



ORIGINAL ARTICLE

Definition of Activity Cut-off Point in Patients with Behçet's Disease Using the Arabic Version of the Behçet's Syndrome Activity Scale

Dalia I Mostafa¹, Doaa E Kamal¹, Amany M. AbdAllah², Shymaa A Sarhan^{1*}

¹ Rheumatology and Rehabilitation Department, Faculty of Medicine, Zagazig University, Zagazig, Egypt

² Family Medicine department, Faculty of Medicine, Zagazig University, Zagazig, Egypt

Corresponding Author:

Shymaa A Sarhan

Email:

shymaasarhan0@gmail.com

ABSTRACT

Background: Behçet's disease (BD) activity assessment is a major concern since a treat-to-target approach may lead to a better prognosis. The first patient-reported assessment instrument, the Behçet's Syndrome Activity Score (BSAS), is useful for routine clinical use.

Aim: To evaluate the validity and reliability of the translated Arabic version of BSAS (Ar-BSAS) in the assessment of BD activity and discriminate its cut-off point or disease activity.

Method: Seventy BD patients were included in the study. The BSAS was translated into Arabic language. The reliability and validity were evaluated.

Results: The Ar-BSAS of each item and the total score demonstrated a high internal consistency and Cronbach's alpha coefficient of 0.881, to 0.997. A significant positive correlation was found between the total score of the BSAS with the BDCAF ($r = 0.891$, $p < 0.001^{**}$) and the BSAS with the MHAQ ($r = 0.813$, $p < 0.001^{**}$), and between the total score of BSAS and ESR and CRP indicating high convergent validity. The BSAS cutoff value for disease activity was 15.5 in comparison with the BDCAF with high area under the curve 0.972 at 95% confidence interval (CI) on the receiver operating characteristic curve (ROC).

Conclusions: The Arabic version of the BSAS (Ar- BSAS) is a reliable, valid, and accurate patient reported measure for disease activity that could be used to evaluate disease activity and enhance the therapeutic management choices in routine clinical practice.

Key words: BSAS, activity, validity, reliability.



INTRODUCTION

Behçet's disease (BD) is a systemic vascular disease with an inflammatory nature with a specific pathogenic mechanism, pathologic picture, and a unique relapsing–remitting course. The underlying causes of BD are still unknown with multiple theoretical explanations that include genetic, environmental, and immune-mediated mechanisms. The clinical presentations of BD vary from mucocutaneous lesions to ocular affections and either arterial or venous vascular thrombotic lesions [1,2].

BD activity varies according to different system involvements from only controlled cutaneous lesions to life-threatening vascular events with highly significant morbidity and mortality outcomes. Therefore, it is very promising to detect effective genes concerned

with the activity of BD for strict control and more favorable outcomes [3,4].

Assessment of BD activity is mandatory for better control and prognosis. It depends mainly on a wide range of clinical presentations. Therefore, there is a great need for a standardized activity evaluation tool to be used in daily clinical practice [5]. For this purpose, the Behçet's Disease Current Activity Form (BDCAF) was developed; it depends mainly on the history of clinical manifestations from which the patient suffered during the last month. BDCAF index records the presence or absence of oro-genital ulceration, skin lesions, and any organ involved irrespective of their durations, numbers, sizes, or severity. Also, it needs a qualified physician to be completed, adding more obstacles to be used in daily clinical practice [6,7].

The BSAS was developed as a novel patient-reported activity measure to overcome the drawbacks of previous tools. BSAS is easily done in busy clinics. It reports the presence of mucocutaneous manifestations during the last month as well as their numbers. Also, it records the ocular, vascular, and gastrointestinal symptoms [8,9].

BSAS was translated and validated to be used in many countries, therefore, we aimed in this study to create a cross-cultural adaptation of the BSAS in the Arabic language and evaluate its reliability and validity in Egyptian patients with BD and also detect low disease activity level as a comparison with BDCAF.

METHODS

Study Design:

This study was conducted on 70 BD patients who were recruited from outpatient and inpatient clinics of the Rheumatology department as a comprehensive sample. All BD patients are fulfilling The International Criteria for Behçet's Disease (ICBD) [9]. They are aged above 18 years and agreed to sign an informed consent. Any patient who had difficulties in understanding a written Arabic language or had marked comorbidities was excluded from the study. The patient was asked to fill out paper-based scales while waiting for his follow-up visit. Then other clinical data were collected by a rheumatologist from the patient's records and examinations including patient's age, disease duration, medication details, and all items of BDCAF. The research protocol number (ZU-IRB#10370/25-1-2023) was authorized by the local institutional review board, Zagazig University, Egypt.

