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Cross-cultural adaptation and validation of the Bangla version of the Psoriasis Disability Index

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Abstract

Background: The Psoriasis Disability Index (PDI) is used for the quality-of-life assessment of psoriasis patients. However, a locally adapted Bangla version of the PDI (*B*-PDI) instrument is currently lacking in Bangladesh. To translate the instrument, adapt, and validate it among psoriatic patients of the country was the objective of the study.

Methods: Translation, adaptation, and back-to-back translation to Bangla were made from the original English PDI. The final Bangla instrument was applied among 83 psoriasis patients twice at 10 days intervals. The psychometric property of the instrument was evaluated. Item-level content-validity index (CVI) was used to check the content validity of the instrument. Convergent validity was tested by comparing the *B*-PDI with the validated Bangla version of Short Form 36(SF-36) and the Psoriasis Area Disability Index (PASI) score. Necessary testing was used to assess internal consistency and test-retest reliability.

Result: The B-PDI was well-accepted by the patients. It showed good internal consistency (Cronbach's alpha = 0.76) and very high test-retest reliability (Pearson $r = 0.92$, $p < 0.001$). The scale demonstrated excellent content validity (Content Valid Index [CVI] = 1). The instrument had satisfactory convergent validity with four components of SF-36. Pearson correlation coefficient for physical, emotional, social, and pain domains of SF-36 was 0.663, 0.644, 0.808, and 0.862, respectively, and for PASI score was 0.812. Factor exploration using Principal Component Analysis revealed four factors reflecting working disabilities, social, and hygienic disabilities, lifestyle difficulties, and leisure-associated disabilities.

Conclusion: This study supports the reliability and validity of the *B*-PDI instrument for measuring health-related quality-of-life for Bangla-speaking psoriasis patients.

Keywords

Psoriasis, disability, quality of life, PDI, Bangladesh

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Introduction

Psoriasis is a non-contagious chronic inflammatory dermatological distressing problem characterized by recurrent episodes of red and scaly skin plaques. Usually the plaques are sharply demarcated from adjacent normal skin.[1] Its prevalence varies from 0% to 2.1% in children and 0.91%–8.5% in adults worldwide.[2]

Living with a chronic skin disease like psoriasis is a difficult and demoralizing experience for an individual. It affects patients' daily living and functioning,[3] feelings, behavior, and self-esteem.[4] They continuously endure pain, and discomfort. Additionally, psychological distress and social stigmatization enhance the burden of the disease,[4] As a result, patients with psoriasis feel their general well-being and quality of life markedly lower compared with general

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population.[5] On the other hand, they suffer from disability and sufferings like patients with other chronic diseases.[6]

Measurement of clinical severity using scales like Psoriasis Area and Severity Index (PASI)[7] are often not sufficient to capture the overall disability of patients. To estimate pay-off of psoriasis on patients' day-to-day activities, self-perception, social life,[8] and most importantly health-related quality of life, it is essential to assess patients comprehensively. Evidence suggests that HRQOL assessment can provide valuable information that helps to make a clinical decision and select suitable health care programs.[9] Several tools have been used to assess Quality of Life (QOL) in psoriasis patients. These measures may be categorized as psoriasis-specific, skin-specific, generic QOL measures, and "mixed" measures. Psoriasis-specific measures are the most sensitive. However, the more general measures facilitate comparisons across diseases.[10]

The Psoriasis Disability Index (PDI) was the first psoriasis-specific QOL measuring tool and has been widely used since its origin. It was originally described in 1985[11,12] and revised in 1990.[11,13] The questionnaire, designed for use in adults, is equally effective in interventions, treatments, and in health service research.[4] This 15-item scale was specifically prepared for self-reported disability in areas of life including day-to-day activities, employment, interpersonal relationships, leisure time, and overall treatment effects.[14] PDI is a well-accepted tool used worldwide in different settings for almost 20 years[15] and has been translated into multiple languages.[12] The effect of dermatological diseases on patients' quality of life is a minimally addressed issue in Bangladesh and data on population level are also limited. To date, PDI had not been formally translated into Bangla and validated in Bangladeshi patients with psoriasis.[16] Hence, this was the aim of this study.

