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Performance of standardized patient reported outcomes developed for spondyloarthritis in primary and concomitant forms of fibromyalgia

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Abstract

Background In spondyloarthritis (SpA) and fibromyalgia (FM), patients suffer from generalized pain. The impact of FM on PRO validated in SpA has not been systematically studied.

Objective Study the performance of PROs developed for SpA in patients with primary (p) FM without chronic inflammatory-rheumatic disease vs. SpA without and with concomitant (c) FM.

Methods Patients with pFM, axSpA or PsA and indication for treatment adaptation were prospectively included. Standardized PROs were assessed: BASDAI, ASDAS-CRP, DAPSA, patient's global assessment, BASFI, LEI, MASES, SPARCC Enthesitis Score and FIQ.

Results 300 patients were included (100/diagnosis). More males were found in axSpA vs. PsA and pFM group (67, 33 and 2/100, respectively), while 12 axSpA (axSpA+) and 16 PsA (PsA+) patients had cFM. pFM patients showed significantly higher scores in all assessments vs. axSpA or PsA, with exception of ASDAS-CRP (3.3 ± 0.6 in FM vs. 3.1 ± 1.0 in axSpA) and duration of low lumbar morning stiffness. Similar results were also found in the subanalysis of female patients only. In addition, patients with axSpA+ or PsA+ showed no differences to patients with pFM, while significantly higher scores were found for FM, axSpA+ and PsA+ for almost all FIQ items compared to axSpA- or PsA-.

Conclusions PROs originally developed for axSpA or PsA need to be interpreted differently in the presence or absence of cFM. ASDAS-CRP and duration of lumbar morning stiffness were not affected by cFM. FM-specific questionnaires also showed high scores in patients with SpA with cFM but not in those without.

Keywords Axial spondyloarthritis, Psoriatic arthritis, Fibromyalgia, Widespread pain, Disease activity

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Introduction

The term spondyloarthritis (SpA) encompasses a group of inflammatory rheumatic diseases with some clinical and genetic similarities, particularly characterized by inflammation of the axial skeleton, peripheral joints and tendon insertions, and association with the major histocompatibility complex (MHC) class I human leukocyte antigen (HLA)-B27 [1]. SpA includes both axial (axSpA) and peripheral forms of the disease, the main representative of the latter being psoriatic arthritis (PsA). With a prevalence of about 0.8%, axSpA is among the most frequent rheumatic diseases [2] and predominantly presents as inflammatory back pain [3], starting in the third decade of life [1], leading to symptoms like stiffness and decreased function and mobility due to osteoproliferative changes in the sacroiliac joints (SIJ) and the spine [4]. PsA, affecting about 0.3% of the population [2, 5] is associated with cutaneous psoriasis and features asymmetric oligoarthritis, dactylitis, and enthesitis [6, 7].

Fibromyalgia (FM), a non-inflammatory chronic musculoskeletal disease characterized by chronic widespread pain and fatigue, affects about 2% of the population, predominantly women [8]. The most characteristic symptom of FM is widespread pain [9]. However, patients with FM may also present with symptoms overlapping with axSpA and PsA, complicating differentiation [10, 11]. In addition, evidence suggests FM occurs frequently [12] with rheumatic and musculoskeletal diseases (RMD), impacting patient-reported outcomes (PROs) in axSpA and PsA [13].

Patient-reported outcomes (PROs) are crucial tools for assessment of several aspects of SpA [14], similar to other inflammatory rheumatic diseases. In routine clinical practice these assessments are well implemented and used on regular basis. Nevertheless, several studies indicate that cFM in patients with axSpA and PsA [15, 16] affects PROs [17–20], yet the extent of this impact remains unclear [20–22].

In the present study, we aimed to prospectively assess the influence of pFM on the performance of disease-specific and general assessments and PROs of axSpA and PsA, both with and without cFM.

Patients and methods

Study population

In a prospective, comparative, cross-sectional study, male and female patients ≥ 18 years of age and a confirmed diagnosis of axSpA or PsA, with (axSpA+ and PsA+) or without (axSpA- and PsA-) cFM or patients with pFM, all confirmed by experienced rheumatologists, and an indication for a treatment adaptation (escalation or change of already existing treatment) were included after informed consent between May 2019 and August 2020. Patients with FM had to fulfill the 2016 ACR diagnostic criteria

[23], while patients with axSpA and PsA had to have the respective diagnosis of axSpA or PsA given by the treating rheumatologist and also fulfill the ASAS [24] and CASPAR criteria [25], respectively. A total population of 300 patients was planned and approved by the ethic committee of the Ruhr Universität Bochum (18-6607-BR). Patients were included consecutively, allocated 1:1:1 to each group until 100 patients were reached in each group.

