

Interobserver agreement in axial spondyloarthritis

TITLE: Advancing early identification of axial spondyloarthritis: An interobserver comparison of extended role practitioners and rheumatologists

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ABSTRACT

Objectives: To compare clinical impression and confidence of extended role practitioners (ERPs) with rheumatologists experienced in axial spondyloarthritis (SpA) according to: 1) evaluation of patients with chronic back pain assessed for axial SpA; 2) MRI recommendation for further investigation of these patients.

Methods: Patients with ≥ 3 months of back pain and age of onset < 45 years were referred for axial SpA evaluation. An ERP assessed consecutive patients and recorded standardized clinical information in written form. Three rheumatologists subsequently evaluated each patient based on the recorded information. Patients were classified as axial SpA or mechanical back pain based on clinical and investigative findings. Level of confidence was noted for classification and MRI indication. Agreement between assessors was evaluated using percent agreement and Kappa coefficient.

Results: Fifty-seven patients were assessed. Inter-observer agreement of clinical impression for all raters was moderate ($K=0.52$). Agreement of clinical impression between ERPs and rheumatologists ranged between 71.2% ($K=0.41$) and 79.7% ($K=0.57$). Agreement of clinical impression amongst rheumatologists ranged from 74.1% ($K=0.49$) and 79.7% ($K=0.58$). All rater agreement for MRI indication was fair ($K=0.37$). ERP agreement with rheumatologist for MRI recommendation ranged from 64.2% ($K=0.31$) and 75% ($K=0.48$). Agreement for MRI indication amongst rheumatologists ranged from 62.9% ($K=0.27$) and 74% ($K=0.47$). Confidence in clinical impression was similar amongst all practitioners.

Conclusion: ERPs with specialty training in inflammatory arthritis demonstrate comparable clinical impression with rheumatologists in the assessment of axial SpA. Incorporation of such roles into existing models of care may assist in early detection of axial SpA.

INTRODUCTION

Axial spondyloarthritis (SpA) is a chronic autoimmune disease, primarily affecting the spine, which manifests in pain, progressive stiffness, involvement of peripheral joints and extra-articular manifestations affecting the ocular, gastrointestinal and dermal systems [1]. The incidence of radiographic axial SpA (i.e. ankylosing spondylitis) can vary from 0.4 to 15.0 per 100,000 patient-years, with prevalence rates per 100,000 persons ranging from 6.5 to 540, depending on geographic region [2]. Early detection is critical in improving long-term outcomes in patients with axial SpA [3, 4]. A recent study demonstrated that 47% of patients with axial SpA waited at least 5 years before receiving a definitive diagnosis for their back pain, with this diagnostic delay extending as long as 10 years [5-8]. Early diagnosis is important for this patient population as it may lead to better control of symptoms, improved functional outcomes and enhanced quality of life in patients with axial SpA, through the timely initiation of appropriate treatments [9-11]. Moreover, access to rheumatology care may be a contributing factor to delayed detection of axial SpA, with provision of rheumatology care often outmatched by demand [12,13]. These factors combine to create a degree of urgency for early detection and treatment, if patients with axial SpA are to avoid prolonged wait times; unnecessary diagnostic procedures and inappropriate interventions.

There are several models that have been proposed to address the lack of rheumatology specialists and to improve access to rheumatology care. Extended scope models of care have used allied health professionals (physiotherapists,

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occupational therapists and nurses) with advanced training to provide assessment and management in order to improve access to care [14-16]. These Extended Role Practitioners (ERPs) practice in a capacity whereby they assume roles beyond their tradition scope through the use of medical directives to order and interpret investigations and thereby make diagnoses within their clinical expertise [14, 15]. There are numerous models found throughout the literature that employ ERPs for triage of musculoskeletal conditions including osteoarthritis and inflammatory arthritis [14,15,17]. Physiotherapists working in extended scope are particularly well positioned to fulfill ERP roles, given their extensive training in the assessment of the musculoskeletal system and its associated pathologies, including degenerative and inflammatory joint diseases [18-20]. Despite the development of such models, none have specifically examined the role of ERPs in the area of axial SpA. The purpose of this study was to compare the clinical impression and confidence of ERPs with rheumatologists experienced in axial SpA according to: 1) the evaluation of patients with chronic back pain being assessed for axial SpA and 2) MRI recommendation for further investigations for these patients.

