Patient-driven assessment of disease activity in Behçet's syndrome: cross-cultural adaptation, reliability and validity of the Turkish version of the Behçet's Syndrome Activity Score

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ABSTRACT

Objective. The *Behçet's Syndrome Activity Score (BSAS) is the first patient reported outcome measure developed to assess the global disease activity in patients with Behçet's syndrome (BS). We aimed to evaluate the reliability and validity of the Turkish version of BSAS for measuring disease activity in BS. We further investigated the performance of Routine Assessment of Patient Index Data (RAPID)3, a patient-reported index originally developed for rheumatoid arthritis, in BS patients.*

Methods. *Patients seen consecutively at a tertiary Rheumatology Centre were requested to complete BSAS and multidimensional health assessment questionnaire (MDHAQ). Besides, all attending physicians filled the Behçet's Disease Current Activity Form (BDCAF). Descriptive statistics and Pearson correlation coefficients were calculated accordingly for the reliability and validity assessments of BSAS.*

Results. *A total of 104 patients completed all three assessments. The test-retest reliability of BSAS has a good level (ICC=0.84, 95% CI [0.69–0.94]). The mean scores for BSAS, BDCAF and RAPID3 were 39±20.8, 3.2±1.4 and 9.2±5.6, respectively. BSAS was correlated with BDCAF moderately (r=0.587), while it was moderately correlated with RAPID3 (r=0.648). The correlation between the RAPID3 and BDCAF was moderate (r=0.403), but lower as compared to the correlations between the other instruments.*

Conclusion. *We found that the BSAS has modest correlation with BDCAF and is a reliable and valid patient reported measure of disease activity that can be used to assess patients with BS. An outcome score composed of only patient-derived observations may have the additional advantage of being easier to use in a routine care setting. Demonstration of a moderate level of correlation between RAPID3 and BDCAF (close to the level of weak relationship), suggests that RAPID3 likely needs more investigations before recommending its use in BS.*

Introduction

Behçet's syndrome (BS) is a chronic vasculitis of unknown etiology, which may involve many organs including mucocutaneous, eye, joints, blood vessels, gastrointestinal, and central nervous systems. The clinicians who take care of any chronic disease would like to know the current status of a patient to manage them properly. In this regard, the need for developing a standardised assessment of disease activity of BS has been a major concern for clinicians for decades. However, due to some complexities associated with the disease itself, it is not an easy task to define and assess the disease activity in those patients. A variable clinical picture, a large range of possible combinations of clinical manifestations and a relapsing-remitting course characterise BS. Moreover, the disease is highly variable in severity. It can be quite mild with infrequently occurring mucocutaneous manifestations or it can be very severe, debilitating, and potentially life-threatening with major vessel involvement. The heterogeneity of the clinical picture of BS can further be increased by the simultaneous presence of manifestations attributable to disease activity and chronic damage (1-5).

A number of instruments to assess disease activity in BS have been developed, while there is no agreement on a single activity index to be used universally. The most widely used indices are the Iranian Behçet's Disease Dynamic Activity Measure (IBDDAM) and Behçet's Disease Current Activity Form (BDCAF). Iranian Behçet's disease

dynamic activity measure was developed almost 20 years ago (6). It is based on an interval scale, and assessment requires patients' accurate recall of symptoms up to 12 months prior to the current visit. Later, the Behçet's Disease Current Activity Form (BDCAF) was developed and presently is most commonly used index (3). It scores the presence or absence of clinical features (oral ulcers, genital ulcers, skin lesions, etc.), which were present during the four weeks prior to the day of assessment. While both of the indices have their own pros and cons, one shortcoming is shared by both of them; a clinical assessor is needed to complete these measures. Indeed, the reason behind the reluctance of physicians to use these indices in everyday practice might be the difficulties to perform these assessments in a busy clinical setting.

