Development and Validation of a Bladder Diary for the South Asian Population

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ABSTRACT

Introduction: Lower urinary tract symptoms (LUTS) represent a significant public health concern worldwide and are associated with substantial functional, psychological, and social consequences. Bladder diaries are widely used clinical tools for the evaluation and monitoring of urinary symptoms, including urinary frequency, urgency, nocturia, and incontinence episodes. Despite their clinical utility, most currently available bladder diaries have been developed within Western healthcare contexts and rely heavily on written instructions and structured tabular formats. These characteristics may limit their usability in populations with varied literacy levels and different cultural toileting practices, such as those commonly encountered in South Asian countries. The present study aimed to develop and validate a culturally adapted pictorial bladder diary suitable for use in the South Asian population.

Methodology: An exploratory cross-sectional study was conducted in two phases. The first phase involved development of the bladder diary through literature review, domain identification, and item generation based on expert input and previously validated bladder diaries. The second phase involved validation of the diary through expert review and pilot testing among individuals with lower urinary tract symptoms.

Results: Seven experts evaluated the diary using the Content Validity Index (CVI) to assess relevance, clarity, simplicity, and comprehensibility of each item. A pilot validation study was subsequently conducted among forty participants recruited from tertiary care hospitals in Belagavi, India. Participants completed the bladder diary for three consecutive days and repeated the recording after one week. Data were analyzed using descriptive statistics, Wilcoxon matched-pairs signed-rank tests, and Spearman rank correlation analysis. The overall scale-level content validity index of the instrument was 0.87, indicating strong expert agreement regarding the relevance of included domains. Several diary domains including urine colour, time, and leakage episodes achieved perfect agreement among experts. Statistical comparison of pre-test and post-test measurements demonstrated no statistically significant differences in recorded input volume, output volume, output breaks, or leakage episodes. Spearman correlation analysis demonstrated significant positive correlations between measurements recorded during the two sessions, suggesting consistency in diary-recorded parameters. These findings suggest that the developed bladder diary demonstrates strong preliminary validity and feasibility.

Conclusion: The pictorial format and culturally relevant design of the diary may improve accessibility and compliance in populations with varied literacy levels. Further large-scale validation studies are recommended to establish the full psychometric properties and clinical applicability of the instrument.

Keywords: Bladder diary, lower urinary tract symptoms, LUTS, South Asian population, validation, content validity index, urinary frequency, urgency, nocturia, incontinence.

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Introduction

The lower urinary tract (LUT) consists primarily of the urinary bladder and urethra and plays a critical role in

the storage and periodic elimination of urine. Normal urinary function requires complex coordination between bladder smooth muscle activity, urethral sphincter mechanisms, pelvic floor support structures, and neural pathways that integrate signals from the brain, spinal cord, and peripheral nervous system. During the storage phase, the bladder accommodates increasing volumes of urine while maintaining low intravesical pressure and adequate urethral closure. During the voiding phase, coordinated detrusor contraction and urethral relaxation facilitate efficient bladder emptying. Disruption of any of these physiological mechanisms may result in lower urinary tract dysfunction and associated clinical symptoms.

Lower urinary tract symptoms (LUTS) are defined as patient-perceived abnormalities related to the storage, voiding, or post-micturition phases of the urinary cycle. The International Continence Society (ICS) classifies LUTS into three primary domains: storage symptoms, voiding symptoms, and post-micturition symptoms. (1)Storage symptoms include urinary urgency, increased daytime frequency, nocturia, and urinary incontinence. Voiding symptoms include hesitancy, slow urinary stream, intermittency, straining, and terminal dribbling. Post-micturition symptoms include post-void dribble and the sensation of incomplete bladder emptying. These symptoms may arise from a variety of underlying pathological conditions including bladder dysfunction, pelvic floor disorders, neurological disease, or behavioral factors.(2)