PATIENTS AND METHODS

Patients with more than 3 months of back pain with onset prior to the age of 45 years (and with no previous diagnosis of axial SpA) who were attending community primary care (primary care physicians or physiotherapists) were referred to the Toronto Western Hospital Spondylitis Screening Clinic for evaluation of possible

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axial SpA. Given that axial SpA can present in isolation or as an overlap with other spondyloarthropathies, patients attending Gastroenterology clinics for inflammatory bowel disease, or Ophthalmology clinics for anterior uveitis, with complaints of back pain (for >3months and no previous diagnosis of axial SpA) were also referred for axial SpA evaluation (See Figure 1). Consecutive patients who met the above referral criteria were initially assessed by an experienced ERP, associated with the Toronto Western Hospital Spondylitis Program for 3 years and certified as an Advanced Clinician Practitioner in Arthritis Care (ACPAC) [21]. The assessment included a thorough back pain history; past medical history (including extra-articular manifestations of SpA (i.e. uveitis, psoriasis and/or inflammatory bowel disease)); medications; physical examination, laboratory studies (erythrocyte sedimentation rate, C - reactive protein and Human Leukocyte Antigen (HLA) -B27 typing) and plain radiographs (anterior-posterior pelvis; anterior-posterior and lateral lumbar and cervical spines). The details of each patient's history and physical exam were recorded on a standardized data collection form. Patients were classified by the ERP as axial SpA [22]; mechanical back pain (MBP) or "other", if indicated, based on clinical and investigative findings. Level of confidence on a 10-point numeric rating scale regarding the ERP's clinical impression (0, indicating no confidence and 10, indicating high confidence) was noted. The ERP also specified whether an MRI for further investigation was indicated.

Evaluation data (i.e. history, physical exam and investigations) were collated for each patient and presented to three rheumatologists (two staff rheumatologists,

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specializing in axial SpA and a rheumatology Fellow) as a “paper patient”. Each rheumatologist was required to review the evaluation data and then classify each patient as either axial SpA or MBP. The rheumatologists were also asked to note their level of confidence on a 10-point numeric rating scale regarding their clinical impression. Lastly, the rheumatologist indicated whether an MRI for further investigation was warranted.

Inter-observer agreements for back pain classification and for MRI recommendation between ERP and rheumatologists and amongst rheumatologists were estimated using percent agreement. A multimodal analysis of inter-observer agreement included Cohen’s KAPPA coefficient and the prevalence adjusted bias adjusted Kappa (PABAK) to ensure validity of results. Confidence in back pain classification was compared using one-way ANOVA, with case-wise omission to account for missing values. The ANOVA results were then confirmed using the Tukey HSD test. SAS Version 9.1 was used for analyses. This study was approved by the University Health Network’s (UHN) research ethics board (approval number: 11-0362-BE). Written informed consent was obtained by all patients participating in the study according to policy and procedures as outlined by UHN’s research ethics board.

RESULTS

A total of 57 patients were assessed by the ERPs and rheumatologists. The majority

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of patients were referred from Gastroenterology Clinics or Primary Care (47% and 44% respectively). Patients were predominantly male (56.1%) and had a mean age of 38.5 (+/- 12.2) years. Table 1 outlines the demographic and clinical characteristics of the patients assessed by the ERPs in the Spondylitis Screening Clinic. Most patient participants reported an insidious onset of back pain, with a mean age of onset of 28 (+/- 10.9) years, most frequently affecting the lumbar and sacral regions of the spine (86.0% and 57.9% respectively) and sacroiliac joints (47.4%). Morning stiffness was present in 87.7% of patients, lasting a mean duration of 73.7 minutes. 14.3% were HLA-B27 present and 12.5% met modified New York Criteria [23].

Impression for axial SpA by the various practitioners ranged from 35.7% (staff Rheumatologist 1) to 55.4% (Staff Rheumatologist 2) of reviewed cases. Recommendation for further investigation (i.e. MRI) ranged from 37% (ERP) to 62.5% (Staff Rheumatologist 2) of reviewed cases.

