ABSTRACT

Background: The Uterine Fibroids Symptom and Health-related Quality of Life (UFSQOL) is a validated questionnaire assessing symptom severity and Health-Related Quality of Life (HRQL) in patients with uterine fibroids. The English version contains 37 items measuring 7 components—symptom severity, concern, activities, energy/mood, control, self-consciousness, and sexual function. To date, no validated Bengali version of the questionnaire is available. We aimed to translate the UFSQOL into Bengali and validate the same.

Methods: The UFSQOL-Bengali version (UFSQOL-B) was produced by standardized forward-backward translations. A cross-sectional, multi-center, observational study was conducted to gather responses by convenience sampling. Reliability was tested using internal consistency and test-retest reliability analyses, while construct validity by exploratory factor analysis (EFA; n = 120) using principal component analysis (PCA; varimax rotation). Subsequently, confirmatory factor analysis (CFA; n = 120) was performed to verify the a priori scales by the goodness-of-fit model.

Results: Both the internal consistency (Cronbach’s α) and the intra-class correlation (ICC) coefficient were 0.92. All the items loaded above the pre-specified value of 0.4. The factor analyses using varimax identified 10 components (activities, energy and control, concern about clothing, mood, sexual function, self-consciousness, associated symptoms, heavy bleeding, cycle disturbance, and concern about flooding); explaining 70.2% of the variation. The Kaiser-Meyer-Olkin (KMO) was 0.801 and Bartlett’s test of sphericity was P < 0.001. The goodness-of-fit of CFA model was mediocre. Therefore, the final version consisted of 37 items, framed within 10 components.

Conclusion: The UFSQOL-B was a valid and reliable questionnaire but measured different dimensions from the English version.

Key words: Bengali language; confirmatory factor analysis; Principal component analysis; reliability; Uterine Fibroids Symptom and Health-related Quality of Life; validity.

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Introduction

Uterine fibroids are the most common, benign, pelvic tumors in women.[3] These are monoclonal tumors of the smooth muscle cells and made up of extracellular matrix proteins collagen and elastin,[2] and are identified as the most common diagnosis associated with a hysterectomy in the United States.[3] The majority of women with uterine fibroids remain asymptomatic; consequently getting less clinical attention and fibroids often remain undiagnosed.[4] However, symptomatic women typically complain about heavy and prolonged bleeding, dyspareunia, non-cyclic pelvic pain, and pressure symptoms,[5,6] thus having serious impacts on Health-Related Quality of Life (HRQL). In recent individual cross-sectional surveys among the Canadian, US, French, and Spanish women, HRQL was significantly impacted by fibroid-related symptoms and thus resulted in significantly greater menstrual duration, more healthcare visits, greater use of prescription analgesics, more direct and indirect costs and loss of days at workplace.[7-12] Similar results were obtained from a survey a decade back from five European countries.[13,14]

The Uterine Fibroids Symptom and Health-related Quality of Life (UFSQOL) is a disease-specific questionnaire that assesses symptom severity and HRQL in patients suffering from uterine fibroids.[15] It consists of an 8-item symptom severity scale and 29 HRQOL items comprising 6 domains: Concern, Activities, Energy/Mood, Control, Self-consciousness, and Sexual Function. All items are scored on a 5-point Likert scale, ranging from “not at all” to “a very great deal” for symptom severity items and “none of the time” to “all of the time” for the HRQL items. Symptom severity and HRQL subscale scores are summed and transformed into a 0–100 point scale. The Symptom Severity scale and HRQL subscale scores are inversely related with higher Symptom Severity scores indicating greater symptoms while higher HRQL subscale scores indicate better HRQL. UFSQOL was further validated[16] and a modified tool was developed, namely UFSQOL hysterectomy questionnaire.[17] Valid translated versions of UFSQOL are available in Chinese[18] and Brazilian Portuguese,[19,20] but not in Bengali. We aimed to evaluate whether the Bengali version of the UFSQOL questionnaire is a psychometrically sound tool to measure the construct and to examine its cross-cultural adaptation considering linguistic equivalence.

Methods

Study design: This cross-sectional, observational, non-interventional, multi-center survey consisted of standardized translation, face validation by pilot testing, and field testing and psychometric evaluation of the UFSQOL-B version.

Study setting: It was conducted for 8 months between mid-April 2018 and mid-November 2018 in three homeopathy hospital settings in West Bengal, namely, (1) National Institute of Homoeopathy (NIH), Kolkata, under Ministry of AYUSH, Govt. of India; (2) The Calcutta Homoeopathic Medical College and Hospital (CHMCH), Kolkata, under the Govt. of West Bengal, India; and (3) Mahesh Bhattacharyya Homoeopathic Medical College and Hospital (MBHMCH), Howrah, under the Govt. of West Bengal, India. Ethics approvals for this study were obtained from the Institutional Ethics Committees of three respective institutions prior to initiation. NIH: 5-23/NH/PG/Ethical Comm/2009/Vol. 5/2684(A/S), dated 28-03-2018; CHMCH: CHMCH/IEC/11/2018, dated 05-01-2018; and MBHMCH: 1252/MBHMCH/CH/PRIN/ADM/17, dated 26-10-17.

