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ORIGINAL ARTICLES

Gender differences in the discriminative value of inflammatory low back pain criteria

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ABSTRACT

Aim: Inflammatory back pain (IBP) is the leading symptom in axial spondyloarthritis (axSpA) and its assessment is crucial for the diagnosis. Our aim was to assess gender specific differences in the discriminative ability of the items and criteria sets in a specific patient population consisting patients with axSpA and other causes of chronic low back pain (LBP).

Methods: Patients with chronic LBP with an onset less than 45 years were included and screened for the Assessment of Spondyloarthritis International Society (ASAS) axSpA criteria. Items of IBP, according to Calin, Berlin and ASAS expert criteria were evaluated in patients with axSpA and non-SpA LBP by a blinded researcher. Discriminative ability of the single items and sets were assessed in terms of sensitivity, specificity and area under the curve (AUC) analysis in male and female patients and compared between genders.

Results: Single IBP items performed similarly well in men and women, as well as criteria sets. Despite similar discriminative performance of IBP items and criteria sets in both genders, women tend to have slightly better performance. Our results revealed similar sensitivity but slightly lower specificity for most of the single items and criteria sets compared to previous reports.

Conclusion: Gender may have an influence on the discriminative performance of some of the IBP items and criteria sets as well. Calin criteria seem to perform slightly better in both genders than Berlin and ASAS criteria sets.

Keywords: Inflammatory; Back pain; Gender; Axial spondyloarthritis.

INTRODUCTION

Axial spondyloarthritis (axSpA) is a chronic rheumatic disease characterized by inflammation of joints and entheses with predilection for axial skeleton. Chronic axial inflammation leads to inflammatory back pain (IBP) which is one of the most prominent features in patients with axSpA. Inflammatory back pain has some characteristic properties which clinically differs from back pain caused by non-inflammatory problems [1]. Indeed, chronic back pain is one of the most frequent musculoskeletal problems which is extremely common all over the world and causes workday loss and induces an enormous economic burden[2]. Axial spondyloarthritis encompasses patients with non-radiographic and radiographic spondyloarthritis[3-5]. Criteria sets which have been extensively used for diagnosis or classification are not sensitive enough to identify patients with most relevant aspects of early disease before development of permanent structural changes.

As the leading and key symptom in patients with axSpA[6], IBP has been reported more often by men as the first symptom of axSpA[7,8]. Regarding gender differences, there are several studies showing that women tend to have more progression in the cervical vertebrae, more peripheral joint pain and enthesitis as well as extra-articular symptoms[7, 9]. Also it takes longer time to diagnose axSpA in women than in men[10, 11].

The criteria sets for the assessment of IBP have been proposed and three criteria sets, Calin[12], Berlin[5] and ASAS[13] became prominent. Discriminative ability of the criteria to correctly classify IBP were widely assessed, however differences in men and women concerning discriminative ability has not been completely clarified. Hence, we proposed to assess gender specific differences in the discriminative ability of IBP criteria in a pop-

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ulation consisting patients with axSpA and chronic low back pain arising from other causes than SpA.

METHODS

Patients with 18 years old or older with a history of chronic LBP (> 3 months) and age of onset less than 45 years were consecutively included into this single tertiary-care center study. Patients who were more than 50 years old, had a previous diagnosis of any type of SpA or with proven and documented causes of non-SpA low back pain were excluded. The IBP criteria were assessed by the same rheumatologist who was blind to the patients imaging, clinical and laboratory data (KG, blinded rheumatologist, R-blinded). All eligible patients were assessed for the items of IBP criteria according to the Calin criteria (Insidious onset, age at onset < 40 year, duration of back pain > 3 months, morning stiffness, and improvement with exercise) which require the presence of four of five criteria[12]. Berlin criteria which include morning stiffness of > 30 minutes, awakening because of back pain during the second half of the night, improvement in back pain with exercise but not with rest, and alternating buttock pain[5]. And ASAS criteria which includes insidious onset, age at onset < 40 years, improvement with exercise, no improvement with rest, and awakening because of back pain during the second half of the night[13,14]. Patients' clinical and demographic variables were recorded by another rheumatologist (KE) consisting all features associated with SpA and included in the ASAS criteria for axSpA as well. Also, pain (visual analogue scale, VAS), patient's and physician's global assessment (PtG, PhG) were assessed. Acute-phase reactants, including ESR (mm/h) and CRP (mg/l) levels were measured. The final judgement was made on the basis of full physical examination, clinical, laboratory and imaging data by three experienced rheumatologists (SO, GK, EK) and consensus was reached for each patient whether the patient met ASAS axSpA criteria or not. The axSpA group consisted patients who met ASAS axSpA criteria. Control group consisted patients with chronic LBP with causes other than SpA and did not meet ASAS criteria for axSpA.

