the RCT were largely resolved following an additional 9 years of OL ADA+MTX treatment. Still, patients who initially received ADA-40 or -20+MTX had significantly lower mean ΔmTSS at Year 10 compared with patients who initially received PBO+MTX [0.7 (ADA-40) and 2.6 (ADA-20) vs 6.2 (PBO); P =0.002 and 0.01, respectively], a result that was driven by ΔmTSS during the RCT (Δ1.3 and Δ0.5 vs 1.9; both P < 0.001). No new safety signals arose following up to 10 years of ADA exposure.

Conclusion: Through 10 years of treatment with ADA+MTX, patients with long-standing RA experienced effective disease control. Initially, treatment with ADA+MTX led to better outcomes than PBO+MTX. The disparities in clinical and functional response rates observed during the RCT were largely ameliorated after treatment with OL ADA+MTX. Notably, radiographic damage remained lower in patients who initially received ADA+MTX, owing to the more extensive damage accrued during the RCT in PBO+MTX-treated patients.

118

Achieving Comprehensive Disease Control in Long-Standing or Early Rheumatoid Arthritis Patients Treated with Adalimumab Plus Methotrexate versus Methotrexate Alone

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Objective: Effective treatment of rheumatoid arthritis (RA) patients aims to suppress inflammation, preserve physical function, and prevent structural damage, together representing the hallmarks of comprehensive disease control (CDC).[1] Advances in therapies and application of targeted approaches to disease management have made CDC a realistic treatment goal.[2] The present analysis evaluated achievement of CDC with adalimumab (ADA) + methotrexate (MTX) vs MTX alone in 3 different randomized, controlled trials (RCTs).

Methods: Data from the DE019, OPTIMA, and PREMIER RCTs were used post hoc to assess achievement of CDC, including the individual criteria, following 1 year of treatment with ADA+MTX combination therapy or MTX monotherapy. CDC was defined as the simultaneous achievement of low disease activity (LDA, DAS28-CRP< 3.2), normal function (HAQ-DI < 0.5), and the absence of radiographic progression (ΔmTSS ≤0.5). DE019 enrolled patients with long-standing RA (mean, 11 years) and an inadequate response (IR) to MTX; OPTIMA and PREMIER enrolled MTX-naïve early RA patients (mean, 0.4 and 0.7 years, respectively). All studies compared ADA+MTX vs placebo (PBO)+MTX. Changes to assigned treatment strategy were only allowed in OPTIMA: PBO+MTX-IR patients could receive open-label (OL) ADA+MTX for an additional year (Rescue ADA arm).

Results: CDC was achieved at 1 year in significantly more patients treated with ADA+MTX than with PBO+MTX in both DE019 and PREMIER (19% vs. 5%, P < .001, and 32% vs. 11%, P< .001, respectively). Similar results were obtained when the disease activity component was replaced by DAS28(CRP) remission (< 2.6). The addition of OL ADA+MTX to PBO+MTX-IR patients in the Rescue ADA arm of OPTIMA permitted 29% (102/348) of early RA patients to achieve CDC following 1 year of treatment, a proportion comparable to the MTX-naïve early RA patients treated with ADA+MTX in PREMIER.

Conclusion: CDC appears to be a realistic treatment goal, in both early and long-standing RA. Combination therapy with ADA+MTX led to significantly higher rates of CDC following 1 year than MTX alone; earlier treatment increased the likelihood of CDC. A targeted treatment approach enabled MTX-IR patients who received OL ADA+MTX for an additional year to achieve CDC in a proportion that was comparable with MTX-naïve early RA patients initiated with ADA+MTX, underscoring the utility of treat-to-target approaches in maximizing comprehensive long-term outcomes. References: 1. Smolen, et al. Ann Rheum Dis 2010;69:631-7; 2. van der Heijde, et al. J Rheum 2010;37:2237-46.

119

Assessment of Patients with Inflammatory Arthritis using Thermography

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Objective: Thermography is a novel and potentially useful tool for evaluating patients with inflammatory arthritis. As tender and swollen joint counts are liable to inter-observer variation, thermography may assist in the detection of active disease. Objective was to determine the reliability of thermography measurements of patients with rheumatoid arthritis (RA) and compare to clinical examination.

Methods: 1) Thermographic examination was performed using a thermography camera "FLIR T300 Shortwave Thermovision System". All subjects rested for a 15 minute acclimation period. The camera was maintained at a fixed distance (0.5 m) over the hands, and subjects used a

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resting hand splint to ensure consistency. The patients were imaged only in the afternoon. 2) Thermographic assessments were completed on 29 control patients and 49 patients with inflammatory arthritis. Controls were healthy volunteers from the University of Alberta without a history of inflammatory or symptomatic joint disease. Patients were recruited from the Rheumatology outpatient clinic at the University of Alberta. Those patients taking vascular medications or with co-existing vascular disease were excluded from the study. 3) Each patient had a separate clinical and thermographic assessment of all MCP and PIP joints. Clinical assessments for swelling and tenderness were completed by a single blinded nurse practitioner trained in joint count assessment. The spot and area temperature of all MCPs and PIPs of each subject was determined using the thermography camera, by a separate examiner.

Results: In total, 2038 joints were analyzed. Inflammatory arthritis patients have a mean temperature 1.58°C warmer than controls of both area and spot temperatures, which is statistically significant ($p \leq 0.0001$). During the patient assessments, overtly swollen joints did not show an increased temperature. Tender joints, however were colder on average, by 0.3°C ($p \leq 0.008$), also statistically significant. A secondary measure was to determine validity of thermography by correlating findings to other outcome measures. For each unit increase (by 1 unit) of the DAS 28, the temperature reduced by 0.47°C, and with each unit increase (by 1 unit) of the clinHAQ, the temperature reduced by 0.67°C.

Conclusion: This study established the ability to assess surface temperatures of MCP and PIP joints in control and inflammatory arthritis patients. It produced reliable, quantifiable measures of joint temperature to assist in the assessment of disease activity in arthritis. Further study would include prospective analysis of individual patients, as the thermography camera may be useful in longitudinal patient assessment. Supported by a CIORA grant.

120

Measuring What Counts: Documenting the Impact of Arthritis on Children's Daily Community Activities

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Objective: Currently, no objective method exists to assess the impact of arthritis and its treatment on the everyday lives of children with juvenile idiopathic arthritis (JIA) in their communities. This pilot trial explored the feasibility of using accelerometers and cellular phones to build records of children's physical activity and community participation before and after a lower-limb steroid joint injection.

Methods: Children with active JIA with clinical indication for a lower limb corticosteroid joint injection, wore an iPhone 3GS and a tri-axial Actigraph accelerometer attached to an elastic belt during waking hours for 7 days before and 7 days after the joint injection. The iPhone used a novel application developed for this study to periodically record geographical location, physical activity and community participation occurring at the time. It also prompted children to report the level of pain and difficulty experienced with activities. The resulting activity records were compared with activity logs and the Physical Activity Questionnaire. Paired t-test statistics compared mean daily step counts, time spent in sedentary or moderate and vigorous activities, daily travel (total and ambulation only), mean difficulty and pain with activities, and ability to engage in highly-valued community activities, before and after the joint injection.

Results: Ten children with JIA (11 to 16 years old, 5 female) provided complete records. After the corticosteroid injection the mean number of sedentary minutes per day decreased from 469 to 428 (p=0.05) and the mean pain with activities decreased from 1.8 to 1.3 (p=0.06). There was little change in the number of steps per day (from 5761 to 6055, p=0.45), minutes of moderate/vigorous activity (from 166 to 161, p=0.56), total daily travel (from 25.1 to 22.1 Km, p=0.49), ambulation daily travel (from 7.2 to 7.3 Km, p=0.89), mean difficulty with activities (from 1.8 to 1.3, p=0.21), and the number of highly valued activities per day (from 2.0 to 1.7, p=0.22).

Conclusion: Direct recording of daily physical activity and community participation can be obtained in children with JIA. In this pilot study, early trends towards decreased sedentary time and less pain with activities after a joint injection are seen. These research techniques have promise as future outcome measures of treatment in JIA.

121

What Matters the Most for Parents, Patients and Clinicians in Predicting the Course of Juvenile Idiopathic Arthritis (JIA)?

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Objective: Prior to developing a tool to predict the course of JIA, we gathered the opinions of parents, youth with JIA, pediatric rheumatologists and arthritis health professionals (AHP) about the clinical features that should be used to define the course of JIA, the terms that should be used to describe the course to families, and the desirable attributes of a prediction tool.

Methods: Five focus groups and reciprocal interview sessions (participants interview each other) were conducted with Anglophone parents (n=9), Francophone parents (n=5), youth with JIA (n=9), pediatric rheumatologists (n=8) and AHP (n=9). Interview findings were recorded by participants in standard forms. Audio recordings of focus groups were transcribed and analyzed.

Results: Parents prioritized medication requirements, side effects, pain, disease flares and flare triggers as features that should be used for defining the course of JIA. Youth with JIA prioritized disease symptoms, need for assistance, ability to attend school, medication requirements, side effects, and disease remission. Pediatric rheumatologists prioritized disease activity, active joint counts, pain, medication requirements, side effects, parent global assessment, quality of life measures and disease remission. AHP prioritized disease activity, swollen joint counts, parent global assessment and disease remission; followed by specific joints involved, function, medication requirements and side effects. Most participants preferred lay terms that were "honest yet left room for hope" and advised against terms with overtly negative connotations (e.g. refractory). Most participants supported the terms remitting, controlled, and persisting; and mild, moderate and severe to describe disease courses. Youth with JIA would like a prediction tool that is responsive to changes over time, simple and available on the internet. Pediatric rheumatologists would like a prediction tool that is reliable, accurate, well-tested and simple to use. Parents and AHP felt JIA is unpredictable. AHP worried that parents might feel "cheated" when predictions did not materialize. Parents would like a tool that links them to resources that fit with their child's JIA, and AHP would like a communication and education tool for counseling families.

Conclusion: While clinicians prioritized traditional outcome measures, parents and patients had different concerns and priorities. Medication requirements and side effects should be included in defining the course of JIA. Straightforward, positive terminology is preferred when describing the course of JIA to families. The experience of parents and AHP with JIA as an unpredictable disease needs to be carefully considered in developing a JIA course prediction tool. Supported by a CIORA grant.

122

A Randomized Controlled Trial of Using Televised Testimonials to Increase Attendance of a Multi-Disciplinary Education Day Program in a Large Rheumatology Clinic

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Objective: Multi-disciplinary care and self-management programs are important in chronic musculoskeletal diseases as adjunctive treatment. Patients often have excuses as to why they don't attend such programs. The purpose of this study was to determine if an intervention of televised testimonials from rheumatologists and allied health professionals increases attendance at a multi-disciplinary education day for rheumatology patients seen in a large university hospital clinic. We have found that the most common reason for attending the program is that their rheumatologist told them to attend.

Methods: This was a randomized controlled trial (RCT) of balanced blocks of 2 (each one month long) of playing a televised interview or not in the waiting room where rheumatology patients were seen. There was a total of 6 months (3 months with and 3 without the televised interview playing). The entire one-day multi-disciplinary program was taped and every few minutes a testimonial from a rheumatologist or staff was inserted as to why the program was important to attend. The program has sessions on coping, education of diseases and treatment including talks from an OT, PT, pharmacist, psychologist, rheumatologist, nurse and patient. The televised testimonials during the education day were played in the waiting room as the intervention; whereas during the control blocks there was no TV playing. All eligible patients were then tracked to determine if they attended a subsequent education day over the next 10 months. The sample size was calculated to have a 15% increase in attendance at the education days.

Results: There was an increase in attendees at the multi-disciplinary education days for patients who saw the televised testimonials. In fact, 64 patients who viewed the testimonials (2.2% of 2896) attended the education day compared to 39 who didn't receive the intervention (1.8% of 2164); p=0.3. The numbers of attendees increased but the rates of attendance were still very low in both groups.

Conclusion: Attendance of eligible patients increased using televised testimonials; which was not significant. Many eligible patients did not attend the program. Other interventions are necessary to encourage attendance as the one day program is the main way of having patients commit to a more intensive evidence based two-week self management program. Supported by a CIORA grant.

123

Self Reported Comorbidity is Common in Early Inflammatory Arthritis and Associated with Poorer Function and Quality of Life and Greater Disease Activity: Results from the Canadian Early Arthritis Cohort

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Objective: Comorbid medical conditions may contribute to poor outcomes in rheumatoid arthritis. The extent of comorbidity may be related to the burden of inflammation and may influence initial treatment choice. We report the association of baseline comorbidity with clinical disease activity, functional status and quality of life in early inflammatory arthritis (EIA) using data from the Canadian Early Arthritis Cohort (CATCH).

Methods: Subjects (n=779) with EIA of symptom duration 6-52 weeks report comorbid medical conditions at baseline, quality of life indices (SF12) annually, and functional status (HAQ), pain visual analogue scale, detailed arthritis clinical assessments and arthritis treatment at each visit. Although there is no formal treatment protocol, participating rheumatologists aim for minimal disease activity. The influence of baseline comorbidity on outcomes while controlling for age and disease duration was tested by linear regression.

Results: Comorbidity was reported by 538 subjects (69%; median conditions 1 range 0-8). Patients with vs without comorbidity were older (45 vs 54 years p< 0.0001) and had higher baseline disease activity primarily due to ESR (37 vs 21 p< 0.001) and CRP (14 vs 11 p< 0.02). Associations between Cardiovascular (CVD) and higher DASCRP3v (4.42(1.3) vs 4.18(1.3) p=0.03) and worse HAQ (1.13(0.73) vs 0.94(0.71) p< 0.001) at baseline were not significant after correcting for age. Baseline SF12 scores were below population averages (Physical Composite Score (PCS) 37(11) and Mental Composite Score (MCS) 47(12)). SF12 correlated with the number of comorbidities: PCS (-0.2 p< 0.0001); MCS (-0.11 p=0.003). PCS scores were lower (worse) in patients reporting the following conditions vs without condition: CVD (34 (10) vs 38 (11) p< 0.0001), endocrine disease (35(11) vs 38(11) p=0.001), GI or renal disease; 35(11) vs 38(11) p=0.03) and respiratory disease (p=0.005). MCS scores were lower in patients reporting the following conditions vs without the condition: neurologic disease (44(12) vs 47(11) p=0.03), mental health conditions (39 (11) vs 48 (39) p< 0.0001) and GI or renal disease (43(12) vs 47(11) p=0.005). Over the first year of followup, patients with any baseline comorbidity had higher averaged DASCRP3v (3.15 (8.1) vs 2.94 (9.1) p=0.004), functional status (HAQ 0.67 (0.54) vs 0.47 (0.46) p< 0.0001), and more pain (3.6 (2) vs 3.2 (2.1) p=0.001), than those without baseline comorbidity. Renal or GI disease had worse DASCRP3v (p< 0.001) over the first year.

Conclusion: Patients with comorbid medical conditions have greater disease activity, poorer functional status and lower self reported quality of life over the first year of followup. This observation has implications for treatment of early arthritis.

124

One-Year Results from the Canadian Methotrexate and Etanercept Outcome (CAMEO) Study: A Randomized Trial of Etanercept and Methotrexate versus Etanercept Alone in Active Rheumatoid Arthritis

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Objective: Combination therapy with a biologic and methotrexate (MTX) usually yields better outcomes than biologic monotherapy in rheumatoid arthritis (RA). However, MTX is often poorly tolerated. As well, recent data suggest that monotherapy with etanercept (ETN) may be effective in patients with inadequate response to MTX. The objective of this randomized, unblinded trial was to determine if withdrawing MTX after 6 months of combination ETN+MTX, in MTX inadequate responders with active RA, is not inferior to continuing ETN+MTX.

Methods: TNF-inhibitor naïve, RA patients with active disease (≥3 swollen joints, DAS28≥3.2) despite stable MTX therapy (≥15 mg/wk, or 10 mg/wk if intolerant) for more than twelve weeks were enrolled. Patients were treated with combination therapy with ETN (50 mg/wk sc) +MTX for six months, followed by randomization to either continue ETN+MTX or switch to ETN monotherapy for an additional 18 months. The primary objective was to demonstrate non-inferiority of ETN vs. ETN+MTX, based on the change in DAS28-ESR, six months after randomization. The non-inferiority margin of change in DAS28 was -0.6, with pre-specified analyses of subsets by disease activity (DAS28< 3.2 vs. DAS28≥3.2).

Results: Two hundred and five patients were randomized. After six months, DAS28 was stable in patients on ETN+MTX (ΔDAS28 [95% CI] = 0.04 [-0.2, 0.3]) and increased slightly in patients on ETN monotherapy (ΔDAS28 [95% CI] = 0.5 [0.3, 0.7]). The primary endpoint of non-inferiority was not achieved with an adjusted DAS28 difference between ETN and ETN+MTX of -0.4 [-0.7, -0.12]. However, if a low disease activity (LDA) was achieved (DAS28< 3.2) at six months, the change in DAS28 was similar for ETN+MTX (ΔDAS28 [95% CI] = 0.57 [0.3, 0.8]) and ETN (ΔDAS28 [95% CI] = 0.7 [0.3, 1.0]). Conversely, for patients on ETN+MTX with DAS28≥3.2 at randomization, disease activity continued to improve over the following 6 months (ΔDAS28 [95% CI] = -0.4 [-0.7,

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-0.1]), while for patients on ETN monotherapy disease activity had slightly worsened (ΔDAS28 [95% CI] = 0.4 [0.1, 0.7]).
Conclusion: Non-inferiority was not achieved. The mean difference between treatment groups of -0.45 may not be meaningful. Patients who achieved LDA by 6 months on ETN+MTX had similar disease activity at 12 months, whether they continued or discontinued MTX. It is possible to discontinue MTX in the subset of patients who reach LDA, while it is preferable to continue MTX in those who do not achieve it.

125

Carotid Intima-Media Thickness as a Measure of Increased Cardiovascular Risk in Inflammatory Arthritis Patients

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Objective: Carotid intima media (cIMT) measurement is a validated surrogate measure of cardiovascular (CV) disease. Our aim was to evaluate baseline cIMTs in a cross-sectional study of northern Alberta inflammatory arthritis (IA) biologic patients to determine if CIMT correlates with traditional CV factors, arthritis activity measures or risk scores.
Methods: CIMT's were performed on 51 IA patients at the Mazankowski Heart Institute as part of their evaluation in the "Cardiovascular Risk Reduction Clinic for Inflammatory Rheumatic Diseases" (CRRC). Baseline CV risk assessment included traditional cardiovascular risk factors, IA disease activity indices and fasting lipids and glucose. Univariable followed by multivariable logistic regression analyses were performed to identify associations between CV and IA risk factors and the composite outcomes of a) cIMT > 0.9 mm or b) presence of plaque or both a) and b).
Results: CIMTs were performed on 51 IA patients, mean age 59.5 (SD 11.8) years, female:male = 39:12. Baseline mean arthritis activity measures included: disease duration 18 (SD 13) years, ESR 18 (SD 20) mm/hr, CRP 6.3 (SD 8.7) mg/L, 34 RF +/ 33 anti-CCP + patients, DAS28 2.44 (SD 1.34). All patients had been on at least one biologic, 34 with past exposure to prednisone, 16 with past exposure to COX2's/NSAIDs. Traditional CV risk factors included: 8 current smokers (15.7 (SD 30.8) pack-year history), 4 diabetics (2 on oral hypoglycemic, 1 on insulin/oral hypoglycemic, 2 on diet), 20 patients with systolic hypertension, 14 patients with dyslipidemia (mean values (mmol/L): total cholesterol 4.9 (SD 0.91), LDL 2.8 (SD 0.72), HDL 1.46 (SD 0.45), total cholesterol/HDL 3.52 (SD 0.84), triglycerides 1.42 (SD 0.68) mmol/L. Eighteen patients had family history of premature CVD, 9 patients with personal history of CVD, mean Framingham 11.9% (SD 8.1), Framingham with EULAR multiplicative factor 1.5 = 20.3 % (SD 12.2). Mean cIMT was 0.709 (SD 0.190) and 25 patients had plaques on at least one of the 6 sites measured. Extra-articular manifestations (OR 11.8 (95% CI 1.9-72.1) were associated with worse cIMTs and plaque while prednisone appeared protective against poor cIMT measures (OR 0.13 (95% CI 0.02-0.81).
Conclusion: CIMT may serve as an inexpensive screening tool for cardiovascular risk stratification in IA patients. Attention should be paid to extra-articular manifestations in IA patients as a surrogate marker of increased cardiovascular risk, as recommended by EULAR. The protection afforded by any past use of prednisone requires further evaluation, given the small sample size of this cohort. Supported by a CIORA grant.

126

An Innovative Strategy to Implement Clinical Practice Guidelines for People Living with Rheumatoid Arthritis and Osteoarthritis through Facebook

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Objective: The purpose of the study is to determine if an online evidence-based educational program on self-management interventions delivered through Facebook to people living with arthritis is effective in improving their knowledge, skills, and self-efficacy of patients regarding effective rehabilitation interventions.
Methods: Adults (>18 years old) with self-reported OA or RA living in the community were eligible for the study. One-hundred-and -eleven participants were recruited from the general public and different arthritis patient organizations throughout Canada. First, twelve participants participated in focus groups to select effective self-management strategies for OA and RA according to level of implementation burden. Ninety-nine additional participants were then selected to participate in the online Facebook intervention which included a "group" web-page providing case-based video clips on how to apply the selected self-management interventions. Over a 3-month period, participants were asked to complete 3 online questionnaires regarding their previous knowledge, intention to use/actual use of the self-management strategies, self-efficacy and confidence in managing their condition.
Results: Post intervention, knowledge acquisition scores improved among participants At 3 months post-intervention, most participants followed through on their intention to use the self-management strategies, however, statistically significant results were only demonstrated for "aquatic jogging" and "yoga" among participants with OA, and "aquatic therapy" among RA participants. Self-efficacy was maintained from immediate post-intervention to 3 months follow-up, and confidence improved as the study progressed.
Conclusion: This online program can provide people with arthritis with the opportunity to learn about and integrate evidence-based self-management strategies for OA and RA in their daily lives.

127

Biologic Therapy - Friend or Foe? A Case of Necrotizing Scleritis in a Rheumatoid Patient on Adalimumab and Previous Etanercept.

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Case Report: In today's modern era of rheumatoid arthritis (RA) therapy, the incidence of severe extra-articular complications of RA has diminished. Some may credit biologic therapy. However, we describe a paradoxical case of a 45-year-old female as follows. Case: Her RA was diagnosed at age 34 in Alberta with a greater than 6 week history of weight loss, polyarthritis and positive rheumatoid factor. She was initially treated with prednisone and hydroxychloroquine for 3 months and then switched to oral methotrexate for a few weeks, all stopped due to nausea. She was switched to subcutaneous methotrexate for 4 years, but stopped when switched to Etanercept due to fatigue. She initially responded well to the Etanercept, however, over the next 6 years, she was compliant only 25-30% due to recurrent cystitis. When she was first seen in Newmarket in 2011, her initial joint count was 5 tender and 3 effused. She received elbow cortisone injections, restarted regular etanercept and in 1 month, her effusions resolved. Over the next year her joints and MDHAQ were stable. In March 2012, she developed eye irritation but a consulting ophthalmologist felt it was follicular conjunctivitis. Around the same time, she developed cardiorespiratory symptoms, which resolved after discontinuing the Etanercept. However, by July 2012, she had 24-hour stiffness, her HAQ was 2.25 and her joint count revealed 20 swollen and 30 tender, she was anemic with a Hgb 111 and elevated inflammatory markers. She was started on Adalimumab 40mg sc q 2weeks. When she was seen 2 months later, she was the worst she had ever been with 61 tender joints, 17 effusions. She had also developed focal scleritis of the right eye but fundi remained normal and no other extra-articular manifestations seen. She was rapidly seen by ophthalmology, who confirmed necrotizing scleritis and was admitted to Southlake Hospital and treated with IV pulse solumedrol, and restarted on Methotrexate 25mg subcut q weekly with dramatic improvement in the ocular inflammation, no perforation. At least 3 cases of etanercept-induced scleritis have been described in the literature. The data is retrospective and

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observational and the strength of the association is still in debate. Currently, switching to Infliximab has been suggested if scleritis develops on Etanercept therapy. Our case is important since it highlights the need to consider Etanercept as a potential culprit of eye disease in the correct setting of RA.