Questionnaire translation stages

1. Forward translation: An expert committee was constructed, consisting of research methodologists, gynecologists, translators, and linguistic experts. First, two independent native Bengali speakers translated the English version of UFSQOL into the target language Bengali (T1 and T2). One of the translators was a gynecologist and therefore aware of the concepts that were being measured with the UFSQOL and the other translator was a language specialist with no medical background.

2. Synthesis of T1 and T2 into T1,2: The two translators then agree upon a new consensus version of the translation (T1,2) that was verified by the expert committee supervising the project.

3. Back translation: For the back translation from Bengali into English, two English language translators (BT1 and BT2, one gynecologist and one linguistic expert) were required. Though born in India, they both have been residing in the United States for over 20 years. Being blinded to the original English version, they both independently translated T1,2 back into English.

4. Committee review: The committee reviewed all the translations (T1, T2, T1,2, B1, and B2) and the written report comparing the back-translations with the forward translation T1,2. Based on those translations, the pre-final version was developed.

5. Face validation: The pre-final version of the questionnaire was tested on randomly (simple random sampling) chosen 15 patients visiting out-patient clinics of the three homeopathy hospitals (5 each). Each completed the questionnaire and was then asked the meaning of each questionnaire item as well as whether or not they had problems with the questionnaire layout, content,
clarity, language, instructions, or response scales. Any difficulties were noted and included in the final report. A detailed report written by the interviewing person, including proposed changes of the pre-final version based on the results of the face validity test was then submitted to the expert committee.

6. Committee appraisal: The final version of the UFSQOL-B was developed by the committee based on the results of the face validity testing and the written report. The final version of the UFSQOL-B can be found as supplementary file. The different translation stages and the complete study flow are presented in Figure 1.

Field testing and validation: Content validity of the UFSQOL questionnaire was previously evaluated of the original English version, and was therefore not tested.
in this study. Additional testing was done to evaluate construct validity.

Inclusion criteria: Premenopausal women aged 18–45 years, diagnosed with uterine fibroids confirmed by pelvic and/or transvaginal ultrasonography, presence of any of the symptoms such as abnormal uterine bleeding (profuse menstruation or intercyclic menstruation), pelvic heaviness, pain during menstruation, pain during intercourse, and pressure symptoms such as urinary frequency, constipation, etc., patient’s ability to read Bengali and written consent to participate. Patients taking Oral Contraceptive Pills (OCPs) will be advised to stop the pills till it exhausts for the ongoing cycle and willing to continue any other alternative method of contraception followed by reassessment of symptoms in the next cycle enrolment. Patients under Hormonal Replacement Therapy (HRT) to be included after a washout period of 3 months.

Exclusion criteria: Asymptomatic fibroids, Patients with calcified fibroid, self-reported coagulation disorders, any fibroid causing hydronephrosis, fibroid with solid ovarian mass, unevaluated gynecological abnormalities; e.g., unexplained vaginal bleeding, cervical dysplasia, pelvic inflammatory diseases (PID) within one month, patients with suspicious adenomyosis, gross developmental defect or congenital abnormalities of the uterus etc., patients with hemoglobin less than 7 gm/dl (severe anemia), recent rapid growth of fibroid; i.e. doubling in size within last one to six months, genito-urinary tract malignancy—suspected or diagnosed, patients with psychiatric diseases, pregnancy, and lactation, cases suffering from uncontrolled systemic illness or life-threatening infections or any vital organ failure, and substance abuse and/or dependence.

Out of 137 eligible patients approached, 120 (response rate 87.6%) returned the questionnaire and these responses were subjected to exploratory factor analysis (EFA) and 120 further responses were subjected to confirmatory factor analysis (CFA).

Sample size: Recommendations for adequate sample size to conduct factor analysis are between 50 and 250 with most authors recommending at least 100 subjects.\(^{21}\) We recruited 120 women to account for attrition.

Sampling: Consecutive sampling was adopted. Patients with uterine fibroids who attended the outpatient clinics on the day of the data collection were consecutively approached and invited to participate in the study.