Methods

Permission for translation

Formal permission was sought from the originator for the translation of the instrument (PDI) to Bangla and test it among Bangla-speaking psoriatic patients of Bangladesh before the study. Then we used psychometric methods to evaluate the reliability and validity of the Bangla version of PDI in patients with psoriasis.

Original Questionnaire

The Psoriasis Disability Index (PDI) was developed by Finlay and Coles to assess the functional lifestyle disabilities of patients with psoriasis.[11] The scale consists of 15 questions or items. These items are further stratified into five subscales: daily activities, work, personal relations, leisure, and treatment. All items record responses on a four-point scale, including the following responses – "not at all," "a little," "a lot," and "very much." These are scored as 0, 1, 2, and 3, respectively. A total score (range: 0–45) is calculated by adding individual item scores. A higher score indicates greater limitations experienced because of psoriasis.

Translation, cross-cultural adaptation, and validation of English PDI into Bangla (Bangla-PDI)

The translation and cross-cultural adaptation procedure for self-report measures laid out by Beaton et al.[17] were followed to translate PDI in Bangla. The procedure was done in five stages. The forward translation of English PDI into Bangla was carried out by two translators whose mother tongue was Bangla. One translator with a medical background was aware of the concepts being translated, and another translator without medical background was neither aware nor informed of the concepts being measured. Thus, two initial Bangla version was produced. In the second stage, a synthesized version was created from these two translations. This common version was then back-translated into English by two translators with good command of the English language, both of whom were blind to the original version. They were unaware and uninformed of the concepts being measured. Thereby, any chance of information bias and unexpected transliteration of items was avoided.

An expert committee executed and directed the whole process. The committee included methodologists, language professionals, guides, observers, and translators (forward and backward). They reviewed and compared all the translations and the original PDI questionnaire to achieve equivalence between the source and the target version. They verified semantic, idiomatic, experiential, and conceptual equivalence between the English and Bangla versions. A consensus was reached on the items, and when necessary, the translation and back-translation process was repeated to clarify how another wording of an item can work. Following this way, the pre-final Bangla version of PDI was developed. For words having many Bangla meanings, the expert committee chose the meaning which was very appropriate, easily understandable, and culturally acceptable.

The translation was straightforward for most of the items except for several items where the wording was changed upon discussion by the expert committee based on the cultural context of Bangladesh. The original word "hairdresser" in item 4 was replaced by "saloon" for conceptual equivalence. The term "life partner" was used instead of "partner" in item no 10. As no "communal bathing" exists in Bangladesh, the combination of the three terms "open pond/washroom/public toilet" was used in item no 13.

Field testing

In this step, two successive tests were performed: comprehensibility testing in children and testing of the pre-final

Bangla version in adults. A general recommendation for questionnaires or tools is that they should be understood by 12-year-old children (roughly grade 6 level of reading).[17] Hence the questionnaire was administered to 12-year-old children of classes five to seven from different socio-cultural statuses. The same pre-final Bangla version was then used in 30 adult (>18 years) psoriatic patients from the Department of Dermatology & Venereology at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh. Based on the comprehensibility of both children and adults during pre-testing, four words were changed with a more meaningful synonym in the Bangla version. However, the combination of words used in item no 13 instead of "communal bathing" didn't appear to reduce ambiguity. After much discussion, the committee decided to use the phrase "showering in ponds/open space" to maintain experiential equivalence.

Psychometric evaluation of the Bangla PDI (B-PDI)

Patients and data collection

A total of 83 psoriasis patients were included. As there is no general agreement about the size of the sample required for validation studies, and a high proportion (almost one-sixth) reported factor analyses based on subject-to-item ratios of only 2:1 or less.[18,19] The sample size for this study was determined based on an item-sample ratio of 1:5. The total item number of PDI is 15. Hence, an initial 75 samples were calculated, which considering a 10% drop-out rate, was raised to a final required sample of 83. Psoriasis cases aged >18 years, confirmed clinically and/or by histopathology from inpatients and outpatients of the Department of Dermatology and Venereology at BSMMU were consecutively approached for inclusion. Patients who had other dermatological, systemic, and psychological diseases and who were unwilling to provide informed written consent were excluded from the study.