Assessment of the disease:

1-Behçet's syndrome activity score:

It is a patient self-administered tool that consists of 10 questions to measure the levels of clinical manifestations of BD. The VAS questions are all scored from 0 to 10 and the remaining are scored categorically, 0, 5, or 10 depending on the response, for a total score of 0–100. The patients complete the BSAS during waiting for their follow-up visits [8].

Translation, cross-cultural adaptation: BSAS is translated into Arabic language by two independent professional translators, and then the translated version was reviewed by a rheumatologist to reach the final form. After that, a back translation was done into English language by an Arabic language expert. The differences between the two BSAS versions were agreed by the rheumatologists conducting this study. The final Arabic version of BSAS (Ar-BSAS) was

conducted on 7 BD patients to test their understanding of all questions [10].

Test re-test reliability: The reliability of an Ar-BSAS was evaluated by a test-retest method where the questionnaire was applied to the patients twice two weeks apart provided that no changes occurred in the condition. The Ar-BSAS was considered reproducible over time as the score remained the same over 2 weeks. The interclass correlation coefficient (ICC) is used to assess agreement between 2 visits, with an ICC ≥ 0.7 indicating a high level of reproducibility. Internal consistency was measured using Cronbach's alpha coefficient.

Internal consistency: Cronbach's alpha coefficient was used to assess internal consistency indicating that each item was related to the scale. Item-total correlations were assessed and a value of ≥ 0.70 was considered a good internal consistency.

Convergent validity was measured by comparing the Ar-BSAS, as a disease activity tool, with BDCAF domains, and the correlations between BSAS questions and BDCAF items were assessed. Also, the Ar-BSAS was correlated with MHAQ.

Discriminant validity was assessed by correlating the Ar-BSAS with the patient's clinical characteristics, patients age, disease duration, body mass index, ESR, CRP, and other laboratory data.

2-The Behçet's Disease Current Activity Form (BDCAF):

It is based on clinical signs related to the disease. Patients are asked about any new symptoms during the last 4 weeks with a total score of 12 [11]. The following symptoms: arthralgia, arthritis, fatigue, headache, oral/genital ulcers, erythema nodosum, superficial thrombophlebitis, pustules, nausea, vomiting, abdominal pain, and bloody diarrhea are graded from 0 to 4 according to how long the illness persisted over the course of the previous four weeks. Different scoring for the eye, CNS, and major vessels is present. Also, 3 visual analog scales for both the patient's perception of well-being and the clinician's perception of the overall disease activity [12].

3-The modified Health Assessment Questionnaire HAQ (MHAQ):

It is a patient-administered tool for the assessment of patient ability and degree of difficulty in doing activities of daily living; it was derived from the original health assessment questionnaire (HAQ) and used in almost all rheumatic diseases [11]. The MHAQ

encompasses 8 classes that evaluate the following daily functions: dressing, grooming, rising, eating, walking, hygiene, reaching, gripping, and chores. All questions take a score from 0 to 3 according to patient capability which is graded from no difficulty in doing the function to inability to complete it respectively [12].

Data Analysis:

Statistical analysis was done using SPSS software (Statistical Package for the Social Sciences) version 26 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp). Categorical variables were described using their frequency and percentage. Quantitative variables were termed using their means and standard deviations or median and interquartile range according to data type. Spearman rank correlation coefficient was used to measure strength and direction of correlation between two continuous variables. The reliability and internal consistency of the Arabic version were calculated using intraclass correlation coefficients (ICC) and Cronbach alpha. The agreement between the BSAS score and the BDCAF and MHAQ was calculated by Spearman’s correlation coefficient. ROC curve was used to determine the best cutoff of certain quantitative parameters in the diagnosis of certain health problems. The level of statistical significance was set at $P < 0.05$.

RESULTS

Regarding the basic demographic characteristic of the patients, 72.9% were males their mean age was 36.37 ± 8.39 with a range from 20 – 58 years, and disease duration median and IQR were 8 (4.75 – 10.25) with a wide range from 1 – 25 years.