Data collection: All the participants were provided with the self-administered questionnaire along with patient information sheets in local vernacular Bengali and informed consents were obtained. To ensure anonymized protection of patient’s privacy, all the patient identifiable information

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Table 1: Socio-demographic features of the respondents (n=120)

| Features                        | Descriptive |
|---------------------------------|-------------|
| Age (yrs)                       | Median (IQR) | Mean±SD   |
|                                 | 38.0 (32.3, 43.0) | 37.6±7.0  |
| Duration of suffering\(^{a}\) (months) | Median (IQR) | Mean±SD   |
|                                 | 12.0 (6.0, 30.0) | 21.8±22.6 |
| Treatment taken                 |             |           |
| Allopathy                       | 52 (43.3)   |           |
| Homeopathy                      | 40 (33.3)   |           |
| Others                          | 16 (13.3)   |           |
| No treatment                    | 7 (5.8)     |           |
| Co-morbidities                  |             |           |
| Atopic dermatitis               | 1 (0.8)     |           |
| Backache                        | 5 (4.2)     |           |
| Breast lump                     | 3 (2.5)     |           |
| Bronchial asthma                | 1 (0.8)     |           |
| Cholelithiasis                  | 3 (2.5)     |           |
| Diabetes mellitus               | 5 (4.2)     |           |
| Dyslipidemia                    | 1 (0.8)     |           |
| Fatty liver                     | 2 (1.7)     |           |
| Hypertension                    | 5 (4.2)     |           |
| Hypothyroidism                  | 9 (7.5)     |           |
| Leucorhea                       | 11 (9.2)    |           |
| Migraine                        | 1 (0.8)     |           |
| Neck pain                       | 2 (1.7)     |           |
| Osteoarthritis knee             | 1 (0.8)     |           |
| Ovarian cyst                    | 2 (1.7)     |           |
| Polycystic ovary                | 2 (1.7)     |           |
| Pityriasis versicolor           | 1 (0.8)     |           |
| Phritis valvae                  | 1 (0.8)     |           |
| Rheumatoid arthritis            | 1 (0.8)     |           |
| Tinea cruris                    | 1 (0.8)     |           |
| Vertigo, nausea                 | 1 (0.8)     |           |
| Body Mass Index\(^{a}\)         | Median (IQR) | Mean±SD   |
|                                 | 24.1 (21.0, 25.8) | 23.6±3.7  |
| Systolic Blood pressure\(^{a}\) (mm Hg) | Median (IQR) | Mean±SD   |
|                                 | 120.0 (110.0, 124.0) | 118.7±10.2 |
| Diastolic Blood pressure\(^{a}\) (mm Hg) | Median (IQR) | Mean±SD   |
|                                 | 76.0 (70.0, 80.0) | 75.0±8.4  |
| Marital status                  |             |           |
| Married                         | 105 (87.5)  |           |
| Single                          | 11 (9.2)    |           |
| Widowed                         | 4 (3.3)     |           |
| Educational status\(^{b}\)      |             |           |
| Class X or less                 | 65 (54.6)   |           |
| Class XI-XII                    | 24 (20.2)   |           |
| Higher than class XII           | 30 (25.2)   |           |
| Employment status               |             |           |
| Business                        | 34 (28.3)   |           |
| Service                         | 29 (24.2)   |           |
| Unemployed                      | 57 (47.5)   |           |
| Family income status\(^{b}\)    |             |           |
| Poor                            | 71 (59.7)   |           |
| Middle                          | 48 (40.3)   |           |

\(^{a}\)six missing data; \(^{b}\)one missing data; Descriptive presented as n (%) unless specified otherwise; SD: Standard Deviation; IQR: Inter-quartile range
was concealed. Another section in the questionnaire sought information regarding patients’ socio-demographic features. The filled-in questionnaires were put inside opaque envelops and sealed at the study site. Thirty randomly chosen participants were selected for retest visits at approximately 2–3 weeks interval to fill the same questionnaire again. All the data were extracted in a specially designed Microsoft Excel master chart that was subjected to statistical analysis.

**Statistical analysis:** It was carried out by using IBM® Statistical Package for Social Sciences (SPSS) ® software, version 20.0 and SPSS Amos ® version 20.0 (IBM Corp., Armonk, NY, USA). First, sampling adequacy was assessed using the Kaiser-Meyer-Olkin (KMO) measure value and appropriateness of data was conducted using the Bartlett’s test of sphericity. The KMO value of more than 0.50[22] with a significant Bartlett’s test of sphericity with a P value of less than 0.05[23] was considered suitable for factor analysis. Then, EFA using principal component analysis (PCA) with varimax rotation (Eigenvalue more than 1) was conducted to examine the UFS-QOL-B dimensionality and construct validity i.e. the number and type of subscales in the instrument. Only factors with values of ≥ 0.40 were considered. Items were planned to be excluded if they revealed weak loadings (failing to load above 0.39 on any component) and showing general loadings of 0.40 on more than one component. Next, reliability of the UFS-QOL-B was assessed using internal inconsistency and test-retest reliability analyses. To represent high internal consistencies, Cronbach’s alpha of 0.5-0.7[24] and average item-total correlation in a moderate range between > 0.3 and > 0.9 were considered as reliable. Cronbach’s alpha value of > 0.9 was considered as excellent, while correlation near 0 indicated no meaningful construct.[25] Intra-class correlation coefficient (ICC) values of > 0.7 indicated that UFS-QOL-B was stable over time, values between 0.4 and 0.7 indicated fair reliability while values of < 0.4 indicated poor reliability.[26] Paired t-tests were used to evaluate whether there was statistically significant change in scores on the UFS-QOL between the test-retest evaluations. The inter-item correlations between domains (item discriminant validity) and the overall UFS-QOL-B (internal item convergence) was assessed using correlation statistics. Correlation value of 0.4 or higher was considered adequate to support the internal consistency of the instrument.[27] Finally a CFA model was developed to verify the a priori scales as suggested by EFA. The goodness of fit of the CFA models were evaluated utilizing the following multiple fit indices: Comparative Fit Index (CFI), Normed Fit Index (NFI), Tucker Lewis Index (TLI), Root Mean