128

The Burden of CardioVascular Risk Assessment in RheumAtology (CV-RARA Study)

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Objective: Objectives Rheumatoid arthritis (RA) is associated with an increased risk of cardiovascular (CV) disease, due to both inflammation and traditional risk factors. Some have recommended that rheumatologists manage disease activity and assess and manage traditional CV risk factors in RA. At present, we do not know 1) if the magnitude of CV risk due to traditional risk factors is different in RA patients compared to rheumatology patients with non-inflammatory problems, and 2) the proportion of rheumatology patients who have primary care physicians (PCP) to manage traditional CV risk factors. This study was designed to estimate the burden of care that would be placed on rheumatologists to undertake CV risk assessment and management of traditional CV risk factors in their patients.

Methods: Methods This prospective, cohort study was set in the rheumatology ambulatory clinic of a tertiary-care, university hospital. Consecutive RA patients were recruited over 6 weeks and matched 1:1 on age and sex to patients with non-inflammatory problems who presented to the same clinic. CV risk was calculated using the Framingham risk score, which calculates 10-year risk of major CV events (fatal and non-fatal) based on age, sex, total cholesterol, HDL cholesterol, systolic blood pressure, treatment for hypertension, diabetes and smoking status.

Results: Results We recruited 61 RA patients and 61 controls. CV risk factors in RA patients and controls were: age 60+14 versus 59+14 years, sex 74% versus 74%, total cholesterol 4.69+1.00 versus 5.10+1.08, HDL cholesterol 1.50+0.43 versus 1.48+0.42, systolic blood pressure 134+23 versus 129+22, treatment for hypertension 29% versus 25%, diabetes 13% versus 15% and current smoking 13% versus 10%, respectively. Ten-year Framingham CV risk scores based on traditional risk factors were moderate and similar in RA patients and controls (13.6% and 14.3%, respectively). Nevertheless, the proportion of RA patients with a history of coronary artery disease was 3 times that of controls (15% versus 5%, respectively). One-fifth (20%) of RA patients and controls did not have a PCP.

Conclusion: Conclusions In rheumatology practice, the problem of elevated CV risk due to traditional risk factors is not unique to RA patients. The burden for rheumatologists of undertaking CV risk assessment and management could be considerable if CV risk due to traditional risk factors is moderate and one-fifth of all clinic patients do not have PCPs. Rheumatologists should manage inflammatory disease and health services should be improved to ensure the optimal management of traditional CV risk factors for all rheumatology patients.

129

Rituximab for Severe Disease Flares in Childhood ANCA Vasculitides

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Objective: Children with ANCA vasculitides frequently present with life-threatening organ manifestations including alveolar hemorrhage, critical subglottic stenosis and renal failure due to rapidly progressive glomerulonephritis (GN). The current initial management for adults includes high-dose steroids and cyclophosphamide. The majority of patients experience a serious disease flare. This study evaluates efficacy and safety of Rituximab for treatment of severe disease flare in children with ANCA vasculitides.

Methods: A single-center cohort study of consecutive children with ANCA vasculitis treated with Rituximab for severe disease flares was performed between January 2009 until July 2011. Children were managed according to a previously implemented protocol. Disease activity was captured by PVAS.

Results: Six children (5 females, 1 male) were included, median age at diagnosis 7.8 years. Diagnosis: All 6 children had lung involvement (hemorrhage in 4), 3 renal disease and 3 ENT involvement, (subglottic stenosis in 2). ANCAs: +c-ANCA +PR3 in 4 patients, + p-ANCA +MPO in 1 and -ANCA + MPO in 1. All children previously received high dose steroids and cyclophosphamide; previous maintenance treatment included: azathioprine (1), MMF (2) and MTX (4). Disease flare: median disease duration until time to flare was 16 months (12-62 months); 5/6 had lung flares and 1 child developed new GN. Treatment: All 6 children received Rituximab (500 mg/m2, 2 doses q2weeks) plus high dose prednisone (2 mg/kg/day, max 60 mg/day) and one patients continued on MTX maintenance. Plasmapheresis just prior to Rituximab was used in 2 children. Efficacy: The median PVAS at time of flare was 6; 4 children had no evidence of active disease at 3 months (PVAS=0), and 5 at 12 months. All patients completely depleted their B-cells. After Rituximab therapy, ANCAs were positive in 4 patients at 3 months and 2 patients after 12 months. Safety: Infusion reactions were uncommon. One child experienced itchiness, fever and myalgias during the 2nd cycle of infusions. One patient developed Pneumocystis Jiroveci pneumonia. All six children received a second course of Rituximab at 6-13 months post- initial course upon return of their B-cells.

Conclusion: A complete response (PVAS=0) was seen in 67% of children with severe disease flares of ANCA vasculitis following treatment with Rituximab. This is a significantly higher response rate than with the current induction treatment for childhood ANCA vasculitides. Retreatment with Rituximab was required in the majority of children. Rituximab therapy was effective and safe; however long-term observations will determine the safety of repeated Rituximab treatment.

130

Treatment and Outcome of ANCA-Associated Vasculitis in Children: A Pilot Study

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Objective: Childhood ANCA vasculitides are rare, yet organ- or even life-threatening systemic vasculitides. Children most frequently present with rapidly evolving, severe disease such as pulmonary-renal syndrome. In 2009, evidence- based EULAR treatment recommendations were published. Treatment efficacy and safety data are largely derived from adult studies. This study reports treatment efficacy and safety of the 2009 EULAR recommendations for severe-moderate disease onset in consecutive pediatric patients with newly diagnosed ANCA vasculitides.

Methods: A single-center cohort study of consecutive children newly diagnosed with ANCA vasculitis since July 2010 was performed. All children were treated according to the implemented EULAR recommendations. Baseline clinical and laboratory characteristics, treatment regimens and their efficacy and safety were analysed. Disease activity was documented using the PVAS.

Results: A total of 8 children (4 female, 4 male) were included, median age at diagnosis was 13.8 years (range 10.9-17.4 years); presenting clinical

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features were nephritis in 7 (including renal failure in 2) and lung disease in 4 (including pulmonary hemorrhage in 3), ENT involvement in 3 (including subglottic stenoses in 2), and eye disease in 3 (1 episcleritis). Laboratory investigation: median ESR was 72mm/h, CRP 99mg/dl. ANCA testing was positive in 7 children (6 c-ANCA, +PR3, 1 p-anca, +MPO). All patients were treated with high dose prednisone, with a tapering scheme, and iv cyclophosphamide pulses, 4/8 received additional plasmapheresis (PLEX) (3 for pulmonary renal syndrome - 1 for renal failure). Seven children completed the induction therapy and were commenced on Azathioprine, with low-dose prednisone for maintenance. Disease activity at diagnosis: median PVAS was 19 (14-29); Follow-up PVAS: 3 (1-5) at 3 month and 3 (1-3) at 6 months. One child presented in renal failure and remains on dialysis. Safety: 50% of the PLEX- treated children developed a central line clot and subsequent pulmonary embolism requiring long-term anticoagulation. No clots were seen in patients not treated with PLEX. Clots are a known complication of central lines though. Pulmonary blastomycosis was confirmed in one child receiving PLEX and cyclophosphamide, who presented with a single lung nodule at 3 months of treatment. She responded rapidly to anti-fungal therapy. No early disease flares were noticed during the follow-up.

Conclusion: A significant decrease in disease activity was seen in all children with newly diagnosed, severe ANCA vasculitis treated according to the EULAR recommendations (PVAS 19 to 3). An increased risk of clots was seen in children treated with adjunctive plasmapheresis.

131

Early Inflammatory Arthritis Detection Using a Self-Administered Tool in a Canadian Francophone Population

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Objective: A self-administered Early Inflammatory Arthritis (EIA) tool has been developed. The purpose of this study is to cross-culturally adapt the developed EIA detection tool for the Canadian Francophone population and to determine its psychometric and discriminative properties. The external validity of a scoring algorithm previously developed in an English-speaking population was tested.

Methods: Three groups were recruited from outpatient clinics at two tertiary care hospitals: 92 EIA; 106 established IA; 94 non-IA. The current study was completed in four phases. Phase I: Translation and adaptation of the English tool into Canadian Francophone culture was conducted independently by two sets of translators. Phase II: A committee adjudicated the translated and adapted items to derive a single cross-culturally adapted tool. Phase III: A pilot validation study of the tool was conducted on a Canadian Francophone sample of 80 participants. Comprehensibility, internal consistency and test-retest reliability of the tool were determined. Phase IV: A full-scale validation study of 292 Canadian Francophone participants was conducted to determine the discriminative properties of the tool.

Results: A translated and cross-culturally adapted to Canadian French version of the EIA Detection Tool, with 100% committee agreement was produced. Comprehensibility approached unity for all tool items. The internal consistency Kuder-Richardson-20 was 0.96 ($p< 0.0001$). The mean test-retest reliability kappa (standard error, SE) was 0.67 (0.03). The intra-class correlation coefficient (ICC) for summed 'yes' responses between test and retest phases was 0.77 ($p< 0.0001$) and for algorithm scores was 0.86 ($p< 0.0001$). The scoring algorithm receiver operating characteristic plot area under the curve (SE) was 0.818 (0.002).

Conclusion: The tool has favorable measurement and discriminative properties. A cross-culturally adapted and validated EIA Detection Tool for Canadian Francophones may improve appropriate care for this population.

132

Needs Assessment for the Development of a New Online Accredited Educational Program on Rheumatoid Arthritis and Osteoarthritis.

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Objective: Primary care providers are faced with challenges in delivering arthritis care and the online dissemination of clinical practice guidelines (CPGs) is one method to address this issue. To develop an evidence-based online program, we identified providers' educational needs and perceived barriers in delivering arthritis care in the community.

Methods: Primary care providers from across Canada were invited to participate in an online survey which asked them to rate priority content areas for online learning related to rheumatoid arthritis (RA) and osteoarthritis (OA), and indicate whether or not they perceived barriers to different aspects of arthritis care (Rheumatology, Physiotherapy (PT), Community Exercise Programs, Social Work (SW), Surgery, Occupational Therapy (OT), Nutritional Counseling). Barriers included unacceptable wait time or travel time, no confidence in the service, funding barriers, service not available or not sure if the service was available. Ratings of educational priorities (1=lowest priority; 10=highest priority) and barriers (no barriers versus 1 or more barriers) were compared across urban/rural status and discipline using non-parametric statistics.

Results: 333 providers (47.1% urban) responded to the survey (physicians: 50.2%, nurses/NPs: 10.5%; PTs: 13.2%, OTs: 7.5%, other: 18.6%). The highest rated priorities for learning were DMARD therapy for RA, followed by OT and self-management education (median priority ratings ≥ 7/10). Priorities differed by discipline and urban/rural status ($p< 0.05$). Education on referral to rheumatology was a higher priority for urban participants, OTs and PTs ($P< 0.05$). Education on intra-articular injections was a higher priority for physicians and education on OT was a lower priority for nurses and PTs ($P< 0.05$). Barriers were most often perceived for access to exercise programs, rheumatology and physiotherapy. Physicians were more likely to perceive barriers to SW ($P< 0.05$). There were no differences in perceived barriers by urban/rural status ($P>0.05$), however the type of barrier did differ with 46.6% of rural respondents indicating that exercise programs were not available compared to 11.3% of urban respondents. Unacceptable wait times was the most commonly identified barrier to rheumatology (urban: 70.3%; rural: 58.3%). Long wait times were also the most frequently identified barrier to surgery (urban: 67.8%; rural: 58.8%).

Conclusion: Primary care providers identified priorities for online learning, in particular, information on DMARDS, OT and support for patient self-management. Discipline specific learning needs will be important to address. To improve arthritis care delivery in primary care, online educational programs also need to address perceived barriers to community exercise programs, PT and to rheumatology.

133

Non-Lymphoma Hematological Malignancies in Systemic Lupus Erythematosus (SLE)

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Objective: To describe non-lymphoma hematological malignancies in SLE.

Methods: An international, multi-site (N=28) SLE cohort was linked to regional tumour registries. We examined the types of non-lymphoma hematological cancers occurring after SLE diagnosis, and their demographic characteristics, including sex, race/ethnicity, and age at time of cancer diagnosis.

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Results: 15,980 patients were observed for an average of 7.5 person-years. Of these, 90% were female and the majority were Caucasian. Based on age-matched general population cancer rates, the standardized incidence ratio for hematological cancers after SLE onset was 2.9 in females (95%CI 2.3, 3.6) and 3.6 in males (95%CI 2.2, 5.5). A total of 115 hematological cancers occurred: 82 lymphoma (75 Non-Hodgkin, 7 Hodgkin's), and 33 non-lymphoma. Of the 33 non-lymphoma cases, 13 were of lymphoid lineage: multiple myeloma, MM (N=5), plasmacytoma (N=3), B-cell chronic lymphocytic leukemia, B-CLL (N=3), lymphocytic leukemia (N=1), and precursor cell lymphoblastic leukemia (N=1). The remaining 20 cases were of myeloid lineage: myelodysplastic syndrome, MDS (N=7), acute myeloid leukemia, AML (N=7), chronic myeloid leukemia, CML (N=2), and 4 unspecified leukemias. All lymphoid malignancies occurred in female Caucasians, except for plasma cell neoplasms, where 4/5 MM cases and 1/3 plasmacytoma cases occurred in blacks. At the time of cancer diagnosis, median age was 49 years (range 45-57) for MM, and 35 years (range 25-62) for the 3 plasmacytoma cases. In the female general population, median age-of-onset is 70 years for MM, and 55 years for plasmacytomas. The median age-of-onset for our B-CLL cases was 65 years (range 58-83), similar to the female general population (74 years). Of 20 myeloid malignancies, 3 (15%) occurred in males, and 6 (30%) occurred in blacks. All 7 AML cases were female, with median age-of-onset of 48 years (range 34-72), versus 66 years in the female general population. The 7 MDS cases (6 females) occurred at a median age of 48 years (range 36-59), versus 76 years in the general population. The age-of-onset for the two CML cases (1 female) were similar to the general population (65 years).

Conclusion: In our SLE cohort, the most common non-lymphoma hematological malignancies observed were myeloid types (MDS and AML). This is in contrast to the general population, where lymphoid types are three times more common than myeloid. Most (80%) of our MM cases occurred in blacks. Most of our non-lymphoma hematological malignancy cases were younger than general population median age-of-onset, although this could simply reflect our cohort demographics.

134

Emotional Pain and Catastrophizing Influence Quality of Life in Fibromyalgia

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Objective: The pain of fibromyalgia (FM) is traditionally measured as intensity with little attention to other qualities. Emotional pain is an important component of the global pain experience, but seldom measured. The McGill Pain Questionnaire (MPQ) evaluates pain beyond intensity. Associations of pain quality as measured by the MPQ with quality of life, psychological status, and function were examined.

Methods: Emotional pain was measured by the affective component of the MPQ in FM patients attending a multidisciplinary pain clinic. The MPQ has 4 subsections, measuring sensory, evaluative, affective, and miscellaneous pain. Other measures included pain intensity by visual analog scale (VAS), patient global assessment (PGA), Fibromyalgia Impact Questionnaire (FIQ), Health Assessment Questionnaire (HAQ), Pain Disability Index (PDI), Pain Catastrophizing Scale (PCS), and Arthritis Impact Measurement Scale (AIMS) for anxiety and depression.

Results: 229 FM patients (91% females, mean age 48, symptom duration 11), pain VAS 6.5, PGA 6.5, MPQ 41. With the exception of unemployment, no demographic variable correlated with the MPQ. MPQ (total and subsections) was significantly correlated with pain VAS, PGA, FIQ, HAQ, PDI, PCS, and AIMS anxiety and depression. Stepwise hierarchical multiple regression analysis examining the association with the MPQ total score retained FIQ, PCS, and HAQ. A MANOVA assessed if there were differences in measures (FIQ, HAQ, PGA, included on clinical judgement) based on a linear combination of MPQ scores, while taking catastrophizing into account. The miscellaneous subsection correlated highly with the sensory subsection ($p < .001$) and was eliminated. A significant effect was found for the affective subscale (Wilks' Lambda $\Lambda = .941$, $F = (3, 222) = 4.64$, $p < .005$, multivariate $\eta 2 = .06$), but not for evaluative or sensory subscales. The main effect of covariation for catastrophizing was significant (Wilks' lambda $\Lambda = .880$, $F (3, 222) = 10.1$, $p < .001$, multivariate $\eta 2 = .12$). Follow-up ANOVAs indicate that affective scores contribute significantly to FIQ and PGA; evaluative scores contribute significantly to PGA, and the sensory scores contribute significantly only to HAQ. Catastrophizing contributes significantly to PGA and FIQ. Catastrophizing is the variable with the largest and significant Beta weights for each of the MPQ variables.

Conclusion: Higher scores on emotional pain and catastrophizing were predictors of poor quality of life, whereas sensory scores better predicted function. Emotional pain, especially when associated with high levels of catastrophization, has important negative effects on well-being for FM patients. Psychological interventions targeting these aspects may offer additional benefits to the standard pharmacological management of pain.

135

Contentious Points in the Formulation of Evidence-Based Guidelines for the Management of Fibromyalgia in Canada

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Objective: Healthcare professionals require guidance for the effective care of patients with fibromyalgia (FM), a condition without any defining test or gold standard of treatment. A national multidisciplinary group, endorsed by the Canadian Rheumatology Association, developed evidence-based guidelines for FM care in Canada in 2012. The objective was that recommendations should incorporate sound evidence, be clinically applicable, and provide direction even when evidence was lacking. The objective of this report is to examine contentious recommendations that generated debate in order to provide insight regarding challenges surrounding FM.

Methods: A multidisciplinary healthcare team developed guidelines for the care of FM patients. Following standard procedures, specific recommendations were drafted and reviewed by a 35 member advisory panel. Eleven of 60 recommendations not reaching 80% approval after first vote were modified according to advisors' input and resubmitted for a second vote at which time all passed, and form the basis of this report.

Results: 1. Diagnostic criteria: Diagnostic criteria, intended for study purposes, must not be applied to the individual clinic patient. Tender point count, although providing physician security, must not be applied for diagnosis. Clinical diagnosis can be validated by the 2010 ACR criteria. 2. Treatments: Limited evidence for complementary and alternative medicine treatments should not preclude use. Contrary to perception, adjuvant pain modulators show only modest effect. Although antidepressants in all classes have shown efficacy, individual bias favoured serotonin norepinephrine reuptake inhibitors. The choice of agent should be patient-tailored according to physicians' knowledge and evidence for efficacy. 3. Terminology: Changing the terminology of antidepressants and anticonvulsants to pain modulators was rejected in favour of promoting their pain modulating effects. 4. Past/triggering events: Previous negative lifetime events should be acknowledged and addressed as needed, without excessive focus which could detract from clinical care. 5. Work and disability: Continued work is ideal and encouraged, but for those on disability, a rehabilitation program to improve function and possible return to work was recommended.

Conclusion: Many issues relating to FM remain contentious requiring consensus within the healthcare community to dispel false notions that can hinder management. These guidelines reflect the available evidence with clinically applicable input from healthcare workers from various disciplines and adhere to strict standards of development. We believe this endeavor will facilitate rational care of persons with FM and galvanize the healthcare community to be confident in management of FM.

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136

A Retrospective Study to Evaluate the Safety, Efficacy, and Drug Survival of Rituximab in Rheumatoid Arthritis Patients in a Single Canadian Practice

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Objective: Rituxan (rituximab) has been shown to be a safe and efficacious therapy for rheumatoid arthritis (RA) patients in clinical trials. Little is known about its effectiveness in the real-world setting. The objective of this study is to evaluate the safety, effectiveness, and drug survival of rituximab for RA patients in a single Canadian practice.

Methods: All RA patients treated with rituximab for a minimum of three months were included in this retrospective cohort study conducted from February 2008 to August 2012. Demographic data regarding age, sex, disease duration, and rheumatoid factor positivity were recorded along with prior and concomitant DMARD/Biologic treatment, rituximab treatment start and stop date, and reason for withdrawal when applicable. Efficacy parameters including swollen joint count (SJC28), tender joint count (TJC28), HAQ score, Patient Global Assessment and DAS28-ESR were recorded at follow-ups and changes over periods of time were assessed. Drug survival rate was calculated through the Kaplan-Meier estimation and reasons for drug discontinuation were noted.

Results: Baseline characteristics for patients meeting the inclusion criteria (n=35) were: mean age (SD) 54.43 ± 9.35 years, 65.7% female, 68.6% RF positive, and 65.7% with disease duration ≥ 10 years. 94.3%, 62.8% and 34.3% of patients had previously failed one, two, or three or more biologics with 90% of seronegative RA patients previously failing a biologic. Mean (SD) drug survival for RF positive and RF negative patients was 42.00 ± 3.88 months and 22.44 ± 5.22 months respectively with 83.3% of RF positive patients and 50.0% of RF negative patients still on drug at study conclusion. 25.7% of patients experienced secondary failure and no primary failures were recorded. Adverse effects reported included infusion reactions (14.28%), increased peripheral oedema (2.85%), burning sensation in feet (2.85%), bronchial infection (2.85%), and GI upset (2.85%). Significant improvements in SJC28, TJC28, and DAS28-ESR were seen compared to baseline. Results also show that rituximab is more effective in patients with seropositive RA than patients with seronegative RA.

Conclusion: This study demonstrates that rituximab is an effective and well tolerated biologic for patients with longstanding RA and have failed multiple biologics. Secondary failures are acceptable especially since these are not biologically naive patients. Rituximab is often prescribed after failure with anti-TNF therapies and results show it is a very effective second line agent in those who have failed said therapies.

137

Efficacy of Denosumab after Implementation of Charlton Patient Advocacy Program

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Objective: The efficacy of Prolia (denosumab) has been well established through several clinical trials. However, it is not an effective therapy unless administered properly. Patients are scheduled to receive the drug every 6 months. If not given on a timely manner, the efficacy may be compromised. The Charlton Patient Advocacy Program was established to ensure patients receive denosumab every 6 months by reminding patients they are due for their injection and providing them with information about their therapy. As a quality control assessment, this study assesses the effectiveness of our program in ensuring timely administration of denosumab. This study also pilots the feasibility of using Bone Mapping as an organizational tool to track patient compliance to the recommended schedule and the resulting drug effectiveness.

Methods: A retrospective chart review of all patients (n=44) who received a subcutaneous injection of Prolia between January 1, 2012 and March 31, 2012 was conducted. Patients receiving their first dose of Prolia and patients without recent BMD scores were excluded from the study. A timeline mapping the dates of denosumab injections and BMD results was plotted. Time between subsequent injections was recorded, along with BMD changes.