Although physicians who deal with rheumatoid arthritis or ankylosing spondylitis are more familiar with patient reported outcomes, this is not the case for BS except for the use quality of life measures in research settings. More recently, a patient-derived assessment tool, Behçet's Syndrome Activity Score (BSAS) has been developed and found as correlated with the BDCAF in a small number of patients with BS (7). BSAS has 10 questions, which consist of visual analogue scales (VAS) for the patient's level of discomfort over the previous month with regards to oral ulcers, genital ulcers, skin lesions, current disease activity along with the number of oral ulcers, genital ulcers, and skin lesions present, and records symptoms attributable to the gastrointestinal, vascular, and eye involvement.

In rheumatology, it is highly desirable to have an outcome measure, which is simple, patient-reported and applicable to most of the rheumatic diseases seen in everyday practice. In this regard, RAPID3, (Routine Assessment of Patient Index Data 3), developed originally for patients with rheumatoid arthritis, seems to be the most promising one (8). Although there are some reports suggesting the usefulness of RAPID3 in rheumatic diseases other than rheumatoid arthritis, it has not been previously tested in patients with BS (9).

The aim of the present study was to evaluate the reliability and validity of the Turkish version of BSAS as a new patient reported tool for measuring disease activity in BS. We further investigated the performance of RAPID3 in BS patients as compared to BSAS and BDCAF.

Patients and methods

Study population and data collection

Consecutive adult BS patients seen at the Rheumatology Centre at Gulhane School of Medicine, Ankara, Turkey between May 1, 2011 and June 25, 2012 were invited to participate. One optional component of the routine visit at our centre is the completion of several patient reported outcome (PRO) questionnaires. During regularly scheduled follow-up clinic visits, patients were given self-administered, paper-based, PRO instruments (MD-HAQ, BSAS) to be completed, while waiting to see the rheumatologist. All participating patients fulfilled the International Study Group criteria for BS. Patients with BS showing at least 2 clinical manifestations at the time of the assessment, including oral ulcer, genital ulcer, ostiofolliculitis, uveitis, arthritis, gastrointestinal, central neural system or vessel involvement was considered as having clinically active disease. Learning difficulties or an inability to comprehend written Turkish were study exclusion criteria. Demographic data and disease history information for each patient was obtained using a questionnaire upon recruitment. Besides, all additional clinical features and treatment protocols were obtained from the patients' files. The clinical disease activity data used in this study (BDCAF) were collected by the attending physician during the patients' routine medical care. Of the 144 patients approached to complete the instruments, 12 declined to participate, 14 did not complete the full battery, and 4 did not fulfill the ISG criteria for BS and were excluded from the analysis. Consequently, 114 subjects participated. One of the authors transcribed responses into a computerised database. All patients signed consent for the results to be sent anonymously to a data centre. The local institutional ethics committee approved the study.

Measures of disease activity

Translation and cross-cultural adaptation

Behçet's syndrome activity score was developed as a patient reported outcome measure to be used in RCT and also routine clinical care of Behçet's patients. It was initially developed by expert consensus by reviewing patient relevant aspects of the disease for external and internal validity and correlations with more accepted outcome measures in Behcet's syndrome (7). Formal validation is currently ongoing at the time of publication (personal communication). The BSAS was adapted to Turkish population using the established guidelines for cross-cultural adaptation (10). Briefly, the following steps were followed for the translation of the instrument: translation to Turkish, synthesis of Turkish translations, back translation to English (source language), synthesis of back translation, and review / decision about the final format of the questionnaire by a panel of experts. All instruments other than BSAS used in this study have previously been validated in Turkish (11, 12).

Behçet's Disease Current Activity Form (BDCAF)

BDCAF scores the presence of different symptoms attributable to organ involvement including headache, mouth ulcers, genital ulcers, skin lesions (erythema, skin pustules), joint involvement (arthralgia, arthritis), gastrointestinal symptoms (nausea/vomiting/abdominal pain, diarrhoea + altered/frank blood per rectum), eye involvement, nervous system involvement, and major vessel involvement over the 4 weeks prior to assessment. Importantly, only the new symptoms over the preceding 4 weeks that the clinician considers as due to BS should be scored. The total score is out of 12.