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**Table 2: Descriptive statistics of 37-items UFSQOL-B questionnaire, grouped into original 7 subscales (n=120)**

| Items          | Mean (SD) | Skewness | Kurtosis | Floor n (%) | Ceiling n (%) |
|---------------|----------|----------|----------|-------------|--------------|
| Overall score | 30.5 (22.4) | 0.0 | -0.4 | - | - |
| Symptom severity | 47.5 (16.3) | 0.5 | 0.2 | - | - |
| Q1 | 3.8 (1.0) | -0.8 | 0.5 | 5 (4.2) | 35 (29.2) |
| Q2 | 2.9 (1.1) | -0.0 | -0.6 | 16 (13.3) | 11 (9.2) |
| Q3 | 2.8 (1.0) | 0.3 | -0.4 | 8 (6.7) | 10 (8.3) |
| Q4 | 2.5 (1.2) | 0.2 | -1.1 | 34 (28.3) | 6 (5.0) |
| Q5 | 2.9 (1.4) | 0.1 | -1.2 | 22 (18.3) | 20 (16.7) |
| Q6 | 2.5 (1.4) | 0.4 | -1.1 | 40 (33.3) | 12 (10.0) |
| Q7 | 2.3 (1.4) | 0.6 | -1.1 | 52 (43.3) | 11 (9.2) |
| Q8 | 3.4 (1.3) | -0.4 | -1.0 | 11 (9.2) | 29 (24.2) |
| Concern | 55.4 (26.3) | -0.3 | -0.7 | - | - |
| Q9 | 3.0 (1.3) | -0.0 | -1.1 | 22 (18.3) | 20 (16.7) |
| Q15 | 2.8 (1.4) | 0.1 | -1.2 | 32 (26.7) | 18 (15.0) |
| Q22 | 2.6 (1.5) | 0.4 | -1.3 | 42 (35.0) | 20 (16.7) |
| Q28 | 3.0 (1.5) | 0.0 | -1.4 | 28 (23.3) | 26 (21.7) |
| Q32 | 2.6 (1.4) | 0.4 | -1.0 | 32 (26.7) | 15 (12.5) |
| Activities | 51.9 (24.1) | -0.1 | -0.6 | - | - |
| Q10 | 3.0 (1.4) | 0.0 | 0.2 | -1.2 | 24 (20.0) | 22 (18.3) |
| Q11 | 2.9 (1.3) | 0.0 | 0.1 | -1.2 | 30 (25.0) | 12 (10.0) |
| Q13 | 2.8 (1.3) | 0.2 | -1.1 | 30 (25.0) | 12 (10.0) |
| Q19 | 3.1 (1.3) | -0.2 | -1.1 | 19 (15.8) | 20 (16.7) |
| Q20 | 2.7 (1.4) | -0.0 | -1.2 | 33 (27.5) | 16 (13.3) |
| Q27 | 3.1 (1.4) | -0.2 | -1.2 | 20 (16.7) | 25 (20.8) |
| Q29 | 2.9 (1.4) | -1.2 | 29 (24.2) | 17 (14.2) |
| Energy/mood | 54.8 (22.5) | 0.2 | -0.9 | - | - |
| Q12 | 3.6 (1.3) | -0.7 | 0.6 | 15 (12.5) | 37 (30.8) |
| Q17 | 3.3 (1.4) | -0.3 | -1.2 | 18 (15.0) | 29 (24.2) |
| Q23 | 3.2 (1.4) | -0.3 | -1.2 | 21 (17.5) | 26 (21.7) |
| Q24 | 3.3 (1.4) | -0.4 | -1.1 | 19 (15.8) | 28 (23.3) |
| Q25 | 3.1 (1.6) | -0.1 | -1.5 | 31 (25.8) | 31 (25.8) |
| Q31 | 3.2 (1.5) | -0.2 | -1.4 | 21 (17.5) | 35 (29.2) |
| Q35 | 3.3 (1.4) | -0.2 | -1.4 | 14 (11.7) | 33 (27.5) |
| Control | 47.2 (28.0) | 0.1 | -0.8 | - | - |
| Q14 | 2.9 (1.4) | -1.2 | 30 (25.0) | 16 (13.3) |
| Q16 | 3.1 (1.2) | -0.2 | -0.7 | 17 (14.2) | 15 (12.5) |
| Q26 | 3.4 (1.4) | -0.5 | -1.0 | 19 (15.8) | 30 (25.0) |
| Q30 | 3.1 (1.5) | -0.2 | -1.4 | 30 (25.0) | 27 (22.5) |
| Q34 | 3.1 (1.4) | 0.0 | -1.3 | 16 (13.3) | 26 (21.7) |
| Self-consciousness | 61.1 (26.3) | -0.5 | -0.4 | - | - |
| Q18 | 2.4 (1.4) | 0.5 | -1.1 | 48 (40.0) | 13 (10.8) |
| Q21 | 2.7 (1.4) | 0.2 | -1.3 | 39 (32.5) | 17 (14.2) |
| Q23 | 3.6 (1.4) | 0.3 | -1.2 | 38 (31.7) | 15 (12.5) |
| Sexual function | 52.2 (35.1) | 0.0 | -1.3 | - | - |
| Q36 | 2.9 (1.5) | 0.0 | -0.0 | -1.3 | 33 (27.5) | 23 (19.2) |
| Q37 | 2.9 (1.6) | -1.6 | 39 (32.5) | 29 (24.2) |
| HRQOL total | 53.4 (19.7) | 0.0 | -0.5 | - | - |

