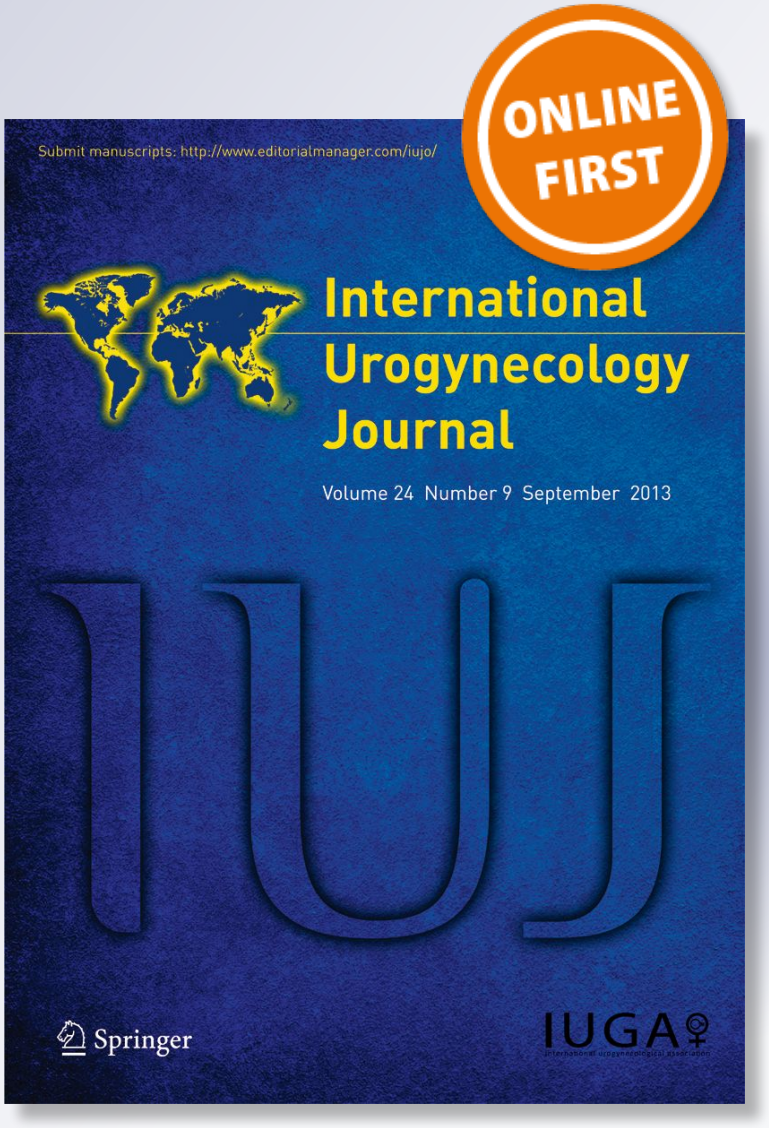
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ORIGINAL ARTICLE

Validation of the Sinhala translation of the International Consultation on Incontinence Modular Questionnaire for female lower urinary tract symptoms among women in Sri Lanka

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Abstract
Introduction and hypothesis The objective of this study was to translate the International Consultation on Incontinence Modular Questionnaire for female lower urinary tract symptoms (ICIQ-FLUTS) into Sinhala and validate the Sinhala translation for use in clinical practice.
Methods The ICIQ-FLUTS was translated into Sinhala in accordance with the ICIQ validation protocol. The Sinhala translation was validated by administering it to 133 women with FLUTS, mainly urinary incontinence and or urgency, and to 118 women with symptoms other than FLUTS during the period 25 October 2013 to 23 December 2016, in the Academic Obstetrics and Gynaecology Unit, Teaching Hospital Mahamodara, Galle, Sri Lanka.
Results The Sinhala translation had good content validity (assessed by a panel of clinicians including a content specialist, and a group of women with and without FLUTS), good internal consistency (Cronbach's alpha coefficient in the range 0.69–0.75) was stable (no significant differences between median test–retest scores in a subgroup of 24 women with FLUTS), had good construct validity (marked difference between median scores in women presenting with and without FLUTS, $p < 0.001$), and good responsiveness (marked improvements between scores before and after treatment, $p < 0.001$).
Conclusions The Sinhala translation of the ICIQ-FLUTS is valid and reliable for assessing Sinhalese-speaking women with FLUTS, especially urinary incontinence and/or urgency.