Assessments

Standardized assessment tools according to the respective diagnosis were applied to patients with axSpA (numerical pain rating scale (NRS pain) [26], Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [27], Ankylosing Spondylitis Disease Activity Score (ASDAS-CRP) [28], Bath Ankylosing Spondylitis Functioning Index (BASFI) [29], Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) [30], Leeds Enthesitis Index (LEI) and Spondyloarthritis Research Consortium of Canada scoring system (SPARCC) [31]) or PsA (NRS pain, Disease Activity score for Psoriatic Arthritis (DAPSA) [32], MASES, LEI, and SPARCC). In addition, patients from both groups also filled out the Fibromyalgia Impact Questionnaire (FIQ) [33]. In patients with pFM, all assessments (NRS pain, BASDAI, ASDAS-CRP, BASFI, DAPSA, SPARCC, LEI, MASES and FIQ) were applied.

Statistical analysis

Descriptive data are shown as absolute numbers and percentages for qualitative variables. Continuous variables are shown as mean values \pm standard deviations. The Mann-Whitney-U test was used for calculation of categorical variables and the t-test was used for continuous variables. A p -value < 0.05 was considered statistically significant. Statistical analysis was performed with SPSS v. 28.

Results

Patients' characteristics

The baseline demographics are shown in Table 1. In brief, the mean age was 52.9 ± 14.1 years in axSpA, 56.4 ± 12.8 years in PsA and 56.4 ± 10.2 years in FM. More male patients were found in the axSpA group (67/100 patients), while the PsA group and the FM group included more female patients (67/100 and 98/100, respectively).

Influence of primary FM on disease-specific and general assessments and PROs of axSpA and PsA

Patients with pFM showed significantly higher scores in almost all assessments as compared to patients with axSpA- or PsA- (Table 2). The only assessments with no significant (but numerical) differences were ASDAS-CRP

Table 1 Baseline characteristics of all patients related to the diagnoses pFM or axSpA or PsA with cFM or without FM

	FM	axSpA-	p-value axSpA- vs. FM	axSpA+	p-value axSpA+ vs. FM	PsA-	p-value PsA- vs. FM	PsA+	p-value PsA+ vs. FM
Age	56.4±10.2	53.5±14.2	0.086	48.7±13.5	0.026	56.0±13.2	<0.001	58.5±10.4	0.962
Male	2%	67%	<0.001	0%	---	38%	<0.001	6%	---
HLA B27 pos.	0%	84%	---	71%	---	16%	---	50%	---
CRP (mg/dl)	0.3±0.5	1.1±2.1	0.001	0.5±0.3	0.035	1.4±3.0	0.001	0.5±0.5	0.031
NRS pain	7.5±1.6	6.1±2.4	<0.001	7.7±1.8	0.768	6.4±2.2	<0.001	7.3±1.1	0.223

Fibromyalgia (FM); axial spondyloarthritis (axSpA); psoriatic arthritis (PsA)

axSpA-: axSpA without concomitant FM (cFM), axSpA+: axSpA with cFM, PsA-: PsA without cFM, PsA+: PsA with cFM

HLA B27: human leucocyte antigen B27; CRP: C-reactive protein; NRS: numerical rating scale

Table 2 Baseline scores of different items of all patients related to the diagnoses pFM or axSpA or PsA with cFM or without FM

	FM	axSpA-	p-value axSpA- vs. FM	axSpA+	p-value axSpA+ vs. FM	PsA-	p-value PsA- vs. FM	PsA+	p-value PsA+ vs. FM
BASDAI	6.9±1.4	5.2±2.0	<0.001	6.9±1.4	0.858	---	---	---	---
ASDAS-CRP	3.3±0.6	3.1±1.0	0.086	3.7±1.2	0.208	---	---	---	---
BASFI	6.4±2.1	5.4±2.5	0.005	7.1±1.8	0.41	---	---	---	---
DAPSA	43.0±17.8	---	---	---	---	32.0±18.6	<0.001	46.5±19.7	0.37
FIQ	68.5±13.5	53.9±21.2	<0.001	72.3±13.7	0.352	57.2±18.3	<0.001	68.5±11.6	0.978
LEI	4.0±1.6	1.5±1.7	<0.001	3.3±1.4	0.179	2.4±2.0	<0.001	3.6±2.0	0.625
MASES	8.6±3.0	3.4±3.3	<0.001	8.2±2.9	0.642	4.2±3.6	<0.001	7.1±3.6	0.101
SPARCC	9.4±3.4	3.5±3.4	<0.001	7.7±3.8	0.139	5.1±3.7	<0.001	8.1±3.9	0.412