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Figure 2: Screeplot
Square Error of Approximation (RMSEA), Standardized Root Mean Square Residual (SRMR), Bayesian Information Criterion (BIC), and Hoelter index. The recommendations for cut-off values indicating a good model fit are CFI/TLI ≥ 0.95, RMSEA ≤ 0.6, and SRMR ≤ 0.8.²⁸,²⁹

Results

Sample characteristics: Socio-demographic characteristics of the representative sample were presented in terms of 10 variables—age, duration of suffering, treatment availed, co-morbidities, body mass index (BMI), blood pressure (BP), residence, marital status, education, employment, and family income status. All are presented in Table 1.

Descriptive statistics: These were presented in terms of means, standard deviations, skewness, kurtosis, and floor and ceiling effects of each individual items and subscales. The details are presented in Table 2.

EFA: The achieved sample size of 120 seemed adequate for factor analysis as the average communalities after extraction was 0.702, much above the preferred cut-off of 0.5. The KMO measure of sampling adequacy was 0.801 [Chi-square: 2452.027, df = 666, P < 0.001], much greater than the minimum Kaiser criterion of 0.5, indicating adequacy of the sample and compactness of correlation patterns. A significant Bartlett’s test of sphericity also indicated that the R-matrix was not an identity matrix. We performed extraction using