Urinary incontinence (UI) represents one of the most prevalent and distressing manifestations of lower urinary tract dysfunction. The International Continence Society defines urinary incontinence as the complaint of involuntary leakage of urine. Urinary incontinence is commonly categorized into stress urinary incontinence, urgency urinary incontinence, and mixed urinary incontinence depending on the mechanism of leakage(3). These conditions are associated with considerable psychological distress, social isolation, reduced quality of life, and increased healthcare costs. Another commonly encountered clinical condition is overactive bladder (OAB), which is characterized by urinary urgency usually accompanied by frequency and nocturia, with or without urgency urinary incontinence.(2)

The prevalence of LUTS varies widely across different populations but remains consistently high. Epidemiological studies conducted in India suggest that a substantial proportion of adults experience at least one urinary symptom, with nocturia and increased urinary frequency being among the most commonly reported complaints. Studies focusing on women have reported urinary incontinence prevalence rates approaching 20–22% in certain hospital-based populations. Despite the high prevalence of urinary symptoms(4), these conditions often remain underreported due to social stigma, cultural barriers, and limited access to appropriate healthcare services.(5)

Clinical evaluation of LUTS typically includes a detailed patient history, physical examination, and diagnostic investigations such as urinalysis, ultrasound imaging, uroflowmetry, and urodynamic studies when indicated. However, patient recall of urinary symptoms is frequently inaccurate. Individuals may overestimate or underestimate urinary frequency, urgency episodes, and fluid intake patterns, particularly when symptoms fluctuate throughout the day.(6) As a result, objective symptom documentation tools have become an important component of LUT assessment.(7)

Bladder diaries, also referred to as voiding diaries or frequency–volume charts, are structured recording tools that document urinary events over a defined period of time, typically three to seven days. These diaries commonly record fluid intake, voiding frequency, urine volume, urgency episodes, and leakage events. Bladder diaries provide clinicians with objective data regarding urinary behavior and are therefore widely recommended in clinical guidelines for the evaluation of lower urinary tract symptoms and overactive bladder.(8)

Although bladder diaries are widely used in clinical practice, existing diary formats have several limitations. Many diaries rely heavily on written instructions and textual recording formats that require a certain level of literacy and familiarity with medical terminology. These features may reduce usability in populations with limited education.(9) Furthermore, most bladder diaries have been developed within Western healthcare systems and may not adequately reflect cultural factors influencing urinary behavior in other populations.

In South Asian countries such as India, sociocultural and environmental factors significantly influence urinary behavior and symptom reporting. For example, many individuals use Indian-style squat toilets rather than Western commodes, which may influence voiding posture and pelvic floor mechanics. Access to restroom facilities may vary depending on workplace or household infrastructure. Additionally, cultural stigma associated with urinary symptoms may discourage individuals from openly discussing bladder problems with healthcare providers.

Another important consideration is the variation in literacy levels across the population. Conventional written diaries may be difficult for individuals with limited reading ability to complete accurately. (10) Previous research has demonstrated that simplified or pictorial symptom-recording tools may improve

comprehension and completion rates in such populations.(11)

Given these challenges, there is a clear need for bladder diaries that are culturally adapted and designed to be accessible to individuals with varying literacy levels. Visual symptom-recording tools incorporating pictorial representations may improve patient understanding and compliance while still providing clinically meaningful information.(12)

Therefore, the present study was undertaken to develop and validate a culturally adapted bladder diary specifically designed for the South Asian population. The study aimed to design a pictorial bladder diary incorporating clinically relevant urinary parameters and to evaluate its preliminary validity and reliability through expert review and pilot testing.

Materials and Methods

The present study employed an exploratory cross-sectional research design. The research was conducted over a period of eight months between September 2025 and March 2026 in tertiary care hospitals and dental hospitals located in Belagavi, Karnataka, India. Ethical approval for the study was obtained from the Institutional Research and Ethics Committee of the KAHER Institute of Physiotherapy prior to the commencement of data collection.

The study was conducted in two sequential phases. The first phase involved the development of a novel bladder diary through systematic review of the literature and consultation with experts in the fields of urogynecology, physiotherapy, and pelvic floor rehabilitation. The second phase involved validation of the developed bladder diary through expert review and pilot testing among individuals experiencing lower urinary tract symptoms.

