Estimation of the Bath Ankylosing Spondylitis Disease Activity Index Cutoff for Perceived Symptom Relief in Patients with Spondyloarthropathies

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ABSTRACT. ***Objective.*** To estimate the best Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) cutoff based on patients' perceptions of symptom relief collected in a large population of patients with spondyloarthropathies (SpA), in comparison to the BASDAI cutoff determined by experts.

Methods. A survey of patient perceptions about current disease control was conducted among the members of Spondylis, one of the main not-for-profit SpA patient organizations in France. BASDAI was among data collected by the questionnaire. To estimate the best BASDAI cutoff for discriminating between poor and well perceived controlled groups, we plotted the receiver operating characteristic (ROC) curve. We also determined the cutoff separately in male and female patients.

Results. Of the 1000 mailed questionnaires, 485 were returned without any missing data regarding perceived disease control and the BASDAI. Of these patients, 55.3% perceived inadequate control of their disease. The mean BASDAI in the overall population was 43.5 ± 22.9, 30.4 ± 19.9 in the well controlled group and 54 ± 19.4 in the poorly controlled group ($p < 0.001$). The best BASDAI cutoff for discriminating between patients in the 2 groups was 39 (sensitivity 74.6% and specificity 72.4%). According to gender, the best cutoff was 44 for women and 36 for men.

Conclusion. The best BASDAI cutoff of 39 based on patients' perceptions was very similar to that selected by international experts, i.e., 40. Gender affected the cutoff for perceived symptom relief in our study. These results need to be confirmed by further studies collecting the opinions of both patients and physicians. (J Rheumatol 2006;33:79–81)

Key Indexing Terms:
ANKYLOSING SPONDYLITIS SPONDYLOARTHROPATHY PATIENT ASSESSMENT
BATH ANKYLOSING SPONDYLITIS DISEASE ACTIVITY INDEX CUTOFF

Disease activity is universally recognized as difficult to evaluate in ankylosing spondylitis (AS) and other spondyloarthropathies (SpA)[1]. The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), a self-administered questionnaire based on visual analog scales, was developed in 1994[2]. It has been validated in various patient populations and languages[3-8]. Today, the BASDAI is recommended for deciding which patients with AS require tumor necrosis factor-α (TNF-α) antagonists and for monitoring the effectiveness of these medications[9]. A cutoff of 4 points on the 10-point scale is used to define active disease[9]. This cutoff was selected based on expert opinion, because no specific studies were available. As pointed out recently[10], it needs to be confirmed in clinical settings. Because no objective marker of disease activity is available as a reference point, patients' views are of interest in determining the threshold of disease activity. Thus, we sought to estimate the best BASDAI cutoff based on patients' perceptions of symptom relief collected recently in a large population[11], in comparison to the BASDAI cutoff proposed by experts.

MATERIALS AND METHODS

Briefly, the survey of patient perceptions[11] was conducted in France in early 2002, before the development of international recommendations about TNF-α antagonists and before the introduction of these drugs on the French market. A questionnaire was mailed to 1000 members of Spondylis, one of the main not-for-profit SpA patient organizations in France, to collect patients' perceptions about current disease control and to compare patients reporting poor control to those reporting good control. Patients were included if they reported a rheumatologist-confirmed diagnosis of either SpA or one of the definite subtypes of SpA. Patients' perception of disease control is mainly based on symptoms; therefore, we elicited their perceptions by the question: "Do you feel that your current treatment provides adequate relief of pain (during the day and at night) and morning stiffness due to your disease?" Respondents were divided into 2 groups based on whether they answered "yes" or "no" to this question. The BASDAI was among data collected by the questionnaire. An example was given in the questionnaire to help patients complete the BASDAI, and study physicians and Spondylis volunteers were available for answering queries

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by telephone throughout the 4 weeks following the questionnaire mailing date. To determine the best BASDAI cutoff for discriminating between the 2 groups, we plotted the receiver operating characteristic (ROC) curve[12], then identified the cutoff yielding the smallest possible number of false negatives (1 – sensitivity) and false positives (1 – specificity). Given previous evidence that gender may exert a major independent influence on BASDAI scores[13], we also determined the cutoff separately in male and female patients.

RESULTS

Of the 1000 mailed questionnaires, 600 were returned; 485 of these had no missing data regarding perceived disease control and the BASDAI. These 485 questionnaires form the basis for this study. Among the 485 patients (Table 1), 75.7% were taking nonsteroidal antiinflammatory drugs and 47.1% were taking methotrexate or sulfasalazine. Slightly more than half the patients (n = 268, 55.3%) perceived inadequate control of their nocturnal pain and morning stiffness. The mean BASDAI in the overall population was 43.5 ± 22.9 — 30.4 ± 19.9 in the well controlled group and 54 ± 19.4 in the poorly controlled group ($p < 0.001$). The best BASDAI cutoff for discriminating between patients in the 2 groups was 39 (sensitivity 74.6% and specificity 72.4%, positive predictive value 76.9% and negative predictive value 69.8%). The ROC curve is shown in Figure 1 (area under the curve, AUC: 0.804; 95% confidence interval, CI: 0.765–0.843). Mean BASDAI scores differed significantly between women (48.4 ± 23.7) and men (38.4 ± 21.0) ($p < 0.001$). The best cutoff was 44 in women and 36 in men.