Regarding organ involvement, 55.7% had musculoskeletal disorders (arthritis and arthralgia). The majority (74.3%) of the patients had mucocutaneous lesions. Only 28.6% had ocular manifestations (active uveitis and retinal vasculitis) and 34.3% with neurobehcets manifestations with vascular gastrointestinal manifestations were 12.9% and 10% respectively. 48 patients (68.6%) were active with BDCAF score median and range was 2 (1 – 3). BSAS median was 20 with a range from 9 to 30.25.

MHAQ was recorded with median 1 and range (0.38– 1.37) (Table 1).

Test re-test reliability of Ar-BSAS:

In the 2-week retest reliability, ICC ranged from 0.788 to 0.993, which was significant for all the scales. Thus, most of the items demonstrated an acceptable internal consistency as well as stability over the short term. Regarding the total score, the ICC was 0.995 which represented an excellent internal consistency as well as stability over the short term. Cronbach’s alpha coefficient ranged from 0.881 to 0.997 for the 10 items and 0.997 for the total score. The corrected item-total correlation values varied between 0.082 and 0.65. The Cronbach’s alpha coefficient was also calculated for each deleted item. As the Cronbach’s alpha (0.622, to 0.688) remained almost the same and none of them was greater than the total scale alpha (0.997), it turned out that the tool has high internal consistency (Table 2).

Convergent validity:

All the studied questions showed a significant positive correlation with the total scale with r value more than the critical value indicating content validity (Table 3). There is a statistically significant positive correlation between the total score of BSAS with BDCAF ($r=0.891$, $p < 0.001^{**}$) and between BSAS with MHAQ ($r=0.813$, $p < 0.001^{**}$) (Fig. 1).

Discriminant validity:

There is a statistically significant positive correlation between the total score of BSAS and ESR, CRP. BSAS (oral ulcers as numbers) and disease duration, BSAS: oral and genital ulcers as a level of discomfort and numbers, gastrointestinal, ocular, and vascular manifestations and MHAQ, BSAS; oral and genital ulcers as a level of discomfort and numbers and ocular manifestations and ESR, CRP (Table 4).

ROC curve for the BSAS:

ROC was plotted to determine the validity of BSAS in the diagnosis of low disease activity in comparison with BDCAF. The curve showed high area under curve 0.972 at 95% CI, also it revealed a Cutoff value for disease activity at 15.5 to discriminate between low and high disease activity of BD, (Table 5, Fig 2).

Table 1: Clinical characteristics of BD patients

Variables	Behcet patients n=70 (%)
Male gender	51 (72.9%)
Married	49 (70%)
Age (year) Mean \pm SD, Range	36.37 ± 8.39 (20 – 58)

Variables	Behcet patients n=70 (%)
Disease duration Median (IQR), Range	8(4.75 – 10.25) (1 – 25)
BMI (kg/m²) Mean ± SD, Range	26.01 ± 4.14(18 – 40)
<i>Organ involvement:</i>	
Musculoskeletal	39(55.7%)
Mucocutaneous	52(74.3%)
Genitourinary	21(30%)
Eye	20(28.6%)
Neuro	24(34.3%)
Vascular	9(12.9%)
GIT	7 (10%)
Main clinical presentation:	
Arthralgia	24(34.3%)
Arthritis	22(31.4%)
Pathergy	18(25.7%)
Mouth ulcer	24(34.3%)
Genital Ulcer	21(30%)
Erythema Nodosum	8(14%)
Skin pustules or acnes	5(7.1%)
Active Uvetitis	10(14.3%)
Retinal vasculitis	15(21.4%)
Headache	13(18.6%)
Deep venous thrombosis	7(10%)
Superficial thrombophlebitis	2(2.8%)
Activity(BDCAF)	
Inactive	22 (31.4%)
Active	48 (68.6%)
BDCAF score Median (IQR), Range	2(1 – 3) (0 – 6)
BSAS Median (IQR), Range	20(9 – 30.25) (0 – 38)
MHAQ Median (IQR), Range	1(0.38 – 1.37) (0 – 2.5)

Table 2: Test-retest reliability and internal consistency of items of Arabic version of score at the first and second visits in patients with BD