Behçet Syndrome Activity Score (BSAS)

BSAS has 10 questions, which consists of visual analogue scales for patient's level of discomfort with regards to oral ulcers, genital ulcers, skin lesions,

Behçet's Syndrome Activity Scale (BSAS)

Your name:_____ **Date of Birth:** _____ **Today's Date:**_____

Your: **SEX:** ☐ Female ☐ Male **ETHNIC** ☐ Asian ☐ Hispanic ☐ Other _____ **GROUP:** ☐ Black ☐ White

1. How much have **ulcers in your mouth** bothered you over the last 4 weeks? Please indicate below

NO ULCERS ○○○○○○○○○○○○○○○○○○○○ **ULCERS WERE A MAJOR PROBLEM**

0 0.5 1 1.5 2 2.5 3 3.5 4 4.5 5 5.5 6 6.5 7 7.5 8 8.5 9 9.5 10

2. How many **ulcers (new or old)** did you have in your **mouth** over the last 4 weeks?

0 ☐
1-3 ☐
More than 3 ☐

3. How much has **ulcers in genital area** bothered you over the last 4 weeks? Please indicate below

NO ULCERS ○○○○○○○○○○○○○○○○○○○○ **ULCERS WERE A MAJOR PROBLEM**

0 0.5 1 1.5 2 2.5 3 3.5 4 4.5 5 5.5 6 6.5 7 7.5 8 8.5 9 9.5 10

4. How many **ulcers (new or old)** did you have in your **genital area** over the last 4 weeks?

0 ☐
1-3 ☐
More than 3 ☐

5. How much has **acne or acne like skin lesions (new or old)** bothered you over the last 4 weeks? Please indicate below

NO SKIN LESIONS ○○○○○○○○○○○○○○○○○○○○ **SKIN LESIONS WERE A MAJOR PROBLEM**

0 0.5 1 1.5 2 2.5 3 3.5 4 4.5 5 5.5 6 6.5 7 7.5 8 8.5 9 9.5 10

6. How many **acne or acne like skin lesions (new or old)** did you have over the last 4 weeks?

0 ☐
1-5 ☐
More than 5 ☐

7. Have you had **abdominal pain and diarrhea** lasting most of the day for most days of the week over the last 4 weeks?

☐**No** ☐ **Yes**

8. Did you have **painful or red eyes and/or blurred or reduced vision** over the last 4 weeks?

☐**No** ☐ **Yes**

9. Did you have any **swelling/discoloration of your lower extremities, or a blood clot** over the last 4 weeks?

☐**No** ☐ **Yes**

10. In terms of your **Behcet's activity, (oral ulcers, genital ulcers, skin problems, joint pains, eye, neurologic problems),** how active would you say your condition has been over the last 4 weeks?

NOT ACTIVE AT ALL ○○○○○○○○○○○○○○○○○○○○ **EXTREMELY ACTIVE**

0 0.5 1 1.5 2 2.5 3 3.5 4 4.5 5 5.5 6 6.5 7 7.5 8 8.5 9 9.5 10

Scoring:

Questions 1, 3, 5, and 10 are scored 0-10

Questions 2, 4, 6, are scored 0, 5 or 10 depending on which of the 3 are checked

Questions 7, 8, 9 are scored 0 or 10

For a total score of 100

Fig. 1. Behçet's Syndrome Activity Score (BSAS).

current disease activity along with the number of oral ulcers, genital ulcers, and skin lesions present, and records symptoms attributable to the gastrointestinal, vascular, or eye involvement. The VAS questions are all scored 0-10, and the remaining are scored categorically, 0, 5 or 10 depending on the response, for a total score of 0–100 (Fig. 1). The patients complete the BSAS at the time of the visit to the treating doctor, with no input from the physician.

