

Revista Brasileira de Reumatologia



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REFERÊNCIA

COSTA, Izaias Pereira da *et al.* Evaluation of performance of BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) in a Brazilian cohort of 1492 patients with spondyloarthritis: data from the Brazilian Registry of Spondyloarthritis (RBE). **Revista Brasileira de Reumatologia**, São Paulo, v. 55, n. 1, p. 48-54, jan./fev. 2015. DOI: <http://dx.doi.org/10.1016/j.rbr.2014.05.005>. Disponível em: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0482-50042015000100048&lng=en&nrm=iso. Acesso em: 10 abr. 2018.



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Original article

Evaluation of performance of BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) in a Brazilian cohort of 1492 patients with spondyloarthritis: data from the Brazilian Registry of Spondyloarthritis (RBE)



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<http://dx.doi.org/10.1016/j.rbre.2014.05.005>

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ARTICLE INFO

Article history:

Received 13 February 2013

Accepted 19 May 2014

Available online 20 December 2014

Keywords:

Spondyloarthritis

Disease activity

BASDAI

Epidemiology

ABSTRACT

Objective: To analyze the results of the application of the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) in a large series of Brazilian patients with the diagnosis of SpA and establish its correlations with specific variables into the group.

Methods: A common protocol of investigation was prospectively applied to 1492 Brazilian patients classified as SpA according to the European Spondyloarthropathies Study Group (ESSG), attended at 29 referral centers of Rheumatology in Brazil. Clinical and demographic variables, and disease indices (BASDAI, Basfi, Basri, Mases, ASQol) were applied. The total values of BASDAI were compared to the presence of the different variables.

Results: The mean score of BASDAI was 4.20 ± 2.38 . The mean scores of BASDAI were higher in patients with the combined (axial + peripheral + enthesal) (4.54 ± 2.38) clinical presentation, compared to the pure axial (3.78 ± 2.27) or pure peripheral (4.00 ± 2.38) clinical presentations ($P < 0.001$). BASDAI also presented higher scores associated with the female gender ($P < 0.001$) and patients who did not practice exercises ($P < 0.001$). Regarding the axial component, higher values of BASDAI were significantly associated with inflammatory low back pain ($P < 0.049$), alternating buttock pain ($P < 0.001$), cervical pain ($P < 0.001$) and hip involvement ($P < 0.001$). There was also statistical association between BASDAI scores and the peripheral involvement, related to the lower ($P = 0.004$) and upper limbs ($P = 0.025$). The presence of enthesitis was also associated to higher scores of BASDAI ($P = 0.040$). Positive HLA-B27 and the presence of cutaneous psoriasis, inflammatory bowel disease, uveitis and urethritis were not correlated with the mean scores of BASDAI. Lower scores of BASDAI were associated with the use of biologic agents ($P < 0.001$).

Conclusion: In this heterogeneous Brazilian series of SpA patients, BASDAI was able to demonstrate “disease activity” in patients with axial as well as peripheral disease.

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Avaliação do desempenho do BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) numa coorte brasileira de 1.492 pacientes com espondiloartrites: dados do Registro Brasileiro de Espondiloartrites (RBE)

ABSTRACT

Objetivo: Avaliar os resultados da aplicação do Índice de Atividade de Doença da Espondilite Anquilosante de Bath (BASDAI) numa série de pacientes brasileiros com EpA e estabelecer suas correlações com as variáveis específicas do grupo.

Palavras-chave:

Espondiloartrites

Atividade de doença

BASDAI Epidemiologia

Métodos: Um protocolo comum de investigação foi prospectivamente aplicado em 1.492 pacientes brasileiros classificados como EpA pelos critérios do Grupo Europeu de Estudo das Espondiloartropatias (ESSG), acompanhados em 29 centros de referência em reumatologia no Brasil. Variáveis clínicas, demográficas e índices de doença foram colhidos. Os valores totais do BASDAI foram comparados com a presença das diferentes variáveis.

Resultados: O valor médio do BASDAI foi de $4,20 \pm 2,38$. Os escores médios do BASDAI foram mais elevados nos pacientes com forma clínica combinada, comparado às formas axiais e periféricas isoladas, nos pacientes do sexo feminino e nos sedentários. Com relação ao componente axial, valores mais altos do BASDAI estiveram significativamente associados à lombalgia inflamatória, à dor alternante em nádegas, à dor cervical e ao acometimento de coxofemorais. Houve associação estatística entre os valores do BASDAI e o comprometimento periférico, relacionado ao número de articulações inflamadas, tanto dos membros inferiores quanto dos membros superiores, e às entesites. A positividade do HLA-B27 e a presença de manifestações extra-articulares não estiveram correlacionadas com os valores médios do BASDAI. Valores mais baixos do BASDAI estiveram associados ao uso de agentes biológicos ($p < 0,001$).