The local Ethics Committee of our institution approved the study protocol and written informed consents were obtained from the patients.

Statistical analysis

All analyses were performed on a personal computer, mean and standard deviations of the parameters and 95% confidence intervals were calculated and analyzed by using MedCalc v12.0 (Mariakerke, Belgium). Parameters and demographic variables in patients with axSpA and non-SpA back pain were compared using *t*-test. For the IBP criteria items and sets calculations were made by using blinded rheumatologist's assessments. Receiver operating characteristic (ROC) curves were used to compare the discriminative ability of single items and the criteria set as a whole and analysis were separately made for men and women. Area under the curve (AUC) were calculated for each item and criteria sets in men and women and statistically compared by using the De Long method[15]. P-values < 0.05 was considered statistically significant.

RESULTS

Of the 290 eligible patients, 31 patients did not meet the inclusion criteria and were excluded. A total of 143 patients (60 women) with axSpA (94 AS, 49 nr-axSpA) and 116 patients (52 women) with non-SpA LBP were included in the analysis. Characteristics of the patients were shown in Table I.

In women, AUC was the highest for insidious onset 0.95 (95% CI 0.89-0.98), followed by alternating buttock pain 0.80 (95% CI 0.72-0.87), improvement with exercise 0.75 (95% CI 0.66-0.83), no improvement with rest 0.71, (95% CI 0.61-0.79), age at onset ≤ 40 years 0.69 (95% CI 0.60-0.78), improvement with exercise/not rest 0.67 (95% CI 0.57-0.76), morning stiffness > 30 min 0.64 (95% CI 0.54-0.73), morning stiffness 0.64, (95% CI 0.54-0.73) and awakening (second half of the night) because of pain 0.63 (95% CI 0.53-0.72) with the least value.

In men, AUC was the highest for insidious onset 0.85 (95% CI 0.78-0.90), followed by morning stiffness 0.79 (95% CI 0.70-0.85), no improvement with rest 0.78 (95% CI 0.71-0.85), alternating buttock pain 0.76 (95% CI 0.68-0.82), improvement with exercise 0.71 (95% CI 0.63-0.78), improvement with exercise/not rest 0.70 (95% CI 0.62-0.78), morning stiffness > 30 min 0.67 (95% CI 0.59-0.75), awakening (second

TABLE I. Characteristics of the patients with SpA and non-SpA low back pain

	axSpA (n=143)	Chronic LBP (n=116)	p
Age, years	34.35±7.86	36.20±7.86	0.061
VAS (pain)	4.98±3.04	5.66±2.61	0.059
Patient's global	4.89±2.80	5.28±2.77	0.260
Physician's global	3.77±2.29	4.16±2.64	0.214
Men:women	83:60	64:52	0.642

Data are mean±SD. axSpA, axial spondyloarthritis; LBP, low back pain; VAS, visual analogue scale.

Table II. Sensitivity and specificity of the single IBP items and criteria sets in men and women as assessed by the blinded rheumatologist.

