

Original Article

Translation, Cross-cultural Adaptation and Validation of Ankylosing Spondylitis Disease Activity Score

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Abstract:

Ankylosing Spondylitis Disease Activity Score (ASDAS) is a very important tool for measuring disease activity in patients with axial spondyloarthritis (axSpA). This study was aimed to develop a culturally adapted, valid and reliable Bengali version of questionnaire for the ASDAS. The original English ASDAS was translated into Bangla and adapted in the local socio-cultural context, following standard international recommendations. Content validity of the adapted Bangla version was assessed by the item-level & scale level content validity indices (I-CVI & S-CVI). A total 120 patients with axSpA were assessed in the study. For construct validity, correlation between ASDAS with BASDAI, ESR, CRP, Maastricht enthesitis score, physician's global assessment and BASMI was assessed by Spearman's rank correlation coefficient. Internal consistency and test-retest reliability were assessed using Cronbach's alpha coefficient and intraclass correlation coefficient respectively. I-CVI for each item was 1 and S-CVI was 1. ASDAS-ESR and ASDAS-CRP showed strong correlation (Spearman's correlation coefficient >0.5) with BASDAI, ESR, MASES and physician global assessment of disease activity. The scale demonstrated excellent internal consistency (Cronbach's alpha=0.703) and test-retest reliability (ICC=0.98). The adapted Bangla version of the ASDAS demonstrated acceptable psychometric properties (validity & reliability) in Bangladeshi patients with axSpA.

Key words: Ankylosing spondylitis, Spondyloarthritis, Adaptation, Validation, Consistency, Reliability, Correlation.

Introduction:

Spondyloarthritis (SpA) is a family of inflammatory disorders which includes ankylosing spondylitis (AS)

and nonradiographic axial spondyloarthritis (nr-axSpA), reactive arthritis (formerly called Reiter syndrome), psoriatic arthritis, SpA associated with Crohn's disease and ulcerative colitis, juvenile onset spondyloarthritis and undifferentiated spondyloarthritis¹⁻¹⁰. AS and nr-axSpA are now considered as different stages on the spectrum of a clinical entity called axial spondyloarthritis¹⁰.

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Two important tools for measuring disease activity in patients with axSpA are the Bath ankylosing spondylitis disease activity index (BASDAI) and the ASDAS. The BASDAI, published in 1994, comprises six questions and is fully a patient-reported measure¹¹. The BASDAI does not weigh individual clinical manifestations, as the variables are simply summed, without taking the relative importance, redundancy and dependency into account. It also lacks specificity for inflammatory processes¹². The ASDAS is a new composite index to assess disease activity in AS which was developed in 2009 by the Assessment of Spondylo Arthritis international Society (ASAS) aiming to improve the construct validity of disease activity measures in axSpA^{13,14}. The ASDAS has many advantages over BASDAI¹⁵⁻²⁷. The ASDAS has been derived from three questions from the BASDAI (BASDAI question-2, 3 and 6) plus the patient global assessment and biological markers of inflammation (either c-reactive protein or erythrocyte sedimentation rate). The ASDAS has been extensively validated. This study aimed to develop a Bengali version of the ASDAS questionnaire and to assess its validity and reliability in Bangladeshi patients with axSpA.

Materials and Methods:

It was an observational study designed in two phases, phase-1 and phase-2. Phase-1 consisted of translation and cross-cultural adaptation of the original English ASDAS into Bengali following the recommendations of standard guidelines²⁸. Phase-2 consisted of assessment of the psychometric properties of the adapted Bengali version of the ASDAS, ie. testing its validity (content and construct validity) and reliability (internal consistency & test-retest reliability). We included adult Bangladeshi patients (>16 years) who were classified as AS according to modified New York criteria for AS or nr-axSpA according to ASAS classification criteria for nr-axSpA. Patients with pregnancy, morbidly sick patients who are unable to communicate, patients having injury on the lumbar vertebrae or femur, patients having previous history of fracture, mentally retarded patients, patients with overlap with other rheumatological diseases, malignancy and patients who were not willing to take part in the study were excluded.

Translation and adaptation of the English ASDAS questionnaire into Bengali were accomplished in five stages: forward translation, synthesis of Bengali version, back translation, expert committee review and test of the pre-final Bengali version. The expert committee reviewed and compared all the translations and the original English ASDAS. The committee verified the semantic, idiomatic, experiential and conceptual equivalence between the English and Bengali versions. Following this way, the pre-final Bengali questionnaire was developed. The pre-final Bengali version of the ASDAS was tested in a sample of 38 adult patients with axSpA. Each subject completing the questionnaire was interviewed to probe about what he or she thought was meant by each questionnaire item and the chosen response. This ensured that the adapted version had retained its equivalence in an applied situation.