RAPID3

Routine Assessment of Patient Index Data (RAPID) 3 is calculated using three of the questions on the MDHAQ (multidimensional health assessment questionnaire). It is an index of the three patient-reported outcome measures; physical function, pain, and patient global estimate scores. The pain and global estimate visual analog scales are in 21 numbered circles to facilitate scoring with the scale of 0–10. There are 10 questions to determine physical function, each are scored from 0 to 3 individually. A template is used to convert 0–3 scores for 10 individual physical function items to a 0–10 composite score.

Table I. Clinical and demographic features and disease activity scores of patients.

Age	35 ± 9.8
Sex, male	69 (66%)
Disease duration (SD)	7.4 ± 6.6
Oral aphta	104 (100%)
Genital ulceration	84 (80.7%)
Skin lesions (acneiform, ostiofolliculitis, etc.)	94 (90.3%)
Erythema nodosum	43 (41.3%)
Pathergy	39/74 (52.7%)
HLA-B51, positive	24/40 (60%)
Mucocutaneous only	43 (41.3%)
Organ involvement	61 (58.7%)
- Ocular	32 (30%)
- Vascular	13 (12.5%)
- Joint (arthritis)	25 (24%)
- Gastrointestinal	3 (2.8%)
- Central nervous system	1 (0.9%)
BDCAF (mean ± SD), (range 0-12)	3.2 ± 1.4
BSAS (mean ± SD), (range 0-100)	39 ± 20.8
RAPID3 (mean ± SD), (range 0-30)	9.2 ± 5.6

BDCAF: Behçet's Disease Current Activity Form; BSAS: Behçet's Syndrome Activity Score; RAPID3: Routine Assessment of Patient Index Data 3; SD: standard deviation.

Table II. The prescribed agents ever used in patients.

Drugs	n (%)
Colchicine	86 (82.6)
Corticosteroids	64 (61.5)
Azathioprine	50 (48)
Cyclosporin A	15 (14.4)
Interferon alpha	6 (5.7)
Cyclophosphamide	5 (4.8)
Sulphasalazine	4 (3.8)
Methotrexate	3 (2.9)
Anti-TNF	3 (2.9)

More than 1 agent might have been used in the same patient.

Instrument evaluation

Reliability

The reliability of the BSAS was assessed by the test-retest method among the first 25 consecutive patients of the original study population. This is an estimate of the instrument's reproducibility over time, assuming that no change in condition has taken place. Patients were asked to complete a second questionnaire at 1 month. Test-retest reliability of BSAS was assessed for those patients indicating that their BS specific health had remained the same at 1 month on a health transition question. The intra-class correlation coefficient (ICC) was used to measure the agreement between test and retest. For group comparisons, levels of reliability >0.70 are required, and for monitoring individual patients' levels of >0.90 have been recommended.

Internal consistency

Internal consistency of the BSAS was assessed by Cronbach's alpha statistics. This statistic indicates the degree of relatedness between items. Both the item-total and the inter-item correlations were assessed and a value of 0.70 or above was taken as reflecting adequate internal consistency.

Validity

Construct validity was assessed to determine how well the BSAS assesses disease activity in patients with BS. Hypothesised theoretical relationships between instruments were considered a priori. While scaling properties are considerably different, several items measured by the BDCAF are within the item content of the BSAS. Therefore a moderate to high level of correlation was hypothesised between the BSAS and BDCAF. Apart from being a patient reported outcome, RAPID3 has only 1 item (patient global assessment of disease activity) common with BSAS, which led us to hypothesise a low to moderate level of correlation between the BSAS and RAPID3. We analysed the correlation between the patient-reported BSAS score and BDCAF as well as RAPID3 using Pearson's correlation coefficient, and utilised a p-value of <0.05 as evidence of statistical significance. We also examined the correlation between the patient-reported and physician-reported assessment of disease activity. Correlation coefficients below 0.3, between 0.3 and 0.7 and over 0.7 were considered low, moderate and high, respectively.