Fibromyalgia (FM); axial spondyloarthritis (axSpA); psoriatic arthritis (PsA), BASDAI: Bath Ankylosing Spondylitis Disease Activity Index BASFI: Bath Ankylosing Spondylitis Functioning Index

axSpA-: axSpA without concomitant FM (cFM), axSpA+: axSpA with cFM, PsA-: PsA without cFM, PsA+: PsA with cFM

Table 3 Baseline scores of different items of all female patients related to the diagnoses pFM or axSpA or PsA with cFM or without FM

	FM	axSpA-	p-value to FM	axSpA+	p-value to FM	p-value within axSpA	PsA-	p-value to FM	PsA+	p-value to FM	p-value within PsA
BASDAI	6.9±1.4	5.3±1.9	<0.001	6.9±1.4	0.886	0.009	---	---	---	---	---
ASDAS-CRP	3.3±0.6	2.9±0.8	0.019	3.7±1.2	0.206	0.019	---	---	---	---	---
BASFI	6.4±2.1	4.8±2.5	0.002	7.1±1.8	0.418	0.015	---	---	---	---	---
DAPSA	42.8±17.4	---	---	---	---	---	34.8±17.7	0.013	47.6±19.9	0.238	0.023
FIQ	68.5±13.6	51.9±21.7	<0.001	72.3±13.7	0.362	0.005	56.6±16.8	<0.001	67.6±11.3	0.725	0.01
LEI	3.9±1.6	2.1±1.8	<0.001	3.3±1.4	0.195	0.031	2.9±1.9	0.001	3.5±2.0	0.435	0.294
MASES	8.6±3.0	3.9±2.9	<0.001	8.2±2.9	0.639	<0.001	5.2±3.6	<0.001	6.7±3.3	0.04	0.117
SPARCC	9.3±3.3	4.6±3.3	<0.001	7.7±3.8	0.146	0.032	6.3±3.4	<0.001	7.9±4.0	0.328	0.075

(3.3±0.6 in pFM vs. 3.1±1.0 in axSpA-) and the duration of morning stiffness in the lower back (question 6 of the BASDAI), with 4.7±2.2 in pFM vs. 4.6±2.7 in axSpA-. The detailed results of all analyses are shown in Table 2.

Subgroup analysis for patients with axSpA or PsA with concomitant FM

Overall, 12/100 and 16/100 patients were diagnosed with axSpA+ and PsA+, respectively. Patients with axSpA+ showed a significantly lower mean age (48.7±13.0 years) as the mean age of the entire axSpA group (52.9±14.1 years), while the mean age of PsA+ patients was not different (58.5±10.4 years) to the mean in the PsA group (56.4±12.8 years) (Table 1).

Patients with axSpA+ and PsA+ showed significantly higher scores in almost all assessments as compared to patients with axSpA- and PsA-, with exception of ASDAS-CRP (3.7±1.2) and the duration of morning stiffness in the lower back (question 6 of the BASDAI) (Table 2). The results of patients with axSpA+ and PsA+ were similar to those obtained when these scores were applied to patients with pFM (Table 2).

Subgroup analysis for female patients only

In the analysis of female patients only, female axSpA+ and PsA+ patients had significantly higher scores in almost all assessments as compared to axSpA- and PsA- patients (Table 3), while the same was found in the comparison

between female patients with pFM vs. axSpA- or PsA- (Table 3). Female patients with axSpA+ or PsA+ showed no differences to patients with pFM.

Comparison of fibromyalgia assessments among patients with fibromyalgia and spondyloarthritis

The analysis of the total FIQ but also of its single items revealed similar results as the analysis of the axSpA-related and PsA-related assessments (Table 2). Patients with axSpA+ or PsA+ showed no differences to patients with pFM for all FIQ items with exception of the item “walk several blocks” (Table 4). On the other hand, significant differences in the FIQ results were found between axSpA+ and axSpA- as well as between PsA+ and PsA- patients (Table 4).

Discussion

To our knowledge, this is the first prospective study that examines the performance of standardized patient-reported outcomes (PROs) for both axial spondyloarthritis (axSpA) and psoriatic arthritis (PsA) in patients with primary fibromyalgia (pFM). Additionally, it compares these outcomes to the subgroups of patients with axSpA and PsA with and without concomitant fibromyalgia (FM) in a real-life setting.