Criterion	Men				Women			
	Sensitivity	95% CI	Specificity	95% CI	Sensitivity	95% CI	Specificity	95% CI
Insidious onset	85.9	75.0-93.4	84.3	74.7 - 91.4	96.2	86.8-99.5	93.3	83.8 - 98.2
Improvement with exercise	85.9	75.0 - 93.4	56.1	44.7 - 67.0	90.4	79.0 - 96.8	60.3	46.6 - 73.0
No improvement with rest	95.3	86.9 - 99.0	61.0	49.6 - 71.6	88.5	76.6 - 95.6	53.5	39.9 - 66.7
Improvement with exercise/not rest	98.4	91.6 - 100.0	42.7	31.8 - 54.1	96.2	86.8 - 99.5	37.9	25.5 - 51.6
Awakening (second half of the night) because of pain	75.0	62.6 - 85.0	51.2	39.9 - 62.4	65.4	50.9 - 78.0	61.0	47.4 - 73.5
Morning stiffness	74.2	61.5 - 84.5	84.2	74.4 - 91.3	43.1	29.3 - 57.8	84.8	73.0 - 92.8
Morning stiffness> 30 min	96.8	88.8 - 99.6	37.8	27.3 - 49.2	84.3	71.4 - 93.0	44.1	31.2 - 57.6
Alternating buttock pain	71.0	58.1 - 81.8	805	70.3 - 88.4	67.3	52.9 - 79.7	93.33	83.8 - 98.2
Calin criteria	88.7	78.1 - 95.3	86.6	77.3 - 93.1	92.2	81.1 - 97.8	93.10	83.3 - 98.1
Berlin criteria	90.0	79.5 - 96.2	67.1	55.8 - 77.1	74.5	60.4 - 85.7	82.76	70.6 - 91.4
ASAS criteria	95.0	86.1 - 99.0	47.4	35.8 - 59.2	97.7	88.0 - 99.9	62.07	48.4 - 74.5

IBP, inflammatory back pain; CI, confidence interval; ASAS, Assessment of Spondyloarthritis International Society

half of the night) because of pain, 0.63 (95% CI 0.55-0.71), and age at onset ≤ 40 years 0.52 (95% CI 0.44-0.61) with the least value. Sensitivity and specificity of the single IBP items and criteria sets in men and women are presented in Table II. Single item AUC values in men were relatively lower in regard to women. However, this difference did not reach statistical significance for most of the single items except insidious onset and morning stiffness items (p=0.03 and p=0.009, respectively). Likewise, men had relatively lower performance than women in the AUC values for IBP criteria sets Also, comparison of AUC values revealed that Calin criteria outperformed Berlin and ASAS criteria in both genders (Table III). However, differences did not reach statistical significance for AUC of any of the criteria sets between men versus women (Fig.1).

DISCUSSION

Inflammatory back pain is considered as a key feature and the most common and earliest symptom in patients with SpA[16, 17]. Criteria for IBP was first mentioned by Calin et al in 1977 and described as a specific clinical feature, differentiating patients with mechanical low back pain from patients with AS[12]. Nearly 30 years later, Berlin group proposed criteria based on a study consisting 101 patients with AS and 112 controls with mechanical low back pain [5]. These criteria for IBP were derived from studies which compared patients with AS with patients having other causes of low back pain i.e. originating from mechanical problems. The ASAS project, proposed the new criteria set based on the physical examination of real patients by SpA experts in a 2-day meeting. These experts reached a decision whether these patients were suffering from IBP or not, without knowledge of their final diagnosis of SpA or non-SpA[1].

Published figures revealed that IBP criteria had a sensitivity between 70.1 to 95%, and a specificity 72.5 to 81.3% in patients with AS/AxSpA according to different studies[1, 5, 12]. In a recent study, the sensitivity of IBP criteria was very similar to the ones reported in published works (74.4-81.1%), but the specificity of these criteria was quite lower (25.2-39.4%) than the

TABLE III. Comparison of AUCs of different criteria sets in men and women

	axSpA vs non-SpA LBP n=136 vs n=111
Men	AUC (95%CI)
CALIN (1) n=76 vs n=61	0.87 (0.80-0.92)
BERLIN (2) n=76 vs n=59	0.77 (0.70-0.84)
ASAS (3) n=76 vs n=60	0.72 (0.63-0.79)
1 vs 2, p value	0.021
1 vs 3, p value	0.001
2 vs 3, p value	0.059
Women	
CALIN (1) n=57 vs n=47	0.92 (0.85-0.96)
BERLIN (2) n=57 vs n=47	0.77 (0.71-0.87)
ASAS (3) n=57 vs n=40	0.80 (0.71-0.85)
1 vs 2, p value	0.001
1 vs 3, p value	0.001
2 vs 3, p value	0.570

AUC, area under the curve; axSpA, axial spondyloarthritis; LBP, low back pain

previously published values[18]. The low specificity value for ASAS criteria for IBP has been also supported by another group[19]. The authors suggested that in some of these previous studies patients with a clear diagnosis of SpA or non-SpA/mechanical low back pain has been selected, which results higher specificity scores. In contrast, Poddubnyy et al[18] which presented lower specificity scores for the IBP items, selected undiagnosed and newly referred patients thereby better reflecting the daily rheumatology practice.