During the development phase, an extensive review of existing bladder diaries and frequency–volume charts was undertaken. Relevant domains used in previously validated bladder diaries were identified through published literature. Experts in pelvic floor rehabilitation and urological assessment were consulted to identify limitations and gaps in existing bladder diaries, particularly those affecting usability in populations with limited literacy. Based on these discussions and literature review, a set of key domains relevant to bladder symptom assessment was identified.(1,7,12)

The domains selected for inclusion in the bladder diary included demographic information, time of voiding, fluid intake volume and type, urine output volume, urinary urgency, leakage episodes, stress activity during leakage, urine colour, urinary stream characteristics, and breaks in urinary stream. These domains were selected to capture both objective and subjective aspects of bladder function while maintaining simplicity of recording.

In order to enhance accessibility for individuals with varying literacy levels, the bladder diary was designed using a pictorial format. Symbols and visual cues representing fluid intake, voiding events, urgency, leakage, and toileting posture were incorporated into the diary layout. These pictorial representations were intended to reduce dependence on written instructions while facilitating accurate documentation of urinary events.

Following development of the preliminary bladder diary, content validation was conducted using a panel of seven experts with experience in urogynecology, physiotherapy, and pelvic health research. Experts were asked to evaluate each diary item for relevance, clarity, simplicity, and comprehensibility using a structured rating scale. The Item-level Content Validity Index (I-CVI) was calculated for each item, and the Scale-level Content Validity Index (S-CVI) was calculated to determine the overall validity of the instrument.

Following completion of the expert validation phase, a pilot validation study was conducted among individuals presenting with lower urinary tract symptoms. Participants were recruited from tertiary care hospitals in Belagavi using simple random sampling. Individuals were eligible for inclusion if they were adult men or women experiencing symptoms of urinary incontinence or other lower urinary tract symptoms and were willing to participate in the study. Individuals were excluded if they were unable to comprehend the diary instructions, had an indwelling urinary catheter, or were currently experiencing an active urinary tract infection.

A total of forty participants were included in the pilot validation study. After obtaining informed consent, participants were instructed on how to complete the bladder diary using the provided pictorial symbols. Participants were asked to record urinary events including fluid intake, voiding episodes, urgency, leakage, and associated activities over a three-day period.(13)

After completing the initial recording period, participants returned the diary to the research team. Participants were then asked to repeat the diary recording after a one-week interval in order to evaluate the stability of recorded parameters over time. Participants were advised not to undergo any major therapeutic interventions during the interval period.(14)

The collected data were entered into Microsoft Excel and subjected to statistical analysis. Descriptive statistics including mean, standard deviation, frequencies, and percentages were used to summarize demographic characteristics and recorded diary variables. The Wilcoxon matched-pairs signed-rank test was used to compare diary-recorded variables

between the pre-test and post-test measurement sessions. This non-parametric test was chosen because the data did not necessarily follow a normal distribution and involved paired observations.

In addition, Spearman rank correlation analysis was performed to examine the relationship between values recorded during the two measurement sessions. This analysis allowed evaluation of the consistency of recorded parameters across repeated measurements. A p-value less than 0.05 was considered statistically significant.

Results

A total of forty participants were included in the pilot validation study. Among these participants, twenty-three were female and seventeen were male. The mean age of the study population was approximately 37.18 years with a standard deviation of 14.43 years. The mean body mass index of the participants was 25.82 kg/m^2 with a standard deviation of 4.86 kg/m^2, indicating moderate variation in body composition across the study population.

Analysis of toileting practices revealed that 62.5% of participants used Western-style toilets, while 32.5% used Indian-style squat toilets. A small proportion of participants reported absence of indoor toilet facilities. These findings highlight the variability in toileting environments within the study population.

Of the forty participants initially recruited for the study, thirty-four returned completed bladder diaries after the first recording period, resulting in a response rate of approximately seventy-five percent. Completion rates were highest during the first recording day and gradually declined across successive days of diary completion. This observation suggests that prolonged diary recording may impose a burden on participants and may influence data completeness.