Recent studies have shown that FM is common not only in the general population [19] but also appears frequently as a ‘secondary’ FM in chronic inflammatory

rheumatic diseases [34] particularly in axSpA [19] and PsA [35], the latter showing prevalences of around 20% of cFM in the examined cohorts. Objective evaluations, such as ultrasound examinations, showed recently that PsA patients present with a higher number of involved entheses and specific patterns of enthesal involvement than patients with FM [36]. However, it remains unclear if these evaluations can distinguish between polyenthesitis and FM in the same patient.

Previous data comparing the performance of some PROs before and after biologic drug treatment have indicated that cFM negatively impacts treatment response in both axSpA [17, 21] and PsA [37]. These studies, which were retrospective and based on existing patient’s records, highlighted the need for a prospective evaluation of whether clinical indices and especially the PROs are influenced by cFM and, subsequently, how these data compare in patients with pFM diagnosis without any other RMD condition.

Our results, which included the most frequently used PROs for both axSpA and PsA, confirm FM as an important comorbidity in these primary chronic inflammatory diagnoses and show that almost all of them well-established PROs used in axSpA and PsA need to be interpreted differently in the presence or absence of cFM both in daily practice but also in the setting of clinical studies.

Importantly we report that especially when it comes to PROs originally developed for assessment of disease

Table 4 Level of the Fibromyalgia Impact Questionnaire (FIQ) in patients with fibromyalgia (FM) with cFM) and without pFM axial axSpA or PsA

	FM	axSpA -	p-value axSpA- vs. FM	axSpA +	p-value axSpA + vs. FM	PsA-	p-value PsA- vs. FM	PsA+	p-value PsA + vs. FM
FIQ total Score	68.5±13.5	53.9±21.1	<0.001	72.3±13.7	0.35	57.2±18.3	<0.001	68.5±11.6	0.98
Shopping	1.4±0.8	0.99±0.943	<0.001	1.8±0.9	0.304	1.2±1.0	0.057	1.5±0.7	0.74
Laundry	1.0±0.8	0.91±1.048	0.216	1.3±1.1	0.449	0.9±1.1	0.083	1.1±0.9	0.803
Cook	1.4±1.3	0.91±0.957	0.005	1.5±0.9	0.555	1.0±1.0	0.024	1.4±1.0	0.564
Wash dishes	1.6±1.0	0.96±1.089	<0.001	1.8±1.0	0.492	1.2±1.1	0.006	1.6±0.8	0.901
Vacuum	1.8±0.8	1.26±1.163	<0.001	2.0±0.7	0.475	1.4±1.0	0.01	1.8±0.9	0.782
Make beds	1.7±0.9	1.14±1.073	<0.001	2.0±0.9	0.306	1.3±1.1	0.008	1.6±0.8	0.752
Walk several blocks	1.6±0.8	1.28±1.102	0.018	2.4±0.7	0.007	1.3±1.1	0.041	2.1±0.7	0.062
Visit friends	1.6±0.9	1.12±1.034	0.002	1.8±1.0	0.421	1.2±1.1	0.016	1.7±0.8	0.787
Yard work	2.5±0.6	1.92±1.08	0.001	2.4±0.7	0.904	2.0±1.0	0.007	2.7±0.6	0.252
Drive a car	1.4±0.9	1.06±1.144	0.014	1.6±1.0	0.743	1.1±1.1	0.02	1.3±1.0	0.647
Climb stairs	1.6±0.7	1.11±0.982	<0.001	1.7±0.7	0.766	1.4±0.9	0.057	1.9±0.9	0.072
Count good days	1.6±1.6	2.49±2.223	0.005	1.3±1.0	0.902	2.6±2.3	0.001	1.5±1.7	0.894
Count miss work days	4.2±2.5	3.2±3.019	0.024	4.7±2.4	0.527	3.8±2.7	0.286	4.2±2.8	0.936
Affected by pain	7.5±2.0	6.34±2.668	0.003	7.9±1.4	0.631	6.7±2.3	0.008	7.4±1.7	0.513
Severe pain	7.8±1.4	6.3±2.4	<0.001	7.7±1.9	0.81	6.8±2.1	<0.001	7.3±1.4	0.08
Fatigue	7.6±2.0	6.1±2.7	<0.001	8.5±1.4	0.09	6.2±2.8	<0.001	8.5±1.6	0.06
Feeling after getting up	8.1±1.9	6.69±2.534	<0.001	8.8±1.5	0.167	6.3±2.7	<0.001	8.5±1.8	0.555
Stiffness	7.1±1.9	6±2.491	0.004	7.4±2.4	0.352	6.1±2.7	0.026	7.7±2.2	0.147
Anxiety	5.5±2.6	4.0±3.0	<0.001	5.9±3.5	0.41	4.2±2.9	0.003	4.9±3.0	0.58
Depression	5.8±2.4	4.11±3.087	<0.001	5.0±3.3	0.474	5.0±3.1	0.102	5.3±3.3	0.681