Results

Patient characteristics

Study population consisted of 104 patients who had complete data available. Almost two-thirds of patients were male, and mean age was 35±9.8 years. Mean disease duration was found to be

Table III. The correlation analysis of activity scores in study group, and subanalyses in patients with mucocutaneous and systemic involvement.

		Mucocutaneous only (n=43)		Systemic Involvement (n=61)		Total study group (n=104)	
		BSAS	RAPID3	BSAS	RAPID3	BSAS	RAPID3
BDCAF	Correlation coefficient	0.599	0.379	0.561	0.342	0.587	0.403
	Significance level *p*	<0.0001	<0.001	0.004	NS	<0.0001	<0.0001
BSAS	Correlation coefficient		0.651		0.662		0.648
	Significance level *p*		<0.0001		<0.0001		<0.0001

BDCAF: Behçet's Disease Current Activity Form; BSAS: Behçet's Syndrome Activity Score; RAPID3: Routine Assessment of Patient Index Data 3; NS: not significant.

7.4±6.6 years. Organ involvement was found in 61 patients (58.7%), while 43 patients (41.3%) have only mucocutaneous involvement. Distribution of organ involvement was as follows; ocular 30%, vascular 12.5%, gastrointestinal 2.8%, central nervous system 0.9%, and joint (arthritis) 24%.

A total of 61 (58.7%) patients were active at the time of the study, 20 of them had major organ involvement, while 41 of them had mucocutaneous only involvement. There was no statistical difference between the mucocutaneous and organ involvement with regard to BSAS scores (43.5±19.4 and 45.0±20.3, respectively; p=0.785). Pathergy test was performed in 74 patients in whom 39 (52.7%) were found to be positive. The HLA-B51 test had been studied in a total of 40 patients; 24 were positive. Clinical and demographic features of the study population are presented in Table I. Among the received treatments, colchicine and corticosteroids were the most commonly used ones (86 and 64 patients, respectively). Azathioprine was the most preferred immunosuppressive agent, while others including cyclosporine A, interferon-α, sulphasalazine, cyclophosphamide, methotrexate, and anti-TNFs were have been used with decreasing order of frequency (Table II).

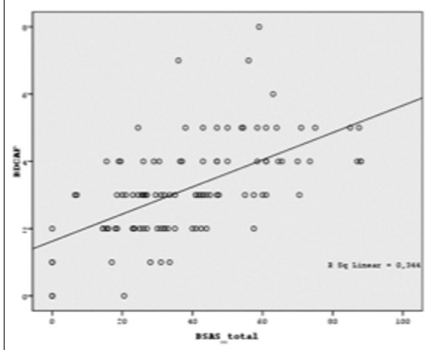
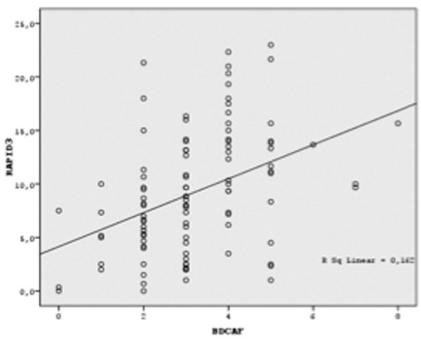
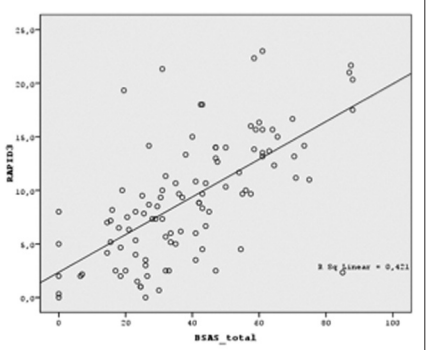
We performed a subgroup analysis to assess whether there is any sex or age related difference in BSAS scores. There was no difference between BSAS scores of male and female patients (p=0.077). To find out any age-related difference, we divided the patient group into two subgroups according to the age 37, which was the median age of the study group and found no difference between the older and younger patients with regard to their BSAS scores (p=0.097).