Items	First visit	Second visit	ICC (95% CI)	Corrected item-total correlation	Cronbach alpha if item removed	Cronbach alpha (standardized)
	Median (IQR)	Median (IQR)				
Q1	2.5(0 – 5)	3(0 – 5)	0.993 (0.989 – 0.996)	0.556	0.631	0.997
Q2	1(0 – 5)	1(0 – 5)	0.918 (0.871 – 0.948)	0.547	0.648	0.957
Q3	1(0 – 1)	4(0 – 5)	0.986 (0.978 – 0.991)	0.545	0.633	0.993
Q4	0 (0 – 0)	1(0 – 1)	0.788 (0.679 – 0.863)	0.471	0.666	0.881
Q5	0 (0 – 0)	0 (0 – 0)	0.962 (0.94 – 0.976)	0.267	0.671	0.981
Q6	0 (0 – 0)	0 (0 – 0)	0.995 (0.992 – 0.997)	0.082	0.683	0.997
Q7	0 (0 – 0)	0 (0 – 0)	0.863 (0.788 – 0.912)	0.165	0.678	0.926
Q8	0 (0 – 0)	0 (0 – 0)	0.957 (0.932 – 0.973)	0.191	0.677	0.978
Q9	0 (0 – 0)	0 (0 – 0)	0.94 (0.905 – 0.962)	0.119	0.685	0.969
Q10	6(3.75 – 9.25)	6.5(3.75 – 9)	0.856 (0.875 – 0.952)	0.615	0.620	0.922
Total	20(9 – 30.25)	20(9 – 31)	0.995 (0.992 – 0.997)			0.997

ICC test-retest interclass correlation coefficient CI Confidence interval

Table 3: Correlation between each item and total score

	R	P
Q1	0.646	<0.001**
Q2	0.594	<0.001**
Q3	0.649	<0.001**

	R	P
Q4	0.702	<0.001**
Q5	0.317	0.007*
Q6	0.297	0.013*
Q7	0.287	0.016*
Q8	0.354	0.003*
Q9	0.255	0.033*
Q10	0.702	<0.001**

Critical value of one tailed Spearman rank correlation coefficient for the studied sample (=0.246)

Table 4: Correlation between BSAS and clinical data of studied patients

		Age	D duration	BMI	BDCAF	MHQL	ESR	CRP	HB	WBCS	PLTS
Q1_b	R	0.017	-0.229	-0.023	0.525	0.531	0.337	0.296	-0.039	-0.163	-0.014
	P	0.890	0.056	0.851	<0.001**	<0.001**	0.004	0.013*	0.750	0.178	0.910
Q2_b	R	-0.005	-0.246	-0.045	0.466	0.5	0.305	0.312	-0.048	-0.105	-0.031
	P	0.965	0.04*	0.711	<0.001**	<0.001**	0.01*	0.008*	0.693	0.386	0.797
Q3_b	R	0.076	0.116	0.010	0.497	0.491	0.330	0.341	0.197	-0.061	-0.144
	P	0.533	0.340	0.935	<0.001**	<0.001**	0.005*	0.004*	0.102	0.617	0.234
Q4_b	R	0.017	0.053	0.001	0.557	0.575	0.344	0.368	0.110	-0.098	-0.088
	P	0.890	0.662	0.994	<0.001**	<0.001**	0.004*	0.002*	0.367	0.420	0.471
Q5_b	R	0.201	0.037	-0.112	0.346	0.209	0.171	0.131	0.028	-0.077	-0.047
	P	0.095	0.760	0.354	0.003*	0.083	0.157	0.279	0.816	0.524	0.702
Q6_b	R	0.184	0.037	-0.112	0.328	0.18	0.145	0.099	0.047	-0.048	-0.041
	P	0.128	0.763	0.358	0.006*	0.137	0.232	0.413	0.701	0.693	0.737
Q7_b	R	0.186	0.030	0.140	0.376	0.313	0.129	0.096	0.028	-0.059	0.123
	P	0.122	0.808	0.249	0.001**	0.008*	0.289	0.431	0.816	0.628	0.312
Q8_b	R	-0.102	-0.063	-0.153	0.329	0.361	0.238	0.334	0.092	-0.023	-0.058
	P	.402	0.605	0.207	0.005*	0.002*	0.047*	0.005*	0.449	0.850	0.631
Q9_b	R	.103	0.106	0.200	0.250	0.24	0.062	0.125	0.089	-0.123	0.106
	P	.395	0.380	0.097	0.037*	0.035*	0.612	0.301	0.464	0.309	0.382
Q10	R	.017	-0.009	0.215	0.596	0.538	0.520	0.472	0.039	0.014*	0.132
	P	.892	0.942	0.073	<0.001**	<0.001**	<0.001*	<0.001**	0.750	0.910	0.276
BSA S	R	.101	-0.022	0.064	0.891	0.813	0.551	0.555	0.177	-0.150	0.017
	P	.404	0.854	0.601	<0.001**	<0.001**	<0.001*	<0.001**	0.142	0.214	0.890

r Spearman rank correlation coefficient

Table 5: Validity of BSAS in diagnosis of low disease activity among patients with BD

