Joint Bone Spine 80 (2013) 393–398

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Original article

Evaluation of spondylarthritis activity by patients and physicians: ASDAS, BASDAI, PASS, and flares in 200 patients

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ARTICLE INFO

Article history:
Accepted 10 September 2012
Available online 1 March 2013

Keywords:
Spondylarthritis
Disease activity cutoffs
Patient-reported outcomes
BASDAI
ASDAS
PASS
Flare

ABSTRACT

Objectives: In patients with spondyloarthritis, to determine Ankylosing Spondylitis Disease Activity Score (ASDAS) cutoffs matching the patient-acceptable symptom state (PASS) and patient-reported levels of disease activity, to assess associations between disease activity levels and presence of depression, and to identify ASDAS and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) cutoffs indicating a flare and indicating a remission.

Methods: Prospective single-center study of patients meeting ASAS criteria for spondyloarthritis receiving follow-up at the Besançon teaching hospital, France, between February 2011 and February 2012. In each patient, the BASDAI, ASDAS, Bath Ankylosing Spondylitis Functional Index (BASFI), patient-acceptable symptom state (PASS) and signs of depression were assessed. Receiver-operating characteristic (ROC) curves were drawn to identify the ASDAS cutoffs separating different levels of disease activity. The kappa coefficient was computed to evaluate agreement between patients and physicians regarding the presence of flares.

Results: Two hundred patients with a mean age of 44.4 ± 12.5 years and mean disease duration of 12.9 ± 10.5 years were included. Mean BASDAI was 4.1 ± 2.2, mean ASDAS-C-reactive protein (CRP) was 2.4 ± 1, mean BASFI was 3.3 ± 2.7, and 58.9% of patients reported being in the PASS. The PASS was associated with BASDAI values inferior or equal to 4.1 and ASDAS-CRP values inferior or equal to 2.3. Mild patient-reported disease activity was associated with BASDAI values inferior or equal to 3.8 and ASDAS-CRP values inferior or equal to 2.3; corresponding values for high patient-reported disease activity were superior to 5.2 and superior to 3.1. Among patients reporting high disease activity, 64.5% had Beck Depression Inventory scores consistent with severe depression. At the time of the visit, 36.9% of the patients and 28.3% of the physicians felt there was a flare. Cutoffs indicating a flare were superior or equal to 5.2 for the BASDAI and superior or equal to 2.3 for the ASDAS-CRP. Agreement between patients and physicians regarding flares was good (Kappa, 0.61). An evaluation in 43 patients indicated that an ASDAS-CRP cutoff inferior or equal to 2.2 separated the 25.6% of patients who reported being in remission from the other patients.

Conclusion: Our results show a significant association between disease activity and depression severity, as well as good agreement between BASDAI and ASDAS. The ASDAS cutoffs for the various levels of patient-reported disease activity differed from the cutoffs suggested by ASAS; a 2.3 cutoff was found for both patient-reported absence of disease activity and PASS, indicating that achieving PASS should be included among our treatment objectives.

1. Introduction

Spondyloarthritis is characterized by inflammation of the axial and/or peripheral joints that progresses by flares and remissions. According to the 2011 update of recommendations issued by the European League Against Rheumatism (EULAR) and Assessment in Ankylosing Spondylitis International Society (ASAS), the preferred first-line agents are analgesics and antiinflammatory drugs [1]. The introduction of biologics has broadened the array of options available to specialists and, similar to developments in rheumatoid arthritis, has brought achieving a clinical disease remission among the reasonable treatment objectives [2].

In everyday practice, disease activity and functional impairments in patients with spondylarthritis are evaluated using the

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doi:10.1016/j.jbspin.2013.01.003

Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and the Bath Ankylosing Spondylitis Functional Index (BASFI), respectively [3,4]. The BASDAI has a number of well-documented flaws [5,6]. Therefore, the ASAS recently developed the Ankylosing Spondylitis Disease Activity Score (ASDAS) based on both clinical and laboratory variables. The ASDAS is a simple, reproducible, and discriminating tool for rapidly separating different disease activity levels [7], although it is not yet used in everyday practice or official recommendations. The ASAS used a Norwegian cohort to identify cutoffs for various levels of disease activity and of treatment-related improvements [8,9]. Furthermore, ASAS/EULAR recommendations require that the patient's perception of disease activity be taken into account [10]. To this end, the patient-acceptable symptom state (PASS) was defined as a level of well-being found satisfactory by the patient, i.e., as a "yes" answer to the following question: "Considering all the different ways your disease is affecting you, if you would stay in this state for the next months, do you consider that your current state is satisfactory?" A recent study established that the PASS indicated a BASDAI no greater than 3.4/10 [11]. No studies have assessed the ASDAS cutoff associated with the PASS.

The primary objective of this study was to define the ASDAS score below which unselected patients seen in everyday practice were in the PASS. The secondary objectives were to assess agreement between ASDAS and BASDAI; between patient-reported levels of disease activity and the ASDAS and BASDAI cutoffs; and between the two ASDAS values obtained using the C-reactive protein (CRP) level and the erythrocyte sedimentation rate (ESR), respectively. We also assessed the potential psychological impact of spondyloarthritis. Finally, our last objective was to identify BASDAI and ASDAS cutoffs indicating a flare and those indicating a remission, as determined by the physician and by the patient.