### Table 3: Total variances explained

| Items | Initial Eigenvalues | Extraction sums of squared loadings | Rotation sums of squared loadings |
|-------|---------------------|-------------------------------------|----------------------------------|
|       | Total | % variance | Cumulative | Total | % variance | Cumulative | Total | % variance | Cumulative |
| 1     | 11.168 | 30.183 | 30.183 | 11.168 | 30.183 | 30.183 | 5.117 | 13.830 | 13.830 |
| 2     | 2.749  | 7.431  | 37.614 | 2.749  | 7.431  | 37.614 | 4.726  | 12.774 | 26.604 |
| 3     | 2.488  | 6.725  | 44.339 | 2.488  | 6.725  | 44.339 | 2.246  | 6.069  | 32.673 |
| 4     | 1.874  | 5.065  | 49.405 | 1.874  | 5.065  | 49.405 | 2.191  | 5.923  | 38.596 |
| 5     | 1.668  | 4.508  | 53.913 | 1.668  | 4.508  | 53.913 | 2.166  | 5.855  | 44.451 |
| 6     | 1.494  | 4.037  | 57.950 | 1.494  | 4.037  | 57.950 | 2.111  | 5.706  | 50.157 |
| 7     | 1.311  | 3.543  | 61.493 | 1.311  | 3.543  | 61.493 | 2.054  | 5.551  | 55.708 |
| 8     | 1.129  | 3.052  | 64.545 | 1.129  | 3.052  | 64.545 | 1.838  | 4.967  | 60.676 |
| 9     | 1.077  | 2.910  | 67.455 | 1.077  | 2.910  | 67.455 | 1.814  | 4.902  | 65.578 |
| 10    | 1.005  | 2.717  | 70.172 | 1.005  | 2.717  | 70.172 | 1.700  | 4.594  | 70.172 |
| 11    | 0.945  | 2.564  | 72.726 |         |        |        |        |        |        |
| 12    | 0.895  | 2.418  | 75.145 |         |        |        |        |        |        |
| 13    | 0.804  | 2.174  | 77.319 |         |        |        |        |        |        |
| 14    | 0.780  | 2.108  | 79.426 |         |        |        |        |        |        |
| 15    | 0.676  | 1.827  | 81.253 |         |        |        |        |        |        |
| 16    | 0.597  | 1.613  | 82.866 |         |        |        |        |        |        |
| 17    | 0.550  | 1.487  | 84.353 |         |        |        |        |        |        |
| 18    | 0.516  | 1.395  | 85.748 |         |        |        |        |        |        |
| 19    | 0.485  | 1.312  | 87.060 |         |        |        |        |        |        |
| 20    | 0.467  | 1.262  | 88.322 |         |        |        |        |        |        |
| 21    | 0.452  | 1.223  | 89.545 |         |        |        |        |        |        |
| 22    | 0.410  | 1.109  | 90.654 |         |        |        |        |        |        |
| 23    | 0.395  | 1.068  | 91.722 |         |        |        |        |        |        |
| 24    | 0.364  | 0.984  | 92.707 |         |        |        |        |        |        |
| 25    | 0.358  | 0.967  | 93.673 |         |        |        |        |        |        |
| 26    | 0.317  | 0.856  | 94.529 |         |        |        |        |        |        |
| 27    | 0.289  | 0.781  | 95.311 |         |        |        |        |        |        |
| 28    | 0.281  | 0.759  | 96.070 |         |        |        |        |        |        |
| 29    | 0.249  | 0.672  | 96.742 |         |        |        |        |        |        |
| 30    | 0.224  | 0.604  | 97.346 |         |        |        |        |        |        |
| 31    | 0.212  | 0.572  | 97.918 |         |        |        |        |        |        |
| 32    | 0.170  | 0.460  | 98.378 |         |        |        |        |        |        |
| 33    | 0.157  | 0.425  | 98.803 |         |        |        |        |        |        |
| 34    | 0.137  | 0.370  | 99.173 |         |        |        |        |        |        |
| 35    | 0.114  | 0.308  | 99.481 |         |        |        |        |        |        |
| 36    | 0.106  | 0.287  | 99.768 |         |        |        |        |        |        |
| 37    | 0.086  | 0.232  | 100.000 |        |        |        |        |        |        |
principal component method for determining how many factors best explained the observed covariation matrix within the data set. The screeplot revealed very high eigenvalue of factor 1 and considerably high values for factors 2–10 and thereafter the curve began to tail off gradually before the final plateau was reached [Figure 2]. The factor component matrix represented information from initial unrotated solution and extracted 10 components explaining 70.2% of the total variance. Each of the components with their respective Eigenvalues and percentage of total variances explained are presented in Table 3. The values were weights that related the item (or variable) to the respective factor. Display of coefficients was sorted by size. Factor loadings were similar to regression weights (or slopes) and indicated the strength of the association between the variables and the factors. Next, the correlation matrix was scanned for values greater than 0.9 for identifying multi-co-linearity and singularity. Determinant of the correlation matrix was 0.087. Thus, multicollinearity was not a problem for these data. All items correlated fairly well and none of the correlation coefficients were particularly large; therefore, there was no need to consider elimination of any item at this stage. We expected that the factors were not correlated, and we selected an orthogonal rotation method (i.e. varimax, with Kaiser normalization). The rotated

| Questions | Components |
|-----------|------------|
|           | 1 (activities) | 2 (energy and control) | 3 (concern about clothing) | 4 (mood) | 5 (sexual function) | 6 (self-consciousness) | 7 (associated symptoms) | 8 (heavy bleeding) | 9 (cycle disturbance) | 10 (concern about flooding) |
| 12        | 0.768       | 0.799              | 0.672                  | 0.661     | 0.580              | 0.554                  | 0.864                    | 0.756                  | 0.714                 | 0.684                  |
| 11        | 0.765       | 0.757              | 0.536                  | 0.523     | 0.523              | 0.558                  | 0.556                    | 0.755                  | 0.481                 | 0.470                  |
| 13        | 0.731       | 0.672              | 0.536                  | 0.445     | 0.445              | 0.554                  | 0.864                    | 0.756                  | 0.433                 | 0.643                  |
| 20        | 0.688       |                   |                       |           |                   |                        |                          |                        | 0.861                 | 0.643                  |
| 23        | 0.595       |                   |                       |           |                   |                        |                          |                        | 0.795                 | 0.783                  |
| 19        | 0.540       |                   |                       |           |                   |                        |                          |                        | 0.747                 | 0.783                  |
| 10        | 0.492       |                   |                       |           |                   |                        |                          |                        | 0.688                 | 0.643                  |
| 24        | 0.484       |                   |                       |           |                   |                        |                          |                        | 0.595                 | 0.556                  |

Table 4: Principal component analysis with rotated component matrix - factor loadings revealing 10 component structures
component matrix was a matrix of factor loadings for each variable onto each factor. The absolute values less than a specified value of 0.4 were suppressed, ensuring that factor loadings within ± 0.4 were not displayed in the output. After conducting factor rotation, the items were looked for that loaded onto the same factor. Ten sub-components of the main construct were identified and named as below: [Table 4]

