Report of the GRAPPA-OMERACT Psoriatic Arthritis Working Group from the GRAPPA 2015 Annual Meeting

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ABSTRACT. The GRAPPA-OMERACT psoriatic arthritis (PsA) working group is in the process of updating the PsA core domain set to improve and standardize the measurement of PsA outcomes. Work streams comprise literature reviews of domains and outcome measurement instruments, an international qualitative research project with PsA patients to generate domains important to patients, outcome measurement instrument assessment, conduct of domain consensus panels with patients and physicians, and evidence-based selection of instruments. Patient research partners are involved in each of the projects. The working group will present findings and seek endorsement for the new PsA core domain set, outcome measurement set, and research agenda at the OMERACT meeting in May 2016. (J Rheumatol 2016;43:965–9; doi:10.3899/jrheum.160116)

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To standardize measurements of disease used in randomized clinical trials, disease-specific groups within the Outcome Measures in Rheumatology (OMERACT) organization have developed core domain sets and core outcome measurement

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sets. A core outcome measurement set defines the minimum measurements that should be collected in randomized controlled trials (RCT), as well as other studies to inform patients, physicians, and others about the status of patients and the efficacy of medication. The core set is recommended for RCT, and is applicable to longitudinal observational studies and to clinical practice. Before developing a core outcome measurement set, working groups must first define the "domains" or constructs of most interest, i.e., the core domain set. Then measurement instruments can be identified and assessed for each domain. OMERACT published specific methodological standards and step-by-step recommendations to guide disease-specific groups in drafting disease-specific core sets, which could then achieve consensus at OMERACT meetings[1,2].

The existing psoriatic arthritis (PsA) core domain set for clinical trials, endorsed at the OMERACT meeting in 2006, contains the following domains: peripheral joint activity, skin activity, patient global, pain, physical function, and health-related quality of life[3]. Since the endorsement of the 2006 PsA core set[3,4], new PsA outcome measures for clinical trials and clinical care have been developed. Patient research partners (PRP) have been included in evaluating the completeness of the core set[4,5,6] and development of measures[7]. Additionally, OMERACT has developed a new "Filter 2.0" framework, which outlines 4 core areas to be covered in each core set. These core areas are relevant across all health conditions and need to be matched with disease-specific domains[2]. The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA)-OMERACT PsA working group is now updating the PsA core domain set with these objectives: (1) to increase patient involvement in elaboration of the core set, and (2) to integrate the use of the OMERACT Filter 2.0 methodology, adopted in 2014[2,8].

The UK is leading a coordinated initiative in which focus groups will be conducted within the "early detection to imPRove OutcoMe in people with undiagnosed Psoriatic arthriTis" (PROMPT) program. PROMPT will determine whether early detection improves outcome in patients with undiagnosed PsA and will ensure that outcome measures encompass aspects of early disease. Focus groups will be held to identify the outcomes important to patients with PsA. Outcomes will then be ranked by patients and mapped with the existing core set of domains and composite measures of disease to identify omissions within both. Finally, existing patient-reported outcome measures will be identified to address these omissions and inform revised full and shortened versions of composite measures. A followup study within PROMPT, assessment of modified COMPARE (COMPosite disease meAsures in REcently diagnosed PsA), will validate these modified composite measures.

As summarized in this report, the GRAPPA-OMERACT PsA working group has made significant progress toward its objectives since the May 2014 OMERACT meeting.

PLENARY PRESENTATIONS

Four plenary presentations were made at the 2015 annual meeting of GRAPPA: (1) an overview of the multiple ongoing projects aimed at achieving patient and clinician consensus on preliminary PsA core sets of domains and outcome measures (Figure 1); (2) a summary of the development of the patient-derived and disease-specific PsA Impact of Disease (PsAID)[9] outcome measure; (3) a presentation of the generic Patient Reported Outcomes Measurement Information System (PROMIS) measures and applicability to PsA; and (4) a patient and clinician focus group project in the United States that identifies how patients and physicians prioritize PsA domains and asks patients about the content validity of PsA outcome measures.

OVERVIEW OF GRAPPA-OMERACT PSA WORKING GROUP ACTIVITIES

Drs. Ana-Maria Orbai, Alexis Ogdie, and Umut Kalyoncu presented the framework, timeline, activities, and preliminary results from the working group. Ongoing projects include (1) 2 systematic literature reviews (SLR); (2) conduct of international focus groups; (3) outcome measures assessment in clinical trial datasets; and 2 domain prioritization projects: (4) separate Delphi exercises with patients and physicians, respectively; and (5) a face-to-face nominal group technique consensus meeting with both patients and physicians. At least 2 PRP are involved in each work stream and a total of 5 PRP are part of the working group. The PsA working group also includes 2 fellows who will be actively involved in conducting the outcome measure literature review, and coordinating the consensus process. Projects are outlined below.