Keywords ICIQ-FLUTS · Sinhala translation · Validation · Sri Lanka

This work was presented at the RCOG World Congress 2016 in Birmingham, UK, by Gayan De Silva.

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Introduction

Although common, female lower urinary tract symptoms (FLUTS) are mostly under-reported worldwide [1–3]. A review of European and American epidemiological studies in elderly populations found a prevalence of FLUTS ranging from 10% to 40% [4]. In a survey published from the Kalutara District of Sri Lanka in 2007, 62.6% women reported having at least one urinary symptom [5]. FLUTS tend to have social, physical and psychological effects on women and adversely affect their sexual health, work productivity and quality of life [6–9]. In a woman with FLUTS, arriving at a correct diagnosis is difficult. The symptomatology is often inconclusive, and has been shown to have poor specificity in diagnosing stress urinary incontinence as well as detrusor overactivity. As stress urinary incontinence is mostly treated surgically and detrusor overactivity is mostly treated medically, depending only on the data obtained from interviewing the patient could lead to patients being treated inappropriately [10, 11].

A widely used questionnaire for evaluating FLUTS is the International Consultation on Incontinence Modular Questionnaire for FLUTS (ICIQ-FLUTS) [12]. The ICIQ-FLUTS was derived from the original Bristol Lower Urinary Tract Symptoms Questionnaire [13], and

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it was designed to assess the patient's symptoms and their severity to establish a tentative diagnosis. However, it also assesses a woman's perception of her problem as well as its impact on her quality of life. The ICIQ-FLUTS contains the three domains of symptoms, that is abnormal filling, abnormal voiding and urinary incontinence, with specific questions in each domain.

In Sri Lanka, data on the prevalence of female urinary incontinence are not available. Furthermore, as urogynaecology is still not established as a subspecialty, bladder diaries and validated questionnaires are not commonly used to assess FLUTS, and facilities for urodynamic assessment are also not freely available. Although approximately 75% of the population in Sri Lanka are Sinhalese, and the majority are not fluent in English, even the validated questionnaires available in English have not been translated into Sinhala and validated for use in Sri Lanka. Therefore it was decided to translate the ICIQ-FLUTS into Sinhala and validate it for use in Sinhalese women in Sri Lanka. This would improve objective assessment of FLUTS in Sinhalese women, and would become an important tool for the follow-up of these women after appropriate treatment. This would also become a useful tool for audits and research in Sri Lanka.

Materials and methods

Permission to translate the ICIQ-FLUTS into Sinhala and validate the Sinhala translation for use in Sri Lanka was obtained from the ICIQ group in accordance with the group's requirement [14]. Ethical approval was obtained from the Ethical Review Committee, Faculty of Medicine, University of Ruhuna, and written informed consent was obtained from all the women who participated in the study. The questionnaires were translated into Sinhala by two sworn Sinhala translators and back-translated into English by another two sworn English translators. All four translators were accredited to carry out such translations for legal purposes in Sri Lanka. The latter two translators were not aware of the original English version. To assess content validity, the translations were then discussed among a panel of clinicians, a content expert and women fluent in both English and Sinhala. Then it was pretested in a group of women with and without FLUTS. During this process necessary amendments were made to the Sinhala translation to ensure clarity. The two forward translations (English to Sinhala), the two backward translations (Sinhala to English), and the consensus Sinhala translation were sent for review by the ICIQ Development Group who recommended a few small amendments. This resulted in the final Sinhala translation which was again sent for approval to the ICIQ Development Group. The Sinhala translation was then validated in accordance with the validation protocol of the ICIQ Development Group [14].

The sample size recommended for validation of a questionnaire is 10–15 subjects per question [15], Therefore, as the ICIQ-FLUTS contains 12 questions, the minimum sample size needed to validate the ICIQ-FLUTS would be 120. During the study period 25 October 2013 to 23 December 2016, the Sinhala translation of the ICIQ-FLUTS was administered to all women with FLUTS presenting to the Academic Obstetrics and Gynaecology Unit, Teaching Hospital Mahamodara, Galle (133 women). It was also administered to a convenience sample of 118 women with symptoms other than FLUTS (including uterovaginal prolapse and abnormal uterine bleeding, but not excluding any other gynaecological problem), presenting to the clinic and consenting to inclusion in the study. Although the Sinhala translation of the ICIQ-FLUTS was self-administered, the authors read out the questions to the women who could not read. The completed questionnaires were marked and scored.