activity in both axSpA and PsA, such results need to be interpreted differently when cFM is present. While ASDAS-CRP and the duration but not the severity of morning low back pain stiffness were not significantly affected by cFM, the BASDAI did show such influence. This discrepancy can be attributed to the nature of these assessments: BASDAI relies on subjective patient-reported outcomes, which are influenced by FM, whereas ASDAS-CRP includes an objective component (CRP levels), providing a more balanced assessment of inflammatory disease activity.

In more detail, the analysis of all individual questions of PROs showed that FM negatively affects all areas of patients' health and daily life. Specifically, fatigue (question 1 of the BASDAI), pain in the entheses and joints, back pain and physical function were significantly worsened by the co-existence of fibromyalgia.

Furthermore, FM-specific questionnaires also showed high scores in patients with SpA with cFM but not in those without. Since widespread pain due to cFM is unlikely to be affected by anti-inflammatory treatment [38], it seems appropriate to capture this comorbidity prior to the start of therapy in patients with no evidence of inflammation but high levels of diffuse pain, including unclear signs of enthesitis [36].

A limitation of our study is the small sample size of axSpA+ and PsA+ (12 and 18 respectively), which might be considered too small to draw definitive conclusions. However, these numbers were dependent based on the prevalence of cFM in axSpA and PsA patients, and expected based on the existing literature [39–41]. Previous studies [17, 21, 22] have used the FiRST questionnaire to screen patients for FM at study inclusion, resulting to somewhat higher prevalences of patients affected by FM, while our study used diagnoses made by experienced rheumatologists and took also into account the revised ACR 2016 criteria, which involve a comprehensive clinical evaluation process that includes both a detailed history and physical examination. That may also explain the small differences to previous results. Furthermore, we did not collect information on possible treatment specifically for FM symptoms. However, since all patients included in this study were admitted due to an exacerbation of their primary inflammatory disease or due to exacerbation of their FM symptoms and were therefore considered 'active', we believe that the possible bias for interpretation of the questionnaires is rather minor.

The strengths of our study include its prospective design and the inclusion of a representative number of SpA and FM patients without any exclusion that could bias outcomes. Furthermore, the high level of clinical activity symptoms in the patients makes our results more relevant to real-life clinical context regarding the influence of cFM on treatment decisions.

Conclusion

In conclusion, the data of the present prospective study underscore the importance of using both subjective and objective measures in disease activity assessment, especially in patients with overlapping conditions like FM and SpA. More research is needed to determine the best approaches for interpreting PROs in these patients. Finally, it is reassuring that ASDAS-CRP seems to not be affected by cFM, while BASDAI does not seem to have such ability – something that needs to be considered also for choosing primary outcomes in clinical studies [42].

Abbreviations

ASDAS-CRP	Ankylosing Spondylitis Disease Activity Score
axSpA	axial spondyloarthritis
BASDAI	Bath Ankylosing Spondylitis Disease Activity Index
BASFI	Bath Ankylosing Spondylitis Functioning Index
cFM	concomitant fibromyalgia
DAPSA	Disease Activity score for Psoriatic Arthritis
FIQ	Fibromyalgia Impact Questionnaire
FM	fibromyalgia
HLA-B27	human leukocyte antigen- B27
LEI	Leeds Enthesitis Index
MASES	Maastricht Ankylosing Spondylitis Enthesitis Score
MHC	major histocompatibility complex class I
MRI	magnetic resonance imaging
NRS pain	numerical pain rating scale
pFM	primary fibromyalgia
PROs	Patient-reported outcomes
PsA	psoriatic arthritis
RMD	rheumatic and musculoskeletal diseases
SIJ	sacroiliac joints
SpA	spondyloarthritis
SPARCC	Spondyloarthritis Research Consortium of Canada scoring system

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Author contributions

ST: Idea, study coordination, interpretation of data, manuscript preparation; PD: Patient recruitment, interpretation of data; MG: Patient recruitment, interpretation of data; PS: Study coordination, interpretation of data; UK: Study coordination, interpretation of data; XB: Idea, study coordination, statistical analysis, interpretation of data, manuscript preparation.

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Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the ethic committee of the Ruhr-University Bochum (18-6607-BR).

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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