Systematic Literature Reviews

Systematic literature review 1. In addition to the existing SLR of outcomes measured in PsA RCT from 2006 to 2010[10], an SLR of PsA RCT from 2010 to 2015 is ongoing (SLR1) to generate lists of domains and outcome measures. We presented preliminary results of SLR1. Most domains identified in PsA RCT mapped not only to the existing 2006 PsA core set domains[3] but also to other domains such as "Resource Use," a core area under the OMERACT Filter 2.0 framework[2]. Some clinical trial domains mapped to more than one core area, e.g., "patient global" mapped to both pathophysiologic manifestations and life impact; and "productivity" to both life impact and resource use. The SLR1 will be expanded to include data from longitudinal observational studies. Further, any additional domains identified from the PsAID outcome measure[9], previous International Classification of Functioning PsA mapping studies[11,12], and the ongoing PsA flare study[13] will also be included to generate a comprehensive list of candidate domains for the updated PsA core domain set.

Systematic literature review 2. This second SLR (SLR2) will

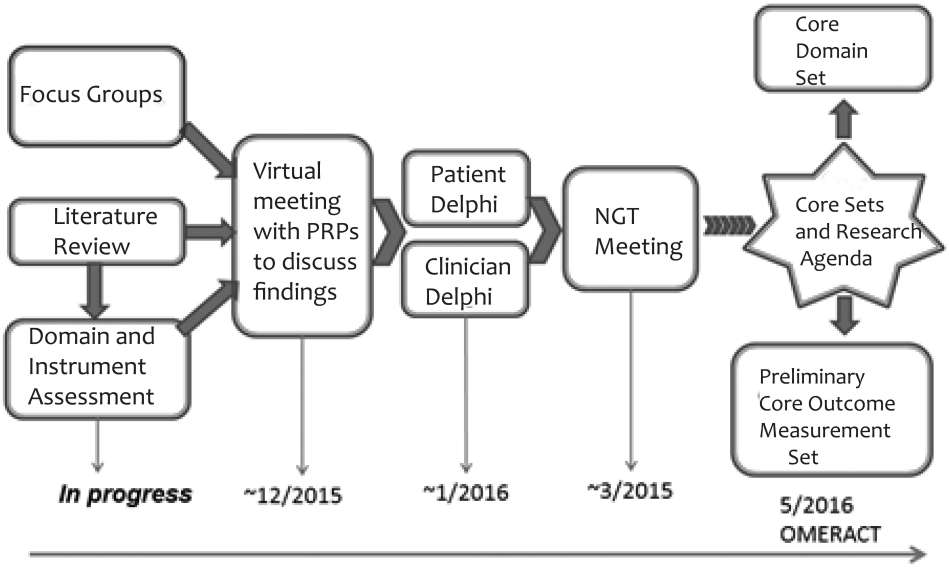

Figure 1. Timeline of the GRAPPA OMERACT psoriatic arthritis working group activities. GRAPPA: Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; OMERACT: Outcome Measures in Rheumatology Clinical Trials; PRP: patient research partners; NGT: nominal group technique.

focus specifically on psychometric properties of outcome measures[14]. The objective is to synthesize data on truth/validity, feasibility, discrimination, availability of meaningful cutoffs, and patient involvement for each PsA outcome measure[2]. SLR2 will follow methodology developed by the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) group to identify all available studies on the measurement properties of all available outcome measures in PsA[15,16]. Using the COSMIN checklist for critical appraisal of the measurement properties of each outcome measure will reveal any potential gaps among existing instruments and the need to revise or develop new outcome measurement instruments.

Qualitative Research

A multinational qualitative research project is ongoing in 7 countries with 2 focus groups in each country (United States, the Netherlands, Australia, Brazil, Canada, France, and Singapore) and 5 to 8 patients in each focus group. The objective is to determine domains of greatest importance to patients with PsA. Qualitative data will be translated into English and analyzed by a core qualitative research team from the United States and the Netherlands, with input from all investigators and PRP. Domains identified in focus groups with PsA patients will be added to the comprehensive list of candidate domains, which will be subject to Delphi rounds and nominal group technique meeting (below), for the updated PsA core set.

Outcome Measurement Instrument Assessment

A thorough assessment of available outcome measures to determine candidate core domains in PsA is also under way. Clinical trial datasets have been requested from 5 pharmaceutical companies for the purpose of assessing outcome measure content and construct validity. This will determine additional domains to be included in the Delphi procedures, a draft set of candidate outcome measures, and subsequent steps required to identify candidate responder index/indices.