DISCUSSION

To our knowledge, this is the first study estimating a BASDAI score cutoff that discriminates between patients with and those without perceived inadequate control of their disease. Interestingly, the cutoff of 39 was very similar to that selected by international experts, i.e., 40[9]. Given the increasing use of the BASDAI for assessing disease activity in therapeutic trials and in clinical practice, better definitions of cutoffs and other dimensions such as minimal clinically important improvement (MCII) would be helpful. A recent study also used patient opinion to estimate the MCII[14].

Our results were collected from members of a SpA patient organization. Conceivably, these patients may have more severe disease than the overall population of patients with SpA. However, they probably provide more reliable evaluations of their disease, most notably via patient-assessed measures of health outcomes. Further, patients in our study self-evaluated their disease under real-life conditions, which was more relevant to our objective than evaluations at the time of clinical trials or during hospital-based followup visits.

The response rate was 48.5% in this survey if we consider the number of questionnaires initially sent. The nonresponse rate could represent a limitation bias. As we described[11], this type of survey was an anonymous process, in particular for deontological reasons, and we were not able to contact patients who failed to respond. However, according to information obtained from 3 patient organization volunteers who conducted an informal evaluation, the main reason for not responding to the questionnaire was its length. We do not think there are differences between respondents and nonrespondents or that the eventual inclusion of nonrespondents would change the results.

The BASDAI was developed to assess the activity of AS. However, it has shown good metrological properties in all patterns of SpA[3] including psoriatic arthritis[15]. Gender, one of the main factors influencing the BASDAI[13,16], affected the cutoff for perceived active disease in our study. There is no definite explanation for this observation, even though hypotheses can be elaborated concerning a real difference in the level of disease activity and/or a difference in perception of pain or other symptoms such as fatigue. This interesting

Table 1. Main characteristics of the 485 patients with SpA who responded to our questionnaire. Good disease control was defined as disease perceived by the patient as well controlled by the current treatment; poor disease control as inadequately controlled by the current treatment. The 2 groups were compared statistically by chi-square and Mann-Whitney tests and p values < 0.05 were considered significant. Results are reported as numbers of patients (%) or as means ± standard deviation, SD.

	Overall, n = 485	Good Disease Control, n = 217	Poor Disease Control, n = 268	p
Sex				
Male	242 (49.9)	125 (57.9)	117 (43.5)	< 0.001
Female	243 (50.1)	91 (42.1)	152 (56.5)	
Disease duration, yrs	17.85 ± 12.5	18.23 ± 12.67	17.5 ± 12.3	NS
HLA-B27-positive (445 patients)	376 (84.5)	174 (80.6)	202 (74.8)	NS
Psoriasis	104 (21.4)	43 (19.9)	61 (22.6)	NS
Uveitis	115 (23.7)	56 (25.9)	59 (21.9)	NS
Crohn's disease	38 (7.8)	12 (5.6)	26 (9.6)	NS
BASDAI	43.5 ± 22.9	30.4 ± 19.9	54 ± 19.4	< 0.001

NS: not significant.

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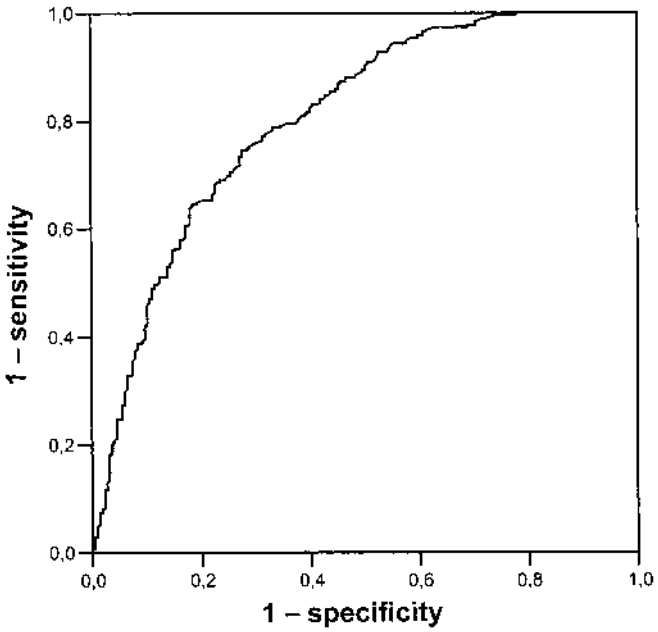

Figure 1. ROC curve identifying the cutoff yielding the smallest number of false negatives (1 – sensitivity) and false positives (1 – specificity).

point deserves further consideration and may warrant different recommendations for men and women regarding cutoffs used to select patients for TNF-α antagonist therapy.

Our objective was to give a first estimation of the BASDAI cutoff according to perceived symptom relief: the cutoff has, thus, been estimated giving the same weight and the same importance to false positives and false negatives. However, the cutoff can vary according to other objectives; for example, the decision to treat the patient with anti-TNF-α drugs needs to ensure that patients with poor disease control and a high BASDAI score are treated. This would minimize false positives, and thus modify the cutoff to higher values.

Our estimate of a BASDAI cutoff for discriminating between patients with and those without perceived inadequate disease control is consistent with the cutoff selected by experts. Thus, a BASDAI cutoff of 40 seems to be effective in separating active from inactive disease. In addition, our findings suggest that using different cutoffs for men and women may be appropriate. These results need to be confirmed by other studies, based on data from both patients and physicians.

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