The ERP agreed with rheumatologist consensus (consensus defined as ≥ 2 out of 3 rheumatologists classifying patients as either axial SpA or MBP) in 75.5% of all cases, representing a Cohen's Kappa of 0.5 and PABAK of 0.51, indicating a moderate level of agreement (See Table 2 for interpretation for Kappa results [24]). Similar findings were observed when the ERP was compared to each individual rheumatologist (Table 3). Amongst the participating rheumatologists, agreement of back pain classification ranged from 74.1% to 79.7%, with Cohen's Kappa ranging from 0.49 to 0.58 and PABAK ranging from 0.48 to 0.59, indicating a moderate level of agreement.

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With respect to MRI recommendation for further investigation for evidence of inflammatory changes in the sacroiliac joints or spine, the ERP agreed with the rheumatologist consensus in 71.1% of cases, representing moderate agreement (Cohen's $\kappa=0.43$, PABAK=0.42). Percent agreement was slightly less when the ERP was compared to each individual rheumatologist, ranging from 64.2% to 75%, with fair to moderate level of agreement (Cohen's κ ranging from 0.31 to 0.48 and PABAK ranging from 0.29 to 0.50). In comparison, percent agreement between rheumatologists ranged from 62.9% to 74%, (Cohen's κ ranging from 0.27 to 0.47 and PABAK ranging from 0.26 to 0.48) representing a fair level of agreement (See Table 4).

Figure 2 illustrates the confidence in back pain classification amongst participating practitioners. The median level of confidence in back pain classification amongst rheumatologists was 6 and ranged from 2 to 10 on a 10-point visual analogue scale. In comparison, the ERPs median level of confidence was 7 and ranged from 3 to 10. There was no significant difference in confidence levels between the ERP and the rheumatologists ($p=0.068$).

DISCUSSION

The above study is the first to compare inter-observer agreement between ERPs and rheumatologists in the detection of axial SpA. The majority of studies to date that have compared inter-observer agreement between ERPs and physicians have

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predominately been conducted in orthopaedics, assessing the detection of a variety of specific musculoskeletal disorders. These studies have shown similar results in agreement, ranging from $k=0.69$ to 0.87 [14, 25-27]. Often included in these studies is the analysis of diagnostic accuracy of the ERP. This outcome was not examined in the above study, as determination of diagnostic accuracy requires a gold standard in order to assess specificity and sensitivity. As is the case for many rheumatological conditions, the gold standard for diagnosis of axial SpA rests with the clinical opinion of the rheumatologist which is based on the overall impression of the patient's history, physical examination and investigative results and takes into consideration both the presence and absence of pertinent findings [28]. Inclusion of diagnostic accuracy in the above study would have relied on the clinical opinion of the rheumatologist and created a circular process in the assessment of diagnosis for axial SpA. In order to avoid this circularity, the objectives of this study were to examine the interobserver agreement between ERP and rheumatologist and between rheumatologists, based on clinical impression using established criteria for disease classification [22].

This study shows ERPs with advanced training in arthritis care demonstrate comparable clinical decision making in patients presenting with back pain to rheumatologists; however, agreement amongst ERPs and rheumatologists in the evaluation of axial SpA was found to be moderate at best. These findings are consistent with findings in the literature reflecting wide inter-observer variation amongst the various domains used in classification of axial SpA, such as imaging

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interpretation of sacroilitis [29, 30]. Furthermore, there was comparable confidence in clinical decision making between ERP and rheumatologists. Other studies have examined the confidence of disease classification in patients presenting with chronic back pain and found similar results with confidence ranging from 5 to 10 on a visual analogue scale [31]. These moderate levels of confidence, in addition to moderate levels of inter-observer agreement, suggest that clinical decision making for this patient population may be challenging for the clinician. Moreover, the phenotypical heterogeneity of the various subsets of axial SpA (i.e. radiographic axial SpA and non-radiographic axial SpA), and the fact that there is no single clinical or investigative feature for the diagnosis of axial SpA, adds to the challenge of accurately identifying patients with axial SpA [3]. Further study into the decision making process of clinicians working with chronic back pain may provide better insight into the clinical reasoning process for patients with axial SpA.