After an initial consultation with the prescribing doctor, patients were interviewed at their convenient time, maintaining proper privacy. Before proceedings for actual data collection researcher explained the whole procedure to the patients and offered informed written consent for the study. At first, the consenting patients were asked about their demographic profiles using a semi-structured questionnaire. Then the Psoriasis Area Severity Index (PASI) tool[7] was applied to assess the clinical severity of the patients. After that, the final Bangla version of the psoriasis disability index (PDI) and four subscales of the Bangla version[20] of Short Form 36 (SF-36) were applied. The SF-36 tool is a generic QoL assessment tool widely used for monitoring health status and outcomes in patients.[21] The 36 questions on the tools are meant to assess health across eight domains, including physical functioning, physical role, pain, general health, vitality, social functioning, emotional role, and mental health. Four domains (physical, bodily pain, social functioning, and emotional) were explored for the purpose of this study. It took approximately 20–25 min to collect data from each participant of the study.

Test-retest reliability

All the participants were requested to come 10 days after the first interview. The Bangla version of PDI was re-applied to all the participants at follow-up, and then the correlation between test and retest responses was analyzed.

Ethics statement

The study protocol was approved by the Institutional Review Board (IRB) of Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh (Memo no BSMMU/2017/13326). All the procedures were conducted following guidelines laid out by the Declarations of Helsinki. Informed written consent was ensured before inclusion.

Statistical analysis

Content validity was assessed by the item-level content validity index (CVI) and was assessed by three dermatologists. Each item were rated by the experts as either 1 (agreed) or 0 (disagreed) based on the question if the particular item is essential for the assessment of psoriasis associated disability. Content Validity Ratio (CVR) was calculated using the following formula $\frac{n_e - \frac{N}{2}}{\frac{N}{2}}$, where n_e = the number of subject matter experts scoring 1, and N = the total number of experts (dermatologists) in the panel. Finally, the CVI of the overall scale was calculated by dividing total score with the number of items in the scale.[22] Convergent validity (criterion validity) was assessed by comparing the Bangla PDI with SF-36 Bangla. The correlation was assessed and expressed as Pearson's correlation coefficient (r). The rule of thumb for interpreting the size of a correlation coefficient was considered as 0.90–1.00 (−0.90 to −1.00): very high positive (negative) correlation; 0.70–0.90 (−0.70 to −0.90) High positive (negative) correlation; 0.50–0.70 (−0.50 to −0.70): Moderate positive(negative) correlation; 0.30–0.50 (−0.30 to −0.50); Low positive (negative) correlation; 0.00–0.30 (0.00 to −0.30): Negligible correlation.[23] The criterion validity was also assessed by comparing it with the PASI score as there is no gold standard test available in Bangla. It was compared using both Pearson's and Spearman's correlations. Correlation is an effect size, and so we can verbally describe the strength of the correlation using the following guide for the absolute value of: 0.00–0.19 "very weak"; 0.20–0.39

Table 1. Demographic characteristics of the respondents ($n = 83$).

Variable	*n* (%)
Age (years), mean (SD)	37.25 (15.48)
Age in years	
18–25	27 (32.53)
26–35	16 (19.28)
36–45	17 (20.48)
46–55	11 (13.25)
56–65	7 (8.43)
66–75	5 (6.02)
Gender	
Male	46 (55.42)
Female	37 (44.57)
Occupation	
Housewife	25 (30.12)
Service	23 (27.71)
Student	12 (14.45)
Others	23 (27.71)
Marital status	
Married	74 (89.15)
Unmarried	9 (10.84)
Level of education	
Primary	32 (38.55)
Secondary	27 (32.53)
Higher secondary	11 (13.2)
Bachelor/Masters	13 (15.66)

"weak"; 0.40–0.59 "moderate"; 0.60–0.79 "strong"; 0.80–1.00 "very strong."[23] Individual-item scores of the Bangla version of PDI were utilized to calculate the internal consistency. The recommended level of Cronbach's alpha is <0.50 "unacceptable," 0.50–0.59 "poor," 0.60–0.69 "questionable," 0.70–0.79 "acceptable," 0.80–0.89 "good," and >0.90 "excellent."[18] The test-retest reliability was assessed using Pearson's correlation. The strength of the reliability coefficient was considered as follows −0.10 "virtually none," 0.11–0.40 "slight," 0.41–0.60 "fair," 0.61–0.80 "moderate" and 0.81–1.0 "substantial."[18] Categorical data were expressed as frequency (percentage) and continuous data as mean (standard deviation). All analysis was carried out in statistical package SPSS version 16. A *p*-value of <0.05 was considered statistically significant.