2. Methods

2.1. Scores

The ASDAS is obtained using an equation based on subjective items from the BASDAI and on an objective laboratory item (CRP or ESR). The ASAS recommends using the CRP and indicates that the same laboratory variable should be used throughout the follow-up of a given patient [9]. We computed both the ASDAS-CRP and the ASDAS-ESR whenever possible but used only the ASDAS-CRP for the data analyses.

To evaluate the psychological impact of spondyloarthritis, we asked the patient to complete the 13-item Beck Depression Inventory (BDI) [12]. The total BDI score can range from 0 to 39, with scores no greater than 3 indicating no depression and scores of 4 to 7 mild depression, 8 to 15 moderate depression, and greater than 16 severe depression.

2.2. Data collection

We conducted a prospective longitudinal single-center study over a 12-month period (February 2011 to February 2012) in patients meeting ASAS criteria for spondylarthritis [13,14] and receiving follow-up at the teaching hospital in Besançon, France. During the first visit, the healthcare team obtained informed consent then gave the patient the questionnaires for the BASDAI, BASFI, ASDAS, and BDI. The patients completed the questionnaires alone or with help from a therapeutic-patient-education nurse. Patients were asked to report the perceived disease activity as mild, moderate, or severe. In patients who were seen more than once during the recruitment period, the disease-activity and BDI scores were determined at each visit. When treatment was changed, the patient was asked at the next visit to describe the effect of treatment changes (none, fair, good). Epidemiological data were collected.

Flares and remissions were assessed by having the patient and physician answer the following questions: "Do you believe *you are/your patient is* currently experiencing a flare?" and "Do you believe *you are/your patient is* currently experiencing a remission?" Patients were asked the question used to determine whether the PASS had been achieved.

2.3. Statistical analysis

To determine the ASDAS and BASDAI cutoffs for the PASS, patient-reported disease activity, flares, and remissions, we constructed receiver-operating characteristic (ROC) curves. We then compared these cutoffs to the reference cutoffs determined by the ASAS. Cutoffs were selected based on optimal sensitivity, specificity, and area under the curve (AUC) values (95% confidence interval, 95%CI). To assess agreement between the patients and physicians regarding flare status, we computed the kappa coefficient (κ) in pairwise comparisons. We also used κ to measure agreement between the ASDAS-CRP and ASDAS-ESR and between the ASDAS and BASDAI. κ can vary from 0 to 1, with 1 indicating complete agreement, 0.61 to 0.8 good agreement, and 0.41 to 0.6 fair agreement. Student's test was performed to compare quantitative variables and PASS and the Chi^2 test to compare qualitative variables. *P* values lower than 0.05 were considered significant. All analyses were performed using SAS 9.3.

3. Results

We included 200 patients, of whom 32.6% were seen at least twice at the outpatient clinic or day-hospital during the study period.

3.1. Patient characteristics

Males contributed 70.3% of the population. Mean age was 44.4 ± 12.5 years and mean disease duration was 12.9 ± 10.5 years. The disease was axial in 79.8% of cases and strictly peripheral in 4%. HLA B27 was present in 85.9% of patients. The mean visual analog scale (VAS) score for disease activity was 3.7 ± 2.6 according to the patients and 2.9 ± 1.9 according to the physicians. The mean BASDAI was 4.1 ± 2.2, mean ASDAS-CRP 2.4 ± 1, and mean ASDAS-ESR 2.4 ± 1. The κ value for the ASDAS-CRP and ASDAS-ESR was 0.63, indicating good agreement. The mean BASFI was 3.3 ± 2.7 and mean BASMI 2.8 ± 2.2. Mean values were 7.9 ± 12.1 mg/L for CRP and 17.5 ± 16.7 mm/h for ESR. Chronic inflammatory bowel disease (IBD) was present in 13.8% of patients and uveitis in 31.7%. Of the 200 patients, 105 (52%) used only nonsteroidal antiinflammatory drugs, 9% took methotrexate, and 63% received TNFα antagonist alone or combined with another disease-modifying drug.

Agreement was good between the ASDAS and BASDAI, with concordance coefficients (*R*) of 0.81 with the ASDAS-CRP and 0.82 with the ASDAS-ESR ($P < 0.0001$).

3.2. Patient-acceptable symptom state cutoffs and Bath Ankylosing Spondylitis Disease Activity Index and Ankylosing Spondylitis Disease Activity Score values

At the time of the evaluation, 115 (58.9%) patients reported being in the PASS; five patients did not understand the question. Among patients in the PASS, 79.5% had axial disease, 15.2% mixed disease, and 5.3% peripheral disease; 15.3% had chronic IBD and 31.2% had uveitis. Mean cutoffs corresponding to the PASS are listed in Table 1. The ROC curve analysis showed that the cutoffs that best matched the PASS were inferior or equal to 2.3 for the ASDAS-CRP