The rate of axial SpA classification was high in this study, with clinicians classifying patients with axial SpA (including imaging and clinical arms), ranging from 37.5% to 57.4% of reviewed cases. This is high compared to other population studies reporting ankylosing spondylitis (AS), a subset of axial SpA, with incidence rates ranging from 0.4 to 15.0 per 100, 000 patient-years and AS prevalence rates ranging from 6.5 to 540.0 per 100, 000 persons [2]. Almost half (47%) of patients reviewed in this study were referred from gastroenterology clinics, with a known diagnosis of inflammatory bowel disease, which may have contributed to an increased pre-test probability of a diagnosis of axial SpA.

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The use of a multimodal analysis of interobserver agreement added to the validity of the results. The inclusion of the PABAK statistic adjusted for potential bias with respect to disagreement between observers and also accounted for potentially very high or very low data distribution by disease classification (i.e. axial SpA versus MBP). The differences between the Cohen's kappa statistic and the PABAK were negligible and the overall interpretation of the kappa statistic did not vary between analyses (See Table 2), suggesting an accurate interpretation of interobserver agreement.

The use of "paper patients" may raise a legitimate question regarding the validity of the rheumatologist's clinical opinion, as the rheumatologists did not assess the patients face to face and perhaps may have come to different clinical decisions, if they had done so. Similar methods have been described in the literature and were used in the development of the ASAS classification criteria for axial SpA [31]. Employing "paper patients" as a form of clinical review was most feasible in our study as it allowed for multiple reviews from a number of rheumatologists on the same patient. In order to optimize validity of the "paper patients" and minimize potential bias, standardized data collection forms were used for the patient history and physical examination. The rheumatologist also had access to all handwritten notes and any investigative results pertaining the axial SpA screening exam in the patient's clinic chart and electronic medical record.

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The criteria used in the diagnosis of axial SpA itself may be a cause for delay in early detection of this patient population. For example, application of the modified New York Criteria for ankylosing spondylitis requires at least a grade 2 bilateral sacroiliitis, or a grade 3 or 4 unilateral sacroiliitis, in addition to at least one criterion from a list of clinical criteria [23]. The inherent problem with these criteria is that the radiographic changes may take several years after the onset of symptoms [3]. Brandt et al have suggested that diagnosis in the non-radiographic stage can be made through a combination of clinical, laboratory and MRI imaging [32]. The inclusion of MRI imaging has been well endorsed by the ASAS consensus criteria for axial SpA and it has been reported that a targeted history, examination and investigation can significantly increase the index of suspicion for SpA from a 5% disease probability, in those with general chronic low back pain, to an 85% disease probability with the appropriate combination of clinical, laboratory and MRI imaging [3]. Unfortunately, in many jurisdictions around the world, access to MRI can be limited. Prolonged wait times for a limited number of MRI machines, in addition to fiscal constraint, remains a clinical challenge in the early detection of non-radiographic axial SpA [33].

The results of this study demonstrated the ERP was conservative in the recommendation for further MRI investigation, compared to the rheumatologists participating in this study. This may be attributed to the fact that current provincial legislation impedes licensed physiotherapists who may be working as ERPs in Ontario, Canada from ordering MRIs [34] and therefore, ERPs may be more

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judicious in their recommendation for MRI investigation. The results of this study showed moderate agreement between ERP and rheumatologist when recommending further investigation, specifically MRI to assess for evidence of inflammatory changes in the sacroiliac joints and/or spine. These findings were comparable to the agreement between participating rheumatologists. By demonstrating comparable clinical judgment between the ERP and rheumatologist for further diagnostic imaging, it is anticipated these results will help to allow for the endorsement of medical directives for ERPs that may help bridge legislative hurdles in the early detection of axial SpA.