Results: Of the 44 osteoporosis patients, mean (SD) age was 66.1 (9.9) years as of March 31, 2012. 89% of these patients had prior osteoporotic treatment. Mean days elapsed between first and second, second and third, and third and fourth denosumab injections, if applicable were 218 days, 188 days, and 179 days respectively. After 1 year of treatment, BMD T-scores increased (by at least 2%) in 70% of patients at the L-spine (LS), 41% at the femoral neck (FN), and 30% at both sites. After 1 year, there was a decrease in BMD T-score (by at least 2%) in 5% of patients at LS, 7% at FN, and 0% at both sites. Ten year global fracture risk remained constant or improved for 93% of patients.

Conclusion: With the program at our center, we found minimal delay in patients receiving subsequent Prolia injections. With subsequent injections, the time gap between injections decreased. The vast majority of patients we audited also had an increase in BMD. To ensure maximal drug efficacy, similar programs should be implemented at other centers. The effectiveness of Bone Mapping was apparent as it allows superimposing multiple BMD results and multiple Prolia injections onto a clear and logical timeline.

138

A Retrospective Study to Evaluate the Effectiveness, Safety and Drug Survival of Tocilizumab in Rheumatoid Arthritis Patients in a Single Hamilton Practice

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Objective: Tocilizumab is the first medication designed to specifically inhibit the biological activity of IL-6. Although several clinical trials have demonstrated both the efficacy and safety of tocilizumab in rheumatoid arthritis (RA) patients, determining the efficacy and safety of tocilizumab in real clinical practice is also of interest. The objective of this study was to assess the effectiveness, safety and drug survival of tocilizumab for RA patients in a Canadian practice and to determine if there is a difference in effectiveness between biologically experienced versus biologically naive patients.

Methods: This retrospective cohort study conducted between July 2010 and August 2012 included RA patients treated with any dose of tocilizumab for a minimum of three months. Baseline data, prior and concomitant DMARD/Biologic use, adverse effects, duration of treatment, and reasons for discontinuing treatment were recorded. Effectiveness was assessed with mean absolute changes in swollen (SJC28) and tender joint counts (TJC28), disease activity between baseline, and over a period of time. We assessed

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drug survival by auditing the reasons for drug discontinuation and estimated by Kaplan-Meier plot.

Results: Patients (n=28) in the analysis had the following baseline characteristics: mean age 53.75 ± 8.81, 20 (71.4%) female, 15 (53.6%) RF negativity, mean disease duration 106.78 ± 113.86 months, and 9 (32%) biologically naïve patients. 14 (50.0%) and 10 (35.7%) patients had used two or more or three or more biologics respectively. Mean drug survival was 20.30 ± 1.66 months and 78.6% of patients were receiving drug at study conclusion. Percentage of biologically naïve patients (77.8%) versus biologically experienced patients (78.9%) still on drug at study conclusion was similar. There were 2 primary failures (1 lack of effectiveness, 1 lack of funds) and 4 secondary failures (4 lack of effectiveness). Significant improvement in the mean SJC28 (p-value < 0.05) from baseline (7.00 ± 3.26) to treatment at 3 months (5.12 ± 2.63), at 7 months (3.33 ± 3.05) and 10 months (4.33 ± 2.23) was observed. Similar efficacy was observed between seropositive and seronegative patients group. Biologically experienced patients showed sustained improvement in disease activity similar to biologically naïve patients.

Conclusion: These results from a Canadian practice show that tocilizumab is effective in treating moderate to severe RA patients. Drug survival rates for biologically naïve and biologically experienced patients are similar with no unexpected safety concerns indicating tocilizumab may be an appropriate first or second line therapy.

139

TEAM-Managed Care of Biological Patients at a Canadian Centre

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Objective: Managing complex arthritic patients with biologics is exacting and time consuming. In January 2008 we established a separate biologic clinic with a clinic manager and team of experienced RNs linked to the general rheumatology clinic and early inflammatory arthritis clinic to assess, initiate, and follow patients with Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), and Psoriatic Arthritis (PsA) needing to transition to biologic treatment and follow-up while on biologics. This team approach using experienced rheumatology nurses allows for triaging and timely access to care.

Methods: 770 patients (60% RA, 20% PsA and 20% AS) are being followed in the biologic program. The clinic is structured using a primary care nursing model which promotes continuity and a patient centered therapeutic approach to care. The clinic operates as a primary point of contact for organizing the management of co-morbidities, infusions, injections and ensures patients are being treated to target. Nurses are responsible for assessing their patients, providing disease and treatment-related health teaching and providing injection training. The nurses also perform clinical outcome measurements including spondylarthropathy measures, joint evaluations and administration/scoring of patient reported outcome questionnaires. The assessment, treatment plans are reviewed by the rheumatologist. The team also reviews routine labs and diagnostics daily, provides follow-up calls to patients to discuss adverse events, flares, concerns and treatment related inquiries. Patients are seen a minimum of 3 times per year, but more frequently if required due to flares, co-morbidities or financial issues. The nurses are occasional speakers at national and regional rheumatology meetings to share best practices on the management of biological patients and how a team-based approach can improve efficiency and promote better patient outcomes.

Results: This rheumatology health team has exponentially grown over a four-year period. The team approach allows one rheumatologist to follow 5-7 times the number of patients seen by the average rheumatologist without team support. Currently in Canada, there is a significant shortage of rheumatologists. A team based approach can help fill this gap by increasing patient access to care and reducing the burden on the health care system with fewer visits to urgent care/Emergency departments.

Conclusion: The goal in the biologic clinic is treating to target for remission or lowest disease activity possible within the shortest period of time. This team approach to care has resulted in improved adherence to therapy, less risks and reported adverse events, improved safety monitoring and better patient satisfaction.

140

Are there Differences between Young and Older Onset Early Rheumatoid Arthritis (RA) and does this Impact Outcomes? An Analysis from the CATCH Cohort

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Objective: The aim of this study was to determine the impact that age has on the outcome of rheumatoid arthritis.

Methods: A systematic review of the literature was performed. Data from the Canadian Early Arthritis Cohort (CATCH) was examined at baseline, 6 month and 12 month visits. Patients were divided into three groups based on age. One-way ANOVA and independent sample t-tests were performed to determine the impact of age on various outcomes. Binary and multinomial logistic regression was performed to determine the influence of age, baseline DAS28 and gender on DAS28 remission at 12 months.

Results: Current literature varies when considering the impact of age on outcome in RA, with the majority of studies finding that older onset results in worse outcomes. Of 1809 patients assessed at baseline, 442 (24.4%) were considered 'young' (< 42 years), 899 (49.7%) were considered 'middle-aged' (≥ 42, < 64 years) and 468 (25.9%) were considered 'old' (≥64 years). A significant correlation exists between age and DAS28 at baseline and 12 months, DAS28 remission at 12 months, HAQ at baseline and presence of erosions where an increase in age leads to a worse outcome in each case. At baseline, 72.9% were female, 63.8% met 2010 ACR/EULAR Classification Criteria for RA, symptom duration at first visit was 186.0 days, DAS28 was 4.9, HAQ score was 1.0, 25.3% had presence of erosions and 7.1% were in DAS28 remission. When evaluating for an increase in age, the number of females decreased ($P < 0.000$), proportion that met 2010 ACR/EULAR Classification Criteria for RA increased ($P < 0.000$), symptom duration at first visit decreased ($P < 0.000$), DAS28 increased ($P < 0.000$), HAQ increased ($P < 0.001$), proportion having presence of erosions increased ($P < 0.000$) and proportion in DAS28 remission decreased ($P < 0.003$). There was not a significant change in DAS28 and HAQ from 0-12 months. DMARD treatments and many varying comorbidities increased with age, while biologics treatment decreased with age. In the binary logistic regression model, gender had a large influence on the proportion of patients in DAS28 remission at 12 months with females having a much lower chance of remission.

Conclusion: Older onset RA patients start and end worse in terms of functional ability, disease activity and radiological damage than younger patients, however there are no differences in response to treatment. Gender appears to have a large effect on the outcome in RA patients.

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141

Inhaled Nitrous Oxide Facilitates Access to Intra-Articular Corticosteroid Injections in Children with Juvenile Idiopathic Arthritis

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Objective: Juvenile idiopathic arthritis (JIA) is the most common rheumatic disease of childhood affecting 1 in 1000 children. Medical management for arthritis often includes intra-articular corticosteroid injections. The inhalation of nitrous oxide (N2O) in painful procedures is widely recognised in adults, yet is underused in children and young people (CYP). We aimed to describe a population of children receiving JIs with N2O at our centre and the wait time for JIs with N2O once a decision to inject was made.

Methods: Data was collected retrospectively from available charts of children receiving JIs with N2O from January 2002 to April 2012. Demographics, number of JIs (including types of joints injected), and number of repeat JIs within a year were recorded. Time from decision point (DP) to JI was calculated for JIs performed in 2011-2012.

Results: 397 JIs with N2O on 292 occasions (140 males, 152 females) were performed from 2002-2012. The median age at time of JI was 13.78 (range 6.38 to 18.97 years). The median number of JIs performed with N2O per year was 24 (range 14-53). In 48 instances, >1 JI was performed in the same calendar year. From 2011-2012, 79 JIs were performed with N2O. The median number of days from a DP to a JI with N2O was 0 (range 0-87 days). 62 patients had JIs within 2 weeks; 11 between 2 and 4 weeks; 2 between 4 to 6 weeks; and, 3 after 6 weeks from DP - in most cases of intervals > 3 weeks this was a family choice i.e. social issues. Documentation of a DP for JIs with N2O was present in 77/79 patients (97.5%). Joints most commonly injected were: knees (80.05%), ankles (14.4%), elbows (3.28%), wrists (1.26%), subtalar (0.5%), fingers (0.31%) and shoulders (0.20%). No major adverse events (including septic arthritis) were reported.

Conclusion: Use of N2O for JIs in CYP with JIA offers expedient and safe analgesia. At our centre, CYP assessed in clinic and who need JIs may be offered one at that visit, performed by the PRh team (clinician and nurse specialist). This has benefits for clinical care (rapid access to the procedure); the patient and family (less time off school, no general anaesthetic risk); health care costs (reduced need for day case access and theatre time); and facilitates preferential access to general anaesthetic lists for younger children, those requiring multiple JIs, or the use of image intensifiers.

142

Assessment of Musculoskeletal Abnormalities in Children with Mucopolysaccharidoses Using a Simple Musculoskeletal Examination (Paediatric Gait, Arms, Legs and Spine)

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Objective: Mucopolysaccharidoses (MPS) are rare inherited disorders with a spectrum of phenotypes resulting from glycosaminoglycans (GAGs) accumulation in cells. Children with MPS often have musculoskeletal (MSK) abnormalities ranging from joint contractures to deforming abnormalities of the extremities and spine. pGALS (paediatric Gait, Arms, Legs, and Spine) is a simple MSK assessment previously validated in school-age children to detect abnormal joints. We aimed to describe the use of pGALS to identify patterns of MSK abnormalities in children with MPS.

Methods: Videos of children with a spectrum of MPS performing pGALS were made at an MPS specialist centre as part of their routine care and independent of the current study. Informed consent for the use of the videos for research was obtained. A piloted proforma to record abnormalities for each pGALS manoeuvre observed in the videos (scored as normal/abnormal/not assessable) was used by 3 observers (2 paediatric rheumatology [PRh] trainees and 1 specialist PRh physiotherapist, all blinded to MPS subtype). Videos were scored independently by the 3 observers and videos re-scored for intra- and inter-observer consistency. Data were pooled and analysed.

Results: 15 videos of children (9 boys, 6 girls, median age 11 years [4-19]) with MPS (8 MPS type I Hurler; 2 MPS type I Hurler-Scheie; 4 MPS type II; 1 mannosidosis). The most common abnormalities detected using pGALS exam were joint restriction of the shoulder (flexion/abduction/external rotation), elbow extension, wrist flexion, and temporomandibular joint excursion (>75% cases). Spinal deformity and restriction were also common (2/3 cases). There was a mean intra-observer Kappa of 0.74 (range 0.65-0.88) and an inter-observer Kappa of 0.62 (range 0.51-0.77). Two manoeuvres within pGALS (hip flexion/internal rotation) were not clearly demonstrated in the videos.

Conclusion: In this observational study, pGALS identifies MSK abnormalities in children with MPS. Restricted joint movement (especially in the upper limbs) was a consistent finding. We acknowledge that further work is needed to include pGALS assessment of the hip and also to test pGALS in an additional population of children with MPS; notably in further children with MPS I-HS as this subtype often has MSK abnormalities as the only feature. The use of pGALS and awareness of patterns of joint involvement may be a useful adjunct to facilitate earlier recognition of these rare conditions and access to specialist care. Further testing in MPS children is planned.

143

Head-to-Head Comparison of Subcutaneous Abatacept Versus Adalimumab in the Treatment of Rheumatoid Arthritis: Key Efficacy and Safety Results from the AMPLE (Abatacept Versus Adalimumab Comparison in Biologic-Naive RA Subjects with Background Methotrexate) Trial

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Objective: AMPLE (Abatacept Versus Adalimumab Comparison in Biologic-Naive RA Subjects with Background Methotrexate) is the first head-to-head study powered to compare subcutaneous abatacept and adalimumab on a background of methotrexate. Here we report key 1-year data from AMPLE including ACR core component data.

Methods: AMPLE is an ongoing, Phase IIIb, randomized, investigator-blinded study of 24 months' duration with a 12-month primary efficacy endpoint. Biologic-naïve RA patients with an inadequate response to MTX were randomized to 125 mg abatacept weekly or 40 mg adalimumab biweekly, in combination with MTX. The primary endpoint was non-inferiority (NI) of abatacept to adalimumab based on ACR20 at 12 months; key secondary endpoints were rates of radiographic non-progression, safety, injection-site reactions and retention. ACR core component data were also analyzed.

Results: A total of 646 patients were randomized and treated; 86.2% of abatacept patients and 82.0% of adalimumab patients completed 12 months. Baseline characteristics were balanced across both arms (mean DAS28[CRP] of 5.5 and disease duration ~1.8 years). At 1 year, 64.8% of abatacept patients and 63.4% of adalimumab patients achieved an ACR20 response, with an estimated difference between the two arms (95% CI) of

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1.8 (-5.6, 9.2) supporting NI of abatacept to adalimumab. The kinetics of response across ACR scores were comparable overall, with an ACR50 of 46.2% and 46.0%, and ACR70 of 29.2% and 26.2% for abatacept and adalimumab, respectively, at 1 year. Responses in some ACR core components were similar in abatacept and adalimumab groups over time, although some differences were observed. At 1 year, the rates of radiographic non-progression were comparable, as were mean changes in van der Heijde-modified total Sharp scores (0.58 vs 0.38, for abatacept vs adalimumab respectively). The rates of AEs, serious AEs, serious infections, and malignancies were comparable. There were more patients with autoimmune AEs (3.1% vs 0.9%) in the abatacept arm; however, none were serious. One patient discontinued in each arm due to an autoimmune event.There were fewer discontinuations with abatacept due to AEs (3.5% vs 6.1%) and due to serious infections (0% vs 1.5%). Injection-site reactions occurred in significantly fewer abatacept-treated patients (3.8% vs 9.1% [p=0.006]).

Conclusion: This first head-to-head study in RA patients comparing biologic agents on background MTX demonstrated that subcutaneous abatacept is comparable with adalimumab by most efficacy measures, including radiographic progression. Safety was generally similar with fewer discontinuations and injection-site reactions observed with abatacept.

144

Changes in Patient-Reported Outcomes in Response to Subcutaneous Abatacept or Adalimumab in Rheumatoid Arthritis: Results from the AMPLE (Abatacept Versus Adalimumab Comparison in Biologic-Naive RA Subjects with Background Methotrexate) Trial

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Objective: To report patient-reported outcomes (PROs) from the first head-to-head study, AMPLE (Abatacept Versus Adalimumab Comparison in Biologic-Naive RA Subjects with Background Methotrexate), comparing subcutaneous abatacept and adalimumab on background MTX.

Methods: AMPLE is an ongoing, Phase IIIb, randomized, investigator-blinded study of 24 months duration with a 12-month efficacy primary endpoint. Biologic-naïve patients with active RA and inadequate response to MTX were randomized to either 125 mg abatacept weekly or 40 mg adalimumab biweekly in combination with MTX. PROs assessed were patient pain, patient global assessment (PtGA), and fatigue, all assessed by 100mm visual analog scale (VAS), with a higher score indicating worse outcome (Minimal Clinically Important Difference [MCID]: reduction=10mm). Physical function was evaluated with the Health Assessment Questionnaire-Disability Index (HAQ-DI; MCID reduction =0.3). Health-related quality of life (HRQoL) was assessed using the SF-36 (including Physical and Mental Component Summary subscores [PCS and MCS]; MCID: improvement =5). The Routine Assessment of Patient Index Data (RAPID3), an index of three patient-reported core dataset measures (physical function, pain, and patient global estimate of status), was also assessed (MCID: reduction =2.0).

Results: Patients (n=646) were randomized and treated with abatacept (n=318) or adalimumab (n=328) on background MTX. Patient characteristics were balanced. A similar proportion of patients achieved a HAQ-DI response from baseline to Year 1 (abatacept, 60.4% vs adalimumab, 57.0%). Improvements in patient pain (mean% ± SE) were 46.5 ± 4.2% vs 35.6 ± 4.1% at 6 months, and 53 ± 6.1% vs 39.2 ± 6.0% at 1 year for abatacept and adalimumab, respectively. Improvements in PtGA were 40.2 ± 7.3% vs 27.6 ± 7.2% and 46.1 ± 3.5% vs 41.2 ± 3.4% for abatacept and adalimumab at 6 months and 1 year. Fatigue decreased from baseline by -22.4 ± 1.5% vs -19.9 ± 1.5% at 6 months, and -23.2 ± 1.5% vs -21.4 ± 1.5% at 1 year for abatacept and adalimumab, respectively. Improvements in all SF-36 domains, including PCS and MCS, observed at 6 months were maintained at 1 year. For RAPID3, the abatacept and adalimumab-treated groups demonstrated improvements (mean ± SE) of -2.7 ± 0.1 vs -2.5 ± 0.1 at 6 months and -2.9 ± 0.1 vs -2.7 ± 0.1 at 1 year.

Conclusion: In this head-to-head comparison, subcutaneous abatacept demonstrated significant improvements with similar kinetics of response in PROs and HRQoL measures over 1 year, which were comparable with adalimumab.

145

Myopathy is a Poor Prognostic Feature in Systemic Sclerosis. Results from the Canadian Scleroderma Research Group (CSRG) Cohort

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Objective: Associations with muscle involvement (myopathy including myositis) in a large contemporary systemic sclerosis (SSc) cohort were determined.

Methods: Data from the CSRG database were used. Surrogates for myopathy were elevated creatine kinase (CK) and physician-reported myopathy. Comparisons were made between myopathy (yes vs. no) and in lcSSc, dcSSc early dcSSc.

Results: In 1143 patients, 5.6% had an elevated CK; 5.7% proximal weakness, 15.6 % were PMScl positive and 9.7 % had myopathy. Those with elevated CK were more likely to be male (24.5 % in elevated CK vs. 12.6 % in normal CK; p< 0.013), younger (52 vs. 56, p< 0.045); have dcSSc, (40.4 % vs. 37.9 %; p< 0.002), physician-reported history of myositis/myopathy (45.3 % vs. 8.5 %, p< 0.000), tendon friction rubs (30.0 % vs. 13.4 %; p< 0.001), FVC < 70 % (23.9 % vs. 13.1 %; p< 0.039), RNP antibody (12.0 % vs. 5.0 %, p < 0.032), Topoisomerase1 antibody (26.0 % vs. 14.4 %, p < 0.026), higher skin scores (MRSS 16.14 vs. 9.81; p< 0.000), and higher HAQ score (0.98 vs. 0.79; p< 0.011). Logistic regression found younger age, male, dcSSc, early dcSSc, tendon friction rubs, higher MRSS, Topo1, RNP, PMScl, and FVC< 70% were associated with elevated CK. Survival was less for myopathy and elevated CK (p< 0.003 and p< 0.025 respectively).

Conclusion: Myopathy has a worse prognosis with respect to function, other organ involvement (ILD) and survival.

146

Correlation of Monosodium Urate Gouty Tophi with Colour Coded Dual Energy Computed Tomography Images

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Objective: To demonstrate that colour coded tophaceous deposits detected by dual energy computed tomography (DECT) are composed of monosodium urate (MSU) crystals by correlation with aspiration-proven microscopic analysis.

Methods: Tophi from consecutive gout patients were aspirated and analyzed under polarized microscopy for crystal analysis. The same patients underwent DECT scans of the peripheral joints and analysis by a radiologist to determine if the same tophi were detected radiographically. DECT utilizes 2 x-ray beams at different energy spectrums at 80 kv and 140 kv that enables it to differentiate and colour code different tissue types within the same space based on the principle that materials with different atomic weights will absorb the x-ray beam to different degrees.

Results: 11 consecutive patients with a diagnosis of gout and clinically apparent tophi were enrolled. All 11 patients underwent tophus aspiration and had MSU deposition confirmed on polarized microscopy. 8 patients subsequently underwent DECT scan of the peripheral joints. The patients varied in age from 50 to 88. 73% were male. The sites of tophi varied and

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included large, medium, and small joints, intra and periarticular, and bursal. In all 8 patients that underwent DECT scan, the aspiration-proven MSU tophi were detected and correctly colour coded by DECT.
Conclusion: Tophaceous deposits composed of monosodium urate are correctly identified and colour coded by dual energy computed tomography.

147

The Development and Validation of Definitions for Digital Ulcers in Systemic Sclerosis

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Objective: The objectives of this study were to develop standard definitions for digital ulcers (DUs) in systemic sclerosis (SSc) and to assess the reliability of these definitions as well as of the measurement of ulcer area.
Methods: Ten rheumatologists with expertise in SSc reviewed multiple photos of DUs, examined 4 SSc subjects with DUs and came to a consensus on the definitions for digital, active, healed and indeterminate ulcers. These ten raters then examined the right hand of 10 SSc subjects twice and the left hand once to classify ulcers and to measure ulcer area. Ulcers were measured with digital calipers in mm to 2 decimal places. The area of each ulcer was estimated by considering it an ellipse. Weighted and Fleiss kappa were used to calculate intra- and inter-rater agreement on classification of ulcers, and intraclass correlation coefficient (ICC) to assess agreement on ulcer area. Because the traditional ICC calculations relied on a small number of ulcers, ICCs were re-calculated using the results of linear mixed models to evaluate the variance components of observations on all the data.
Results: The group developed definitions of the different categories of DU in SSc. A digital ulcer is an area with visually discernable depth and a loss of continuity of epithelial coverage, which could be denuded or covered by a scab or necrotic tissue. In active ulcers, denudation is clearly visible at any part of the base and the de-epithelialized bed can be seen. If the examiner is not able to determine whether an ulcer is active or not, then it is classified as indeterminate. Ulcer healing is considered to be complete when total re-epithelialization of an ulcer is observed. Intra-rater kappa for classifying DU as not an ulcer/healed ulcer versus active/indeterminate ulcer was substantial (0.76) and inter-rater kappa was moderate (0.53). The ICC for ulcer area using the linear mixed models was moderate both for intra-rater (0.57) and inter-rater (0.48) measurements.
Conclusion: After a training session, rheumatologists with expertise in SSc are able to reliably classify DUs and to measure ulcer area. The definitions proposed in this study and the method to measure ulcer area could be used in future trials of therapy for DUs in SSc.