1. Items 12, 11, 13, 20, 35, 14, 16, 19, and 10: “Activities”
2. Items 23, 24, 26, 30, 31, 34, and 25: “Energy and Control”

Table 5: Internal consistency of the UFSQOL-B questionnaire

| Cronbach’s alpha | ICC coefficient |
|------------------|-----------------|
| Overall UFSQOL-B | 0.921           |
| UFSQOL-B components: | | |
| Activities | 0.898 |
| Energy and Control | 0.876 |
| Concern about clothing | 0.743 |
| Mood | 0.740 |
| Sexual function | 0.810 |
| Self-consciousness | 0.588 |
| Associated symptoms | 0.674 |
| Heavy bleeding | 0.623 |
| Cycle disturbance | 0.689 |
| Concern about flooding | 0.736 |

Table 6: Correlations matrix between the UFSQOL-B subscales and the overall score

| Activities | Energy and control | Concern about clothing | Mood | Sexual function | Self-consciousness | Associated symptoms | Heavy bleeding | Cycle disturbance | Concern about flooding | Overall score |
|------------|--------------------|------------------------|------|-----------------|-------------------|---------------------|-----------------|---------------------|------------------------|---------------|
| Activities | 1                  | 0.731*                 | 0.540* | 0.712*          | 0.162             | 0.353*              | 0.108          | 0.260*              | -0.025                 | 0.505*         |
| Energy and Control | 0.731* | 1                  | 0.503* | 0.618*          | 0.120             | 0.404*              | 0.122          | 0.234*              | -0.028                 | 0.482*         |
| Concern about clothing | 0.540* | 0.503*          | 1                  | 0.466*          | 0.315*             | 0.442*              | -0.026        | 0.377*              | 0.078                  | 0.641*         |
| Mood | 0.712* | 0.618*          | 0.466*             | 1                  | 0.118             | 0.354*              | 0.058          | 0.203*              | -0.001                 | 0.412*         |
| Sexual function | 0.162 | 0.120             | 0.315*             | 0.118             | 1                  | 0.075              | -0.032        | 0.087               | -0.053                 | 0.286*         |
| Self-consciousness | 0.353* | 0.404*          | 0.442*             | 0.354*            | 0.075             | 1                  | 0.080         | 0.092               | 0.133                  | 0.435*         |
| Associated symptoms | 0.108 | 0.122             | -0.026             | 0.058             | -0.032             | 0.080              | 1              | 0.029               | 0.424*                 | 0.040          |
| Heavy bleeding | 0.260* | 0.234*          | 0.377*             | 0.203*            | 0.087             | 0.092              | 0.029         | 1                   | 0.115                  | 0.349*         |
| Cycle disturbance | -0.025 | -0.028          | 0.078              | -0.001            | -0.053             | 0.133              | 0.424*        | 0.115               | 1                      | 0.037          |
| Concern about flooding | 0.505* | 0.482*          | 0.641*             | 0.412*            | 0.261*             | 0.435*              | -0.040        | 0.349*              | 0.037                  | 1.670*         |
| Overall score | 0.870* | 0.843*          | 0.743*             | 0.738*            | 0.286*             | 0.565*              | 0.241*        | 0.373*              | 0.156                  | 0.670*         |

*CORRELATION IS CONSIDERED SIGNIFICANT AT THE 0.01 LEVEL

Table 7: Test-retest reliability analysis of the UFSQOL-B questionnaire (n=30)

| Components | Test score: mean±sd | Retest score: mean±sd | Score difference: mean (95% CI) | P |
|------------|---------------------|-----------------------|---------------------------------|---|
| Activities | 40.5±21.9           | 40.0±21.1             | 0.5 (-0.2, 1.1)                 | 0.136|
| Energy and Control | 37.1±24.4 | 36.8±23.9             | 0.4 (-0.3, 1.0)                 | 0.260|
| Concern about clothing | 50.9±26.5 | 50.2±25.9             | 0.6 (-0.1, 1.3)                 | 0.083|
| Mood | 36.9±25.0           | 37.2±25.0             | -0.3 (-1.3, 0.7)                | 0.579|
| Sexual function | 42.1±37.9 | 41.3±37.4             | 0.8 (-0.4, 2.0)                 | 0.161|
| Self-consciousness | 51.4±22.1 | 51.1±21.4             | 0.3 (-0.7, 1.3)                 | 0.576|
| Associated symptoms | 61.7±26.7 | 61.4±26.5             | 0.3 (-0.7, 1.3)                 | 0.573|
| Heavy bleeding | 33.8±19.5 | 33.3±18.7             | 0.4 (-1.1, 1.9)                 | 0.573|
| Cycle disturbance | 60.0±21.9 | 59.6±21.2             | 0.4 (-1.1, 1.9)                 | 0.573|
| Concern about flooding | 50.0±31.8 | 49.2±31.0             | 0.8 (-0.4, 2.0)                 | 0.161|

SD = Standard deviation; CI = Confidence Intervals

Internal consistency: The Cronbach’s alpha value for the overall UFSQOL-B was 0.921 and ICC was 0.922. The Cronbach’s alpha values for the 10 subscales ranged between 0.6 and 0.9 indicating acceptable to good reliability [Table 5]. The correlations between the overall and UFSQOL subscales were found to be generally higher than correlations between subscales. [Table 6].