Gender specific issues have been increasingly recognized in patients with axSpA. With the adoption of a wider axSpA concept, which includes an earlier stage of the disease (namely nr-axSpA), axSpA seems to be equally prevalent both in men and women[20]. A cohort study assessing the prevalence of IBP in the UK primary care population reported relatively higher prevalence of IBP in women although not statistically significant [21]. Similarly, a study from Turkey reported higher prevalence of IBP in women than in men among the employees of a university[22]. On the other hand, United States National Health and Nutrition Examination Survey revealed that IBP prevalence was similar between men and women[23].

A number of issues arises regarding differences in males and females with axSpA. Longer diagnostic delay, impaired health related quality of life, increased severity of pain, more frequent sleep disturbances and fatigue discrepancies in treatment response are reported in female patients with axSpA in regards to men counterparts[24-27]. Also, a large body of evidence suggesting perception of pain differs between male and female genders accumulated in the last decade. Modulation of pain differs between men and women, based on an interaction between genetic, hormonal, anatomical and psycho-social factors[28-30]. IBP criteria sets and items have crucial role for diagnosis or classification of patients therefore we focused on potential differences in discriminative ability of these sets and items between male and female genders. We showed that IBP criteria sets did not have statistically significant differences between men and women, however AUC values seem relatively higher in women, and single item AUC values of insidious onset and morning stiffness showed slight differences between genders.

Insidious onset is an important item to discriminate inflammatory and mechanical back pain. One of the possible explanations why women perform better reporting the insidious onset may lie on the differences on pain perception between men and women. The expression of pain is more socially acceptable among women and men are less willing to report pain than women[28]. Women are more concerned about how their health condition and medication use could influence their fertility, pregnancy, nursing or ability to care their young children[25]. All these factors may have an incremental effect on their awareness about the onset of pain including back pain. Therefore, women may be more successfully recall time of onset and course of their back pain than men.

Morning stiffness of the lumbosacral spine is a frequent symptom in patients with low back pain, either have mechanical or non-mechanical origin. In elderly back-pain populations, the association between self-reported morning stiffness (even lasting more than 30 minutes) and lumbar disc degeneration has been reported[31-33]. In our study population, it seems that the tradeoff between sensitivity and specificity of morning stiffness was lower in women. On the other hand, AUC figures are quite similar between men and women when morning stiffness more than 30 minutes is the case. We can only speculate that hormonal and social factors may play role in this discrepancy between men and women. Stiffness at the spinal level should be considered as a result of complex mechanisms involving all spinal and paraspinal structures, such as ligaments, tendons, joint capsules as well as intervertebral disc and disco-vertebral structures. Menstrual cycles and hormonal fluctuations may play important roles on the muscle and tendon stiffness in women which may contribute short-lived morning stiffnes[34, 35]. In axSpA, attribution of morning stiffness to the inflammation of the sacroiliac joints or lumbar spine may be reasonable,