Reliability and internal consistency

The test-retest reliability of BSAS was assessed by correlating the two sets of scores for those 13 patients who indicated no change on the general health transition question at 1 month. The instrument has a good level of test-retest reliability (0.84, 95% CI [0.69–0.94]) that makes it suitable for use in groups of patients. The BSAS also has an acceptable internal consistency with a Cronbach's alpha of 0.73, 95% CI (0.65–0.87).

Validity

BSAS, BDCAF and RAPID3 scores of all participants were calculated. Among the study population, BSAS (range 0–100) mean ± SD score was 39±20.8; BDCAF (range 0–12) mean ± SD score was 3.2±1.4; and RAPID3 (range 0–30) mean ± SD score was 9.2±5.6 (Table I). In BS patients with only mucocutaneous involvement (n=43), BSAS, BDCAF and RAPID3 scores were 38.3±20.6, 3.0±1.3, and 8.5±5.3, respectively. BSAS, BDCAF and RAPID3 scores of patients with major organ involvement (n=61) were

BSAS vs. BDCAF	RAPID3 vs. BDCAF	RAPID3 vs. BSAS
		
r=0.587; p<0,0001 95% CI (0.445-0.700)	r= 0.403; p<0,0001 95% CI (0.229-0.552)	r= 0.648 p<0,0001 95% CI (0.521-0.747)

BDCAF: Behçet's Disease Current Activity Form; BSAS: Behçet's Syndrome Activity Score; RAPID3: Routine Assessment of Patient Index Data 3; CI: confidence interval.

Fig. 2. The scatter plots of individual correlations.

41.6±22.6, 3.8±1.6, and 11.8±6.4, respectively. Correlation analyses have been carried out among the 3 measures tested in this study and each pair showed statistically significant but different degrees of correlations (Table III). BSAS was correlated moderately with the BDCAF (r=0.587). RAPID3 was also correlated with BDCAF, at somewhat lower levels than BSAS (r=0.403). The highest correlation was found between the RAPID3 and BSAS, (r=0.648). The scatter plots of individual correlations are presented in Figure 2. Besides, we performed an additional correlation analysis for disease activity measures among BS patients with systemic and mucocutaneous involvement. There was no significant difference between these subgroups as well as between the subgroups and the total group of BS patients with regard to their correlation coefficients (Table III). We further analysed the correlation of patient global assessment and physician global assessment with BSAS, BDCAF, and RAPID3. Strength of correlations between patient global assessment and BSAS, BDCAF, and RAPID3 were good r=0.767, r=0.583, and r=0.686, respectively, p<0.001 for all). On the other hand, the correlations between physician global assessment and BSAS, BDCAF, and RAPID3 were poor, r=0.308, r=0.284, and r=0.337, respectively, p=0.001, p=0.03, and p<0.001, respectively).

Discussion

Quantitative assessment of activity in a chronic disease has been a major concern for several disease entities. Indeed, quantitative measures have advanced clinical care in many diseases including rheumatic disorders. For instance, several studies have shown that guiding treatment of RA patients with quantitative measures is associated with better outcomes than the usual non-quantitative care (13). Before the clinical application of disease activity assessments and collecting quantitative data, rheumatologists were unaware of the actual prognosis of RA (14). However, the clinical implementation of composite measures in RA has led to the targets such as a low disease activity or remission (15). Besides, it has been suggested that the most important issue in the management of patients with RA is monitoring the disease activity with one of the validated measures, no matter which one is preferred (16). On the other hand, in systemic vasculitis, and especially in BS defining and quantifying the remission or disease activity is much more complex (17). Despite the existence of validated measures of disease activity in BS, patient care of most of the BS patients generally involves non-quantitative history, and physical examination and the decisions to guide treatment are based on these non-quantitative clinical impressions. The only quantitative measures included are laboratory tests, which often are not helpful and/or not available at the time of the visit.