Test-retest reliability: The scores on the UFSQOL-B subscales were largely stable with mean score differences ranging between -0.3 (mood) and 0.8 (sexual function and concern about flooding), thus reflecting acceptable reliability. [Table 7].

CFA: The indices of CFA that confirmed model fit were: CFI = 0.796, NFI = 0.611, TLI = 0.768, RMSEA = 0.072,

Concern about flooding
Cycle disturbance
Heavy bleeding
Self-consciousness
Sexual function
Mood
Concern about clothing
Energy and Control
Activities

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SRMR = 0.132, BIC = 1512.707, and Hoelter index (at α = 0.05) = 81, thus indicating mediocre fit. Estimates of the covariances among the 10 domains could not be calculated as it resulted in too many iterations (n = 49) to be plotted in the model.

Discussion

UFSQOL is a validated English questionnaire consisting of 37 questions and assessing symptom severity and quality of life in patients suffering from uterine fibroids; but, until now, no validated Bengali version of the questionnaire is available. The English questionnaire underwent standardized forward-backward translation to produce the UFSQOL-Bengali version. In contrast with the original 7 subscales English version, EFA using PCA of the UFSQOL-B identified 10 components and the overall model goodness of fit was further confirmed by CFA. Thus, UFSQOL-B was found to be valid and reliable with adequately high Cronbach’s α and ICC coefficient and test-retest reliability within acceptable limits.

One of the major strengths of this study was to apply EFA and CFA on two different samples as recommended.[30-32] Our study shows that the overall and individual subscales UFSQOL-B scores were comparable to other studies. Usually, floor and ceiling effects between 1 and 15% are considered as optimal.[33] However, inclusion of responses on this basis would have eliminated majority of the questionnaire items; hence we refrained from pre-specifying any cut-off values in this aspect. Thus, there was considerable floor and ceiling effect in this study that might have affected the outcomes. Unlike other validation studies, there was no control (normal/healthy) group; hence, assessment of discriminant validity was not possible. Besides, responsiveness of the questionnaire was not assessed because the treatment provided by the study sites was homeopathy and that was not an accepted standard treatment for uterine fibroids. Our findings have also shown that the internal consistency for overall UFSQOL-B is high and comparable to all the existing versions. Similarly, the inter-item correlations among the subscales were found to be satisfactorily high. Sample size achieved by us was similar to the original UFSQOL development and validation study and other translations, but we were unable to confirm the 7-component structure model in the factorial examination in patient responses to UFSQOL-B instrument; rather our analysis identified 10 components. Our findings suggest that 70.2% of the UFSQOL-B variability was explained by items 1 to 10, which contributes to 6 various components – 1, 3, 4, 7, 8, and 9. Conventionally, a loading of an absolute value >0.3 is considered with a sample size of 300.[34] With a sample size of 120, a higher loading was chosen to be significant. Sixty two percent (23/37) of the items had strong factor loadings of 0.60 and above.[35] Secondly, the UFSQOL-B was administered to the patients who were able to read and understand the Bengali language. Therefore, the findings of this study could only be generalized to Bengali population only. Finally, the 10-component model had only a mediocre fit and the acceptability was only ordinary in CFA. Thus, there is a need to translate and validate this questionnaire into other Indian languages and on larger sample to give better utilization in a multi-ethnic Indian population. For item discriminant validity, we were not able to test the hypothesized scales with other measurement tool as none were available in the Bengali language. Other limitation includes the consecutive sampling method used in this study which may be vulnerable to sampling bias.

Thus, the validated UFSQOL-B served as an important patient reported instrument to measure the symptom severity and HRQOL in patients suffering from uterine fibroids. Future research should also include utilization of the UFSQOL-B as outcome measure in clinical trials. So, the responsiveness, or sensitivity to change of the UFSQOL-B to measure symptoms and life-impact of treatments need to be tested in future investigations. The original English version of the questionnaire was found to be highly responsive to conservative treatment.[36] Finally, in order to confirm the UFSQOL-B can measure the impact of clinical treatment, the final step in this instrument’s development will be to define a minimally important difference of change in this scale that reflects a clinically meaningful difference in a women’s life. Further validation using larger sample size and more specific Rasch analyses is warranted to check goodness of fit and confirm whether the sequence of the questionnaire requires any readjustment in future.

Conclusion

The UFSQOL-B contains 37 items which are framed within 10-component model. It is a reasonably valid and reliable tool which can be used to measure the symptom severity and HRQOL in Bengali patients suffering from uterine fibroids. However, further analysis is recommended to strengthen the validity of the UFSQOL-B.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other
clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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