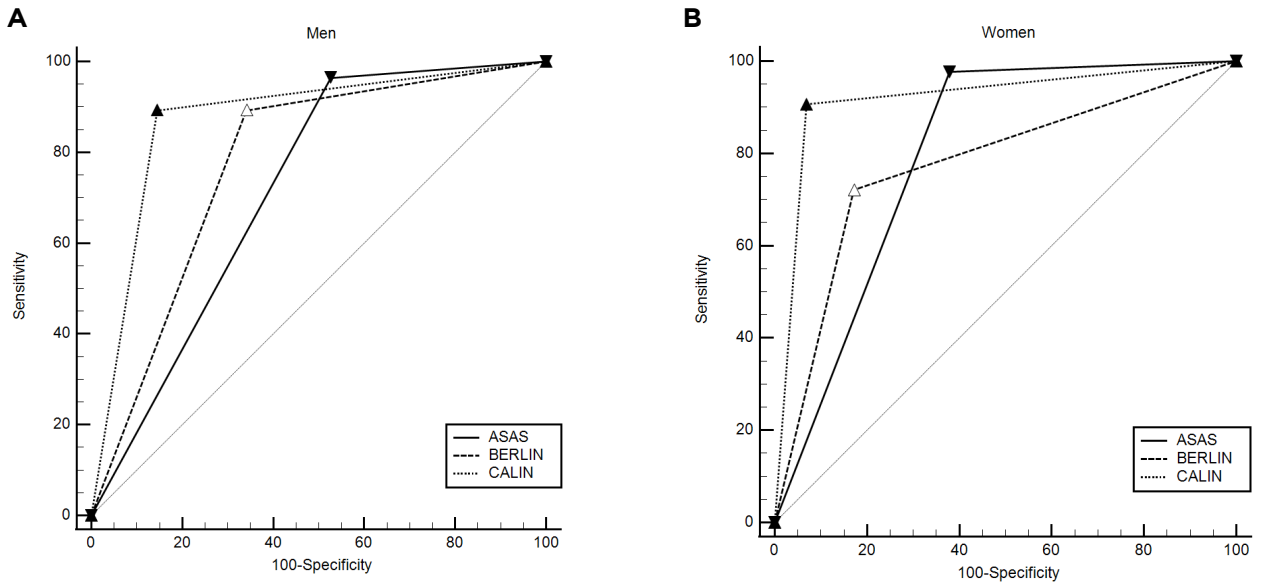

Figure 1. Receiver operating characteristic curves (ROC) of 3 criteria sets Calin, Berlin and ASAS in men (A) and women (B). There is no statisticaly significant difference between men vs women in the area under the curve (AUC) of criteria sets

since the association between bone marrow edema of sacroiliac joints on MRI and morning stiffness has been documented [36, 37]. However, possible gender differences for this clinical and imaging associations are still obscure. In our study we could not document all these hormonal and social factors, as well as imaging differences and associations which may be considered as a limitation. The performance of previously defined IBP criteria with an addition of "diurnal variation" item has been assessed by means of classification utility in additive, weighted or "diurnal variation alone" forms[38]. The newly suggested item "diurnal variation" had a highest combination of sensitivity and specificity, outperforming the Calin and ASAS IBP criteria. Additionally, although the sample size was small and 95% CI were wide, the performance of the classification utility was higher in women than in men[38].

Our study revealed that discriminative ability of IBP criteria in women, which was assessed by means of AUC analysis, was relatively higher than men. The sensitivity of the IBP criteria according to the published figures changes between 70.1%-95% in patients with AS/axSpA[1, 5, 12]. Although there are slight differences between men and women, these values were similar to the figures that we calculated in our sample consisting patients with chronic back pain associated with SpA or non-SpA. Specificity values in our study were relatively lower for Berlin and ASAS IBP criteria and similar for Calin criteria compared to the previous reports (72.5%-81.3%)[1, 5, 12]. However, recently published studies underscore the low specificity and lower LR+ for these criteria and also low balanced accuracy values suggesting some precautions for the diagnostic value of IBP criteria and/or some of the items [18, 19, 38, 39]. Our study contributively underscored the slight discrepancies of the items between men and women.

The diagnostic accuracy of the criteria or the items is also closely related with the study population. The discriminative ability of a criteria may change according to the study population in which the criteria items are tested. The selection criteria, diagnostic work up, experience of the researchers, and the referral strategies or the attribution of the reference centers may explain different specificity and sensitivity values.

To our knowledge, this is the first report that formally identifies the performance of IBP items and criteria sets between men and women in a selected population of chronic back pain associated with SpA and non-SpA causes.

As a strength of our study, we blinded the assessor of the criteria items to the diagnosis of patients in order to reduce review bias. Our population included undiagnosed chronic LBP patients with onset of less than 45 years, and may not entirely reflect the daily rheumatology clinical practice, which may be a limitation. However, our aim in this study was to assess any difference in the performance of the criteria between genders in a selected study population. Our data may promote further researches assessing the role of gender differences in IBP criteria and items in selected samples like primary care or referral populations.

Our study had also some limitations. As a general knowledge, axSpA in women tends to present itself with atypical features which leads to longer diagnostic delay. Restricting our study population to patients that fulfill ASAS criteria may inevitably excluded some fe-

male patients, therefore hard to generalize our results for the primary or secondary care populations or daily rheumatology practice.

In summary our study results put forward that despite similar figure in the performance of IBP criteria in both genders, women tend to have slightly better performance. Moreover, Calin criteria outperformed Berlin and ASAS criteria in both genders.

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