Conclusão: Nesta série heterogênea de pacientes brasileiros com EpA, o BASDAI conseguiu demonstrar “atividade de doença” tanto nos pacientes com acometimento axial quanto naqueles com envolvimento periférico.

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Introduction

The denomination spondyloarthritis (SpA) defines a heterogeneous group of diseases that share genetic and clinical characteristics, as well as structural changes in imaging studies. The positivity of HLA-B27 and the absence of rheumatoid factor are common to this group of diseases, and the high frequency of inflammatory processes of the spine, sacroiliac joints and enthesitis is considered the main clinical criteria for the diagnosis of SpA.¹ Other clinical manifestations occur in varying degrees of involvement in the group of SpA; more often, skin, ocular, intestinal and urogenital injuries and, less frequently, pulmonary, cardiac, renal and neurological involvement.¹

This group of diseases consists of ankylosing spondylitis (AS), psoriatic arthritis (PA), reactive arthritis (ReA), arthritis associated with inflammatory bowel diseases (also known as enteropathic arthritis – EA) and undifferentiated spondyloarthritis (USpA).¹

With the advent of new therapeutic modalities for the group of SpA, the elaboration of measures of disease activity that could be used in long-term follow-up was necessary.² Currently, to evaluate and monitor clinical disease activity in SpA, the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) has been used. This index is obtained by summing the values of a visual analog scale (VAS) that evaluates six items, namely: fatigue, axial pain, peripheral pain, enthesitis, duration and intensity of morning stiffness.³ BASDAI does not use any marker of inflammatory activity in its calculation, since these tests were not standardized at the time of its proposition.³ BASDAI values are internationally used (BASDAI ≥ 4 is deemed as “high disease activity”) for the indication of biological agents in the treatment of SpA, when there was no response to conventional treatment with nonsteroidal anti-inflammatory drugs or with conventional remissive drugs.^{4,5}

When the patient reaches BASDAI 50 (improvement in the BASDAI score of $\geq 50\%$) in the first 12 weeks of treatment, this can be considered as a very good clinical response.⁶ Due to its importance, BASDAI has been translated and validated in several languages, including French,⁷ Swedish,⁸ German,⁹ Spanish,¹⁰ Turkish,¹¹ Arabic¹² and Portuguese.¹³ Recently, the Ankylosing Spondylitis Disease Activity Score (ASDAS) was created¹⁴; this index associates the presence of a marker of inflammatory activity, erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP); nowadays, ASDAS has its cut-off scores to differentiate “moderate”, “high” and “very high” activity.¹⁵

This paper analyzes the application of BASDAI in a heterogeneous Brazilian cohort of 1492 patients with SpA.

Methods

This is a prospective, observational, multicenter study, conducted with 1492 patients from 29 referral centers participating in the Brazilian Registry of Spondyloarthritis (Registro Brasileiro de Espondiloartrites – RBE). All patients fulfilled the criteria of the European Spondyloarthropathy Study Group (ESSG).¹⁶ Data were collected from June 2006 to December 2009. RBE participates in the RESPONDIA group (Registro Iberoamericano de Espondiloartrites), consisting of nine Latin American countries (Argentina, Brazil, Costa Rica, Chile, Ecuador, Mexico, Peru, Uruguay and Venezuela) and the two countries of the Iberian peninsula (Spain and Portugal).

The joint investigation protocol included demographic variables (gender, race, family history, HLA-B27, exercise), osteoarticular (inflammatory low back pain, buttock pain, neck pain, hip pain, lower limb arthritis, upper limb arthritis, enthesitis, dactylitis) and extra-articular (uveitis, inflammatory bowel disease [IBD], psoriasis, urethritis) disorders, and laboratory data (erythrocyte sedimentation rate – ESR and

C-reactive protein – CRP), as well as the treatment (nonsteroid anti-inflammatory drugs – NSAIDs, corticosteroids and conventional and biological remissive drugs).

For the diagnosis of AS, the New York criteria were used¹⁷; for psoriatic arthritis, the participants had to meet the criteria of Moll and Wright.¹⁸ The diagnosis of reactive arthritis was considered if asymmetric oligoarthritis of the lower limbs were present, with enthesopathy and/or inflammatory low back pain arising after an enteric or urogenital infection,¹⁹ and spondyloarthritis/arthritis associated with inflammatory bowel disease, if the patient had an inflammatory axial disorder and/or peripheral joint involvement, associated with confirmed Crohn's disease or ulcerative colitis.