148

Addition of a Nurse to Outpatient Rheumatologic Practice Can Enhance Patient Care and Potentially Increase Adherence to Treatment, while Decreasing Burden on Family Physician Services

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Objective: To describe the clinical characteristics of patients referred for nursing review and the nursing interventions performed in three different out-patient rheumatologist offices following the implementation of a new multi-disciplinary billing code.
Methods: The electronic charts of patients seen by a rheumatology nurse between January and March 2012 in three different Vancouver-based, out-patient rheumatologists' offices were reviewed. Patients were identified using billing codes. Data was extracted using a standardized data collection tool and included patient characteristics, disease specific information and nursing interventions.
Results: Data was extracted on 300 patients. The most common disease referral was rheumatoid arthritis (RA) (160 patients), followed by connective tissue disease (CTD) (53 patients), ankylosing spondylitis (AS) (33 patients), psoriatic arthritis (PsA) (33 patients), and other diagnosis (OD) (21 patients). In total, 895 interventions by nursing staff were performed with the most common types including general education (169), rheumatic disease counselling (167), other interventions (167), disease-modifying anti-rheumatic drug (DMARD) counselling (135), immunizations (127), methotrexate (MTX) subcutaneous first start (48), MTX subcutaneous administration (25), biologic subcutaneous and intravenous education (19 and 13 respectively), tuberculosis (TB) skin testing (11), and biologic subcutaneous and intravenous administrations(10 and 4 respectively). Most patients received three interventions (91 patients), follow by two interventions (78 patients), and four interventions (47 patients) on a single visit. A total of 26 RA patients received biologic related intervention, followed by AS (11 patients), PsA (6 patients), and other diagnosis (3 patients). Rheumatic disease counselling, DMARD counselling, and general education were implemented in a total of 277 patients. MTX and biologic subcutaneous administration and/or education were given to 81 patients. TB skin test and immunization were also performed on a total of 135 patients. Drug monitoring was the most common activity in the 'other interventions' category.
Conclusion: Education was the most common intervention offered to patients referred for nursing assessment, along with immunizations and TB skin tests. Addition of a nurse with training in rheumatology to the outpatient rheumatology setting enhances patient care by providing services such as education and vaccinations that are not traditionally offered by the rheumatologist, yet are key elements of ACR and EULAR recommendations for the management of patients with inflammatory rheumatic diseases. Addition of a nurse to outpatient rheumatologic practice can enhance patient care and potentially increase adherence to treatment, while decreasing burden on family physician services.

149

The Use of the International Classification of Function, Disability and Health as a Conceptual Framework for Comparison of the Content of Core Outcome Instruments with the Patient Perspective in Vasculitis

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Objective: The International Classification of Functioning, Disability and Health (ICF) is a health model endorsed by the World Health Organization. It describes health along 4 domains: body functions, body structures, activities and participation, and environmental factors. The objective of this study is to use the ICF for examining the extent to which the outcome assessment tools currently used for ANCA-Associated Vasculitis (AAV) capture the impact of AAV relevant to patients.
Methods: Outcome measures included in the current Core Set for AAV were linked to the corresponding ICF categories according to the previously established ICF linkage rules. Two focus groups involving 9 patients were conducted. Patients were asked to identify aspects of disease that have an important impact on their lives. Focus group transcripts were analyzed according to standard qualitative analytic techniques. Identified concepts were linked to ICF categories. Coverage of various ICF domains by the Core Set tools was compared to coverage by the items identified by patients.
Results: All items of the Core Set's measures of disease activity and damage linked to categories of the ICF domains 'body functions' and 'body structures'. In contrast, the majority of items of the patient-reported

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outcome measure Short Form-36 (SF36) linked to categories of the ICF domain 'activities and participation', with the remaining smaller number of items linking to categories of 'body functions' domain. AAV Core Set instruments and patients focus on different aspects of the ICF domain 'body functions'. The Core Set tends to cover specific organ functions (e.g. hearing) while patients focus on sensations associated with these functions (e.g. ear fullness); similarly, the Core Set covers pain in specific body parts, while patients identify generalized and multifocal pain as most relevant. Sleep, temperament and personality, and exercise tolerance were areas in the ICF 'body functions' domain identified by patients as important but not measured by any of the Core Set tools. One broad area in the ICF domain 'activities and participation' that was identified as crucial by patients but not covered by the Core Set is "interpersonal interactions and relationships". Similarly, environmental factors are not part of the AAV Core Set, while patients identify a number of such factors as relevant in establishing the impact of AAV (various products and technology, support and relationships, attitudes, and services).

Conclusion: The ICF model is useful for identifying areas of health important to patients but not covered by the currently utilized AAV outcome tools.

150

All Cause Hospitalizations in Systemic Lupus Erythematosus from a Large Referral Center Demonstrate More Intensive Care and Longer Length of Stay

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Objective: To determine factors affecting morbidity and mortality in a contemporary cohort of hospitalized patients with Systemic lupus erythematosus (SLE) which is a chronic autoimmune disorder with a remitting and relapsing course, and variable clinical presentation. With increased disease understanding survival amongst SLE patients has substantially improved, however disease morbidity remains a significant issue.

Methods: A retrospective chart review was done of all patients admitted to London Health Sciences Centre and St. Joseph's Health Centre in London, Ontario over a 3.5 year period (January 2006-June 2009).

Results: There were a total of 102 patients meeting inclusion criteria hospitalized during this time period for a total of 160 hospitalizations. The most common reasons for hospitalization included disease flare (21.3%), infection (15%), and adverse drug reaction (8.8%). Acute coronary syndrome (2.5%) and venous thromboembolic events (1.9%) were less common causes of hospitalization. Intensive care unit admission (ICU) was required in 22 cases (13.8%), and mortality was significantly higher amongst ICU admitted patients (p= 0.000) with 27.3% of ICU admitted patients dying during their hospitalization. Overall mortality in SLE hospitalized patients was 5.6%. ICU admissions were also associated with a longer length of stay in hospital (p = 0.006), where average length of hospitalization in all patients was found to be 8.5 (±11) days. Readmitted patients had a significantly higher Charlson co-morbidity score (p=0.004), were more likely to have a history of SLE cerebritis (p=0.031), and were on a higher dose of prednisone at first admission (p=0.009).

Conclusion: In this contemporary cohort, SLE flare and infection remain the top reasons for hospitalization. The frequency of admission for these causes and mean length of stay are consistent with previous studies conducted in North American populations. The number of ICU admissions was substantially higher in this population, and was significantly associated with increased mortality and length of hospitalization.

151

Treatment of Asymptomatic Hyperuricemia for the Prevention of Gouty Arthritis, Renal Disease and Cardiovascular Events: Systematic Review

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Objective: Hyperuricemia (HU) has been associated with an increased risk of gout in large observational studies. An association with adverse renal and cardiovascular (CV) outcomes has also been suggested. However, it is unclear whether treatment of HU can prevent gouty arthritis, renal disease or CV events in asymptomatic patients.

Methods: A systematic literature search was conducted as part of the 3E initiative on gout using the Cochrane library, OVID MEDLINE, and EMBASE (1948 - October 2011) for interventional studies involving adults with no prior history of gouty arthritis, who were treated for HU. Outcomes of interest included gouty arthritis, renal disease (i.e. renal insufficiency, urate nephropathy, and nephrolithiasis) and CV events (i.e. myocardial ischemia, heart failure, and ischemic stroke). Abstracts from the ACR and EULAR meetings (2010-2011) were also searched as well as the clinical trial registries of the WHO and the U.S. NIH. Search results were reviewed and studies selected by two reviewers (OV, MW), who also extracted the relevant data.

Results: A total of 1683 articles were identified as well as 11 abstracts from the ACR/EULAR/Clinical trials databases. Three studies met the inclusion criteria, none of which pertained to the prevention of gouty arthritis or cardiovascular events. Due to between-study heterogeneity and high risk of bias, they were not amenable to meta-analysis. Two studies (N=174) assessed the prevention of renal disease by treating HU in asymptomatic patients and one study (N=54) evaluated the potential for delaying progression of renal disease by treating HU. In hyperuricemic patients without renal disease, treatment resulted in improved eGFR compared to baseline (86.3 ±19.4ml/min to 89.6 ± 12.6ml/min P< 0.05, and 79.2 ± 31.9ml/min to 92.9 ± 36.8ml/min, P< 0.05). In hyperuricemic patients with renal disease, treatment resulted in no significant elevation of serum creatinine over a one year follow-up compared to baseline (1.64 ± 0.63mg/dl to 1.99 ± 0.92mg/dl, P>0.05). However, differences in urine protein and renal function between the treatment and no-treatment groups were not statistically significant.

Conclusion: Limited data are available on the treatment of HU in asymptomatic patients. Although changes in renal function were noted in patients treated with uric acid lowering therapy, the clinical significance of these changes is unclear. In addition, the identified studies include small sample sizes and are of short follow up duration considering the target outcomes. Therefore, there is currently insufficient empiric evidence to support treating hyperuricemia in asymptomatic patients for the prevention of gouty arthritis, renal disease or CV events.

152

Kimura's Disease and Steroid-Sparing Immunosuppressive Therapy

Pari Basharat (Western University, London); Roaa Alsolaimani (St. Joseph's Health Care, London)

Case Report/Objective: A previously healthy 27 year old man presented to rheumatology clinic with a 3 year history of a right parotid mass. He had a high peripheral eosinophil count, and a biopsy of the mass was consistent with Kimura's disease. Kimura's disease is a chronic inflammatory disorder, the exact cause of which is still unknown. It is associated with eosinophilia and a high serum concentration of IgE, and diagnosed histopathologically by the presence of marked tissue infiltration by eosinophils. Occurrence of unilateral cervical lymph node enlargement or subcutaneous masses in the head and neck region is the most common presentation. Although a benign condition, the lesions are often chronic and tend to reoccur. Many types of treatments have been attempted, including radiation, surgery, and immunosuppressive therapy, but there are only a limited number of case reports available. Reports of a high incidence of recurrence when immunosuppressive therapy is withdrawn, and the drawbacks of potentially disfiguring surgical intervention, have made the optimal treatment of Kimura's disease up for debate. The objective of our case report was to review the literature in order to prescribe steroid-sparing treatment to our young patient with Kimura's disease. He had initially responded to oral Prednisone treatment, but unfortunately when steroids

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were withdrawn the mass re-occurred, and it was not in a location easily amenable to surgery.

Methods: We undertook a review of the available literature regarding the use of both steroids, and steroid-sparing immunosuppressive therapy, in the treatment of Kimura's disease.

Results: There are only a few case reports documenting the treatment of Kimura's disease with steroids and steroid-sparing agents, alone and in combination. Steroid sparing agents included the use of cyclophosphamide and MMF, leflunomide, azathioprine, and cyclosporine. Many of these reports don't detail the exact treatment regimen used or the precise duration of follow-up. Moreover, many of these case reports don't have a prolonged duration of follow-up. In addition, immunosuppressive treatment regimens do not appear to be standardized, and are often in combination with other treatments, including oral prednisone.

Conclusion: Because of the detrimental effects of long-term steroid usage, there have been attempts to treat patients with Kimura's disease with steroid-sparing agents; however, there is a paucity of data regarding this issue and only a handful of published case reports available in the literature.There seems to be a need for studies specifically addressing these issues.

153

Transient Elastography (Fibroscan) for Monitoring of Liver Fibrosis in Methotrexate-Treated Patients with Inflammatory Disorders: A Systematic Review

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Objective: Methotrexate has been used for the treatment of Psoriasis (Ps) Psoriatic Arthritis (PsA) and Rheumatoid Arthritis (RA) and Crohn's Disease (CD). American Colleges of Gastroenterology and Rheumatology guidelines suggest that patients on methotrexate be monitored for abnormalities in their AST or ALT. Liver enzyme elevations are neither specific nor sensitive for detecting liver fibrosis. Liver biopsy is an imperfect gold standard with its own limitations. Fibroscan is a non-invasive technique used to evaluate liver fibrosis. Fibroscan has been validated in Hepatitis C in comparison to the METAVIR fibrosis staging system. The objective of this study was to review the literature to characterize the utility of Fibroscan for detection of liver fibrosis compared to biopsy in a methotrexate-taking population.

Methods: A systematic literature search was carried out in Medline, Embase, Cochrane Library Databases (1950 to October 2012) evaluating the use of Fibroscan for the detection of liver fibrosis in a methotrexate, inflammatory disorder population. Abstracts from the scientific meetings of the ACR, EULAR, AGA, CAG, ACG and ECCO were also searched. The search was limited to studies involving subjects greater than 18 years of age, meeting criteria for the diagnosis of CD, RA, Ps or PsA. Studies where liver biopsy was not performed were excluded.

Results: Among 16 references identified, five publications met the criteria. Two studies were prospective case-control studies and three were cross-sectional studies (n=21-518). The cutoffs for significant or severe fibrosis based on Fibroscan score differed amongst the studies (7kPA-8.7kPa). The METAVIR system was used in 3 studies, the Roenigk fibrosis staging system was used in 2 studies and the Kleiner fibrosis staging system was used in 1 study. Results from the latter 3 studies were not interpretable as Fibroscan has not been validated against these staging systems. Of the 3 studies using the METAVIR system, the Fibroscan score did not reflect biopsy findings in a large portion of patients (40%-69%). The accuracy of Fibroscan for the detection of no or mild fibrosis (F< 2) ranged from 0%-88%. The accuracy of Fibroscan for the detection of significant fibrosis or cirrhosis (F2-4) ranged from 0%-30%.

Conclusion: The accuracy of Fibroscan for detecting liver fibrosis in a methotrexate-taking population with inflammatory disorders is not supported by the existing publications.

154

The Role of Phospholipids Profile in Disease Activity and Surrogate Markers of Cardiovascular Disease in Systemic Lupus Erythematosus

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Objective: The ratio of phosphatidylcholine (PC) to phosphatidylethanolamine (PE) is an important determinant of cell membrane integrity and it may reflect inflammation. Our objectives are to test if there are any associations between plasma phospholipids profiles and: 1) lupus disease activity, 2) previous arterial thrombovascular events (TE) and 3) surrogate markers of cardiovascular disease (CVD) such as carotid artery intimal-medial thickness (CIMT) and presence of carotid plaque (CP).

Methods: 166 women with systemic lupus erythematosus (SLE) (ACR criteria) from the University of Toronto Lupus Clinic were enrolled and 124 had ultrasound studies to determine the CIMT and CP. Plasma phospholipids profile was determined by gas chromatography. Demographics, CVD risk profile, SLE disease activity index-2000 (SLEDAI) and SLICC damage index (SDI) and; a fasting blood lipid profile was collected. Plasma PC/PE ratio was compared between patients with and without previous history of TE using un-paired t-test and chi-square test. Pearson correlation was used to assess associations.

Results: Among the 166 women, 37 had a TE. Subjects with TE were older [52(14) vs. 44(14) years, p=0.006], had higher: systolic [128(16) vs.118(15) mmHg, p=0.001)] and diastolic blood pressures [77(8) vs. 74(9) mmHg, p=0.056)], CIMT [659(111) vs. 585(87) mm, p=0.005] and presence of CP [64% vs. 15.3%, p=0.001)] compared to those without a TE. PC/PE ratio was significantly lower in those with TE [17.7(9.0) vs. 21.5(12.2), p= 0.041] and this was driven by a trend towards a lower PC content [50.9(25.7) vs. 56.5(23.5) ug, p=0.26]. We then compared patients with and without detectable anticardiolipin antibody (ACA). In ACA positive subjects (n=21), there was a trend towards a lower PC content [50.1(21.4) vs. 56.1(26.7) ug, p= 0.25] and PC/PE ratio [17.5(7.1) vs. 20.9(12.2), p=0.072]. There were significant negative correlations between plasma PC/PE ratio and: SLEDAI (r=- 0.202, p=0.011) and SDI (r=-0.173, p=0.03). There was no correlation between CIMT and PC/PE ratio.

Conclusion: A low PC/PE ratio may be predictive of an active disease in SLE and may play a role in the pathophysiology of atherosclerosis, although the cut-off will need to be determined in a larger study. The low PC/PE ratio was mainly driven by depletion of PC and that may be explained by the presence of autoantibodies in patients with SLE as those with the presence of ACA also had a lower PC/PE ratio and trend towards a lower PC content.

155

Limitations of Estimated FRAX® 10-Year Fracture Risk at the Time of Incident Fracture and Upon Refracture: Results from the OPTIMUS Initiative

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Objective: To estimate the performance of the FRAX® scores to identify patients sustaining an incident Fragility Fracture (FF) and those who will sustain recurrent FF over 4 (mean 2) years of follow up.

Methods: An ongoing prospective cohort of men and women over 50 years of age was followed up in the OPTIMUS study. After inclusion, participants were counselled about osteoporosis and its relationship to FF. A letter was sent to their Family Physician (FP) to stress the importance of treating osteoporosis unmasked by a FF, with reminders to FP of patients still untreated. At year 1, use of anti-osteoporosis medication was checked with the patients' pharmacists and confirmed in 56%. New FF were reported

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during phone follow-ups with patients. FRAX scores (excluding BMD) were calculated from baseline and follow-up information; High risk was defined as ≥20% for Major FF and/or ≥3% for Hip FF.

Results: From January 2007 to July 2011, 1172 patients (963 women) with FF were included. FRAX score could not be calculated in 20 patients because of missing data. Before the incident FF, 596/1152 (51.7%) were scored at Low, 70 (6.1%) at Moderate, and 486 (42.2%) at High risk. After the incident FF, 27.3% patients were still considered at Low, 18.8% at Moderate and 53.9% at High Risk. FRAX scores were still estimated Low in 6.2%, 23.8%, 25.7%, 29.4%, 48.5% and 37.0% of patients with incident FF at the Hip, Proximal Humerus, Wrist, Vertebra, Ankle and Other Minor sites, respectively. Over 2285 patient-years of follow-up, 99 recurrent FF occurred in 86 patients. Rates of FF were 5.46, 4.28, 3.70, 2.89 and 6.71 FF/100 patient-years after FF at Hip, Wrist, Proximal Humerus, Ankle and Other Minor sites, respectively. The estimated 10-year risk was High in 57 (66.3%) patients before the recurrent FF. Odds ratios (ORs) for recurrent FF were 1.77 [CI 1.01-3.09] for High relative to Low risk and 1.02 [CI 0.48-2.19] for Moderate relative to Low risk.

Conclusion: FRAX® High-risk category identified 74% of patients presenting an incident Hip FF but only 34% of those with an incident non-Hip FF; its exclusive use to target patients for primary prevention is unlikely to decrease subsequent non-Hip FF. Once a FF has occurred, a High risk score was a moderately sensitive (66%) but NOT clinically useful (OR < 2) predictor for subsequent FF, possibly in part because of a higher rate of treatment. Nonetheless, Minor FF and Moderate/ Low risk patients had similar high rates of recurrent FF, suggesting all FF patients might be considered for treatment.

156

Discrepancy Between Patient and Physician Global Assessments Over Time in Early Rheumatoid Arthritis

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Objective: The purpose of this study is to assess whether baseline PGA-MDGA discrepancy predictors change after one year in patients with early RA

Methods: Patients with RA were recruited from the Canadian Early Arthritis Cohort (CATCH) a prospective cohort where data is collected according to a standardized protocol. CATCH patients were considered for this analysis if they initiated DMARDs at baseline, were biologic naïve and had ≥12 months follow up. PGA and MDGA were scored out of 100. PGA-MDGA discrepancy was calculated by subtracting MDGA from PGA at baseline. A clinically meaningful discrepancy was considered a difference of ≥30 (PGA-MDGA > 30: Positive (Pos) and PGA-MDGA < -30: Negative (Neg)). Linear regression analysis was used to evaluate factors associated with the PGA-MDGA discrepancy, MDGA and PGA when adjusted for potential confounders at baseline and at 1 year separately. To address the variability of the rheumatologists' influence on the discrepancy we included CATCH recruiting "site" as one of the predictors. Sites with more than 25 patients were considered for analysis

Results: Baseline characteristics of the 480 RA patients who met inclusion criteria for this study included: 74% female, mean (SD) age 54(14.5), disease duration 0.5(0.24) years, TJC 8.6 (6.8), SJC 8.7 (6.3) (of 28), DAS28 5.2 (1.4), ESR 28.6 (22.6), CRP 15.0 (19.6) mg/L, PGA 58.7 (29.4) and MDGA 51.6 (24.8). Discrepancy rates are shown in Table 1. At baseline significant predictors of PGA-MDGA were Pain (p< .0001), SJC (p< .0001), TJC (p=0.008), ESR (p=0.02) and "site" (p=0.0006). At 12 months significant predictors of PGA-MDGA were Pain (< .0001), SJC (p< .0001), TJC (p=0.02), age (0.04) and "site" (p=0.0002). At baseline PGA was significantly associated with pain, HAQ, SJC, age and "site" and at 12 months with pain and "site" only. Baseline factors associated with MDGA were SJC, TJC, pain, ESR, HAQ and "site" and at 12 months ESR and HAQ were no longer significant.

Conclusion: PGA-MDGA discrepancy rate decreases over time but the pattern remains the same in early RA. Pain and SJC significantly influence PGA-MDGA discrepancy at baseline and this persists after one year when the disease is better controlled. Although previous studies have emphasized the pain score as a major factor affecting the PGA-MDGA discrepancy; we have also demonstrated a significant influence of the SJC

157

Prevalence of Peri-Articular Manifestations (Enthesitis and Dactylitis) and Disease Activity in Psoriatic Arthritis Patients: Impact of Treatment with TNF Inhibitors in a Real-World Canadian Population

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Objective: To determine the point prevalence of peri-articular manifestations (PAMs) in psoriatic arthritis (PsA) patients treated with anti-TNF in a real-world, Canadian, routine clinical practice setting.

Methods: BioTRAC is an ongoing, prospective, registry of patients initiating treatment for PsA, AS or RA with infliximab or golimumab as first biologics or after having been treated with a biologic for < six months. In this analysis of data collected since 2010, 91 PsA patients with available baseline information on PAMs were included: enthesitis (n=62), dactylitis of hands (n=76) or feet (n=77), nail pitting of hands (n=76) or feet (n=75).

Results: Baseline characteristics included mean (SD) age, disease duration of 48.7 (10.3), 6.5 (6.9) years, respectively, and mean (SD) DAS28-CRP score of 4.1 (1.2). Among all patients at baseline, 50 (54.9%) had a PAM. Dactylitis (feet - 39.0%; hands - 15.8%) was the most common PAM followed by enthesitis (27.4%), and nail pitting (hands - 26.3%; feet - 24.0%). Patients with enthesitis had greater mean (SD) DAS28-CRP (4.7 (1.0) vs. 3.9 (1.3); P=0.042) and HAQ-DI (1.33 (0.73) vs. 0.94 (0.77); P=0.076) compared to patients without enthesitis. However, mean (SD) age (47.0 (10.0) vs. 48.8 (9.5) years; P=0.544), disease duration (6.1 (7.3) vs. 6.0 (6.2) years; P=0.937), and morning stiffness (52.6 (43.4) vs. 56.7 (45.2) min; P=0.750) were comparable between-groups. Among patients with/without dactylitis, baseline mean (SD) parameters were: age (46.8 (12.5) vs. 50.5 (8.9) years; P=0.145), disease duration (6.2 (6.8) vs. 7.0 (7.7) years; P=0.666), DAS28-CRP (4.5 (0.9) vs. 4.0 (1.4); P=0.105), HAQ-DI (1.08 (0.69 vs. 1.09 (0.69); P=0.925), and morning stiffness (73.2 (44.8 vs. 51.6 (42.0) min; P=0.033). Upon six months of treatment, significant improvement in all disease activity parameters studied was observed. Six-month PAM data were available for 50 (54.9%) patients. Overall, the prevalence of PAMs decreased from baseline to six months post-treatment (P=0.001). Among patients with available six-month information that had a PAM at baseline (n=33), (48.5%) did not present any manifestation after six months. The incidence of new PAMs by six months was minimal.