Turkstra *et al*. have found that in comparison to 1991, the patients with BS are being treated more intensively (18). Although it might be interpreted as a consequence of increased awareness about the importance of patient follow up, no single measure for monitoring the patients with BS has been globally accepted and validated yet. While no formal study was found about the preferred disease activity measures and their extent of use in the everyday care of BS patients, our impressions based on the personal communication with colleagues suggest that the use of quantitative measures in the management of BS patients is so exceptional. There might be several explanations regarding the lack of interest among the rheumatologists to use these quantitative measures for BS. One important reason might be the difficulties to perform these assessments in a busy clinical setting due to time restraints. Increasingly, patient-reported outcomes are being emphasised in the development of instruments that assess disease activity or health status. Disease activity can be quantified by using self-administered questionnaires and indices. In other rheumatologic diseases like RA, patient-reported measures of disease activity are found to be as or even more informative than physician-driven measures (19, 20).

With regard to BS, BSAS is the first index that was developed to measure disease activity using patient responses only. Although its development and validation in a group of BS patients from United States dates back to 2008, this index needs to be tested in several countries, particularly the ones where the disease is prevalent, to be sure that cultural or language differences do not interfere with the results of the assessments.

This study represents the first application of this instrument in a representative population of Turkish BS patients and evaluation of instrument measurement properties and acceptability. The results of test-retest reliability as well as internal consistency of the BSAS have not been reported previously. In this regard, our study has also provided information regarding these important aspects of the instrument's measurement properties. We showed that BSAS has acceptable levels of test-retest reliability as well as internal consistency.

In the present study, BSAS showed a moderate correlation with BDCAF, which met a priori hypothesis. Although the correlation found between BSAS and BDCAF was far from being excellent, the magnitude of the correlation was sufficient to suggest that the instrument is measuring the related aspects of disease activity. Moreover, the level of correlation found in the present study is almost identical to the correlation detected by Forbess *et al*. (7). Given the fact that the level of disease activity both measured by BSAS and BDCAF in the present study is quite similar to the ones measured in the study by Forbess *et al*. (mean scores of BSAS and BDCAF were 38.6±20.8 and 4.3±2.2), similar levels of correlations (correlation between BSAS and BDCAF was 0.597 in reference 7) found in both studies can be further taken as an evidence of acceptable validity of BSAS in different populations.

We have also tested another patient reported outcome, RAPID3, derived from the MDHAQ. It is neither specific nor developed for BS. Pincus et al. have suggested that RAPID3 can be effective in the assessment of patients with all rheumatic diseases, when the similarities of the problems unique to rheumatic diseases in physical func-

tion, pain, or global status, as quantified by RAPID3 scores, are considered (21). It is easy to calculate and takes less than 10 seconds, as demonstrated noted previously (21). On the other hand, it should be noted that most of the features of BS have not been included in RAPID3. Accordingly, we found a moderate (lower, as compared to BSAS and BDCAF) level of correlation between RAPID3 and BDCAF. Interestingly, best correlation in this study was found between the RAPID3 and BSAS, which might be due to the patient reported nature of both of the indices. However, RAPID3 likely needs more investigations before recommending its use in BS.

Sensitivity to change is a very crucial property of a disease activity measure. To evaluate the sensitivity to change was not within the context, and may be a limitation, of the present study. In this regard, further studies in a large cohort of BS patients followed longitudinally are needed.

In conclusion, this study demonstrated that Turkish version of BSAS is a reliable and valid patient reported measure of disease activity that can be used to assess patients with BS. It is obvious that there is a need for patient reported outcome measures to use both in daily practice and clinical research for patients with BS. It would have been desirable to obtain a higher correlation between BSAS and BDCAF to use BSAS instead of BDCAF. However, considering that BSAS is the first patient reported outcome measure developed so far, and it does not put additional work to the side of the physician, we think that it can be used not instead of but along with the BDCAF. In this regard, BSAS may provide a promising approach to introduce patient reported quantitative measurement in BS to standard clinical care. However, further prospective studies with a large number of patients are needed to evaluate the role of this instrument in clinical research and routine practice.

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