BASDAI is a tool for evaluation of disease activity that contains six questions.³ The responses were marked on a horizontal line measuring 10 cm (from 0 to 10 cm), where the patient evaluates how he feels in relation to each item in the last week, marking on the scale: if the patient is fine ("very well"), he/she marks zero cm, gradually increasing until "very poor", corresponding to a 10-cm mark. The six questions comprising BASDAI are as follows: (1) How would you describe the degree of fatigue or tiredness you have had?; (2) How would you describe the overall level of neck, back and hip pain related to your illness?; (3) How would you describe the overall level of pain and edema (swelling) in other joints, apart from neck, back and hip?; (4) How would you describe the overall level of discomfort you felt to the touch or compression in the painful regions of your body?; (5) How would you describe the intensity of morning stiffness you have had, from the time you wake up?; (6) How long does your morning stiffness take, from the time you wake up?

Statistical analysis

The variable categories were compared using² and Fisher's exact tests, and continuous variables were compared using ANOVA. A value of $P < 0.05$ was considered significant; and $0.05 > P > 0.10$ was considered as a statistical trend.

Results

The mean score of total BASDAI was 4.20 ± 2.38 . Among the six items that make up the final value of BASDAI, the item 2 (related to axial pain; 5.05 ± 3.20) had the highest mean, and the item 3 (related to peripheral component; 3.28 ± 3.18) was that with the lowest value. The mean values of BASDAI to all the questions that make up the index are described in Table 1.

Table 1 – Results of BASDAI per item.

BASDAI	Mean	Standard deviation
Total	4.20	2.38
Question 1	4.21	2.99
Question 2	5.05	3.20
Question 3	3.28	3.18
Question 4	4.28	3.34
Question 5	4.59	3.29
Question 6	3.85	3.36

Table 2 – Results of BASDAI according to specific SpA.

	%	Mean	SD	P
Primary AS	67.6	4.21	2.36	
Psoriatic AS	4.6	4.38	2.32	
Enteropathic AS	2.6	4.70	2.41	
Psoriatic Arthritis	14.2	4.13	2.47	0.305
USpA	6.8	4.35	2.28	
Reactive Arthritis	3.4	4.12	2.57	
Enteropathic Arthritis	0.8	4.37	3.05	

There was no significant difference between the mean values of BASDAI and any specific disease within the SpA group. The mean values of BASDAI for each disease within the group are shown in Table 2. As to the clinical presentation, the mean values of BASDAI were significantly higher in enthesitic (4.96 ± 2.22) and combined (axial and peripheral; 4.50 ± 2.38) forms, compared to pure forms, both axial (3.78 ± 2.28) and peripheral (3.87 ± 2.23) (Table 3).

With regard to demographic variables, BASDAI was significantly higher in females ($P < 0.001$) and in those patients who did not exercise regularly ($P < 0.001$). Ethnicity, HLA-B27 and family history of SpA did not influence the results of BASDAI (Table 4).

Numerous clinical variables influenced BASDAI scores. Inflammatory low back pain ($P = 0.039$), buttock pain ($P < 0.001$), neck pain ($P < 0.001$), hip pain ($P < 0.001$), arthritis of lower ($P = 0.004$) and upper ($P = 0.025$) limbs, and enthesitis ($P = 0.040$) were significantly associated with higher mean values of BASDAI. Extra-articular manifestations such as uveitis, psoriasis,

Table 3 – Results of BASDAI according to clinical form.

	%	Mean	SD	P
Mixed	48.5	4.50	2.38	
Axial	34.5	3.78	2.28	<0.001
Peripheral	11.0	3.87	2.23	
Enthesitic	6.0	4.96	2.22	

Table 4 – Results of BASDAI according to epidemiological data.

	%	Mean	SD	P
Gender				
Male	72.3	3.97	2.95	<0.001
Female	27.7	4.84	3.05	
Race				
White	67.4	4.03	2.38	0.057
Non-white	32.6	4.30	2.40	
Exercise				
Yes	40.8	3.89	2.35	<0.001
No	59.2	4.42	2.38	
Family history				
Yes	18.0	4.32	2.49	0.413
No	82.0	4.18	2.36	
HLA-B27				
Positive	69.0	4.16	2.33	0.391
Negative	31.0	4.33		2.50

Table 5 – Results of BASDAI according to clinical data.