The means with 95% confidence intervals (95% CI) were calculated and compared using the *t* test for parametric variables, and the medians with interquartile ranges (IQR) were calculated and compared using the Mann-Whitney *U* test for nonparametric variables. Construct validity of the Sinhala translation was assessed by comparing the scores obtained in women presenting with FLUTS and women presenting with symptoms other than FLUTS. Internal consistency of questions within the three domains of the questionnaire was measured using Cronbach's alpha coefficient. The Cronbach's alpha was also recalculated for each domain after omitting one question in the domain at a time. From the first 50 women presenting with FLUTS, 24 subjects were randomly selected and the questionnaire was re-administered when they presented for their scheduled follow-up visit at 2 weeks with no treatment between the two assessments. The stability of the questionnaire was assessed by comparing the median test–retest scores using the Mann-Whitney *U* test in this subgroup of 24 women with FLUTS. The questionnaire

Table 1 Distribution of lower urinary tract symptoms using the Sinhala translation of the International Consultation on Incontinence Modular Questionnaire for Female Lower Urinary Tract Symptoms (n = 133)

Symptom	Women with FLUTS (n = 133)
Related to abnormal bladder filling	130 (98%)
Related to abnormal voiding	61 (45%)
Related to urinary Incontinence	130 (98%)
No identifiable symptoms	1 (0.75%)

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Table 2 Construct validity of the Sinhala translation of the International Consultation on Incontinence Modular Questionnaire for Female Lower Urinary Tract Symptoms: comparison of scores between symptomatic and asymptomatic women

Domain	Total score	No. of women affected	Score						p value[a]
			Women complaining of urinary symptoms (n = 133)			Women not complaining of urinary symptoms (n = 118)			
			Median	IQR	Range	Median	IQR	Range	
Abnormalities of filling	16	130	5.38	3.34–8.45	0–15	2	0–3	0–6	<0.001
Abnormalities of voiding	12	61	0.82	0–2.76	0–10	0	0–1	0–4	<0.001
Incontinence	20	130	8.11	5.09–11.53	0–20	0	0–1	0–5	<0.001

[a] Mann-Whitney U test, as the total individual scores were not parametrically distributed

was administered again 3 to 6 months after treatment to the first 46 women who underwent transobturator tape (TOT) insertion, and repeat scores were obtained. The scores from before and after treatment were compared to assess responsiveness.

Results

The panel of clinicians fluent in both English and Sinhala, the content expert and the group of women with and without FLUTS in whom the Sinhala translation was pretested agreed that the final Sinhala translation made sense and assessed what was needed to be assessed, and that no important aspects had been omitted. The final Sinhala translation was also approved by the ICIQ Development Group, confirming content validity.

The women with FLUTS were older than the women without FLUTS (mean age 50.3 years, 95% CI 48.6–51.9 years, range 30–74 years vs. mean age 39.6 years, 95% CI 37.0–42.2 years, range 18–73 years; $p < 0.001$). Using the Sinhala translation of ICIQ-FLUTS, symptoms related to abnormal bladder filling and urinary incontinence were found in 130 (98%) of the women presenting with FLUTS, with one having no abnormality. An abnormality of voiding was found in 61 (45%) of women with FLUTS, although they did not present with this complaint (Table 1). In each domain of the questionnaire, markedly high scores were noted in the women with FLUTS in comparison with the women without FLUTS, confirming construct validity (Table 2). All the domains had Cronbach's alpha of approximately 0.7 or more, indicating good internal consistency (Table 3). Omitting any of the questions in a domain did not change the Cronbach's alpha of a domain.

The mean age of the 24 women who participated in the test–retest was 49.3 years (standard deviation 9.5, range 36–72) and there was no significant difference in age distribution ($p = 0.6$) compared with the 133 women presenting with FLUTS. No significant differences were observed between the median scores obtained on test–retest, indicating that the questionnaire was stable (Table 4). Of the first 46 women who underwent TOT insertion, 42 had urodynamic stress incontinence and four had mixed urinary incontinence. As 15 of these women defaulted on follow-up, the effectiveness of the treatment could be assessed in only 31 women. On follow-up of these women after treatment with TOT, significant improvements in symptoms ($p < 0.001$) were detected by the questionnaire, indicating good responsiveness (Table 5).