Cutoff	AUC	Sensitivity	Specificity	PPV	NPV	Accuracy	P
≥15.5'	0.972	91.7%	86.4%	93.6%	82.6%	90%	<0.001**

AUC area under curve, PPV positive predictive value, NPV negative predictive value, **p≤0.001 is statistically highly significant.

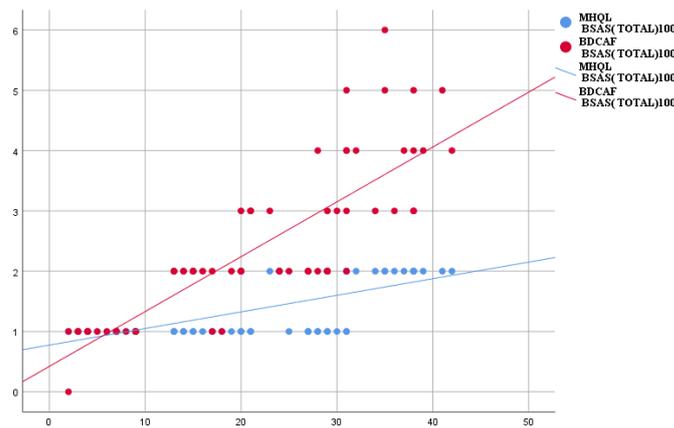


Figure 1. Scatter dot plot showing significant positive correlation between BSAS and all of BDCAF and MHQL

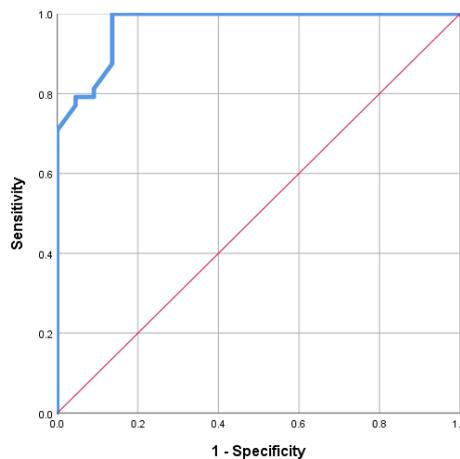


Figure 2. ROC curve for the validity of BSAS compared with BDCAF

DISCUSSION

Throughout the course of the disease, Behçet's disease has a varied pattern of organ involvement that takes place in recurrent bouts of acute inflammation in the form of remission and exacerbation [13,14].

It is more difficult to define and measure the remission or the disease activity in systemic vasculitis and particularly in the BD [11]. Despite the fact that there are validated measures of disease activity in BD, the majority of BD patients' care typically consists of the qualitative history and the physical examination, therefore the treatment decisions are based on these non-quantitative clinical perceptions. Laboratory markers are the only quantitative measurements used and they are frequently unavailable or not helpful at the time of the visit [15]. The patient-reported measures of disease activity have been found to be as informative as or even more so than physician-driven measures in other rheumatologic disorders like RA [16].

The European League Against Rheumatism recommends that each BD patient's treatment

should be customized, and the therapeutic decisions should be taken through shared decision-making by both the patient and the doctor leading to better outcomes [17,18].

The BDCAF has already been validated in Arabic [5]. But in a busy clinical context, it is exceedingly time-consuming for physicians to complete a BDCAF for every patient. Through the use of self-administered questionnaires and indices, disease activity can be easily measured.

In terms of BD, the BSAS is the first index that was created to assess the disease activity solely based on the patient's reactions and does not require the doctor to perform additional tasks. The BSAS has been developed and validated in a sample of American individuals with BD. It is essential that a global cross-cultural modification of the original BSAS be produced for an extra international recognition due to the ethnic and geographic inconsistency of BD and the intercultural difference of patients' perceptions of the effect of the condition. It was previously validated in Turkey [7], Korea [19], and Brazil [20]. The current study marks the first use of the

instrument in a sample of Arabic BD patients to evaluate the validity and the reliability of the translated Arabic version of the BSAS (Ar - BSAS) in the assessment of BD activity and discriminate its score in low and high disease activity so can be used as treat to target tool.