Conclusion: In this Canadian real-world cohort of PsA patients, a high prevalence of PAMs was observed at treatment initiation. Patients with enthesitis or dactylitis had increased disease activity compared to patients without PAMs. Infliximab or golimumab treatment for six months was associated with a significant improvement in patient parameters and reduction in the prevalence of PAMs.

158

Real-World Effectiveness of Infliximab in the Treatment of Psoriatic Arthritis over 12 Months: The Canadian Experience

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Objective: The efficacy of anti-TNF in the management of psoriatic arthritis (PsA) has been demonstrated in numerous controlled clinical trials. Longitudinal observational studies assessing the real-world effectiveness of anti-TNF agents are essential in order to demonstrate the true benefits. The objective of this study was to assess in Canadian routine clinical practice the 12-month outcomes in patients with PsA treated with infliximab.

Methods: BioTRAC is an ongoing, prospective registry of patients initiating treatment for RA, AS, or PsA with infliximab or golimumab as first biologics or after having been treated with a biologic for less than six months. People with PsA treated with infliximab who were enrolled between 2005 and June 2011 were included in this study. Descriptive statistics were produced for clinical outcome measures and patient reported outcomes at baseline and six or 12 months of treatment. Within-group changes were assessed for statistical significance with the Wilcoxon test.

Results: A total of 103 PsA patients were included in the analyses. Mean (SD) age of the patient cohort was 49.0 (9.7) years and mean (SD) duration since diagnosis was 7.8 (9.2) years. The majority of patients were male (56.8%). Upon six months of treatment, statistically significant ($P< 0.05$) and clinical meaningful improvements were observed in all parameters analyzed, which were sustained over 12 months of treatment. Mean (SD) patient parameters at baseline and 12 months of treatment were: DAS28-CRP: 4.2 (1.3) vs. 3.0 (1.3), $P< 0.001$; C-reactive protein (CRP): 20.8 (49.1) vs. 7.9 (12.3) mg/L, $P=0.028$; erythrocyte sedimentation rate (ESR): 22.6 (22.5) vs. 12.5 (13.1) mm/hr, $P=0.007$; morning stiffness: 64.1 (44.9) vs. 38.4 (41.8) min, $P=0.001$; tender joint count (TJC28): 6.2 (5.4) vs. 2.8 (4.1), $P< 0.001$; swollen joint count (SJC28): 4.1 (3.9) vs. 1.4 (2.5), $P< 0.001$; health assessment questionnaire (HAQ-DI): 1.5 (0.6) vs. 1.2 (0.6), $P=0.003$; patient global assessment of disease activity (PtGA): 5.3 (2.8) vs. 3.4 (2.8) cm, $P< 0.001$; physician global assessment of disease activity (PhGA): 5.8 (2.1) cm vs. 2.5 (2.1), $P< 0.001$; pain: 47.7 (26.5) vs. 31.5 (27.4) mm, $P=0.001$.

Conclusion: The results of this Canadian longitudinal observational study have shown that a significant burden of illness is observed at initiation of infliximab in PsA patients in routine clinical practice. Treatment with infliximab was effective in reducing symptom severity and improving outcomes in patients with PsA over 12 months.

159

Thiopurine Methyltransferase Measurements in Saskatchewan Rheumatology Patients

Regina Taylor-Gjevre (University of Saskatchewan, Saskatoon); John Gjevre (University of Saskatchewan, Saskatoon); Bindu Nair (University of Saskatchewan, Saskatoon); Dietrich Matern (Mayo Clinic College of Medicine, Rochester)

Objective: In patients treated with azathioprine, deficient thiopurine methyltransferase (TPMT) activity is associated with haematologic toxicity. Our objectives in this study were to determine what proportion of Saskatchewan rheumatologists routinely pre-screen TPMT activity before prescribing azathioprine and to retrospectively review results from pre-screening in one patient cohort to determine the frequency of deficient activity.

Methods: Saskatchewan adult rheumatologists were polled by telephone as to whether they routinely pre-screen rheumatology patients for TPMT activity level prior to initiating azathioprine. Additionally, one rheumatologists clinical practice was reviewed retrospectively to determine the percentage of patients undergoing such routine pre-screening who fell into the laboratory set ranges for normal, carrier status, and deficiency.

Results: All Saskatchewan adult rheumatologists responded to the telephone survey. Six of the ten provincial adult rheumatologists reported routinely pre-screening for TPMT activity compared to 40% who never screen. Chart review of 42 rheumatology patients who were pre-screened for TPMT activity before initiation of azathioprine revealed, 76.2% fell within the normal range, 21.4% within the carrier status range with diminished activity, and 2.4% were deficient in TPMT activity.

Conclusion: In Saskatchewan, 60% of rheumatologists routinely pre-screen for TPMT activity before starting azathioprine. Diminished TPMT activity was observed in 23.8% of patients in a retrospective chart review from one clinical practice.

160

Physical and Functional Manifestations of Ulnar Deviation in Rheumatoid Arthritis

Allison Mitchell (Saskatoon); Regina Taylor-Gjevre (University of Saskatchewan, Saskatoon); Michelle Street (Saskatoon); David Leswick (Saskatoon)

Objective: A significant proportion of rheumatoid arthritis (RA) patients historically developed ulnar deviation (UD) at their MCP joints. This deformity was associated with disease severity, but there has been uncertainty as to the precise mechanism of development. The objectives of this study were to 1. utilize MRI to assess associated bone/soft tissue involvement towards identifying the mechanism by which UD may develop, (This radiologic data will be presented at a future date) and 2. to evaluate extent of objective and subjective functional capacity impairment associated with UD in participating patients.

Methods: Fifteen RA patients with and 11 RA patients without ulnar deviation agreed to participate in this study. All patients underwent a joint examination followed by a functional hand assessment. This included the Minnesota Manual Dexterity Test and Perdue Pegboard. Active range of motion measurements were taken bilaterally at the wrists, MCP joints, and interphalangeal joints. Grip strength and pinch strength (both lateral and tripod) were measured using a Jamar Dynamometer and pinch meter. Participants also completed the Patient Rated Wrist/Hand Evaluation, a standardized 15-item questionnaire designed to measure wrist/hand pain and disability in activities of daily living.

Results: On physical examination, the average number of swollen joints in UD group was 7.2 joints compared to 7.6 in the non-UD group. The mean natural positions of the right and left wrists were 6.9±3.4 degrees and 3.0±2.4 degrees radially in the UD group compared to 1.1±2.4 degrees and 0.9±2.9 degrees respectively in the control group. This was concordant with the greater severity of ulnar deviation at the MCPs of the right hand compared to the left. Bilateral grip strength, lateral pinch strength and tripod position pinch strength were all decreased in the UD group compared to controls. Perdue Pegboard and Minnesota Manual Dexterity test results also indicated an average decrease in functional capacity in the UD group. However, the scores for the Patient Rated Wrist/Hand Evaluation remained similar to slightly lower in the UD group compared to the control group.

Conclusion: Patients who developed UD in the course of RA have a measurable associated radial deviation at the wrist. Objective functional assessment indicates overall decreased functional capacity in those with ulnar deviation compared to RA patients without UD, however this difference in function was not reflected in the patient-scored questionnaire on pain and disability in activities of daily living.

161

Hip Pain in Younger Adults: Consider Femoroacetabular Impingement

Heather Hansen (University of Saskatchewan, Saskatoon); Regina Taylor-Gjevre (University of Saskatchewan, Saskatoon); Haron Obaid (Saskatoon); Rajiv Gandhi (University of Toronto, Toronto); Anthony King (Saskatoon)

Case Report: A 32 year old woman with a family history of rheumatoid

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arthritis presents with a 10 year history of progressive right knee and hip discomfort. Her symptoms are predominantly mechanical in description. On physical examination she had restricted range of motion and a positive hip impingement test maneuver. Radiographs of the hips demonstrated anatomic relationships which were consistent with femoroacetabular impingement (FAI). FAI has been postulated to represent a 'pre-arthritic' state which may progress to osteoarthritis, however, the longterm natural history is incompletely understood. FAI may be suspected in a younger adult presenting with hip or groin discomfort which is often aggravated by hip flexion activities. Hip impingement physical examination tests are helpful in the diagnostic evaluation. Both plain radiographs and MRI are useful imaging modalities in assessment of FAI.

162

Stroke, Headache and Multi-Infarct Dementia in Patients with Intracranial Giant Cell Arteritis (GCA): A Case Series

Roaa Alsolaimani (St. Joseph's Health Care, London, London); Lillian Barra (London)

Objective: Intracranial GCA is rare but has been reported in the literature. Patients with intracranial involvement generally present with cerebrovascular accidents (CVA) and multi-infarct dementia. CVA is reported in 3 to 4% in patients with GCA during the course of the disease. We are reporting three Canadian cases with intracranial GCA.

Methods: We did a retrospective chart review for all GCA patients in a large rheumatology tertiary center for patients with GCA with intracranial involvement diagnosed by CT and /or MR angiogram consistent with large vessel vasculitis.

Results: We identified three patients with intracranial GCA. Two of them, had temporal artery biopsies that proved GCA, the third had classic polymyalgia rheumatica (PMR) symptoms and evidence of optic neuropathy secondary to vasculitis. The first patient presented with carotid and vertebrobasilar territory strokes secondary to vasculitis two and, six weeks after the diagnosis of GCA, respectively. He was treated with steroids and cyclophosphamide with gradual improvement in his neurologic symptoms, but persistent cognitive impairment. The second patient presented with classic symptoms of GCA involving the temporal artery and progressive decline in her cognitive function three month after the diagnosis of GCA. She had distal vertebral artery occlusion secondary to vasculitis. The third patient, presented with headaches and polymyalgia rheumatica symptoms found to have carotid territory (MCA) vasculitis on angiogram. The second and third patients were treated with steroids and methotrexate and they had resolution of headaches with no new neurological symptoms.

Conclusion: A high index of suspicion of intracranial GCA should arise in patients presenting with neurological symptoms at the time of or after the diagnosis of giant cell arteritis or polymyalgia rheumatica. Rapid initiation of therapy with immune suppressive treatment is necessary to prevent severe neurologic outcomes or death.

163

Achieving Ankylosing Spondylitis Disease Activity Score-C-Reactive Protein Major Improvement and Inactive Disease in Patients with Ankylosing Spondylitis after Treatment with Golimumab is Associated with Normalized Health Related Quality of Life: 2-Year Results from GO-RAISE

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Objective: We examined association of ASDAS major improvement and inactive disease with improvements in HRQOL and reduction of disease on work productivity, and maintenance over 2yrs.

Methods: In GO-RAISE, 356 pts with definite AS per modified NY criteria were randomized (1.8:1.8:1) to SC golimumab 50 or 100mg or placebo q4wks. HRQoL was assessed using PCS and MCS of the SF-36. Self-reported employability data, defined as currently working or able to work if a job is available,were collected. Impact of disease on productivity in daily work, school or home was assessed using VAS(0-10), with higher values indicating greater impact. ASDAS (based on CRP) inactive disease was defined as a score of < 1.3 and major improvement was defined as an improvement from baseline ≥2.ANOVA on van der Waerden normal scores was used for numeric comparisons and chi-square tests for dichotomous comparisons.

Results: At wks14 and 24 the combined golimumab groups had greater median improvements in ASDAS scores vs placebo (1.6vs.0.4 and 1.7vs.0.3, respectively, p< 0.001 for both). At wks52 and 104, when all pts received golimumab,all groups had comparable improvements in ASDAS, ranging from 1.9 to 2.3. For all pts, 33.9% and 41.6% achieved ASDAS inactive disease at wk52 and 104. Pts with major improvement for these time points were 49.1% and 52.9%.For pts achieving ASDAS inactive disease at wks52 and 104, 57.1% and 65.5%, respectively, had PCS ≥50. Inactive disease pts had 64.8% and 74.14% with MCS ≥50. Pts with ASDAS major improvement had 37.9% and 48.3% with PCS ≥50 and 62.1% and 65.31% with MCS ≥50 for these time points. Improvements in productivity were greater for pts with ASDAS inactive disease compared with non-inactive disease at wks52 and 104 (5.8 vs. 2.9 and 5.8 vs. 3.1, p< 0.001 for both). Similar results were achieved for ASDAS responders compared with non-responders (5.4vs.2.4 and 5.8 vs.2.6, p< 0.001 for both). At baseline,40pts were unemployable because of AS. At wk52, 6/16 (37.5%) pts who achieved inactive disease regained employability, while 11/16 (68.8%) pts who had major improvement regained employability. At wk104,7/18 (38.9%) pts who achieved inactive disease regained employability,while 13/18(72.2%) pts who had major improvement regained employability.

Conclusion: Achieving ASDAS inactive disease or major improvement in AS pts after golimumab is associated with improvements in HRQoL and productivity. A trend towards regaining employability was observed for pts with clinical improvements, but this association would need to be substantiated in larger studies.

164

Safety in Patients Receiving BiOlogic Therapies (SPOT study)

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Objective: To determine the frequency of adverse events associated with biologic therapies in children using a patient/parent self-administered questionnaire and to examine the feasibility of using the SPOT questionnaire as a screening tool.

Methods: Consented pediatric rheumatology patients at SickKids who have received/currently receiving a biologic therapy were provided with the SPOT and feasibility questionnaire for completion by the patient/parent. The SPOT questionnaire is a standardized self-administered question form used to collect information and identify any potential adverse events associated with biologic treatment. The feasibility questionnaire collects qualitative information regarding the completion of the SPOT questionnaire from a patient/family perspective.

Results: Forty-three patients (21 M: 22 F, age 3 to 18), enrolled between June-Aug 2012, all reported treatment with one of the 8 biologic agents listed on the SPOT questionnaire and 19% (N=8) had exposure to more than one biologic agent. In 23% (N=10), no adverse effects were reported. Of 77% reporting any adverse effect, pain was the most common complaint, occurring in 44% patients (N=19, 89% joint/arthralgias and 16% abdominal). Signs of infection occurred in 28% (N=12) and

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allergic/anaphylactic reactions in 19% (N=8, 2 patients requiring acute treatment). Rashes were reported in 14% (N=6, 60% localized, 40% generalized, 2 new cases of psoriasis). New neurological issues occurred in 9% (N=4) with headaches being the most common complaint although 1 patient reported unexplained loss of bladder control. Uveitis (new/flare) was reported in 7% (N=3) patients. No malignancies were reported. Abnormal lab tests was reported in 9% (N=4) but 5 patients were unaware of the status of their lab tests. Medical intervention was needed in 28% (N=12) including 3 hospital admissions and 3 patients that required stoppage/discontinuation of their biologic therapy. Feasibility analysis showed a completion rate with no missing data of 88% (N=38) with a high rate of patient satisfaction. On average, it took 3.63 minutes to complete the survey (data available in 38 patients) and 95% of patients took less than five minutes. Only 3 patients needed help filling out the questionnaire and all patients reported that the questions were clear, comfortable to answer and enough space was given for responses.

Conclusion: Children often (up to 75%) experienced potential adverse effect(s) while on biologic therapy with pain and infections reported as the most frequent adverse effects. The SPOT questionnaire is a feasible and useful screening tool to monitor potentially adverse events associated with biologic therapies in addition to informing both the physicians and patients/families.

165

Low Prevalence of Myocardial Fibrosis by Cardiac Magnetic Resonance Imaging in 39 French Canadian Systemic Sclerosis Patients: Comparison of the CHUM Cohort with other World Cohorts

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Objective: In systemic sclerosis (SSc), myocardial disease is an important cause of pulmonary hypertension (PH) and a major predictor of mortality. At autopsy, myocardial fibrosis (MF) is reported in 70-100% of patients. By cardiac magnetic resonance imaging (cMRI), MF prevalence ranges from 20-63%. Intriguingly, we found few cases of MF by cMRI in the CHUM French Canadian SSc cohort. Therefore, we compared this cohort with other world cohorts to study differential prevalences of MF as detected by cMRI.

Methods: cMRI was performed in 39 consecutive CHUM French Canadian SSc patients to evaluate MF prevalence. Pubmed and Medline reviews were performed using "systemic sclerosis", "scleroderma" and "cardiac magnetic resonance imaging" key words. Review of ACR and EULAR annual meetings abstracts was also performed. Clinical and cMRI data were compared with our cohort.

Results: In the CHUM SSc cohort, only one (2,5%) patient had MF on cMRI imaging. This patient had longstanding diffuse SSc (24 years) and PH due to left heart disease (LHD). Comparison with 12 published studies revealed that patient populations and cMRI techniques were heterogeneous and precluded statistical analysis. Thus, a descriptive analysis was performed. The number of patients in each study differed significantly (range 4-81 patients). Data considered essential in MF evaluation were not systematically reported. Major differences noted between our cohort and other cohorts were: longer mean disease duration (CHUM cohort 14.7 years vs world cohorts 8.2 years), more frequent use of calcium channel blockers and immunosuppressants, and ethnicity. Although variations in the cMRI protocole were observed, this was unlikely to explain the varying results.

Conclusion: The prevalence of MF in SSc by cMRI is heterogeneous. In French Canadian SSc patients, the prevalence of MF by cMRI is low compared to the literature, despite prolonged followup. Our cohort is the first French Canadian SSc population reported and is one of the largest to report cMRI evaluation. The data raise the question whether aggressive treatment with calcium channel blockers and immunosuppressants may delay MF. Emerging cMRI modalities may be an important future assessment tool for subclinical myocardial disease in SSc.

166

Dyspnea in Pregnancy Secondary to an Atrial Mass in a Patient with Antiphospholipid Syndrome

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Case Report: We report a 26-year-old gravida 7, para 1 woman with a known history of antiphospholipid syndrome (APS). She had a history of recurrent venothromboembolic events and recurrent pregnancy losses. She presented at 25 weeks gestational age (GA) complaining of dyspnea. She had previously decided against medical advice to remain on warfarin, as she had attributed the cause of previous pregnancy losses to warfarin. Her INR had been maintained between 2.0-3.0 recently. She was admitted to hospital for further investigations and management. Investigations included an echocardiogram and cardiac magnetic resonance imaging, which revealed a large mobile mass in the right atrium. The mass was suspicious for either a thrombus or atrial myxoma, and her clinical presentation was considered to be secondary to embolic phenomena from the mass. Warfarin was discontinued, and she was started on aspirin and unfractionated heparin. Resection of the mass was judged to be necessary due to the risk of possible catastrophic embolic events. A combined surgery was planned with cesarean section followed by atrial mass resection at 29 weeks GA. She remained in hospital until surgery for close surveillance. At 29 weeks GA, she delivered a healthy baby by cesarean section. The patient was subsequently placed on cardiopulmonary bypass (CPB), and the atrial mass was removed. She tolerated both procedures well. Pathology of the mass revealed thrombosis. Although there are numerous cardiac manifestations of APS, there are fewer than 10 case reports of intracardiac masses in patients with APS. The two main differential diagnoses in this context are intracardiac tumors and thrombosis, which are frequently difficult to distinguish on imaging. There are approximately 20 case reports of cardiac myxomas discovered during the antepartum period. The majority of these cases underwent successful removal of the tumor during pregnancy. There are, however, multiple considerations in the pregnant patient undergoing cardiac surgery and CPB. In a pregnant patient with APS, management is further complicated. To our knowledge, this is the first reported case of surgical excision of an atrial mass in a pregnant patient with APS.

167

Using Jumping Mechanography to Assess Muscle Function in a Paediatric Population

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Objective: Children with juvenile idiopathic arthritis (JIA) are less physically active and less physically fit than their healthy peers or those afflicted with other chronic diseases. Emerging evidence suggests that improving physical activity (PA) favourably influences disease course and outcomes in JIA. The assessment of kinematic and kinetic parameters deriving from motor performance has become a recognized method for investigating the effects of muscular activity on bone mass and strength. Considering the importance of physical fitness on disease outcomes, a better understanding of reference values in healthy active children is required. Objective: To assess the muscle function (peak jumping force and peak jumping power) in a group of healthy children and youth using jumping mechanography and relate these data to anthropometric characteristics and physical activity levels.

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Methods: Children aged 8-16 years old were recruited to participate. Informed consent was obtained from all individuals and their parents. Muscle force and power were measured by mechanography using the "Leonardo" force platform. Maximum power generated during a two legged counter movement jump (S2LJ) and muscle force during a multiple one-legged hop (M1LH) was assessed. Anthropometric characteristics of the study population as well as the Physical Activity Questionnaire (PAQ) were also collected and the relationship between muscular parameters, body size and physical activity was examined.
Results: Data were successfully collected from 75 participants (48 male, 27 female, average age 12.9y, average height 155.75cm, average weight 48.14kg). There was a statistically significant difference in the power generated from the S2LJ between males and females. In addition, peak jump power increased as children mature; whereas, peak jump force from the M1LH remained consistent between males and females and over time when expressed per body weight. Physical activity level was found to decrease as children mature and was not found to statistically contribute to power or force generation in the jumps assessed in this study.
Conclusion: Height, weight and sex are predictors of total power, but physical activity (as measured by the PAQ) does not play a role in predicting muscle function. There must be an understanding of normal lower limb muscle function in a healthy group of children before this innovative technique can be useful in determining muscle function in a diseased cohort.

168

Regular Physical Exercise Incorporated into a Rheumatology Fellowship Curriculum: A Qualitative Survey of Participants

Shannon Lockhart (University of British Columbia, Vancouver); Shahin Jamal (University of British Columbia, Vancouver); Kamran Shojania (Vancouver)

Objective: The health benefits of regular physical exercise have been well documented in the literature, as have the benefits of exercise for rheumatology patients. Physician exercise habits have been found to be a determinant in the quality and frequency of exercise prescription. The aim of this study is to examine the uptake, short-term effects, and potential areas for improvement of a regular physical exercise "boot camp" incorporated into a Rheumatology fellowship.
Methods: Five rheumatology fellows participated in a one-hour, circuit-training-style exercise program every Friday afternoon for 12 weeks, as a part of their academic half-day. A qualitative survey was distributed to the fellows during the ninth week of the program. Fellows completed the survey anonymously and responses were analyzed for emerging themes.
Results: All fellows indicated that they enjoyed the program and that it was an effective use of their time and program resources and that it was preferable over lecture-format teaching on exercise physiology and prescribing/counseling. Four out of five fellows stated they would like focused instruction on which exercises could be beneficial for their patients. Three out of five fellows stated that participating in the exercise program had increased their confidence in exercise prescribing/counseling. All stated that their work and academic training posed a significant barrier to independent regular physical exercise. The fellows found that participating in the boot camp had modified their diet, stress, sleep habits, mood, learning and time-off activities. Prior to the boot camp, three out of five fellows had not participated in any regular physical exercise while two had done so twice per week. Since the boot camp, four out of five fellows complete one to three sessions of physical exercise greater than 30 minutes during which they break a sweat, in addition to the boot camp session.
Conclusion: Incorporating regular physical exercise into the academic education curriculum was well received by the fellows. Creating healthy habits early in their career was stated as a perceived benefit and perhaps stands to influence future exercise habits as well as future exercise prescribing habits. Several fellows noted improved confidence in exercise prescribing/counseling. A common theme among the fellows was interest in incorporating additional education on how to relate the exercise program to the needs of their patients. All fellows had found that participating in the exercise boot camp had improved other areas of their life.