Delphi Exercises to Narrow Candidate Domains

A single comprehensive list of domains will be created by merging domains identified through the aforementioned work streams. This list will be discussed with PRP and subsequently with the entire PsA working group. The discussion with PRP will center on face validity and completeness of the initial domain list, redundancy, and inclusion of missing domains as needed. The final draft list of domains will be the basis for 2 parallel domain-ranking Delphi exercises with patients and rheumatologists, using a Web-based platform. Diverse international representation will be ensured, with 100 participants in each group. PRP will help to evaluate and optimize comprehensibility for the patient Delphi, using up to 3 rounds of surveys. At the conclusion of the Delphi rounds, the most highly ranked domains will be shown on 2 lists, one each from patients and physicians.

Consensus Meeting with Patients and Healthcare Providers

A face-to-face consensus meeting including 12 patients and 12 rheumatologists is planned for mid-March 2016. The meeting will be moderated by a methodologist not involved in the working group and using a modified nominal group

technique to ensure there is no bias in including both the PRP and rheumatologist perspectives. The objective of the meeting is to reconcile the 2 domain lists and to define a preliminary core domain set for presentation, consensus, and endorsement at the OMERACT meeting in May 2016.

PSORIATIC ARTHRITIS IMPACT OF DISEASE

Dr. Laure Gossec presented the development and validation of the European League Against Rheumatism (EULAR) PsAID outcome measure[9]. The PsAID was patient-derived, with active involvement of patients on different levels[7]. Domains were identified by PRP from 11 European countries who participated in a meeting to choose PsA health domains. These domains were then subject to prioritization by 139 patients to exclude the 4 domains with the lowest priority of the initial 16 domains. There are 2 versions of the PsAID questionnaire: one with 12 domains recommended for clinical care, and one with 9 domains recommended for clinical trials. The PsAID was validated in a sample of 447 people with PsA from different European countries. The relation with other well-known outcome measures was evaluated cross-sectionally, and reliability and sensitivity to change in smaller samples was validated longitudinally (N = 80 and 71, respectively). The measures appeared to perform well, and reliability was high (ICC = 0.95, 95% CI 0.92–0.96). The PsAID questionnaires are available free of charge in several languages from the EULAR Website (www.eular.org/tools_products.cfm). External validation is ongoing.

PATIENT REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM

Dr. Ana-Maria Orbai summarized the steps and methodology used in the development of the PROMIS. PROMIS, developed with US National Institutes of Health support, is a library of generic health measures meant to be used across chronic health conditions. PROMIS uses state-of-the-art qualitative, quantitative, and psychometric methodology from health concept definition to outcome measure testing and validation in a large US population sample (n = 21,000). Each item was tested in about 900 people from the general population and 500 people living with a chronic disease. PROMIS measures are available free of charge (http://assessmentcenter.net) and are being translated and validated in multiple languages by the PROMIS International organization[17,18]. The implementation and expansion of PROMIS measures are currently focused on validation studies in specific health conditions[19,20,21,22,23], including testing in PsA in an ongoing longitudinal project at Johns Hopkins[24].

PROJECT FOCUS GROUPS WITH PATIENTS AND PHYSICIANS

Dr. Philip J. Mease presented the plan for a US multicenter qualitative study to identify how patients and physicians prioritize health domains in PsA. A second objective is to examine patient perceptions of outcome measures that are either currently being used or are candidate measures for use in PsA clinical trials. The project addresses the content validity of these measures and will inform outcome measure selection for the PsA core outcome measurement instrument set.

DISCUSSION

An update of the 2006 PsA Core Domain Set is under way to ensure that it incorporates the patients' perspectives and reflects the subsequent accumulated knowledge in the PsA field. For example, we now have a better understanding of patient preferences and priorities from development of new outcome measures for PsA as well as PsA pathophysiology since the discovery and approval of new therapeutics. Researchers in the GRAPPA-OMERACT PsA working group are using OMERACT Filter 2.0 methodology[2,8,25] to build on prior work through SLR and secondary data analyses of outcome measures used in clinical trial datasets. The qualitative research work stream with PsA patients is pivotal in eliciting concepts of importance to patients and ensuring PsA assessments are based on a valid and complete conceptual framework for PsA domains. Equal input from patients and healthcare providers is essential because their priorities complement each other in deciding on core domains through Delphi and consensus meeting components. This is exemplified by the OMERACT 2006 patient perspective workshop[26] and the Rheumatoid Arthritis (RA) Flare Delphi exercises[27], where PRP participation led to the inclusion of fatigue in RA assessments and of additional domains for RA flare assessment. The findings in RA parallel the evolution of PsA data related to fatigue, where fatigue was the third most important domain prioritized by patients (after pain and skin) in the PsAID questionnaire[9], but has yet to be included in the current PsA core domain set. This situation may be similar for other PsA domains. Concurrently, PsA outcome measurement instruments are being evaluated for their completeness as well as fulfillment of OMERACT Filter 2.0 standards.

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