Results

Sociodemographic characteristics of the participants

A total of 83 adult psoriasis patients were enrolled in the study. The mean age of the respondents was 37.25 (15.48) years (SD), and the majority of patients were in the age group 18–25 years (32.5%). Of all, 55.42% of patients were male. The majority of patients were housewives (27.72%), married (89.15%), and educated up to the primary level (38.5%). Table 1 showed the sociodemographic characteristics of the study population.

Reliability statistics

The *B*-PDI showed very good reliability (internal consistency) statistics (Cronbach's Alpha (α): 0.76) in our sample. The mean *B*-PDI score of individual items ranged from 0.17 to 1.40. The highest score was 1.40 for item-13 ("Have you been unable to use, criticized, or stopped from using communal bathing or changing facilities?"), and the lowest score was 0.17 for item-14 ("Has your psoriasis resulted in you smoking or drinking alcohol more than you would do normally?") Item-total correlation of individual items ranged from 0.22 to 0.63. The highest correlation coefficient was 0.63 for item-7 ("How much has your psoriasis prevented you from doing things at work or school over the last four weeks/How much has your psoriasis altered the way in which you carry out your normal daily act ivies over the last four weeks?"), and the lowest score was 0.22 for item-4 (How much of a problem has your psoriasis been at hairdressers?). The test-retest reliability measured by Pearson correlation showed a very high positive correlation between test and retest scores ($r = 0.92$, $p < 0.001$) (Table 2).

Content validity

Content validity of the adapted version was assessed using the Content Validity Index (CVI) by three dermatologists and found it excellent. The average content validity ratio (CVR) of each item in the *B*-PDI was 1 and the average content validity index (CVI) was also 1 indicating an excellent content validity of the scale (Table 3).

Convergent validity

The distribution of correlation coefficient between *B*-PDI and four domains of SF-36 ranged from 0.64 to 0.86. The highest score was 0.86 for the pain component and the lowest score was 0.64 for emotional domain of the tool. All the components of SF-36 showed moderate to strong correlation except the emotional domain. The latter revealed a moderate correlation. PASI score showed a high positive correlation (convergent validity) with PDI ($r = 0.812$, $p < 0.001$) (Table 4).

Dimensions of the Bangla version of PDI (B-PDI)

Communalities of factors in the *B*-PDI scales were extracted using principal component analysis (Table 5). The extracted communalities represent the proportion of each variable's variance that can be explained by the retained factors. All components of Bangla PDI had a high value indicating a

Table 2. Descriptive statistics of Bangla PDI scores ($n = 83$).

Item statistics	Mean	Std. deviation	Corrected Item-total correlation*	Test-retest reliability*	Cronbach's alpha
Q1	1.27	0.78	0.55		
Q2	1.24	2.12	0.27		
Q3	0.52	0.62	0.43		
Q4	0.64	0.73	0.22		
Q5	0.25	0.47	0.32		
Q6	1.28	0.75	0.57		
Q7	1.13	0.78	0.63		
Q8	0.47	0.64	0.36	0.92	0.76
Q9	0.48	1.40	0.35		
Q10	0.69	0.68	0.48		
Q11	1.23	1.36	0.23		
Q12	0.27	0.55	0.35		
Q13	1.40	2.52	0.28		
Q14	0.17	0.42	0.28		
Q15	0.31	0.57	0.54		

*As assessed by Pearson correlation.

Table 3. Content Validity Index (CVI) of the adapted Bangla version of PDI.

