Original Article

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# Translation and Validation of Bristol Female Lower Urinary Tract Symptoms (BFLUTS) Questionnaire for Nepali-Speaking Women

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## ABSTRACT

**Background:** The Bristol female lower urinary tract symptoms questionnaire (BFLUTS) was designed to identify the lower urinary tract symptoms (LUTS) in women. It aids in determining the severity of lower urinary tract symptoms and how they affect sexual function and quality of life.It can be employed in research and therapeutic practice. It is not available in the Nepali version. As a result, our goal is to translate and validate the Bristol female lower urinary tract symptoms questionnaire in Nepali.

**Methods:** The Bristol female lower urinary tract symptoms questionnaire has been translated into Nepali. From March 1, 2020, to February 28, 2021, 225 Nepalese patients with lower urinary tract symptoms were evaluated using a Nepali version of the Bristol female lower urinary tract symptoms questionnaire adapted from the English version. Internal consistency, test-retest reliability, validity, and change responsiveness were all assessed.

**Results:** A total of 225patients were enrolled in the study. The missing data was less than 2%. The Nepali version of the Bristol female lower urinary tract symptoms questionnaire showed good reliability ($\alpha = 0.76$; ICC= 0.934). Test-retest reliability was assessed with weighted kappa ($\kappa$) ranging from 0.71 to 0.83.It showed good sensitivity to change before and after the treatment. Mean Bristol female lower urinary tract symptoms scores correlated strongly with the symptoms of lower urinary tract symptoms reported in the bladder diary with $\rho$ ranging from 0.689to 0.859.

**Conclusions:** The Nepali version of the Bristol female lower urinary tract symptoms questionnaire is reliable, valid and consistent for measuring lower urinary tract symptoms and their effect on sexual function and quality of life.

Keywords: BFLUTS; LUTS; Nepali; reliability; validity.

## INTRODUCTION

The nomenclature for female lower urinary tract symptoms (LUTS) is defined in accordance with the guidelines proposed by the International Continence Society (ICS) report.[1]Due to the intimate nature of symptoms, LUTS is underreported.[2]LUTS is present in 10% to 40% of elderly people in different researches.[3, 4]

Lower urinary tract symptoms have a social, physical, and psychological impact on sexual health and quality of life.[5,6] Self-administered questionnaires are designed to provide an objective measurement of how a patient experiences symptoms and to assess the disease's influence on QoL.[7,8] They are of value in the appropriate assessment and management of these patients.[9-11] The Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire isamong one of them.[12] Nepali is the mother language of Nepal.[13] Nepali version of BFLUTS would improve objective assessment and management and can be a useful tool for follow-up and research as well.

## METHODS

The study was approved by the Institutional Review Committee (IRC) of BP Koirala Institute of Health Sciences (BPKIHS). Informed consent was taken.

The following steps were taken during the translation and validation of BFLUTS into Nepali:

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The BFLUTS survey was translated from English to Nepali by two independent translators. Both translators were native Nepalese speakers who spoke both languages fluently and merged into one.

Another independent bilingual native Nepali speaker blinded to the original questionnaire in English translated the Nepali-translated version into English and the translated version was compared to the original version in order to improve the translation.

A gynecologist, a urologist, and a Urogynecologist who were proficient in both Nepali and English reviewed the final translated Nepali version to ensure that it measured what it was supposed to measure.

Piloting was done on 20 patients to see if the questions were clear and easy to understand.

Final adjustments were made, and the psychometric features of the translated Nepali version of the BFLUTS questionnairewere tested.

Patients with lower urinary tract symptoms (LUTS) and who could read and understand Nepali were included. Patients who refused to give consent or could not read Nepali were excluded.The researcher was close and ready to answer any questions or respond to the query. All patients underwent a cough stress test before and after micturition. Patients were asked to keep a three day bladder diary and requested to return after one week with a bladder diary, urine routine microscopy, culture sensitivity and, if necessary, ultrasonography. Patients were followed up after 6-8 weeks on medication, 6-8 weeks after surgery and asked to fill the questionnaire for the second time.