Regarding BD activity in the present study, (68.6%) of patients were active with BSAS mean was 20.41 ± 12.04 and the BDCAF score mean was 2.3 ± 1.28 .

Higher disease activity scores were recorded by other studies. Yilmaz et al [7] in Turkey revealed that the mean scores of the BSAS and the BDCAF were 38.6 ± 20.8 and 4.3 ± 2.2 respectively. Colman et al [20], in the Brazilian study, stated that between 0 and 100, the mean BSAS score was 31,29 (SD 24,54), while between 0 and 12, the mean BDCAF score was 3,41 (SD 2,34).

In this study, as a measure of reliability, the 2-week retest was done. The BSAS for each item and the total score demonstrated an acceptable internal consistency as well as stability and a high Cronbach's alpha coefficient ranged from 0.881 to 0.997 for the 10 items and 0.997 for total score indicating a high internal consistency.

Similarly to Choi et al in the Korean study [19] for test-retest reliability, all 10 of the BSAS questionnaire's items and the overall BSAS score were strongly associated in the two evaluations (ICC, 0.925; $p < 0.001$). Also, in agreement with the Turkish study [7], which stated that the BSAS test-retest reliability had a good ICC (ICC=0.84, 95% CI [0.69–0.94]).

In the Brazilian study, the BSAS demonstrated strong test-retest reliability (ICC=0.839, 95% CI [0.596-0.943]). With a Cronbach's alpha of 0.773 developed for additional international recognition, internal consistency was also considered satisfactory [20].

Regarding convergent validity in the current study, there is a high significant positive correlation between the total score of the Ar-BSAS with the BDCAF ($r=0.891$, $p<0.001^{**}$), and between the BSAS with the MHAQ ($r=0.813$, $p<0.001^{**}$) indicating high validity.

Similar results were reported by a Korean study [19] as the BSAS and the BDCAF had a strong correlation, whereas the BSAS and the patient/physician VAS and the BDQOL (quality of life) had a moderate correlation ($p < 0.01$). Forbes et al [8] and the Turkish study [7] stated that a moderate correlation between the BSAS and the BDCAF ($r=0.587$) RAPID 3 ($r=0.648$) was found. In addition, there was a significant association between the BR-BSAS and BR-

BDCAF scores in the Turkish study ($r=0.750$) [20].

To confirm the divergent validity, a statistically significant positive correlation was reported in the current study between the total score of Ar-BSAS and ESR, CRP. BSAS (oral ulcers as numbers) and disease duration, BSAS: oral and genital ulcers as a level of discomfort and numbers and gastrointestinal, ocular, and vascular manifestations. Therefore, the BSAS as an indicator of the disease activity can guide therapy modifications and be used as a treat to target tool for BD. In accordance with Yazici et al [21] who concluded that Early on, when disease activity was at its lowest, BSAS was also helpful. Patients with Behcet syndrome may benefit from using a patient outcome measure like the BSAS to track treatment outcomes during routine care.

A novel finding in the present study is the cutoff value for the Ar-BSAS to determine low or high disease activity in comparison with the BDCAF that the ROC curve showed a high area under the curve 0.972 at 95% confidence interval (CI). Also, it revealed a cutoff value for the disease activity at 15.5 to discriminate between the low and high disease activity of BD.

In disagreement with Yazici et al [22] who used a different index the Routine Assessment of Patient Index Data 3 (RAPID3) to estimate the BSAS scores levels into remission, low, moderate, and high and reported that the proposed BSAS severity categories with a concordance correlation with RAPID were; near-remission = [0-10], low = [10-30], moderate = [30-60], and high = [60-100].

As the first cross-cultural adaptation of the BSAS in the Middle East, the study's main contribution is that it provided an accurate, simple-to-use tool for assessing BD activity in Arabic language.

Limitations: Relatively small sample size and being recruited in one center are considered one of the study limitations

CONCLUSION

This study showed that the Arabic version of the BSAS is a reliable, valid, and accurate patient-reported measure of disease activity that could be used to evaluate disease activity and guide therapy modification in both routine clinical practice and research.

Declaration of interest

The authors report no conflicts of interest. The authors along are responsible for the content and writing of the paper.

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