Domain	Item	Score by			CVR*
		Expert 1	Expert 2	Expert 3	
Daily activities	Item 1	1	1	1	1
	Item 2	1	1	1	1
	Item 3	1	1	1	1
	Item 4	1	1	1	1
	Item 5	1	1	1	1
	Item 6	1	1	1	1
Work or school	Item 7	1	1	1	1
	Item 8	1	1	1	1
Personal relationship	Item 9	1	1	1	1
	Item 10	1	1	1	1
Leisure	Item 11	1	1	1	1
	Item 12	1	1	1	1
	Item 13	1	1	1	1
	Item 14	1	1	1	1
Treatment	Item 15	1	1	1	1
				CVI=**	1

CVI = Content Validity Index; CVR: Content Validity Ratio.

$$\frac{n_e - \frac{N}{2}}{\frac{N}{2}}$$

*CVR is calculated using the following formula , where n_e = the number of subject matter experts scoring 1, and N = the total number of experts (Dermatologist) in the panel; **CVI is calculated by dividing total score by the number of items in the scale.

good representation of each component in the factor space. All of the 15 items of B-PDI was retained in the exploratory factor analysis using the criterion of highest loading (i.e. above 0.40 and at least 0.10 stronger than the next). Total four factors were derived in varimax rotation. These may reflect working disabilities, social, and hygienic disabilities, lifestyle difficulties, and leisure disabilities.

Discussion

Participants of this study were, on average, 37.25 years old, which is similar to that found in Turkey,[24] China,[25] and Egypt,[26] But studies from West Bengal[16] and Norway[27] reported a high mean age of 43.8–46.5 years, respectively. However, the proportion of male psoriatic patients was

Table 4. Convergent validity between PDI Bangla and four components of SF-36 Bangla scale, and PASI scale.

Correlations*	PDI Bangla	Components of SF-36 Bangla Scale			
		Physical	Emotional	Social	Pain
Components of SF-36 Bangla Scale					
PDI Bangla	1				
Physical	0.663**	1			
Emotional	0.644**	0.807**	1		
Social	0.808**	0.748**	0.667**	1	
Pain	0.862**	0.676**	0.600**	0.798**	1
PASI	0.812**	–	–	–	–

PASI: Psoriasis area severity index; PDI: Psoriasis Disability Index; SF-36: Short form 36.
*As assessed by Pearson's correlation.
**Correlation is significant at the <0.001 level (two-tailed).

Table 5. Principle component analysis showing distribution rotated component matrix and communalities of Bangla PDI ($n = 83$).

Items	Description	Communalities (Extraction)	Rotated component matrix			
			1	2	3	4
Q1	House/garden work	0.58	**0.68**	0.27	0.12	0.16
Q2	Different clothes	0.57	0.13	**0.59**	−0.06	−0.05
Q3	Change/wash clothes	0.66	0.29	**0.73**	−0.15	0.15
Q4	Hairdresser problem	0.64	0.04	−0.05	0.36	**0.71**
Q5	More frequent baths	0.73	−0.12	**0.74**	−0.06	0.41
Q6	More time off from work	0.78	**0.86**	0.19	0.08	0.04
Q7	Prevented from doing work	0.83	**0.88**	0.23	0.04	0.03
Q8	Career affected	0.55	**0.65**	−0.09	0.10	0.33
Q9	Sex difficulties	0.62	0.13	0.10	−0.17	**0.40**
Q10	Problems with social relations	0.54	0.44	**0.48**	0.09	0.07
Q11	Social activity affected	0.66	0.24	**0.35**	0.12	−0.25
Q12	Sport activity affected	0.65	0.22	0.15	0.02	**0.76**
Q13	Problems in communal changing	0.76	0.24	0.05	**0.84**	−0.03
Q14	More smoking/ drinking	0.70	0.04	0.01	**0.83**	0.06
Q15	Treatment related burden	0.71	0.14	**0.79**	0.26	0.05

Extraction Method: Principal Component Analysis; Rotation Method: Varimax with Kaiser normalization. Bold values in the rotated component matrix represent the highest loadings for each variable.

higher than females in all of these studies, including the present one. Sex-based differences in psoriasis are age-dependent,[28] and the overall prevalence appears to be equal in pooled estimates.[29] Therefore, the high male prevalence of these studies is probably the result of a higher consultation of males in the hospitals.

The B-PDI instrument showed a good internal consistency as revealed by Cronbach's Alpha of 0.70. Similar results were observed in other language versions of the instrument.[16,25,26,30,31]

The test-retest reliability showed a very strong positive correlation between the scores at two points separated in

time. The test and retest intervals varied across different studies conducted around the world. It primarily depended on the researchers' choice and study feasibility. But the overall correlation coefficient found in Turkey ($r = 0.854$)[24] is concordant with that of our findings.