Testing of the validity and reliability of the Bengali version of the questionnaire was carried out in 120 patients in the second phase. During statistical analysis a p-value of < 0.05 was considered significant. Content validity was assessed by the item-level content validity index (I-CVI) and the scale-level content validity index (S-CVI). Spearman's rank correlation coefficient (r_s) was used to demonstrate construct validity. Correlation coefficients of >0.50, 0.35-0.50 and <0.35 was considered strong, moderate and weak correlations respectively. Internal consistency was measured by Cronbach's alpha (a). An a of 0.7 or higher was acceptable to us. Test-retest reliability was assessed by

demonstrating the correlation between the test responses and retest responses using intraclass correlation coefficient (r). An r of 0.7 or higher indicated good test-retest reliability.

Results:

During pretesting, several Bengali words were also put in front of the respondents for their understandability, chosen responses and any alternate suggestions. Summary of the understandability of the items has been represented in table 1.

During probing, items 1, 2 and 4 were understood by all (100% of the respondents). The expert committee decided to keep two Bangla options for the word "Morning stiffness" in the item 3 of English questionnaire and developed two options [3(1) and 3(2)] for pretesting. During pretesting, the first [3(1)] and second [3(2)] options for item 3 in the prefinal version were understood by 84% and 97% of the participants. Although very high percentages of the participants understood both the options, for the adapted version the expert committee decided to keep both the Bengali options besides one another in a single sentence so that all the target population could be able to understand the item. Thus, the items best understood and best chosen were compiled to produce the adapted version.

Content validity of the adapted version was assessed by four rheumatologists. Item-level content validity index (I-CVI) was found to be 1 (Table-II) for each item and scale-level content validity index (S-CVI) was therefore 1 by the averaging calculation method. Table-I depicts the rating of each item by each of the experts, corresponding I-CVIs and the S-CVI.

ASDAS-ESR showed strong correlation (Spearman's correlation coefficient >0.5) with BASDAI, ESR, MASES and physician global assessment of disease activity, but weak correlation with BASMI (table-III). ASDAS-CRP also showed strong correlation with BASDAI, ESR, MASES and physician global assessment of disease activity, but moderate correlation with BASMI (table-IV).

Rating by each expert (rheumatologist) for all 4 questions: 1= not relevant, 2= somewhat relevant, 3= quite relevant, 4= highly relevant; S-CVI/Ave** = (1.0+1.0+1.0+1.0)/4=1.0; *I-CVI, item-level content validity index; I-CVI is the proportion of expert giving a rating of either 3 or 4; **S-CVI / Ave, scale-level content validity index, averaging calculation method; Proportion relevant, proportion of questions that are quite or highly relevant; Excellent content validity means S-CVI/Ave \geq 0.9; Item, individual question.

Table-I: Understandability and chosen response in pretesting of items

Item	Understandable (n)	Understandable (%)	Not Understandable (n)	Understandable (%)	More suitable (n)	Both suitable (n, %)
Item-1	38	100	00	00	-	-
Item-2	38	100	00	00	-	-
Item-3 (1)	32	84	6	16	10, 26	2, 5
Item-3 (2)	36	97	2	3	19, 50	
Item-4	38	100	00	00	00	-

n, number of patients; %, Percentage of patients; Item, individual question

Table-II: Content validity of the Adapted Bangla Version of the ASDAS

Item	Rating by Expert				I-CVI*
	1	2	3	4	
Item-1	4	4	4	4	1.0
Item-2	4	4	4	3	1.0
Item-3	3	4	3	4	1.0
Item-4	4	4	4	4	1.0
Proportion Relevant [^]	4/4=1.0	4/4=1.0	4/4=1.0	4/4=1.0	Mean I-CVI=1.0

Table-III: Spearman rank correlation of ASDAS-ESR with BASDAI, ESR, CRP, PhGA, MASES and BASMI

ASDAS-ESR 1 with	Correlation coefficient (r)	p-value
ASDAS-ESR 2	0.980	<0.001
BASDAI	0.722	<0.001
ESR	0.827	<0.001
CRP	0.662	<0.001
PGA	0.865	<0.001
MASES	0.599	<0.001
BASMI	0.294	0.001

Table-IV: Spearman rank correlation of ASDAS-CRP with BASDAI, ESR, CRP, PhGA, MASES and BASMI

ASDAS-CRP 1 with	Correlation coefficient	p-value
ASDAS-CRP 2	0.980	<0.001
BASDAI	0.718	<0.001
ESR	0.688	<0.001
CRP	0.788	<0.001
PGA	0.816	<0.001
MASES	0.564	<0.001
BASMI	0.362	<0.001

ASDAS, Ankylosing spondylitis disease activity score; ASDAS-ESR 1, ASDAS-ESR calculated at first visit of patient; ASDAS-ESR 2, ASDAS-ESR calculated at second visit of patient; ESR, Erythrocyte sedimentation rate; CRP, C-reactive protein; PGA, Physician global assessment of disease activity; MASES, Maastricht enthesitis score; BASMI, Bath ankylosing spondylitis meterological index; r, Spearman rank correlation coefficient; p-value <0.05 means significant.