	%	Mean	SD	P
Inflammatory low back pain				0.049
Yes	67.6	4.29	2.31	
No	32.4	4.02	2.53	
Buttock pain				<0.001
Yes	33.1	4.59	2.39	
No	66.9	4.01	2.36	
Neck pain				<0.001
Yes	30.8	4.64	2.32	
No	69.2	4.01	2.39	
Hip pain				<0.001
Yes	25.1	4.63	2.35	
No	74.9	4.06	2.38	
Arthritis, lower limb				0.004
Yes	48.9	4.38	2.35	
No	51.1	4.03	2.30	
Arthritis, upper limb				0.025
Yes	22.1	4.46	2.40	
No	77.9	4.13	2.37	
Enthesitis				0.040
Yes	27.1	4.41	2.41	
No	72.9	4.13	2.37	
Dactylitis				0.423
Yes	9.1	4.04	2.48	
No	90.9	4.22	2.37	
Uveitis				0.926
Yes	19.1	4.22	2.53	
No	80.9	4.20	2.35	
Skin psoriasis				0.849
Yes	17.8	4.23	2.42	
No	82.2	4.20	2.38	
Inflammatory bowel disease				0.106
Yes	4.7	4.67	2.46	
No	95.3	4.18	2.38	
Urethritis				0.326
Yes	4.4	4.51	2.57	
No	95.6	4.19	2.37	

inflammatory bowel disease and urethritis did not influence BASDAI scores (Table 5).

With regard to treatment, only the use of anti-TNF biological agents was significantly associated with lower scores of BASDAI ($P < 0.001$), while the use of NSAIDs, corticosteroids, methotrexate and sulfasalazine did not influence the values of BASDAI (Table 6).

Discussion

This study aimed to evaluate the activity of SpA using BASDAI as a clinical activity index; this is a tool traditionally used in patients with SpA. The results showed that BASDAI could demonstrate “disease activity”, both in patients with an axial component as in those with peripheral involvement, even in patients with SpA but with no diagnosis of AS. In view of the fact that BASDAI evaluate “axial” (question 2) and “peripheral” (questions 3 and 4) components, an important finding in this study was represented by the highest mean scores in patients who had an involvement described as “combined” (where the “axial” and “peripheral” components are observed in the same patient) – a common characteristic of Brazilian patients.²⁰ Similarly, an European multicenter

Table 6 – Results of BASDAI according to treatment.

	%	Mean	SD	P
NSAID				0.888
Yes	67.6	4.21	2.35	
No	32.4	4.19	2.45	
NSAID on-demand				0.713
Yes	24.9	4.16	2.40	
No	75.1	4.22	2.38	
Corticosteroid				0.297
Yes	35.3	4.29	2.37	
No	64.7	4.16	2.39	
Methotrexate				0.866
Yes	51.7	4.21	2.32	
No	48.3	4.19	2.45	
Sulfasalazine				0.934
Yes	44.7	4.21	2.44	
No	55.3	4.19	2.34	
Biologicals				<0.001
Yes	20.4	3.73	2.47	
No	79.6	4.32	2.35	
Infliximab				<0.001
Yes	15.3	3.58	2.50	
No	84.7	4.32	2.35	
Etanercept				0.104
Yes	2.8	4.78	2.30	
No	97.2	4.19	2.38	
Adalimumab				0.164
Yes	2.3	3.70	2.06	
No	97.7	4.22	2.39	

study evaluating 214 patients with SpA found higher values of BASDAI in those participants with a peripheral component (4.4 ± 2.3) compared to patients with an isolated axial component (3.1 ± 1.9) ($P < 0.001$).²¹ Also important was the fact that the mean values of BASDAI were significantly elevated, both in presence of axial (inflammatory low back pain, buttock pain, neck pain and hip pain) and peripheral (lower and upper joints) clinical variables, in addition to enthesitis.

In the spectrum of SpA, psoriatic arthritis is that disease where the peripheral component is most striking. Our study showed that BASDAI can also be effective in the evaluation of patients with PA, as shown in recent studies,^{22,23} even when compared to ASDAS.²⁴

With the proposition of ASDAS as a valid method of assessing disease activity in cases of AS,^{14,15} it will be important to apply this tool to patients with SpA in the second phase of RBE, to compare its effectiveness versus BASDAI. There is no established consensus about what is the best method for assessment of disease activity in patients with AS (if ASDAS is better than BASDAI). Meanwhile, BASDAI has been shown as an efficient index in the therapeutic follow-up of patients with AS.^{6,25,26} The combination of BASDAI with the functional index BASFI (Bath Ankylosing Spondylitis Disease Activity Index)²⁷ made it possible to obtain important characteristics of patients in the Brazilian Registry of Spondyloarthritides.²⁸

Although representing only 27.7% of the patients, women had higher mean BASDAI scores, when compared to men. These results certainly may vary with the population evaluated.²⁹

Regarding the skin color of the patients, there was no significant difference, as previously described,³⁰ and no significant

difference in BASDAI scores in relation to HLA-B27, family history and extra-articular manifestations was found.

In short, BASDAI showed to be an efficient method of assessing disease activity in a heterogeneous population of Brazilian patients with SpA.

Conflicts of interest

The electronic version of the Brazilian Registry of Spondyloarthritides is supported by a grant from Wyeth/Pfizer Brazil, which has no influence on the capture and analysis of data, as well as in the writing and publication of articles. Dr. Percival Sampaio-Barros received a research grant from Federico Foundation.

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