This is the first study comparing the clinical impression of non-physician health care professionals (i.e. ERPs) with rheumatologists in the evaluation of patients with chronic back pain assessed for axial SpA. As such, there are number of limitations to be addressed. First, this study takes place in an academic tertiary referral centre, and therefore patients with high-risk for axial SpA from specialty clinics (i.e. patients with inflammatory bowel disease and uveitis) comprised the majority of participants. It may be argued the pre-test probability of identifying patients with axial SpA is higher given the presence of extra-articular manifestations associated this form of inflammatory arthritis. However, the aim of this study was to determine the clinical impression agreement between health care professionals, regardless of final diagnosis. Therefore, the fact that these patients may have had a higher pre-test probability of axial SpA should not factor into the comparison of clinical impression between ERP and Rheumatologist. Second, the results of this study

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utilize a single ERP for the initial axial SpA screen, suggesting external validity of the results may be limited. However, the advanced training undertaken by the participating ERP is from a competency-based credentialed program offered through an academic institution [35] and therefore similar results would be expected from other ERPs who have received similar training. Lastly, this study did not undertake an a-priori examination of the validity of the ERP assessment compared to the rheumatologists' assessment. Future studies addressing the validity of ERPs' and Rheumatologists' assessment of axial SpA is recommended in order to confirm findings outside the context of this study.

In an era of policy shift of fiscal constraint and limited access to timely health care, the use of non-physician health care professionals (i.e. ERPs) who are highly skilled in the assessment of axial SpA has the potential to positively impact a number of patient and system-related outcomes (e.g. patient and provider satisfaction, wait times). The above study contributes to the growing body of literature supporting the use of non-physician health care providers to enhance access to appropriate arthritis and musculoskeletal care. In the case of axial SpA, ERPs with advanced training demonstrated comparable clinical judgement as rheumatologists in the assessment of axial SpA. Utilization of such extended practice roles, in collaboration with physician colleagues, may assist in improving the early detection of axial SpA, thereby facilitating early treatment and improving overall outcomes in this patient population.

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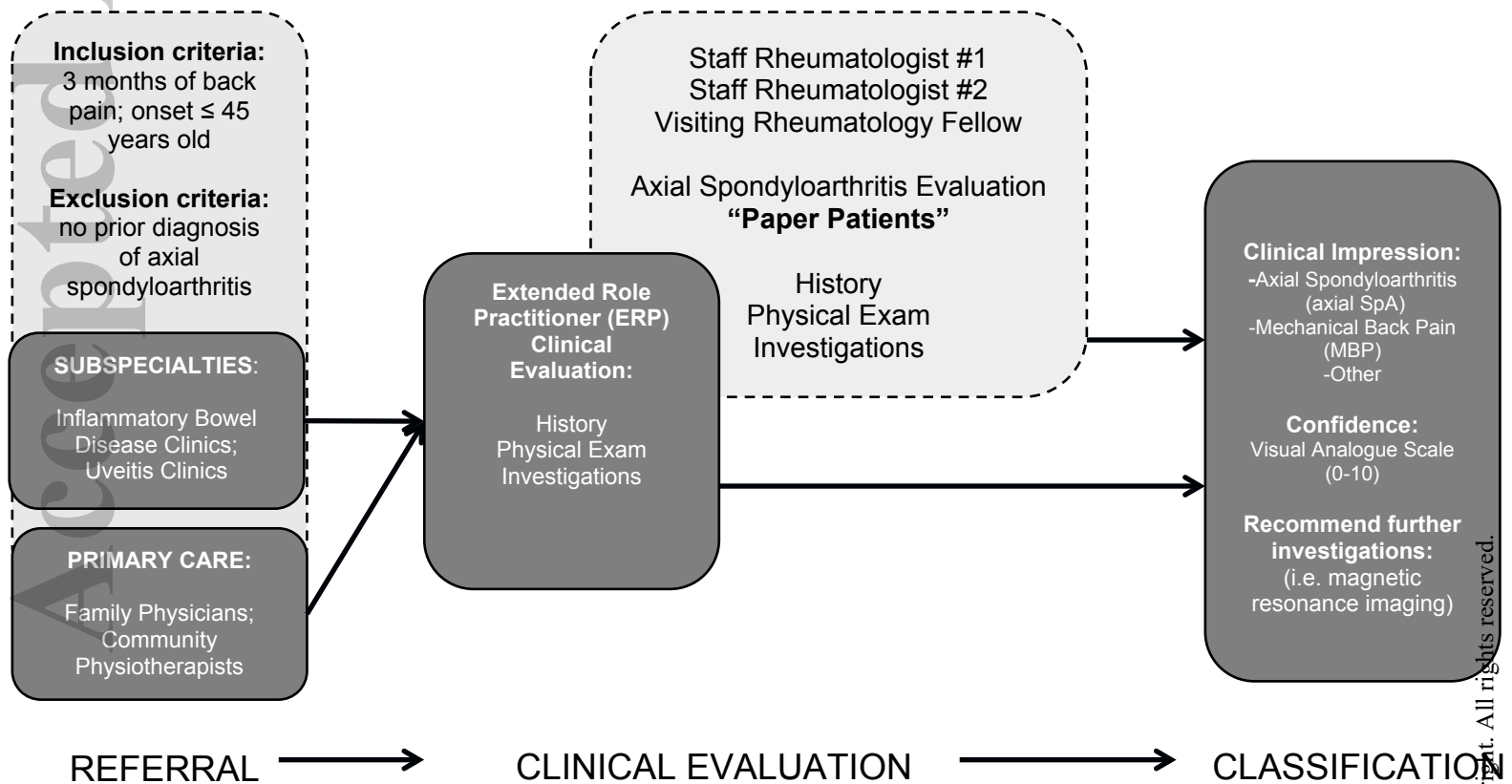
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Figure 1: Methods