Discussion:

The ASDAS is one of the most commonly used assessment and monitoring tools for the patients with axSpA. The ASAS has recommended BASDAI for measuring disease activity in patients with ankylosing spondylitis in 1994. But BASDAI does not weigh individual clinical manifestations, as the variables are simply summed, without taking the relative importance into account. Inflammatory markers are ignored for

assessing disease activity in BASDAI. Therefore, ASDAS, as a new composite assessment tool for disease activity and cut-off values for disease severity was developed by the ASAS group of experts in 2009 with the aim to improve the construct validity of disease activity measures in AS.

ASDAS is composed of four questions. Three of the questions have been derived from BASDAI. The fourth question stands for patient's global assessment for disease activity. Although both BASDAI and ASDAS have been extensively validated in different countries, none of them were validated in our country. Therefore, with these four questions, the 'ASDAS questionnaire' was collected together and was regarded as an original English questionnaire for translation with cultural adaptation into Bangla and its validation in assessing diseases activity in patients with axSpA in our country.

In our study, we enrolled 120 patients with axSpA including AS and nr-axSpA according to the modified New York criteria for AS²⁹ and the ASAS criteria for axSpA³⁰. Inflammatory back pain which was an essential feature required for modified New York criteria for AS was determined according to the ASAS expert criteria for inflammatory back pain³¹. Radiographic sacroiliitis was determined according to New York grading of radiographic sacroiliitis³².

During cross-cultural adaptation of the original ASDAS English questionnaire we concentrated mainly on semantic and conceptual forms of equivalence. As the items in the original English questionnaire do not represent any idiom or experience that does not prevail or is uncommon in the Bangladeshi culture, no modification was required to achieve conceptual and experiential forms of equivalence. For the purpose of facilitation of probing, two translations of item 3 were retained as an alternative to each other in the prefinal version approved by the expert committee. The expert committee again reviewed after pretesting among thirty eight patients with axSpA and although both translations were understood by a high percentage of respondents, the committee decided to keep two alternate words in a single sentence so that it could be understood by all. Understandability and chosen responses were also tested two alternate Bangla translations of a word in item 1 and 4. The best understood (100%) and the best chosen items by the participants were chosen from the prefinal version to constitute the adapted version.

The adapted version of the scale was found to have acceptable content validity in the form of ICVI (=1), S-CVI (=1). At the first visit, ASDAS questionnaire was

applied to the patients to record the individual scores of four questions by patient himself/herself (self administered) and the investigator calculated the total score (ASDAS-ESR 1 and ASDAS-CRP 1) by applying the ASDAS calculator and using the values of individual questions and acute phase reactants (ESR and CRP). The patients' BASDAI score and BASMI scores were also measured at the first visit. Retest of the patient was conducted after seven days. The patients were instructed to come back for second visit with ESR and CRP values measured again seven days later. In the retest, individual item score and total ASDAS scores (ASDAS-ESR 2 and ASDAS-CRP 2) was determined.

Statistical analysis showed a strong correlation of ASDAS-ESR 1 with ASDAS-ESR 2 [$r_s=0.980$, $p<0.001$], BASDAI [$r_s=0.722$, $p<0.001$], ESR [$r_s=0.827$, $p<0.001$], CRP [$r_s=0.662$, $p<0.001$], PGA [$r_s=0.865$, $p<0.001$] and MASES [$r_s=0.599$, $p<0.001$] but poor correlation with BASMI [$r_s=0.294$, $p=0.001$]. Similarly, ASDAS-CRP 1 showed strong correlation with ASDAS-CRP 2 [$r_s=0.980$, $p<0.001$], BASDAI [$r_s=0.718$, $p<0.001$], ESR [$r_s=0.688$, $p<0.001$], CRP [$r_s=0.788$, $p<0.001$], PGA [$r_s=0.816$, $p<0.001$] and MASES [$r_s=0.564$, $p<0.001$], and poor but significant correlation with BASMI [$r_s=0.362$, $p<0.001$]. Strong correlation of ASDAS score with ESR, CRP, PGA and MASES indicates that value of these clinical and laboratory parameters correlate with disease activity (inflammation). On the other hand, BASMI may not always correlate with disease activity. Not only generalized inflammation, but also previous damage (without current inflammation) also affect BASMI.

A study in China, aim of which was to validate the ASDAS, showed high correlation of the ASDAS with ESR, CRP and PGA. ASDAS correlated well with patient global score (r ranged from 0.65 to 0.72), ESR (r ranged from 0.57 to 0.81) and CRP (r ranged from 0.51 to 0.70) both at baseline and in the changes following therapy³³. Our study revealed comparable good correlation of the ASDAS with ESR and CRP and PGA, and better correlation with PGA.

The Bengali version of the ASDAS showed excellent internal consistency (Cronbach's $\alpha=0.703$). The test-retest reliability was also excellent (ICC=0.98).

Conclusion:

The adapted Bengali version of the ASDAS demonstrates acceptable psychometric properties, that is, content validity, construct validity, internal consistency and test-retest reliability in Bangladeshi adult patients with axial spondyloarthritis.

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