169

A Regional Rheumatology Program to Facilitate Access to Appropriate Rheumatology Care

Sherry Rohekar (University of Western Ontario, London); David Arnott (Schulich School of Medicine, London); Janet Pope (University of Western Ontario, London); Warren Nielson (St. Joseph's Hospital, London)

Objective: To describe the design, implementation, and evaluation of a continued education (CE) pilot program delivered to nurse practitioners in Southwestern Ontario. Southwestern Ontario is highly underserviced in rheumatology and relies heavily on primary care workers in the management of rheumatologic conditions. The purpose of the program was to improve the diagnosis and management of rheumatologic conditions in primary care.
Methods: The core element of this program was a series of 17 interactive webcasts delivered over a period of 18 months. The content of the lecture series was designed around an assessment of the educational needs of nurse practitioners (NPs) in Southwestern Ontario. Lectures covered key aspects in diagnosis and management of rheumatologic conditions. Impact of the program was measured through use of a knowledge assessment, a general survey, and chart review analysis. All program measures were completed pre- and post-program. NPs were also invited to have clinical preceptorships that were needs based, including identifying early inflammatory arthritis and performing joint injections. Outreach grand rounds were also given. A program evaluation was completed following program competition. Basic statistical analysis was performed.
Results: A total of 16 nurse practitioners participated in the program from 12 different communities across Southwestern Ontario. All 16 participants completed the baseline and post-program knowledge assessment. Chart reviews were completed at baseline and post-program by 12 of the nurse practitioners, with each participant completing 10 chart reviews. Upon program completion, participants reported lower estimated referral times to a rheumatologist, greater ease in contacting a rheumatologist and an increase in the quality of interaction with rheumatologists. There was a non-significant increase in the average knowledge score of participants. Chart review showed significant changes to history taking ($P< 0.01$) and comfort with management of disease ($p< 0.02$). Appropriate referrals to other health professionals also increased and there was an increase in the portion of patients with follow up appointments booked. The CE program was well received with an average rating of 9.13/10 from participants. 8 also participated in the preceptorships with rheumatologists.
Conclusion: Nurse practitioners are playing an increasingly important role in the care of patients with rheumatic conditions. This program has shown an effective method for continued education in rheumatology for primary care workers across a wide geographic area.

170

Non-Radiographic Axial Spondyloarthritis Has Greater Work Instability than Other Spondyloarthritis Subtypes

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Objective: Clinical subsets of spondyloarthitis (SpA), such as ankylosing spondylitis (AS) and psoriatic arthritis (PsA) can be associated with significant impact on work performance and attendance. Prior to becoming completely work disabled, patients will commonly be in a state of work instability (WI). The characteristics of WI in a large population of patients with SpA have not yet been thoroughly examined.
Methods: Patients were recruited from two large, well established cohorts of AS and PsA. WI was evaluated using a validated questionnaire, the AS-WIS. Standard protocols were completed at the time of completion of

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the AS-WIS which included a detailed history, examination, physician-reported outcome measures and patient-reported outcome measures.
Results: 414 SpA patients completed the questionnaire (222 PsA, 160 AS, 18 undifferentiated SpA [uSpA], 12 non-radiographic axial SpA [nr-axSpA] and 2 reactive arthritis [ReA]). Mean age was 47.2 (SD 14.4), 66.9% male. Mean duration of disease in PsA was 17.4 years in AS was 11.9 years. Mean WIS scores were low in AS (8.0, SD 6.1), PsA (6.7, SD 6.0), ReA (7.5, SD 9.2) and uSpA (8.0, SD 6.9). However, those with nr-axSpA had significantly greater WIS scores than the other groups, placing them in the moderate risk category (mean 12.6, SD 6.6). Higher WIS scores were significantly correlated with female gender ($r=-0.18$, $p< 0.001$), lower education ($r=-0.17$, $p=0.001$), lung disease ($r=0.15$, $p=0.003$), GI disease ($r=0.15$, $p=0.003$), diabetes ($r=0.15$, $p=0.004$), peripheral joint involvement ($r=0.19$, $p< 0.001$), NSAID use ($r=0.23$, $p< 0.001$), tender joint count ($r=0.19$, $p< 0.001$), fibromyalgia tender point count ($r=0.24$, $p< 0.001$), MD global assessment of disease activity ($r=0.46$, $p< 0.001$), EQ5D ($r=-0.70$, $p< 0.001$), Dermatology Life Quality Index ($r=0.35$, $p< 0.001$), pain ($r=0.58$, $p< 0.001$), stiffness ($r=0.61$, $p< 0.001$), Health Assessment Questionnaire ($r=0.58$, $p< 0.001$), Fatigue Severity Score ($r=0.744$, $p< 0.001$), Bath AS-Global ($r=0.68$, $p< 0.001$), Bath AS Disease Activity Index ($r=0.70$, $p< 0.001$), Bath AS Functional Index ($r=0.64$, $p< 0.001$), AS Quality of Life ($r=0.76$, $p< 0.001$), Functional Assessment of Chronic Illness Therapy ($r=-0.79$, $p< 0.001$), SF-Physical Component Scale ($r=-0.70$, $p< 0.001$), SF-Mental Component Scale ($r=-0.56$, $p< 0.001$), and patient global assessment of disease activity ($r=0.60$, $p< 0.001$).
Conclusion: WI was significantly higher in nr-axSpA than other types of SpA. WI was correlated with a number of features, with stronger associations with patient-reported outcomes such as the Bath Indices, ASQOL, FACIT, SF-36 subscales and patient global assessment of disease activity. Supported by a CIORA grant.

171

Applying Integrative Knowledge Translation to Pediatric Antibody-Mediated Inflammatory Brain Disease: Identifying and Filling the Knowledge Gap

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Objective: Antibody-mediated inflammatory brain diseases (IBrainD) are increasingly recognized, devastating conditions affecting previously perfectly healthy children. Patients may develop hallucination, abnormal movements, refractory seizures, dysautonomia or coma. Aggressive treatment with plasma exchange, chemotherapy and high dose corticosteroids is often rapidly initiated. Families are desperate for information. The objective of this knowledge translation study was to explore the current knowledge gap for IBrainD and develop freely available, trust-worthy resources for patients and families as they struggle with these rare, but devastating diseases.
Methods: The conceptual framework for this project was the integrated knowledge-to-action cycle, in which researchers and knowledge users jointly design, implement and monitor a knowledge tool. The current knowledge gap was explored by 1) reviewing all available online resources for IBrainD and 2) by conducting comprehensive interviews in focus groups of patients, families and health care providers. Evidence generated from the qualitative and quantitative approaches was synthesized and translated into plain language for dissemination to patients and families. The tools were reviewed by knowledge users and integrated into the SickKids web-based platform containing graphics, animations and video footage that is easily understandable and accessible for all patients and families (AboutKidsHealth.ca).
Results: An internet search using the most common search engines of 'antibody-mediated inflammatory brain disease' as well as each of the five most commonly recognized conditions (NMDAR encephalitis, neuromyelitis optica, limbic encephalitis, Hashimoto's encephalitis, PANDAS) failed to return any comprehensive and understandable open-access resources. Focus groups of patients and families confirmed this dramatic knowledge gap. Interviews with IBrainD patients and families generated disease -related information that was structured into the following sections: A) Breaking down the basics: inflammation and the tools of our immune system B) What is inflammatory brain disease? C) What are antibody-mediated inflammatory diseases? D) Diagnosing antibody-mediated inflammatory disease E) Treating antibody-mediated inflammatory disease F) Living with antibody-mediated inflammatory disease G) Patient stories: a video account of existing experiences H) Inflammatory brain disease glossary
Conclusion: Freely accessible, trustworthy information is crucial for families when facing the diagnosis of a rare, newly recognized disease that mandates rapid initiation of aggressive therapy. This study was generated by knowledge users creating the first online resource for antibody-mediated inflammatory brain diseases accessible in the framework of aboutKidsHealth.ca. The utilization will now be evaluated in designated traffic reports capturing hit rates and duration of web-site visits.

172

Systemic Sclerosis Classification Criteria: Developing Methods for Multi-Criteria Decision Analysis

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Objective: Classification criteria for systemic sclerosis (SSc) are being developed. Twenty-three candidate criteria have been identified, but need to be reduced. The objectives of this study were to: 1) develop a SSc-specific instrument for use in a forced-choice study and evaluate its sensibility (comprehensibility, clarity, face and content validity, and feasibility); 2) use forced-choice methods to reduce and weight criteria; and 3) explore the agreement between SSc experts on the probability that cases were classified as SSc.
Methods: A standardized instrument was tested for attributes of sensibility. The instrument was applied to cases of SSc from 20 cohorts covering a range of probabilities that each case had SSc (very likely to not at all). SSc experts rank-ordered cases from 1 (highest probability) to 20 (lowest probability). Experts then reduced and weighted the 23 criteria using forced choice-conjoint analytic methods and subsequently re-ranked the cases. Consistency in both rankings was evaluated using an intraclass correlation coefficient (ICC).
Results: Experts endorsed clarity of the form (83%), comprehensibility of the instructions and response option (100%), face and content validity (100%) and feasibility. Experts identified 'skin thickening of the fingers and proximal to the metacarpophalangeal joints' as a sufficient criterion for SSc classification. Other criteria were reduced and weighted (weight in points): skin thickening of the fingers (14-22), finger tip lesions (9-21), finger flexion contractures (16), telangiectasia (10), abnormal nailfold capillaries (10), puffy fingers (5), calcinosis (12), Raynaud's phenomenon (13), tendon/bursal friction rubs (21), pulmonary fibrosis/pulmonary hypertension (13), renal crisis (11), esophageal dilation (7) and SSc-related antibodies (15). The ICC for agreement across experts was 0.73 (95% CI 0.58, 0.86) and improved to 0.80 (95%CI 0.68, 0.90).
Conclusion: Our SSc-specific instrument for classification has demonstrable sensibility. The number of criteria were reduced by 35% (from 23 to 15) and weighted. The experts had substantial agreement in rank order. The next phase of criteria development will evaluate a threshold. Our methods

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reflect the rigors of modern psychometric science, and serves as a template for developing classification criteria in other diseases.

173

Sex Disparities in Survival of Systemic Sclerosis-Associated Pulmonary Arterial Hypertension and Idiopathic Pulmonary Arterial Hypertension Patients

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Objective: Systemic sclerosis (SSc) associated pulmonary arterial hypertension (PAH) and idiopathic PAH (IPAH) are conditions with poor survival. Prognostic markers are needed to identify patients who should be screened and aggressively treated. There is some evidence to suggest that sex affects survival. The primary objective of this study was to evaluate the effect of sex on survival in SSc-PAH and IPAH. We secondarily evaluated the effect of sex on disease onset, time to diagnosis, disease progression and treatment.

Methods: Patients were included if they attended the Toronto Scleroderma Program or the University Health Network Pulmonary Hypertension Programme; had a diagnosis of SSc-PAH or IPAH defined as a mean pulmonary artery pressure (mPAP) ≥25mmHg and pulmonary capillary wedge pressure (PCWP) < 15 mm Hg by cardiac catheterization; and age > 16 years. Sex was defined as self-reported biological and physiological characteristics at birth (male, female). The primary outcome was the time from diagnosis to death from all causes. Patients who are alive as of May 1, 2012 were censored. Secondary outcomes were sex differences in age of diagnosis, disease duration, scleroderma manifestations. Cox proportional hazards model were used to evaluate survival adjusting for baseline differences.

Results: Fifty-two male and 267 female SScPAH patients; and 47 male and 107 female IPAH patients were identified. Male SSc patients had a shorter mean (standard deviation) time from SSc diagnosis to PAH diagnosis (5.6±8.7) versus 8.4±9.6, p=0.047), increased frequency of renal crisis (19% versus 9%, p= 0.042), interstitial lung disease (67% versus 49%, p=0.02), and digital ulcers (29% versus 19%, p< 0.001). Male IPAH patients had a higher frequency of diabetes (30% versus 12%). Despite adjusting for these differences, male SScPAH patients have decreased 1-, 2-, 3-, and 5-year survival (82.6%, 70.6%, 60.8%, 48.2%) compared to females (84.4%, 73.4%, 64.2%, 52.8%). Similarly, male IPAH patients have decreased 1-, 2-, 3-, and 5-year survival (93.4%, 87.9%, 84.8%, 77.7%) compared to females (94.5%, 91.0%, 88.7%, 83.2%). The sex-based differences were not statistically significant, due to reduced power.

Conclusion: Sex disparities appear to exist in survival of SSc-PAH and IPAH patients. Further investigation is needed to evaluate this disparity, mechanisms for disparity, and the role of a targeted screening and treatment approach.

174

Survey of Traditional Cardiovascular Risk Factors in Patients with Moderate to Severe Rheumatoid Arthritis on Biologic Therapy

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Objective: While the increased cardiovascular risk in rheumatoid arthritis (RA) is well-recognized, the contributions of traditional cardiovascular (CV) risk factors in addition to inflammation remain in debate. The objective of this study was to describe the traditional CV risk factors in a cohort of moderate to severe RA patients who are on biologic therapy to better understand where risk reduction should be focussed.

Methods: Patients in northern Alberta (part of the RAPPORT database(>3500 patients) on biologic therapy were invited to complete a self-report questionnaire describing their traditional CV risk factors as part of their regular nurse mail-outs for insurance reimbursement. The questionnaire included a fasting lab requisition and RA disease activity measures.

Results: Questionnaires for 190 inflammatory arthritis patients with a medication history of at least one or more biologics (135 female:55 male) were returned, mean age 59 (SD 13.5) years. Twenty-five (13%) patients were current smokers with mean 8.7 (SD 23.1) pack-years. Disease duration was 17.8 (SD 13.1) years, 103 (54%) were RF +, 113 (59%) anti-CCP +, and 92 (48%) RF +/ anti-CCP +. Mean ESR was 19.6 (SD 19.5) mm/hr, and CRP was 7.3 (SD 12.7) mg/L. Seventeen patients were diabetic (8.9%), 3 on insulin, 10 on oral hypoglycemics, 1 on insulin/diet and 1 on insulin/oral hypoglycemic. Mean fasting glucose was 5.3 (SD 1.2), HbA1C was 5.8 (SD 0.6) Fifty-five (55) patients reported abnormal cholesterol (28.9%), with mean fasting cholesterols (mmol/L) as follows : total cholesterol 4.74 (SD 0.95), LDL 2.69 (SD 0.80), HDL 1.44 (SD 0.41), total chol/HDL 3.48 (SD 1.01), triglycerides 1.33 (SD 0.68), apolipoprotein B 0.86 (SD 0.23), lipoprotein A 0.41 (SD 0.48). Thirty-two (32) patients reported using cholesterol medications including 18 patients on statins. Hypertension was reported in 66 (35%) patients. Family history of premature CV disease was reported in 59 patients (31%) and personal history of CV disease in 37 (19%) patients.

Conclusion: This cohort of moderate to severe RA patients had normal LDL and total cholesterol/HDL ratios and modest reports of personal CV disease. Hypertension, often undertreated by rheumatology, was reported. The paradoxical normalization of cholesterol during inflammation is an important consideration in interpreting these values. Prospective evaluation with age- and sex-matching is needed through our risk reduction clinic. Supported by a CIORA grant.

175

Epidemiology of Cancer in Systemic Sclerosis Systematic Review and Meta-Analysis of Incidence, Predictors and Impact on Mortality

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Objective: The aim of this study is to improve our understanding of the epidemiology of cancer in systemic sclerosis (SSc), as it is fundamental for accurate interpretation of the cancer risk associated with novel therapeutic interventions. We evaluated the 1) incidence; 2) prevalence; and 3) risk of overall and site-specific malignancies SSc.

Methods: MEDLINE, CINAHL, EMBASE and the Cochrane Library (inception-2012) were searched for studies reporting malignancy rate in SSc, risk factors, proportion of deaths caused by malignancy, and the relative risk of malignancy in SSc in comparison with the general population (measured by standardized incidence ratios (SIR)). Estimates were combined using a random effects model. Consistency was evaluated using the I^2 statistic.

Results: Of the 4,876 citations identified, 47 studies fulfilled inclusion criteria. The average incidence of malignancy in SSc was 15 cases/1000 persons-years; the prevalence ranged between 4.2%-22%. Cancer was the leading cause of non-SSc related deaths, accounting for on average 38% of deaths. The mean SIR for all-site malignancy risk was 1.91 (95%CI 1.52,2.40; I^2 78%); for males 2.03 (95%CI 1.62,2.55; I^2 16%) and for females 1.38 (95% CI 1.16,1.63; I^2 39%). There is a greater risk of lung (SIR 4.75, 95%CI 2.73,8.24; I^2 93%) and haematological (SIR 2.37, CI 95% 1.53,3.68; I^2 0%) malignancies, including non-Hodgkin's lymphoma

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(SIR 2.55, 95%CI 1.40,4.67; I^2 0%). SSc patients may be also at higher risk of leukemia (SIR 2.79, 95%CI 1.22,6.37; I^2 0%), malignant melanoma (SIR 2.92, 95%CI 1.76,4.83; I^2 35%), liver (SIR 4.75, 95%CI 3.09,7.31; I^2 0%), cervical (SIR 2.28, 95%CI 1.26,4.09; I^2 54%) and oropharyngeal (SIR 5.0, 95%CI 2.18, 11.47; I^2 58%) cancer; but this was only supported by < 4 studies. Risk factors for malignancy include seropositivity for a-RNAP I/III antibodies, male sex, and late onset SSc. Smoking and long duration of interstitial lung disease (ILD) increase the risk of lung cancer; longstanding gastroesophageal reflux disease with Barrett's esophagus and a positive family history of breast cancer, respectively, increase the risk of esophageal adenocarcinoma and breast cancer. Immunosupressive therapy (methotrexate, cyclophosphamide) and SSc subtype are not associated with increased risk of cancer.

Conclusion: SSc patients have an approximately two-fold increase in all-site malignancy, and greater risk of lung and haematological malignancies that contribute significantly to mortality. Vigilance and screening should be considered in SSc patients with a-RNAP I/III antibodies, male sex, smokers, late disease onset, a positive family history of breast cancer, long duration of ILD, Barrett's esophagus.

176

Preliminary Data Supporting the Feasibility and Construct Validity of PROMIS Fatigue Scale and RA Core Set Variables in an Academic Rheumatoid Arthritis Clinic.

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Objective: The Patient-Reported Outcomes Measurement Information System (PROMIS) initiative of the US National Institutes of Health has created a highly precise and efficient standardized approach to measuring patient-reported outcomes across domains relevant to chronic medical conditions. The PROMIS system includes item bank libraries and Assessment Center, a secure online management tool. PROMIS is available without charge to assess physical, mental and social well-being in research and clinic settings. However, the feasibility of using PROMIS scales in busy settings as part of clinic visits and the validity of most PROMIS measures in persons with rheumatoid arthritis has not been demonstrated. We present preliminary data on the feasibility and construct validity of the PROMIS Fatigue short form in an academic RA clinic. Fatigue is often reported as one of the most disabling symptoms of RA.

Methods: Consecutive RA patients enrolled in a longitudinal study completed selected patient reported outcomes (PROs) at the Johns Hopkins Arthritis Center. PROMIS fatigue items were administered using paper-based short forms given along with other legacy measures immediately before a routine clinic visit. Variables were transformed as needed and descriptive statistics and bivariate correlations were calculated using IBM SPSS ver 20.

Results: The first 26 RA participants had a mean (SD) age of 58.3 ± 14.2 yrs and RA duration of 11 ± 9 yrs, who were mostly female (85%), white (92%) and well educated (62% had some college). Half (n=13) were on biological therapies. PROMIS fatigue t-scores ranged from 37 to 73, with a mean of 55.4 ± 9.4. Scores were highly correlated with fatigue VAS ratings (r=.81) and stiffness intensity (r=.77), patient global (r=.64), pain VAS (r=.62), and HAQ (r=.54), as well as disease activity indices (DAS r=.54, swollen and tender joints r=.53, CDAI r=.58)(all p's< .01). Patients with any level of disease activity reported fatigue levels on average 1 SD higher than those in CDAI remission (59.1 ± 8.3 vs. 49.6 ± 8.3; p< .01).

Conclusion: Our study contributes preliminary evidence of the feasibility of using the PROMIS fatigue short form as part of routine RA visits in a busy setting and of construct validity with both PROs (global impact, pain stiffness and disability) as well as clinician and patient RA disease activity ratings. Further testing and validation including use of PROMIS computer adapted tests in RA populations is needed.

177

Self Management Strategies of Rheumatoid Arthritis Patients Experiencing a Disease Flare

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Objective: Though disease flares are common, little is known about how RA patients self manage (SM) flares. We asked patients to identify SM strategies and explored potential predictors.

Methods: 512 patients in the Canadian early ArThritis CoHort (CATCH) completed the OMERACT preliminary flare questionnaire (PFQ) at clinic visits from 11-2011 through 4-2012. Patients who self-identified as being in a flare provided ratings of severity, pain, disability (HAQ) and described SM strategies. Rheumatologists rated whether their patient was in a flare and performed joint counts. Groups were stratified based on Patient-MD agreement of flare status and compared using ANOVA. Multivariable regression was used to identify potential predictors of flare SM.

Results: 512 patients with early RA who were mostly female (75%), white (82%) and well educated (57% > HS) answered the PFQ. Patients had a mean (SD) age of 53 (14) yr, 18% smoked, 65% RF+, 53% CCP+ and 24% had erosions. Mean HAQ was 1.03 (.70) and pain was 56 (27). 149 (29%) patients self-identified flare whereas MDs identified 169 cases of flare (31%); patients and MDs agreed about flare status 72% of the time (K=.34). Patients who were female, current smokers, RF+, Anti-CCP+, minority, living alone and ≤ HS were significantly (p< .05) more likely to be classified as flaring. The most common SM strategy was taking more analgesics (51%); few patients reported taking more steroids (5%) and 34% tried to manage the flare without medications. Several strategies differed by patient/MD agreement on flare status. When patients and MDs agreed the patient was in a flare, 87% reported using SM strategies; when patients but not MDs identified flare, 65% used SM strategies (p=.001). Patient/MD agreement about flare was associated with a significantly (p< .05) greater likelihood of activity reduction/avoidance. Although few patients (11%) contacted the care team for help prior to the visit, patient/MD agreement about flare status was associated with >5 fold increase in asking for help. Across strategies, predictors of SM included patient/MD agreement, female sex, and higher disability; other sociodemographic and disease characteristics were not reliably associated with SM.

Conclusion: Flares are common at routine visits in early RA. Most patients recognize when they are flaring and their rheumatologists agree. Patients use several flare SM strategies including taking more analgesics and reducing activities. Patient/MD agreement, female sex and higher disability are predictors of flare SM efforts. Notably, few patients experiencing flare reported contacting care providers for help prior to the scheduled visit.

178

Febuxostat in the Treatment of Chronic Tophaceous Gout in a Renal Transplant Patient

Tangri Vikram (London); Andrew Thompson (University of Western Ontario, London)

Case Report: Gout is a common arthritis associated with increased uric acid levels. Febuxostat is newer selective xanthine oxidase inhibitor used to treat this disorder by lowering serum uric acid levels. We report a case of a renal transplant patient with chronic tophaceous gout successfully achieving lower uric acid levels with febuxostat treatment. There were no discernible interactions with mycophenolate mofetil or tacrolimus. Our experience supports the use of febuxostat therapy in renal transplant patients with chronic tophaceous gout.

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179

Autoantibodies in Systemic Sclerosis and Risk of Organ Involvement: Results from a Large SSc Cohort (Canadian Scleroderma Research Group)

Tangri Vikram (London); Carly Hewson (London); Murray Baron (McGill University and Jewish General Hospital, Montreal); Ashley Bonner (McMaster University, Hamilton); Marvin Fritzler (University of Calgary, Calgary); Janet Pope (University of Western Ontario, London); Canadian Scleroderma Research Group (CSRG; SMBD Jewish General Hospital, Montréal)

Objective: Serum from SSc patients was analyzed centrally to determine how autoantibodies within the extractable nuclear antigen (ENA) were distributed between lcSSc and dcSSc and associations with organ involvement.