The BFLUTS questionnaire contains 19 questions. Each item's score in multiple domains ranges from 0 to 4. The total score for each domain was calculated.

SPSS software version 22.0 was used for all statistical analyses. The sample size was predicted to be 190 based on a statistically significant score of 0.05, a power of 80%, and an interclass correlation coefficient (ICC) of 0.80. Internal consistency and test re-test analysis were used to determine reliability. Cronbach's coefficient alpha was used to assess internal consistency. The sensitivity to change was determined by comparing pre-and post-treatment differences in questionnaire scores over a period of at least 6-8 weeks. The bladder diary and examination sheet were used to assess the questionnaire's validity. Spearman's correlation coefficient (ρ) was used to assess the relationship between the symptoms in the questionnaire and the bladder diary and examination sheet.

## RESULTS

In total, 225 patients were enrolled in the trial, with an average age of 54.5 years. (Table 1)

**Table 1.Baseline characteristics.**

| Baseline characteristics | Frequency (n) | Percentage (%) |
|---|---|---|
| Age | | |
| Pre-menopause | 85 | 37.78 |
| Menopause | 140 | 62.22 |
| Parity | | |
| Primi | 46 | 20.45 |
| 2-4 | 128 | 56.88 |
| >4 | 51 | 22.67 |
| Education | | |
| Primary (Grade 1-5) | 129 | 57.33 |
| Secondary (Grade 6-12) | 51 | 22.67 |
| Higher (Bachelor and above) | 45 | 20.00 |

Frequency was the most prevalent symptom, followed by urgency and nocturia. (Table 2)

**Table 2. Chief complaint of patients**

| Chief complaint | Frequency (n) | Percentage (%) |
|---|---|---|
| Nocturia | 89 | 39.5 |
| Frequency | 111 | 49.33 |
| Urgency | 107 | 47.55 |
| Dysuria | 21 | 9.33 |
| Urgency incontinence | 15 | 6.66 |
| Stress urinary incontinence | 61 | 27.1 |
| Mixed urinary incontinence | 35 | 15.55 |
| Continuous urinary incontinence | 8 | 3.55 |
| Straining | 8 | 3.55 |
| Intermittency | 3 | 1.33 |

All the domains of the questionnaire had Cronbach's alpha of 0.70 or more indicating good internal incontinency. It indictes that the questionnaire is a valid and reliable

tool. 170 patients who returned 7-10 days after their initial appointment to complete the questionnaire again were tested for test re-test reliability. It was graded using a weighted kappa (κ) scale that varied from 0.71 to 0.83. (Table 3) There was agreement for each item between the baseline visit and 7-10 days after the first visit (κ > 0.8). (Table 4).

**Table 3. Reliability of the Nepali version of the BFLUTS questionnaire.**

| Domain | Cronbach's alpha score (n=225) | Weighted kappa (κ) n=170 |
|---|---|---|
| Storage symptoms | 0.74 | 0.71 |
| Voiding dysfunction symptoms | 0.71 | 0.76 |
| Incontinence symptoms | 0.82 | 0.83 |
| Sexual function | 0.71 | 0.81 |
| Quality of life | 0.70 | 0.80 |

**Table 4. Test-retest reliability of the items in the BFLUTS questionnaire.**

| BFLUTS | Kappa (κ) | Confidence interval (CI 95%) |
|---|---|---|
| BFLUTS total score | 0.89 | 0.851-0.932 |
| Frequency | 0.88 | 0.815-0.943 |
| Urgency | 0.89 | 0.856-0.964 |
| Nocturia | 0.86 | 0.804-0.995 |
| Dysuria | 0.75 | 0.714-0.851 |
| Hesitancy | 0.81 | 0.756-0.875 |
| Straining | 0.82 | 0.805-0.895 |
| Intermittency | 0.81 | 0.806-0.854 |
| Urgency incontinence | 0.89 | 0.843-0.976 |
| Continuous urinary incontinence | 0.85 | 0.821-0.905 |
| Stress urinary incontinence | 0.86 | 0.803-0.925 |