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Figure 2: Confidence in back pain classification amongst participating practitioners
(n=57)

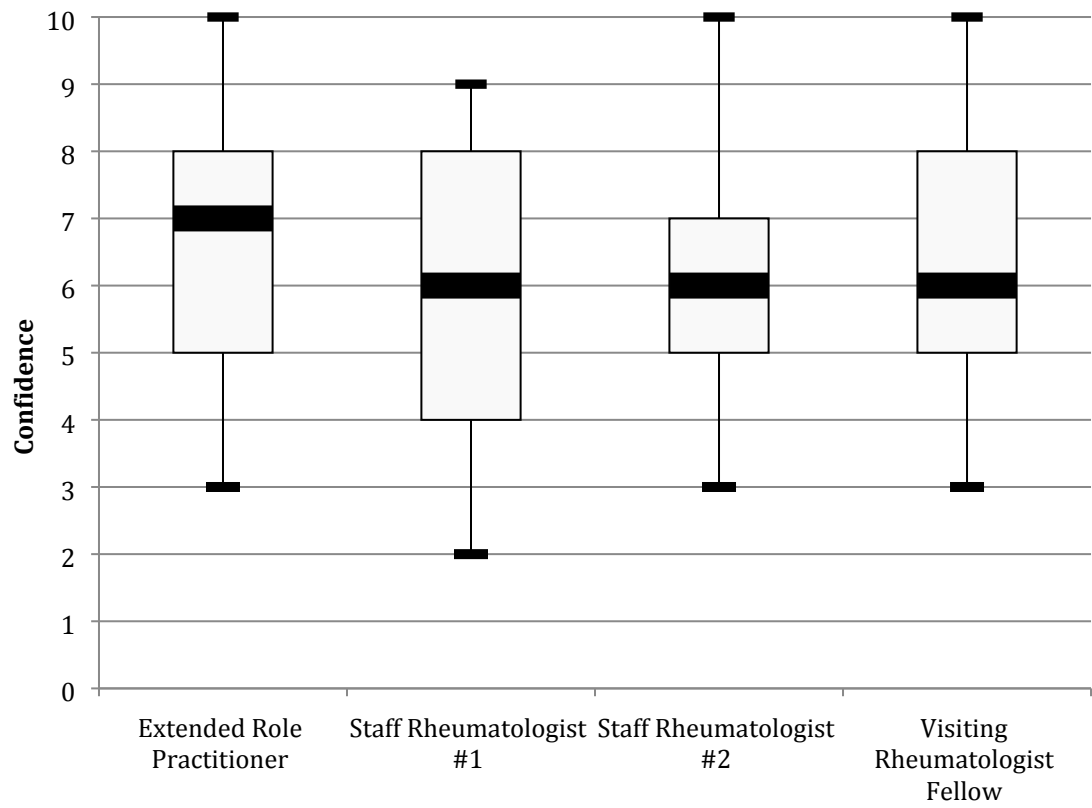


Table 1: Demographics and back pain characteristics

	n=57
Demographics	
Male (%)	56.1
Mean age (SD) in years	38.5 (12.2)
Back pain characteristics	
Onset, insidious (%)	80.7
Mean age of onset (SD) in years	28 (10.9)
Mean Oswestry [36] score (SD)	22.2 (12.4)
Location of pain (%)	
cervical	26.3
thoracic	40.4
lumbar	86.0
buttocks	43.9
sacrum	57.9
sacroiliac joint*	47.4
Presence of morning stiffness (%)	87.7
Mean duration of morning stiffness (SD) in minutes	73.7 (56.7)
Improvement with activity (%)	69.6
Improvement with rest (%)	42.9
Alternating buttock pain (%)	24.6
Nocturnal back pain (%)	63.2
NSAID responsive (%)	47.3
Presence of extra articular manifestations (%)	
inflammatory bowel disease	50.8
psoriasis	15.8
uveitis	8.8
Positive SpA family history (%)	33.3
Mean (SD) BASMI	2.2 (0.8)
Results of investigative findings	
Elevated ESR (%)	17.0
Elevated CRP (%)	11.5
HLA-B27 presence (%)	14.3
Meets modified New York Criteria [22] (%)	12.5

* located in proximity to the posterior superior iliac spine (i.e. dimples of Venus)

NSAID=nonsteroidal anti-inflammatory drug

SpA=spondyloarthritis

BASMI = Bath Ankylosing Spondylitis Metrology Index

ESR=erythrocyte sedimentation rate

CRP=C-reactive protein

HLA-B27=human leukocyte antigen B27