A systematic assessment of face validity was carried out during the translation and back translation process as well as at the time of the interview by assessment of responses. The expert committee assessed every item of the translated Bangla version by comparing the translations and back translations. Content validity was also systematically assessed and maintained during the translations and back translations as well as by the expert committee. Moreover, item wise content validity index was assessed and found adequate to retain the item in the construct.

The mean PDI Bangla score of individual items showed a wider range (0.17–1.40) than that of the West Bengal version (1.1–1.9).[16] Similar to their observation, the mean score was lowest in item 14 (increased smoking/alcohol drinking) in the current study, reflecting the religious and traditional practices of lower alcohol consumption and alcohol intake in these regions.

The Bangla PDI scale developed in our project showed a good convergent validity with both the PASI score and pain domain of SF-36. But a moderate convergence was noted for the emotional domain of SF-36. In the Arabian version, a positive linear association between PDI and PASI[26] was reported, similar to this study. However, the association could be explained mainly by the involvement of visible areas rather than the covered areas of skin as explored in the Persian version.[30] The Chinese study[25] found that PDI and four subscales of the SF-36 had moderate to good correlations. In the Norwegian version of PDI.[27] similar to our result, the bodily pain health scales showed the highest correlation with PDI.

The observed measurements' factorial structure was explored using principal component analysis with varimax rotation. Based on the sample size of this study, the Kaiser-Meyer-Olkin (KMO) Measure of sampling adequacy and Barlett's Test of Sphericity were applied to check the fitness of data for factor analysis. The tests revealed a sampling adequacy of 0.72 (a value of ≥ 0.5 indicates good sampling adequacy)[18] and a significant level of sphericity ($p < 0.001$). The estimates of variances in each variable as determined by the factor solution are expressed as extraction communalities. The extraction communalities of PDI Bangla in the current study revealed a good value across the items as none of the variables had a value below 0.5. This means all the items fitted well in the solution.

The factors loadings in varimax rotation of PDI Bangla ranged from 0.40 to 0.88. Four components were extracted, proving the multidimensionality of the translated scale. These components reflected workplace disabilities, social, and hygienic disabilities, personal disabilities, and recreational disabilities. In comparison, the factor analysis in the West Bengal version of PDI[16] revealed three factors, namely, social activities, concern, and personal activities.

The item groupings in the PDI scale were based on common sense during its development and no factor analysis was carried out initially. Later on Kent and al Abadie[32] used the scale among a sample of 340 patients with psoriasis and other skin diseases and performed a factor analysis on the 15-item version of it. Other skin diseases were included because some items applied to other skin patient groups in addition to psoriasis. Their analysis revealed two subscales—most aspects of everyday activities were included in one and the other subscale was related to specific public situations such as the use of communal facilities.[32] The differences in results from the present factor analyses and the study by Kent and Al-Abadie could be due to differences in sample characteristics, methods of investigation of the components, and the cultural context of the population studied. In the Norwegian version, results from both the factor analyses and the discriminative analyses showed that the PDI is not a unidimensional instrument.[27] Similarly the scale was also found to be multidimensional in a US study.[33]

The present study was limited in that the study participants were included from a tertiary care hospital which might render it non-representing of patients in the community. But our study produced a reliable and valid Bangla translation of the PDI, which could be used in future studies for disability assessment in Bangla-speaking psoriasis patients.

Conclusion

The Bangla version of the Psoriasis Disability Index was developed following standard procedure. It was found to be a reliable and valid measure for evaluating the quality of life of Bangladeshi psoriasis patients, which demonstrated good internal consistency and significant test-retest reliability. All the validity measuring parameters satisfied the criteria of a valid tool for the translated instrument.

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Authors' contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethics approval and consent to participate

Approval of the study protocol was obtained from the Institutional Review Board/Ethical Clearance Committee of Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh prior to the commencement of the study (Memo no: BSMMU/2017/13326). Informed written consent was obtained from each patient before recruitment.

Consent for publication

All participants gave consent for publication.

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Availability of data and material

Patient-level data will be available on request from the corresponding author.

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