Seventy-two patients (32% of the total) underwent medical and surgical treatment but only 62 could be followed up and completed the BFLUTS questionnaire after completion of treatment. Chief complaints of these patients were: pure SUI in 12, OAB-dry 21, OAB-wet 11, mixed urinary incontinence in16, continuous urinary incontinence in eight, and voiding difficulty in four. Among them 30 underwent surgery (SUI 22 and genitourinary fistula 8), 38 patients received anticholinergic drugs and four patients underwent treatment for voiding difficulty (urethral dilatation). In the post-treatment visit, most patients indicated (54/62) they had improved. One patient with genitourinary fistula, five patients with MUI, and two patients with voiding difficulty didn't have improvement because of treatment failure.Marked improvement was seen after thetreatment in most items of the questionnaire. (Table 5)

**Table 5. Comparison of BFLUTS questionnaire items betweenbaseline and post-treatment.**

| BFLUTS item | Baseline n % | Post-treatment n % | p-value |
|---|---|---|---|
| Frequency | 46 63.89 | 18 25.00 | <0.001 |
| Urgency | 44 61.11 | 14 19.44 | 0.043 |
| Nocturia | 36 50.00 | 12 16.67 | 0.038 |
| Dysuria | 10 13.89 | 03 4.16 | 0.025 |
| Straining | 21 29.1 | 15 20.8 | 0.385 |
| Intermittency | 17 23.6 | 09 12.5 | 0.412 |
| Hesitancy | 08 5.56 | 04 2.78 | 0.034 |
| Urgency incontinence | 34 47.22 | 15 20.83 | <0.001 |
| Continuous urinary incontinence | 08 11.11 | 02 2.78 | <0.001 |
| Stress urinary incontinence | 22 27.78 | 06 8.33 | <0.029 |

Mean BFLUTS scores correlated strongly with the symptoms of lower urinary tract symptoms reported in the bladder diary with ρ ranging from 0.689 to 0.859. (Table 6)

**Table 6. Correlation of BFLUTS scores with the frequency of symptoms in a bladder diary.**

| Bladder diary | Correlation (ρ) | p-value |
|---|---|---|
| Number of frequency episodes | 0.763 | 0.045 |
| Number of urgency episodes | 0.687 | 0.034 |
| Number of Nocturia episodes | 0.853 | 0.028 |
| Number of UUI episodes | 0.758 | <0.001 |
| Number of SUI episodes | 0.859 | <0.001 |

## DISCUSSION

The Nepali versions of BFLUTS has good content and construct validity, as well as good internal consistency and test-retest reliability. It was also aware of variations in symptoms before and after treatment. The majority of the patients who were recruited were literate, thus understanding the questions was not a problem. They returned with minimal missing data in any BFLUTS items because it was a self-administered questionnaire. This reflects the questionnaire's ease of use and readability.

The BFLUTS questionnaire has been translated into many languages with good reliability and validity (Korean, Turkish, and Chinese).[14-16] Brookes et al studied the use of the BFLUTS questionnaire for comparing TVT with colposuspension in patients with SUI and concluded that it was useful for both clinical and research purposes.[17] In 2010, Kim et al used the BFLUTS questionnaire to assess the long-term effect of TVT in Korea.[18] DilekBiglic et al in 2018 used the BFLUTS questionnaire in 436 women to see the sexual and urinary incontinence symptoms in perimenopausal women.[19]

In the questionnaire, more patients reported more sexual symptoms as a result of LUTS than when responding to the attending physician. This could indicate that the Nepali version of BFLUTS is effective in revealing symptoms that patients may be hiding owing to embarrassment or trouble expressing.

The study's strength is that it went through a thorough translation and validation procedure with a sufficient sample size. One weakness of this study was the lack of urodynamic testing, which would have been extremely valuable in determining the validity of the complaints. We used clinical diagnosis and a bladder diary to validate the questionnaire.

## CONCLUSIONS

The Nepali version of the BFLUTS questionnaire is equal to the original English form in terms of content and construct validity, test-retest reliability, internal consistency, and responsiveness.


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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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