Table 2: Categorization of interobserver agreement by Kappa index [24]

Kappa (κ)	Agreement level
0.81-1.00	Almost perfect
0.61-0.80	Substantial
0.41-0.60	Moderate
0.21-0.40	Fair
0-0.20	Slight
<0	Poor

Table 3: Interobserver agreement for clinical impression between Extended Role Practitioner and rheumatologists (n=57)

Clinical Impression	Percent Agreement	Cohen's Kappa (κ)	95% Confidence Interval	PABAK
ERP and Rheum consensus	75.5	0.50	(0.26-0.73)	0.51
ERP and Rheum 1	79.7	0.57	(0.35-0.79)	0.59
ERP and Rheum 2	77.7	0.56	(0.33-0.77)	0.55
ERP and Fellow	71.2	0.41	(0.17-0.67)	0.42
Rheum 1 and Rheum 2	76.8	0.55	(0.35-0.75)	0.54
Rheum 1 and Fellow	79.7	0.58	(0.37-0.8)	0.59
Rheum 2 and Fellow	74.1	0.49	(0.26-0.71)	0.48

ERP=extended role practitioner

Rheum=rheumatologist

PABAK=prevalence adjusted, bias adjusted Kappa

Table 4: Interobserver agreement for MRI recommendation between Extended Role Practitioner and rheumatologists (n=57)

MRI Recommendation	Percent Agreement	Cohen's Kappa (κ)	95% Confidence Interval	PABAK
ERP and Rheum consensus	71.1	0.43	(0.2-0.66)	0.42
ERP and Rheum 1	75	0.48	(0.23-0.72)	0.50
ERP and Rheum 2	64.2	0.32	(0.1-0.5)	0.28
ERP and Fellow	64.7	0.31	(0.13-0.55)	0.29
Rheum 1 and Rheum 2	63.7	0.29	(0.06-0.53)	0.27
Rheum 1 and Fellow	62.9	0.27	(0.02-0.52)	0.26
Rheum 2 and Fellow	74	0.47	(0.24-0.71)	0.48

ERP=extended role practitioner
Rheum=rheumatologist
PABAK=prevalence adjusted, bias adjusted Kappa