Discussion

The Sinhala translation of the ICIQ-FLUTS had good content validity and internal consistency, was stable, and had good construct validity and responsiveness in women with FLUTS, especially urinary incontinence and or urgency, and is therefore suitable for the assessment of these symptoms, before and after treatment, in Sinhala-speaking women. The main strength of this work was that a rigorous translation and validation process was carried out in collaboration with the ICIQ Development Group, and the

Table 3 Internal consistency of the Sinhala translation of the International Consultation on Incontinence Modular Questionnaire for Female Lower Urinary Tract Symptoms (n = 133)

Domain	Cronbach's alpha
Abnormalities of filling	0.693
Abnormalities of voiding	0.703
Incontinence	0.747

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Table 4 Stability of the Sinhala translation of the International Consultation on Incontinence Modular Questionnaire for Female Lower Urinary Tract Symptoms (n = 24)

Domain	Total score	Score						p value[a]
		Test (n = 24)			Retest (n = 24)			
		Median	IQR	Range	Median	IQR	Range	
Abnormalities of filling	16	5	2–8	0–14	5	2–7	0–15	0.76
Abnormalities of voiding	12	0	0–2	0–10	0	0–2	0–6	0.98
Incontinence	20	6	4–11	1–20	6	3–12	2–14	0.95

[a] Mann-Whitney U test, as the total individual scores were not parametrically distributed

group approved the Sinhala Translation of the ICIQ-FLUTS to be used in Sinhala-speaking women.

Although ICIQ-FLUTS was designed to evaluate all FLUTS, 130 symptomatic women in the current study presented with urinary incontinence and/or urgency and only two women presented with voiding difficulties. However, the Sinhalese translation of the ICIQ-FLUTS detected another 59 women who appeared to have some voiding difficulty although they did not complain about it. This low prevalence of voiding abnormalities in the study populations would account for the low scores for voiding abnormalities obtained by the Sinhala translation of ICIQ-FLUTS. In Sinhalese-speaking women, the questionnaire was able to exclude any significant underlying FLUTS in the majority of asymptomatic women as well to measure the impact of FLUTS in symptomatic women.

As FLUTS are more commonly seen in elderly women, women with FLUTS were older than those with symptoms other than FLUTS. The Sinhala translation of the ICIQ-FLUTS was read out to some of these elderly women who could not read. However, this would not have had any significant impact on the results. The test–retest reliability could not be assessed in women with symptoms other than FLUTS because it was difficult to obtain consent from randomly selected women who did not present with FLUTS for the administration of a questionnaire not relevant to them at the 2-week scheduled follow-up visit.

The current study was not designed to assess response to treatment. Therefore, although there was a 30% loss to follow-up after treatment with TOT of the first 46 women who needed such treatment, and the reassessments were carried out only 3–6 months after the treatment, the marked reductions in the scores for abnormalities of filling and urinary incontinence in the ICIQ-FLUTS indicate that the questionnaire has good responsiveness and is useful for objective assessment of treatment outcomes. However, the occurrence or worsening of symptoms such as urgency and voiding difficulties, which are known to occur after procedures such as TOT insertion, can result in alteration in posttreatment scores in the questionnaire. This Sinhala translation will be of value even when urodynamic assessments are available, not only for pretreatment evaluation but also to objectively monitor response to treatment of FLUTS in Sinhalese women. In addition, it is better to evaluate outcome from the patient's perspective and the lived experience rather than clinical parameters only. Others are designing a Tamil translation for use in Tamil-speaking women in Sri Lanka.

In conclusion, the Sinhala translation of the ICIQ-FLUTS is valid and reliable for assessing Sinhalese-speaking women with urinary incontinence and/or urgency, and will be very useful for assessing Sinhala-speaking women with FLUTS, especially urinary incontinence and or urgency, before and after treatment.

Table 5 Responsiveness of the Sinhala translation of the International Consultation on Incontinence Modular Questionnaire for Female Lower Urinary Tract Symptoms assessed in women treated with transobturator tape insertion for urodynamic stress incontinence (n = 31)

Domain	Total score	Score						p value[a]
		After treatment			After treatment			
		Median	IQR	Range	Median	IQR	Range	
Abnormalities of filling	16	5	3–8	2–12	1	0–2	0–5	<0.001
Abnormalities of voiding	12	0	0–2	0–5	0	0–2	0–4	0.838
Incontinence	20	8	5–11	3–15	2	0–3	0–5	< 0.001

[a] Mann-Whitney U test, as the total individual scores were not parametrically distributed

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Compliance with ethical standards

Conflicts of interest None.

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