Content validity analysis demonstrated strong agreement among experts regarding the relevance of most diary domains. The overall scale-level content validity index of the instrument was calculated as 0.87. Several domains including urine colour, time of recording, and leakage episodes achieved perfect agreement among experts, indicating high perceived relevance and clarity of these items. Other domains such as fluid intake quantity, urinary breaks, and stress activity also demonstrated high validity scores. However, the domain representing duration of urinary stream received comparatively lower validity ratings, suggesting the need for refinement of this item in future iterations of the diary.

Descriptive analysis of diary-recorded variables focused on four primary parameters: input volume, output volume, output breaks, and leakage episodes. Mean input volume recorded during the pre-test phase ranged from approximately 1646 mL to 1759 mL across the three recording days. Mean output volume ranged from approximately 1405 mL to 1505 mL across the same period. Similar values were observed during the post-test recording phase, indicating relative stability in recorded parameters.

Comparison of pre-test and post-test measurements using the Wilcoxon matched-pairs signed-rank test demonstrated no statistically significant differences for any of the four primary variables analyzed. The mean difference in input volume between the two sessions was approximately 27.55 mL, which was not statistically significant. Similarly, differences in output volume, output breaks, and leakage episodes were small and did not reach statistical significance.

Spearman rank correlation analysis revealed significant positive correlations between pre-test and post-test measurements for all four parameters. Correlation coefficients ranged from moderate to very strong values. These findings indicate that participants who recorded relatively higher values during the first measurement session tended to record similarly higher values during the second session, suggesting consistency in the measurement of urinary parameters using the developed bladder diary.

Discussion

The present study aimed to develop and evaluate a culturally adapted bladder diary suitable for use in the South Asian population. The results provide encouraging preliminary evidence regarding the validity and feasibility of the developed instrument.

One of the major strengths of the study lies in the strong content validity demonstrated by the expert evaluation. The overall scale-level content validity index of 0.87 indicates that experts considered the majority of diary items to be relevant and appropriate for assessing bladder function and urinary symptoms. High agreement for domains such as urine colour, time of voiding, and leakage episodes suggests that these items were clearly understood and considered clinically meaningful.(12)

The inclusion of pictorial symbols represents an important innovation in the design of the bladder diary. Visual representations may significantly improve comprehension among individuals with limited literacy and may therefore enhance completion rates and data accuracy. (15)Previous studies have demonstrated that simplified visual symptom assessment tools can improve usability in populations with limited educational backgrounds.

Another notable feature of the developed diary is the inclusion of culturally relevant variables such as toileting posture and toilet type. These variables are rarely included in conventional bladder diaries but may influence urinary behavior and pelvic floor

mechanics in populations where squat toilets are commonly used.(16)

The gradual decline in diary completion rates across successive recording days observed in the present study is consistent with findings from previous bladder diary studies. Multi-day diary recording may impose a burden on participants and may lead to incomplete data. For this reason, several researchers have suggested that shorter diary durations may provide a balance between data reliability and participant compliance.(17)

The absence of statistically significant differences between pre-test and post-test measurements suggests that the diary-recorded parameters remained stable across repeated observations. Furthermore, the strong correlations observed between measurement sessions indicate that the relative ranking of participants remained consistent over time. These findings support the potential reliability of the instrument.(18)

However, it is important to note that correlation does not necessarily indicate agreement, and further studies using dedicated reliability designs are required to establish test-retest reliability and measurement error.

Conclusion

The present study successfully developed a culturally adapted pictorial bladder diary tailored for the South Asian population. The instrument demonstrated strong preliminary content validity and encouraging consistency in recorded urinary parameters.

The pictorial format and culturally relevant design of the diary may improve accessibility and compliance among individuals with varied literacy levels. These features may make the diary particularly useful in diverse clinical settings where traditional written diaries are difficult to implement.

Although the results are promising, further large-scale validation studies are required to establish the complete psychometric properties of the instrument, including reliability, responsiveness, and clinical utility.

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