Methods: 1145 patients from the Canadian Scleroderma Research Group (CSRG) had ANA and ENA analyzed by indirect immunofluorescence on HEp-2 substrate at a screening serum dilution of 1/160. Most ENA antibodies [Sm. U1-RNP, Ro52, SS-A/Ro60, topoisomeraseI (Topo1), SS-B/La, chromatin, ribosomal P and Jo1] were measured by laser bead immunoassay; and RNA polymerase III (RNAP) by ELISA.

Results: ANA was positive in 95% (same in lcSSc, and dcSSc). Centromere pattern was present in 34%, 22% speckled, 18% nucleolar, 16% homogeneous and speckled (H&S), 6% multiple nuclear dots, and other patterns in less than 1% . Anti-centromere Ab (ACA) occurred in 52% of lcSSc and 17% of dcSSc; P=0.0001. The only ENAs that differed between lcSSc and dcSSc subsets were Topo1 (OR 2.2, P=0.0001) and RNAP (OR 6.7, P=0.00004) both more common in dcSSc. Overall, 17% had positive Topo1usually with a H&S pattern (67%); Topo1 was associated with ILD (OR 1.8-3.8). RNAP occurred in 17%. (36% in dcSSc vs. 8% in lcSSc). Scleroderma renal crisis (SRC) was 13 times more likely if RNAP positive; P=0.00.

Conclusion: ACA was significantly more common in lcSSc; ANA homogeneous pattern alone is rare in SSc. Many ENAs are equal in lcSSc and dcSSc except RNAP and Topo1. RNAP has the highest OR of SRC. Topo1 is less strongly associated with ILD.

180

Quantitative Proteomic Analysis of Synovial Fluid Identifies Putative Psoriatic Arthritis Biomarkers

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Objective: Early diagnosis of Psoriatic arthritis (PsA) will lead to improved outcomes. There is a high prevalence of undiagnosed PsA in psoriasis patients seen in dermatology clinics. Identifying soluble biomarkers for PsA will help in screening psoriasis patients for appropriate referral to a rheumatologist. Potential PsA biomarkers are likely to originate in sites of inflammation such as inflamed joints, and subsequently enter systemic circulation. Our purpose was to identify candidate PsA biomarkers by conducting high-throughput quantitative proteomic analysis of synovial fluid (SF) obtained from patients with PsA.

Methods: SF was obtained from swollen knee joints of PsA patients. The SF was confirmed inflammatory in nature and other causes of inflammation were ruled out by appropriate investigations. SF from age and sex matched controls with early osteoarthritis (defined as only a partial thickness cartilage defect in any knee compartment as well as only a grade I/II lesion by the Outerbridge classification) was also obtained during arthroscopy. Using strong cation exchange chromatography, followed by liquid chromatography and tandem mass spectroscopy on a linear ion trap/orbitrap mass spectrometer, we extensively characterized the proteomes of pooled SF from ten PsA and ten controls. All samples were analyzed in triplicates, and extracted ion current (XIC) intensities were used to calculate protein abundance ratios. Averages of the replicate PsA/control ratios were calculated and were used to identify upregulated proteins (PsA/control ratio>2).

Results: We identified and quantified 444 proteins from both groups (False Discovery Rate < 0.05). Only 44 proteins represented upregulated proteins in PsA SF ($p< 0.05$). These were investigated using two publicly available databases (Ingenuity Pathway Analysis and DAVID Bioinformatics Resources 6.7) to identify disease relevant proteins. Twenty-eight of the 44 proteins are related to the defense response pathway, representing the predominant network, followed by tissue remodeling, complement activation, cell growth and proliferation, and leukocyte migration. The top related diseases and disorders were "connective tissue disorders" and "dermatological disease and conditions" (p=9.03E-10 - 2.41E-2 and p=6.92E-8 - 4.02E-2, respectively). The top upstream regulators related to the networks generated by the upregulated proteins were IL6 (p=2.5E-10), IL1B (p=2.34E-7), OSM (p=7.22E-7), IL22 (p=4.41E-5), and IL17A (p=1.71E-4). The candidate proteins identified also included COMP, CD14 and MMP2.

Conclusion: Proteomic analysis of PsA SF has identified several candidate biomarkers and provided insights into disease pathogenesis. Verification and validation of these markers in SF and serum, respectively, is essential and is currently under way.

181

Safety Update on Certolizumab Pegol in Patients with Active Rheumatoid Arthritis with Long Term Exposure

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Objective: The safety of certolizumab pegol (CZP) in rheumatoid arthritis (RA) has been reported in previous pooled analyses of clinical trials. An update of long term safety data of CZP in RA with a cut-off date of 30 Nov 2011 is presented

Methods: The pooled analysis included 10 completed randomized controlled trials (RCTs) of CZP in RA and their open-label extensions (OLEs). Pooling was done across all doses. Some patients received CZP 400 mg Q2W (twice the approved dose) as per protocol. Adverse events were defined as those occurring after first dose and within a maximum of 84 days of last dose. Serious adverse events (SAEs) were defined conservatively by the regulatory definition with the addition of opportunistic infections (OIs), malignancies and medical events important to the investigator. Serious infectious events (SIEs) were defined according to the regulatory definition with addition of the need for IV antibiotics. All cases of death, SIEs (including OIs) and malignancies were validated by the study authors. Deaths were categorized as cardiovascular, infectious, malignant or other causes. Malignancies were classified as non-melanoma skin cancer, solid tumors or lymphoma. Incidence rates (IR) and event rates (ER) per 100 patient-years (PY) are presented.

Results: 4049 RA patients had received CZP in all studies for a total of 9277 PY. Mean exposure to CZP in all studies was 2.1 years; median exposure was 0.7 years. SIEs were the most common SAEs. In total, 43 tuberculosis infections occurred in 43 patients, of which 39 occurred in Central and Eastern Europe. 58 deaths occurred in CZP patients (IR: 0.63/100 PY) as a result of 19 cardiovascular events, 13 infections, 13 malignancies and 18 other causes. 65 CZP patients in all studies developed malignancies (ER: 0.72/100 PY), with 60 patients developing solid tumors (ER: 0.67/100 PY) and 5 developing lymphoma (0.05/100 PY).

Conclusion: No new safety signals associated with CZP have emerged in this updated long-term safety analysis. While SIE rates were higher for CZP than for placebo in the RCTs, they did not increase with continued exposure to CZP. Due to the shorter duration of placebo treatment compared with CZP, comparisons between the CZP and placebo groups should be interpreted cautiously. The rates of malignancies and serious infections are in line with CZP data reported in the product label and anti-TNF registry data.

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182

Rheumatology Patient Triage: Family Physician Preferences and Feedback

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Objective: Due to a shortage of rheumatologists, patient wait times between family physician referral to specialist appointment can be long. Triage systems for rheumatologists in a group practice setting have been implemented to ensure equal wait times for patients. However, this may be at the expense of the rheumatologist-family physician care relationship. We surveyed Northern Alberta family physicians to determine their knowledge and opinions on a rheumatology group triage system.

Methods: Over a 2 month period, a brief questionnaire was distributed to all family physicians that referred a new patient to one of eight rheumatologists at the University of Alberta hospital in Edmonton. Family physicians were asked if they were aware of current patient wait times from referral to appointment, awareness of the triage system implementation, and whether they preferred their patient to be seen by the first available rheumatologist or the specific physician named in their referral letter. Physician gender, years in practice, and practice location were collected.

Results: 37/178 (20.8%) family physicians completed the questionnaire. 50% of physicians practiced outside the City of Edmonton and 56% were male. Working experience was diverse with 44.4% in practice for less than 10 years and 38.9% in practice for greater than 20 years. The average wait time perceived by family physicians was 12 weeks, which compares to actual wait times during the survey of 7 and 22 weeks for urgent and routine referrals respectively. 64% of physicians felt their perceived wait time was unacceptable. All physicians surveyed were in favour of their patient seeing the first available rheumatologist, while the majority (94%) was in favour of the rheumatology triage system, although 75% were unaware of its existence. The three recurring themes which would oblige family physicians to request a specific rheumatologist were if a patient-physician relationship already was established (56%), patient preference (31%), or if a rheumatologist had training or interest in the specific condition (13%).

Conclusion: Family physicians prefer a rheumatology triage system despite the potential loss of the rheumatologist-family physician care relationship.

183

Incidence and Characteristics of Atypical Femoral Fractures

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Objective: Many publications have reported the emergence of atypical subtrochanteric or shaft femoral fractures. Such fractures are characterised by a unique fracture line, generally affecting the proximal third of the femur, by a medial bone spike and by a localised periosteal reaction of the lateral cortex. The objective of this study was to estimate the incidence of atypical femoral fractures on a 18 month period in Quebec City, and to collect all clinical characteristics likely to constitute an atypical fracture risk.

Methods: We reviewed medical records of patients hospitalised for hip or femoral fracture, in Quebec City between June 1st, 2009 and December 31st, 2010. We selected atypical femoral fractures according to the ASBMR workgroup criteria, and calculated their incidence. We collected all data likely to influence an atypical fracture occurrence, from medical, pharmacological records and patient interviews. For each variable, data analysis consisted of comparing patients with an atypical fracture during the last five years (including the observation period for the incidence estimation), with two controls with hip or femoral osteoporotic fracture or traumatic fracture, paired for age and gender.

Results: We identified 36 atypical fractures during the observation period, corresponding to an atypical femoral fracture incidence of 0.034 (0.024-0.047) case per 1000 persons-years. We collected 56 atypical fractures in the last five years, including the observation period, and we found a significant association with the use of bisphosphonates: $p = 0.0001$, OR = 29.03 [6.98-120.84], of proton pump inhibitors: $p = 0.02$, OR = 2.33 [1.12-4.84], of statins: $p = 0.03$, OR = 2.05 [1.06-3.97], of vitamin D intake: $p = 0.0002$ OR = 7.66 [2.64-22.26] and of calcium supplementation: $p = 0.0006$, OR = 6.61 [2.26-19.34]. There was a significant association with a personal history of osteoporosis: $p = 0.0002$, OR = 5.16 [2.20-12.08], a previous fracture: $p = 0.02$, OR = 2.60 [1.13-5.96], and a higher body mass index: $p = 0.03$, OR = 1.18 [1.02-1.36]. We found no association of atypical femoral fractures with oral corticosteroids use, smoking, diabetes, autonomy status or living place before fracture.

Conclusion: The incidence of atypical femoral fracture in our city is similar to others reported in the literature. Our retrospective study shows a significant association between atypical fractures and exposure to bisphosphonates and pump proton inhibitors. Surprisingly, we observed an association of atypical femoral fractures with statins intake, although these drugs are known to have a protective effect against osteoporotic fractures.

184

Electrocardiogram Abnormalities in Systemic Sclerosis - Systematic Review of the Literature

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Objective: Electrocardiogram (ECG) disturbances have been reported in patients with systemic sclerosis (SSc). However, few studies have addressed this in a systematic fashion and the prevalence of specific findings has varied between studies. We undertook a systematic review of the literature to identify the type and prevalence of ECG abnormalities associated with SSc.

Methods: A search of MEDLINE and EMBASE was conducted according to PRISMA guidelines. Original studies over 20 patients containing quantitative data on specific ECG findings in SSc patients were included. The Newcastle-Ottawa Scale (NOS) was used to assess study quality. The type and prevalence of abnormalities was extracted and a meta-analysis was performed for studies that had control data.

Results: Thirty-three (33) studies with a total of 1742 subjects were included in the systematic review. There were 6 cohort studies, 24 cross-sectional studies and 4 interventional trials. The median quality score using the NOS was 3 out of a possible 9, reflecting a widespread lack of control data (68%) and longitudinal observation. Only 7 studies provided data for controls, and only 1 assessed clinical outcomes prospectively. Fifty-seven (57) different ECG abnormalities were identified. The most common abnormalities were P-mitrale (26.5%), non-specific ST-segment/T-wave changes (17.6%) and P-pulmonale (15.9%). Abnormalities indicative of heart enlargement were common, including left ventricular hypertrophy (8.7%), right ventricular hypertrophy (8.2%), and left-axis deviation (10.7%). Ischemic changes were described, including an infarction pattern in 7.4% and pathological Q waves in 6.3% of subjects. Disturbances of the cardiac electrical conduction system were found most frequently as right bundle branch block (RBBB) (5.22% complete RBBB; 12.4% incomplete RBBB), left anterior fascicular block (9.9%) or 1st degree heart block (6.1%). Disorders of rhythm included ventricular premature beats (7.0%). Preliminary results of the meta-analysis indicate a higher prevalence of certain abnormalities over the control population, including long QTc intervals, infarction pattern, left anterior fascicular block, ventricular premature beats and certain signs of hypertrophy. Most other abnormalities were not different in SSc subjects compared to controls.

Conclusion: ECG abnormalities are common in SSc, and may be

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associated with focal myocardial fibrosis, ischemia or cardiac stress secondary to pulmonary hypertension. However, the accuracy of the reported rates was limited by the small sample size of many studies, lack of control data, and uncertain reporting criteria within existing studies. There is need for additional controlled data in a large sample of subjects, using uniform diagnostic criteria.

185

Reliability of the Early Erosions in Rheumatoid Arthritis Software when Quantifying Bone Loss

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Objective: MRI is an important modality to detect rheumatoid erosions at early stages. Instruments such as the Outcome Measures in Rheumatology Committee RA MRI scoring system have limited usefulness due to inconsistencies in both intra and inter-rater reliability. Semi-automating erosion quantification is one approach to increase reliability between readers. The Early Erosions in Rheumatoid Arthritis (EERA) software is a semi-automated approach to quantify RA erosions using an amalgamation of conventional Region Growing and Level-Set Segmentation algorithms. The objective of this study was to determine intra and inter-rater reliability when applying EERA software for the quantification of metacarpal phalanges (MCPs) erosions in RA patients.

Methods: Two readers, R1 and R2, trained to use the EERA software but otherwise inexperienced with conventional quantification techniques evaluated erosions captured by MRI in the 2nd-5th MCPs of 50 RA patients (based on 1987 ACR criteria). A 1T-magnet, 100mm diameter cylindrical transmit and receive coil, and a 3D spoiled gradient echo sequence were used to acquire images. Images were evaluated by each reader twice with a 72 hour period between runs. Intra and inter-rater reliabilities for total volume measures between the two readers and between two runs were assessed via intra-class correlations, ICC(2,1), with 95% CI. For runs one and two, volume measures from each reader were graphed against each other in Bland-Altman difference plots to visually capture the degree by which scores varied.

Results: 50 participants were evaluated (16 males, 34 females). The mean age was 57 years (SD=11.5), mean weight of 78 kg (SD=15.6), and mean height of 169 cm (SD=13.9). Readers identified 64±1 erosions: 15 occurred in the second MCP, 33±1 in the third MCP, 12 ± 1 in the fourth MCP, and 4 in the fifth MCP. The mean erosion size determined by R1 during the first and second run were 87.9mm3 (SD=118.9) and 88.1mm3 (SD=121.2) respectively. R2's measurements had mean erosion volumes of 90.7mm3 (SD=130.1) for the first run and 103.2mm3 (SD=151.0) for the second run. For both runs, agreement between readers was better for smaller sized erosions, decreasing appreciably beyond 100mm3. The intra-rater reliability had an ICC value of 0.956 with a 95% confidence intervals ranging from 0.935 to 0.970. Between R1 and R2, the inter-rater reliability had an ICC value of 0.921 with a 95% confidence interval from 0.886 to 0.946.

Conclusion: Results obtained suggest that EERA software can be applied to acquire MCP erosion volume measures in a reliable manner. Supported by a CIORA grant.

186

Vitamin D in Obesity (VIDeO): Assessing Vitamin D Deficiency in the Bariatric Population, a Quality Assurance Initiative

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Objective: Gastric bypass surgery (GBS) is an increasingly common intervention for morbid obesity. Little is known about the effects of GBS on bone metabolism. Adiposity has been inversely associated with vitamin D levels across a range of BMI. Our goal was to assess the prevalence of vitamin D deficiency pre-operatively, and post-operatively. As a quality assurance initiative, we also wanted to assess the rate of vitamin D and calcium supplementation in this population, and if aggressive screening and treatment of deficiencies had any effect on 25-hydroxyvitamin D levels.

Methods: In a retrospective chart review of 173 bariatric patients, baseline 25-hydroxyvitamin D, PTH and calcium levels were obtained pre-operatively and post-operatively at 3 and 6 months. We also assessed the percentage of patients on oral vitamin D and calcium supplementation at baseline and at each follow-up visit, and the number of patients receiving aggressive treatment with 50,000 IU Vitamin D2 weekly.

Results: Of the 173 patients, 170 had undergone laparoscopic roux-en-y bypass, 3 received a gastric sleeve. Mean baseline BMI was 46.0 and weight of 126.8 kg. Baseline 25-hydroxyvitamin D levels were 55.4, PTH levels of 5.68, and Calcium of 2.46. From 164 patients with baseline blood work, 76(46.3%) had baseline vitamin D deficiency (< 50mmol/l) and 130(79.3%) had vitamin D insufficiency (< 75mmol/L). A total of 32/93(34.4%) patients were vitamin D insufficient at 3 months, and 19/67(28.4%) at 6 months follow-up. Regarding vitamin D deficiency, 5/93 (5.4%) patients were vitamin D deficient at 3 months, and 2/67 (3.0%) at the 6 months follow-up. All 100% of patients at the 3 month follow-up assessment were on oral supplementation with calcium and vitamin D, and 75% were on supplementation at the 6 month follow-up.

Conclusion: The bariatric population is at high risk due for fractures due to their low baseline vitamin D levels, even before GBS. Post-op, there is a high risk of developing severe vitamin D deficiency and secondary hyperparathyroidism due to malabsorption. In this quality assurance study, we have shown that with vigilant monitoring of metabolic complications, promoting preventative measures with supplementation of vitamin D and calcium, and aggressive supplementation with weekly vitamin D2 in the deficient patients, it is possible to have much lower rates of vitamin D deficiency than those seen in the existing literature. The key will be the education of other bariatric centers on the importance of screening and supplementation to help prevent metabolic bone disease in this susceptible population.

187

Are there Gender Specific Differences in Patient Characteristics at Initiation of Biologic Treatment in Rheumatoid Arthritis?

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Objective: The prevalence of rheumatoid arthritis (RA) is 2-4 times higher in women compared to men depending on age. Furthermore, in women RA incidence increases from the age of menarche peaking around menopause, while it is rare in men under the age of 45 years (1). Several studies have shown that treatment outcomes are worse in women (2). This analysis examined gender-specific differences with respect to patient and disease parameters at initiation of the first anti-TNF agent for the treatment of RA in a Canadian routine clinical practice setting.

Methods: BioTRAC is an ongoing Canadian registry of RA, AS or PsA

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patients initiating treatment with infliximab (IFX) or golimumab (GOL) as first biologics or after having been treated with a biologic for less than six months. This analysis is based on 781 biologic naive RA patients initiating infliximab treatment between 2002 and 2012.

Results: Among the 781 patients, 593 (75.9%) were female and 188 (24.1%) were male. Mean age and disease duration at initiation of infliximab treatment were comparable between groups. Overall patient characteristics differed significantly between genders. Mean morning (AM) stiffness (p=0.012), HAQ-DI (p< 0.001), pain (p=0.019), patient global assessment of disease activity (PtGA) (p=0.012), CDAI (0.012), and RAPID 3 (p< 0.012) were statistically significantly higher in female patients. Furthermore, a higher proportion of women were rheumatoid factor (RF) positive (p=0.028) and unemployed (p< 0.001). However, physician assessment of global disease activity (MDGA), TJC, SJC, CRP, DAS28-CRP, and SDAI were comparable between genders.

Conclusion: Objective measures (SJC, TJC, CRP) were similar for male and female patients at infliximab initiation. However, patient reported outcomes (morning stiffness, HAQ-DI, Pain and PtGA) were worse at baseline for female patients at initiation of biologic treatment in this Canadian rheumatoid arthritis population. The results of this analysis show that there is a gap between subjective and objective assessment of disease activity and suggest that gender and patient reported outcomes should also be considered when making clinical decisions. References 1. Wilder RL. J Rheumatol Suppl. 1996 Mar;44:10-2. 2. Forslind K. et al. Ann Rheum Dis. 2007 Jan;66(1):46-52. 3. Tengstrand B. et al. J Rheumatol. 2004 Feb;31(2):214-22.

188

Identification of Four Parameters that Drive the Discordance between the Patient and Physician Global Assessment in Rheumatoid Arthritis

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Objective: Patient (PtGA) and physician (MDGA) global assessment of disease activity are standard outcome measures used to ascertain patient and physician subjective perception of disease activity in rheumatoid arthritis (RA). Given that the PtGA and MDGA measure the same construct from two different perspectives, assessing their discordance may provide valuable insight on patient and physician differences with respect to the relative importance placed on specific disease parameters.

Methods: BioTRAC is an ongoing, prospective registry of patients initiating treatment for RA, AS, or PsA with infliximab or golimumab as first biologics or after having been treated with a biologic for less than six months. PtGA and MDGA were measured at baseline using a 10cm VAS. Using tertiles of the baseline MDGA-PtGA distribution every patient was classified as having higher assessment than the physician (range: -10.0 to -0.5), agreement (range: -0.4 to 1.1) or lower assessment than the physician (range: 1.2 to 8.0).

Results: 841 patients with baseline data for both PtGA and MDGA were included. Among these 623 (74.1%) were female, mean age was 57.0 yrs and mean disease duration was 9.8 yrs. Mean (SD) PtGA and MDGA were 6.1 (2.4) and 6.5 (2.1), respectively, and the mean (SD) PtGA - MDGA was 0.4 (2.4) with a median of 0.3; for 6.4% of the patients the PtGA-MDGA was nil. Significant differences between patients with lower, equal or higher assessment relative to the physician assessment were identified. When compared to patients with higher PtGA relative to MDGA, patients with lower assessment of their disease activity had lower morning (AM) stiffness, pain, and HAQ-DI but higher SJC. AM stiffness, SJC, TJC, and HAQ-DI were highest in patients with PtGA-MDGA agreement. Age, gender, and SJC/TJC ratio were not different for the three groups. Linear regression using backwards selection identified pain (P< 0.001), SJC (P< 0.001), and HAQ-DI (P=0.056) as independent predictors of PtGA-MDGA.

Conclusion: The relative importance of morning stiffness, pain, HAQ, and SJC in assessing disease activity may be different between patients and physicians. These results have implications for development of assessment tools that better represent both patient and physician perspectives of disease activity.

189

First Report of Golimumab Real-World Effectiveness in Low/Moderate and High Disease Activity in Patients with Rheumatoid Arthritis

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Objective: Although the efficacy and tolerability of golimumab in patients with rheumatoid arthritis (RA) has been demonstrated in several controlled clinical trials, assessment of its real-world effectiveness is essential in order to demonstrate true population-based benefits. The aim of this analysis was to describe the baseline profile of RA patients treated with golimumab in a Canadian routine clinical practice setting and to assess the effectiveness of golimumab in real-world use.

Methods: BioTRAC is an ongoing, prospective, registry of patients initiating treatment for RA, AS, or PsA with infliximab or golimumab as first biologics or after having been treated with a biologic for less than six months. In this analysis, RA patients treated with golimumab between 2010 and 2012 and who had 6 months of follow-up were included. Analyses were performed for the total cohort and stratified by level of disease activity (DA) at baseline, defined as a CDAI ≤ 22 (low/moderate DA) or CDAI >22 (high DA). Effectiveness outcomes included the changes between baseline and 6 months in DAS28, SDAI, CDAI, HAQ-DI, SJC, TJC, patient's (PtGA) and physician's (PhGA) global assessment of DA and pain. Within-group improvements over time and between-DA group differences were assessed for statistical significance with the Student's t-test.

Results: A total of 49 RA patients were included, the majority of whom were females (n=37; 75.5%). Mean (SD) age was 58.2 (14.0) years and mean (SD) disease duration was 9.8 (8.9) years. At baseline, 18 (36.7%) and 31 (63.3%) had low or moderate DA and high DA, respectively. Upon 6 months of treatment, clinically important and statistically significant improvements in DAS28-ESR (-1.94 (1.60); P< 0.001), SDAI (-18.19 (18.88); P< 0.001), CDAI (-15.38 (17.50); P< 0.001), HAQ-DI (-0.24 (0.69); P=0.018), SJC28 (-5.71 (7.54); P< 0.001), TJC28 (-5.90 (6.92); P< 0.001), PtGA (-1.84 (3.79); P=0.002), PhGA (-2.87 (3.00); P< 0.001) and pain (-2.08 (3.43); P< 0.001) were observed. Similar results were observed within the patient subgroups by baseline disease activity; however, patients with high DA at baseline experienced greater improvements compared to the low/moderate subgroup.

Conclusion: The results of this real-life observational study show that 6-month treatment with golimumab is effective in reducing symptom severity and improving outcomes in RA patients with either low/moderate or high DA. Furthermore, significantly greater improvement in effectiveness outcomes was observed among patients with high DA at treatment initiation.

190

Validation of SNAPSHOT © ™ As a Rheumatoid Arthritis Clinical Assessment Tool

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Objective: Accurate measurement of Rheumatoid Arthritis (RA) in the clinical situation has remained an elusive goal for clinicians, patients and researchers. The current "gold standard" of DAS 28 ESR/DAS 28 CRP has been found wanting due to variability in patient and physician global assessment, tender joint count and ESR/CRP. Recently CDAI has been used as a simpler way of assessing disease activity. For 7 years our clinic has used a visual tool, SNAPSHOT ©™ which is an instant visualization of swollen joint count(SJC), tender joint count(TJC), patient and MD global assessment on a background picture summarizing disease status. By linking the patient global assessment and swollen joint count it gives a score of 1-10 showing both doctor and patient where they stand instantly and visualizes where treatment should be directed towards disease remission/LDA.

Methods: 98 sequential RA patients were assessed by a single nurse for SJC, TJC, patient and MD global assessment and ESR and CRP. From this a calculation was made for DAS 28 ESR, DAS 28 CRP, CDAI and SNAPSHOT© ™. 350 reports were generated in the follow up of 98 patients. Group 1 is all records including follow-ups (N=350). Group 2 is the baseline visit only (N=98). Group 3 is the patient with both baseline and 6 month follow up visits (N=60). Statistical analysis was performed using dispersion and distribution of the data with Spearman's rank correlation coefficient. Criteria validity and construct validity were assessed and responsiveness and sensitivity to change of the SNAPSHOT© ™ tool were assessed by effect size and standard response.

Results: Group 1-the correlation of SNAPSHOT to DAS 28 ESR, DAS 28 CRP and CDAI was .82, .92 and .96 respectively on a Spearman's ranked correlation coefficient. Group 2-baseline assessment showed a correlation of SNAPSHOT to DAS 28 ESR, DAS 28 CRP and CDAI at .86, .94 and .96 Spearman's ranked correlation coefficient. Group 3-showed a correlation of SNAPSHOT to DAS 28 ESR, DAS 28 CRP and CDAI at .82, .90 and .96 respectively.

Conclusion: SNAPSHOT © ™, a clinical visualization tool correlates tightly with DAS 28 ESR, DAS 28 CRP and CDAI in a clinical situation, both at baseline and in follow up. The advantages of instant visualization, patient buy-in, direction to treatment to target and showing discordance between subjective and objective parameters makes SNAPSHOT © ™ a clinically useful global assessment tool.

AUTHOR INDEX

A

Abbas M, 56
Abdollah H, 62
Abrahamowicz M, 33
Adachi J, 87, 185, 186
Adams K, 8, 59
Aghdassi E, POD7, 154
Ahluwalia V, POD11
Ahmet A, 91
Akhavan P, POD8, POD10, 156
Alnaqbi K, 26
Alsolaimani R, 11, 152, 162
Alten R, 88, 115
Anderson K, 63
Angelo P, 21
Anis A, 108
Anvari M, 186
April P, 155
Archibald D, 69
Ardern R, 80
Arendt C, 181
Arnold M, 140
Arnott D, 169
Arundine M, 28
Aslanov R, 72, 73, 74, 75
Averns H, 62
Ayearst R, 170

B

Bélanger S, 8, 59
Bacher A, 1
Backman C, 44
Badley E, 132
Baer P, 105
Bagovich M, 127
Bain L, 68, 69, 70
Baker M, 188
Bansback N, 108
Baranchuk A, 62
Barbosa J, 185
Bardakjian S, 128
Barnabe C, POD2, 106, 107
Baron M, POD5, 1, 4, 17, 25, 128, 145, 147, 172, 179, 184
Barra L, 64, 65, 153, 162
Barrowman N, 91
Bartlett S, 176, 177
Basharat P, 152, 153
Batruch I, 180
Baxter-Jones A, 71
Bayoumi A, 95
Beach J, 119
Beattie K, 185
Beaudoin C, POD7
Beaulieu M, 155
Belisle P, 3, 102
Bell M, 126, 131, 132
Bell D, 65
Bell-Peter A, 129, 130
Belliveau M, 8, 59
Belzile E, 183
Bennett C, 60
Benseler S, POD12, 121, 129, 130, 171
Bensen W, 12, 19, 20, 29, 43, 85, 86, 87, 88, 89, 90, 96, 105, 136, 137, 138, 139, 157, 158, 185, 187
Bensen R, 12, 85, 86, 136, 137, 138, 190
Berard R, 121
Bergeron C, 9
Bergeron L, 3
Berkson L, 128
Bernatsky S, POD2, POD4, POD11, 2, 3, 17, 23, 24, 102, 109, 133
Bernstein C, 111
Bessette L, 3, 19, 89
Beukelman T, 95
Bhavsar S, 166
Bingham C, 7, 176, 177
Bissonauth A, 174
Bissonnette V, POD7
Bobba R, 185
Boilard E, POD7
Boire G, POD6, 3, 45, 51, 94, 123, 140, 155, 156, 177
Bombardier C, POD10, POD11, 10, 151
Bonner A, 179
Bookman A, 100
Boon H, 61
Boonen A, 149
Borg R, 149
Boudabbouz H, 9
Boulet D, 183
Boumpas D, 88
Bourré-Tessier J, 57
Bowlby D, 27
Boyd S, 106
Branch M, 87
Braun J, 163
Breedveld F, 36, 37, 118
Brienza V, 58, 91
Brooks S, 126
Brosseau L, 126
Brown J, 183
Brown M, 98
Brown K, 137, 139
Buchbinder R, 151
Buchignani M, 128
Buie H, 106
Burmester G, 88
Burnett H, 95
Burrell A, 11
Butt D, POD11
Bykerk V, 45, 51, 92, 94, 123, 140, 156, 177, 181

C

Cabana F, 155
Cabral D, POD12
Cairns E, 65
Canadian Early Arthritis Cohort Investigators, 45, 123, 156
Canadian FM Guidelines Committee, 135
Canadian Scleroderma Research Group, 1, 17, 179, 184
Castillo E, 166
Cavallo S, POD14
Ceko M, 78
Celluci T, POD12, 71
Chaker N, 40
Chakraborty S, 49
Chan M, 141, 142
Chan K, 2
Chandran V, 14, 15, 101, 180
Chandran S, 175
Charlton A, 9
Chartier M, 88
Chartrand S, 165
Chartrand-Lefebvre C, 165
Chau C, 99, 173, 175
Chedeville G, POD12
Chetaille A, 3
Chhina H, 46
Chin A, 165
Choi H, 146
Choquette D, 28, 29, 30, 43, 57, 96, 113, 114, 157, 187, 188, 189
Chow S, 31
Chow A, 19, 29, 30, 89, 104, 105, 157, 189

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Downloaded on November 14, 2026 from www.jrheum.org

Choy E, 177
Choy T, 51
Chung L, 147
Cibere J, POD9, 48,
Citera G, 143
Cividino A, 7, 8, 59, 185
Clarke A, POD4, 2, 3, 23, 24, 109, 133
Cloutier N, POD7
Cohen R, 115
Colmegna I, 5, 93
Cossette P, POD6
Cretu D, 180
Curran V, 132
Cush J, 181

D
Da Costa D, 23
De Angelis G, 126
De Brum-Fernandes A, POD6
de Longueville M, 181
Deamude M 12, 136, 138, 139, 190
Dekis A, 2, 3, 4
Delaet I, 115
Dell S, 129
Dennis J, 92
Deodhar A, 163
Dhillon N, 150
Diamandis E, 180
Dixit S, 19, 20, 89, 189
Donovan B, 74
Doyle M, 39, 81
Duffy C, 61, 67, 91, 121, 167
Duffy S, 67, 167
Dumont J, 183

E
Eder L, 101
Edward Z, 184
Edwards A, 119
Edwards C, 10
Egan M, 126
Ehrmann Feldman D, POD14, 3
El-Gabalawy H, 107
Emery P, 7, 39
Eng D, POD7
Enns E, POD2
Esdaile J, POD2, POD9, 33

F
Faccin F, 118
Fallavollita S, 93, 128
Fallon L, 18
Faraawi R, 20, 30, 43
Faregh N, 134
Feldman B, 71, 95
Fitzcharles M, 76, 77, 78, 134, 135
Fleet L, 132
Fleischmann R, 7, 39, 143, 144
Florentinus S, 36, 118
Fortin P, POD7, POD10, 3, 154,
Fortin I, 19, 40, 41, 42, 89, 105, 157, 187
Foster H, 141, 142
Francisca dos Santos M, 119
Fransen J, POD5, 172
Fransoo R, 111
Fraser K, 56
Fritzler M, 107, 179
Frost L, 80
Fu E, 108
Fudge K, 75
Furst D, 7, 144

G
Gagnon F, 92
Galeazzi M, 88
Gandhi R, 161, 180
Garland A, 111
Gathany T, 163
Genovese M, 38, 39, 115
Gensler L, POD3
Giac F, 128
Gibbons R, 67, 167
Ginsburg L, 68, 70
Gjevre J, 159
Gladman D, POD13, 6, 13, 14, 15, 82, 83, 84, 97, 101, 170, 180
Goldsmith C, 22
Gong Z, 103
Gordon C, POD4, 109, 185
Got M, 136, 137, 138
Gottlieb A, 81
Gou P, 165
Goulet J, 165
Granton J, POD8, 99, 173
Grodzicky T, 165
Grondin C, 183
Guermazi A, POD9, 48
Guh D, 108
Guzman J, 120, 121
Gyger G, 128, 147

H
Haddad A, 15
Haig S, 11
Hall W, 46
Hamilton S, 6, 80
Han C, 38, 39, 163
Hanna B, 158
Hansen H, 161
Haraoui B, 18, 19, 20, 45, 51, 89, 94, 96, 114, 123, 124, 140, 177
Hardy E, 142
Harniman E, 21
Haroon N, POD3, 26, 35, 112
Harth M, 11
Harvey E, 130
Hawke C, 26
Hawker G, 60
Hawkins L, 166
Hayes S, 8, 59
Hazlewood G, 45
Heap D, 85, 86, 139
Hebert D, 130
Hemmati I, 47, 48
Hemmelgarn B, POD2
Hensman P, 142
Herman-Kideckel S, 31
Herrick A, 147
Hewson C, 179
Hilyer L, 154
Hitchon C, 45, 51, 94, 110, 111, 123, 140, 156, 177
Hochberg M, 115
Homik J, POD2, 119
Houghton K, 71, 120
Hsia E, 38, 39
Hsu B, 163
Huber A, POD12, 9, 71
Hudson M, 1, 3, 17, 128, 145, 147, 184
Hull P, 56
Hummers L, 147
Humphrey-Murto S, 49

I
Ibanez D, POD13, 13, 82, 83, 84, 97
Ibrahim Q, 125
Inman R, POD3, 6, 26, 34, 35, 112, 163, 170
Ioannidis G, 185
Ivers N, POD11

J
Jaakkimainen L, POD11
Jaeschke R, 186
Jamal S, 9, 148, 168
Jean S, 3, 183
Jeong J, 64
Jin J, 56
Johnson S, POD5, POD8, 99, 172, 173, 175
Jones A, POD2
Jones C, 21
Jones M, 176
Jorgensen P, 32
Joseph L, 3, 24, 102
Jovaisas A, 20, 96
Jung M, 145
Jurencak R, 58, 91, 121

K
Kaczorowski J, 46
Kaine J, 115
Kan M, 106
Kanellos M, 85, 86, 139
Kargard M, 107
Karsh J, 9
Katz S, 182
Kavanaugh A, 81, 117, 118
Kayhan C, 19, 89
Keeling S, 125, 174
Kelsall J, 29, 30, 96
Keng A, POD9
Kennedy C, 69
Keystone E, 7, 36, 37, 38, 39, 45, 51, 92, 94, 115, 116, 117, 118, 123, 124, 140, 156, 177
Khalid Z, 186
Khanafer M, 122
Khanna D, POD5, 144, 147, 172
Khraishi M, 72, 73, 74, 75, 104, 105, 157, 158
Khraishi S, 75
King A, 161
King J, 126
Kirby F, 132
Kirton A, POD12
Kislinsky D, 137, 139
Kislinsky K, 139
Klareskog L, 38
Klassen J, 63
Klinkhoff A, 187
Koenig M, 165
Koh M, 185
Kopec J, POD9, 48
Kron A, 99, 173, 175
Kung T, 92
Kupper H, 36, 117, 118
Kur J, 47, 148
Kuriya B, 94
Kwok K, 18
Kydd A, 9, 10

L
Légaré J, 9
Labrecque J, 109
Lacaille D, 32, 33, 46, 108
Landewé R, 37
Landolt-Marticorena C, POD13
Lao W, 23
Larché M, 185
Lau A, 85, 86, 87, 136, 137, 138, 139, 185, 186, 190
Lavender L, 32
Laxer R, 130
Lazer H, 23
Lazure P, 8, 59
Le Bars M, 88
Learch T, POD3
Leask A, POD1
Leclerc J, 183
Leclercq S, 107
Lee J, 23, 150
Lee P, 99, 173
Legault K, 185
Lehane P, 7
Lehman A, 20, 29, 30, 32, 90, 96, 104, 105, 157, 158, 187, 188, 189
Lemieux J, 58, 91
LePage J, 69
Leswick D, 160
Levstik M, 153
Li S, 81
Liang P, POD6
Lin L, 74
Lineker S, 132
Little K, 19, 89
Liu S, POD1, 36, 37, 117, 118
Lockhart S, 168
Loew L, 126
Lora M, 5, 93
Lorenz H, 88

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Downloaded on November 14, 2026 from www.jrheum.org

Low Horn C, 107
Lu M, 133
Luca N, 95
Luijtens K, 181
Lupton T, 9

M
Ma D, 154
Ma Y, 92
Ménard H, 93
Mack M, 163
Mahendira D, 31
Mahjoub Z, 183
Majnemer A, POD14
Maksymowych W, 6, 98, 170
Maldonado M, 143, 144
Manisha S, 171
Mariette X, 181
Marina R, 19, 89
Maroof A, 67, 167
Marrie R, 111
Marshall D, POD2
Martin L, 106
Marwick R, 171
Masetto A, POD6
Massie C, 184
Matern D, 159
Matheson L, 67, 167
Matucci-Cerinic M, POD5, 172
Mayes M, 147
McDonald-Blumer H, 31
McGowan J, 60
McInnes I, 81
McLeish L, 122
McMurray J, 12
McMurtry M, 125
McNeal S, 54
Mech C, 12, 136, 138, 139, 190
Mehbob A, 7
Ménard H, 5
Mendelsohn A, 81
Merkel P, 149
Michael K, 62
Michaud J, 49
Michou L, 183
Midzic I, 49
Mierdel S, 69
Mill C, 23
Miller L, 165
Milman N, 149
Mineyko A, POD12
Mintsioulis S, 107
Mitchell A, 160
Mittoo S, 1, 16
Moher D, 61
Moore L, 27
Morris D, 112
Morrison S, POD7, 154
Morton R, 26
Mosher D, 107
Mozaffarian N, 37, 117
Muangchan C, 25
Muller-Ladner U, 4
Munn A, 6, 80
Musial M, 171

N
Naden R, POD5, 172
Nair B, 159
Nam S, 70
Nantel F, 20, 29, 43, 96, 105, 189
Nash P, 115
Nashi E, 2, 23, 24
Neville A, 23
Neville C, 23
Nevskaya T, 175
Nguyen L, 66
Nicolaou S, POD9, 48, 146
Nielson W, 169
Nurmohamed M, 88
Nüßlein H, 88

O
O'Brien E, 24
O'Connor A, 60
O'Rielly D, 6
Obaid H, 161
Obermeyer K, 79
Odenbach J, 125
Oen K, 71, 121
Omar S, 120
Ong J, 21
Orbai A, 176
Otawa S, 20, 29, 30, 90, 96, 104, 105, 157, 158, 187, 188, 189

P
Pagnoux C, 130
Pangan A, 79, 98
Panopalis P, 135
Papaioannou A, 87, 186
Pasarikovski C, 99, 173, 175
Passalent L, 26
Paterson G, 44
Paterson M, POD11
Pavelka K, 88
Pavenski K, 55
Peddle A, 80
Pelet S, 183
Pellett F, 180
Peschken C, POD2, 110, 111
Peter H, 88
Petty R, 121
Pineau C, POD4, 2, 3, 17, 23, 24, 102
Pizzuto K, 62
Platt R, POD4
Pohl D, POD12
Poitras S, 126
Poncet C, 88
Pope J, 9, 11, 25, 45, 50, 51, 52, 92, 94, 122, 123, 124, 140, 145, 147, 150, 156, 169, 172, 177, 179
Poulin-Costello M, 124
Provost Y, 165
Puig L, 81
Purcaru O, 89

R
Rader T, 60
Radha J, 65
Rahman P, 6, 79, 80, 81, 157, 158, 170
Rainer F, 88
Rampakakis E, 20, 29, 30, 90, 96, 104, 105, 158, 187, 188
Ramsey-Goldman R, 109
Rapley T, 142
Rathmann S, 98
Rauch C, 88
Raynauld J, 113, 114
Redfearn D, 62
Reed J, 50
Reid G, 146
Reis J, 56
Reveille J, POD3
Rich E, 165
Riese R, 18
Rioux E, 40, 41, 42
Rioux M, 42
Ritchlin C, 81
Roberts K, 32
Roberts-Pennell K, 80
Rodrigues J, 29, 96, 104
Rohekar G, 11
Rohekar S, 11, 169, 170
Rollin B, 121
Roos A, 99, 173, 175
Rosenberg A, POD12, 71
Ross H, 139
Roth J, POD12, 67, 71, 91, 167
Roux S, 155
Rubin L, 21, 55

S
Saarimaki A, 44, 60
Sadeghi S, POD8
Saldanha P, 139
Saleh M, 164
Sampalis J, 29, 30, 90, 96, 104, 105, 157, 158, 187, 188, 189
Saraon P, 180
Sauvageau D, 113, 114
Sayre E, POD9, 33, 48
Schiff M, 143, 144
Schmeling H, POD12
Schneider R, 129
Schwartz G, 95
Scinocca M, 65
Scott S, POD4
Selvanayagam J, 119
Sen E, 142
Senécal J, 165
Seth R, 10
Shah A, 12, 85, 86, 136, 138, 147, 190
Shaikh S, 19, 89, 90
Shawi M, 20, 29, 30, 90, 96, 104, 105, 157, 158, 187, 188, 189
Sheikh S, POD12, 130, 171
Sheriff M, 29, 90, 157
Shiff N, POD12, 121
Shir Y, 76, 77
Shojania K, 146, 168
Sholter D, 105, 158, 189
Shu J, 52
Sieper J, 79, 98
Silverberg M, 26
Silverman E, 164
Silverman J, 100
Siminovitch K, 92
Simpson C, 62
Singer W, 23
Singer J, POD9, 48
Singer L, 16
Singh J, 53, 54
Systemic Lupus International Collaborating Clinics, 109
Smith R, 13
Smolen J, 39
Smuczek J, 52
Sowerby L, 24
Stacey D, 60
Ste-Marie P, 76, 77, 78, 134, 135
Steele R, 147
Steen V, 147
Steiman A, POD13, 13
Steinhart H, 26
Stinson J, 61
Stokes W, 182
Street M, 160
Strunin L, 149
Sun H, 108
Sun M, 148
Sun Y, 116
Sweezie R, 132

T
Taghavi-Zadeh S, 82
Tatibouet S, 1, 128, 147, 184
Tavares R, 185
Tavares R, 131
Taylor-Gjevre R, 63, 66, 159, 160, 161
Tessier-Cloutier B, 109
Thavaneswaran A, 14, 15, 35, 101
Thenganatt J, 99
Thomas O, 28
Thompson A, 103, 178
Thompson K, POD1
Thorne C, POD11, 9, 45, 51, 68, 69, 70, 90, 92, 94, 96, 123, 124, 127, 140, 156, 177
Thorne A, POD9, 48
Tiboni M, 186
Tiller J, 171
Tin D, 45, 68, 70, 94, 177
Tingey P, 122
Tingey T, 52
Tobin Y, 80
Tomlinson G, POD10
Torregrosa M, 57
Touma Z, 82, 83, 84, 97
Toupin April K, 44, 60, 61

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Tran A, 58, 91
Tse S, 71, 164
Tsoukas A, 5, 102
Tsoukas G, 4
Tu K, POD11
Tucker L, 71, 120, 121
Tugwell P, 44, 60, 61, 132, 149
Tupper S, 71
Twilt M, POD12, 129, 130, 171
Tyndall A, POD5, 172
Tyson N, 7
Tytus S, 185

U
Uddin M, 6
Ueng J, 55
Uh M, 146
Ungar W, 95
Uppal R, 164
Urowitz M, POD13, 13, 82, 83, 84, 97

V
Vaillancourt J, 157
Valdez H, 18
Valente R, 143
van den Bosch F, 79
van den Hoogen F, POD5, 172
Van der Heijde D, 10, 37, 98, 117, 118, 143, 151, 163
Van der Pol C, 49
Van Vollenhoven R, 7, 118, 181
Vanstone L, 139
Veinot P, 131
Veres A, 68
Vieira A, 124
Vikram T, 178, 179
Vinet E, POD4 2, 17, 24
Vinik O, 151
Voaklander D, POD2

W
Wallis D, 34, 35
Wang X, 100
Wang Y, 81, 109
Ward M, POD3
Watts C, 158
Weber D, 116
Wechalekar M, 151
Weinblatt M, 115, 143, 144
Weisman M, POD3
Welch V, 60
Wells G, 60, 126
Whiskin C, 85, 86
White K, 74
White T, 107
Widdifield J, POD11
Williams L, 16
Wilson A, 153
Wither J, POD13
Wolman S, 26
Wong H, POD9
Wong-Pack W, 87
Wraith E, 142
Wyllie R, 141

X
Xie G, 92
Xiong J, 94, 116, 156, 177
Xu S, 38

Y
Yacyshyn E, 119
Yazdani A, 16
Yazdani R, 6, 80
Yohannes S, 32

Z
Zhang W, 108
Zhao A, 131
Zhao C, 143
Zhuoxuan C, 17
Zummer M, 9, 30, 131, 189
Zurel H, 73

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