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ORIGINAL ARTICLE

Validation of the International Consultation on Incontinence Questionnaire–Vaginal Symptoms (ICIQ-VS) in two south- Asian languages

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Abstract

Introduction The multifaceted nature of pelvic floor disorders means that a systematic evaluation is required for optimal treatment outcome. It is also generally acknowledged that a valid tool is necessary to objectively assess symptoms reported by affected women.

Methods The International Consultation on Incontinence Questionnaire—Vaginal Symptoms (ICIQ-VS) questionnaire was translated to Sinhala and Tamil and a validation study carried out among women attending gynecology clinics at North Colombo Teaching Hospital, Ragama, and the district general hospitals Mannar and Vavuniya.

Results Content validity was assessed by the level of missing answers, which was < 4% and 2% for each item in Sinhala and Tamil, respectively. Construct validity was assessed by the ability of the questionnaire to differentiate between patients and controls. Both differentiated patients from controls on vaginal symptoms score (VSS) ($p < 0.001$), sexual symptoms score (SSS) ($p < 0.01$), and quality of life (QoL) ($p < 0.001$). There was a strong positive correlation between Pelvic Organ Prolapse Quantification (POP-Q) scores and VSS (Sinhala $r_s = 0.64$, $p < 0.001$, Tamil $r_s = 0.65$, $p < 0.001$), and QoL (Sinhala $r_s = 0.49$, $p < 0.001$, Tamil $r_s = 0.60$, $p < 0.001$). Internal consistency as assessed using Cronbach's coefficient alpha: 0.78 (0.76–0.78) and 0.83 (0.80–0.84) in Sinhala and Tamil, respectively. Test–retest reliability was assessed by weighted kappa scores (Sinhala 0.58–0.88 and Tamil 0.76–0.90). Both questionnaires were sensitive to change and showed that VSS and QoL improved following surgery (Wilcoxon matched-pairs signed-rank test $p < 0.001$).

Conclusion The validated Sinhala and Tamil translations of ICIQ-VS will be useful for assessing vaginal and sexual symptoms among women speaking Sinhala and Tamil.

Keywords Pelvic organ prolapse · Psychometric analysis · Sinhala and Tamil validation · Vaginal symptoms · Sexual symptoms · Quality of life

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Introduction

Pelvic floor dysfunction is an extremely common problem in up to 40% of women attending gynecology clinics [1]. Pelvic organ prolapse (POP) is frequently implicated in women with vaginal and sexual symptoms [2] and often leads to physical, psychological, social, occupational, and sexual limitations to their lifestyles. In women with pelvic floor dysfunction, vaginal symptoms often coexist with lower urinary tract and lower bowel symptoms [2]. Symptoms of pelvic floor dysfunction, especially vaginal and sexual problems, may not be divulged during the clinical interview due to embarrassment and cultural issues. The multifaceted and stigmatizing nature of pelvic floor disorders may result in an unreliable clinical interview, thus underestimating such issues. Patients may either not seek treatment or be hesitant to reveal the true extent of the

problem when they finally seek treatment, which could mislead the clinician.

As symptoms often do not correlate with examination findings, patients may be under- or overtreated if there is evidence of POP despite the absence of vaginal or sexual symptoms [3–5]. Furthermore, patients may not voluntarily express symptoms of sexual dysfunction. In addition, as POP adversely affects the patient's quality of life (QoL) [6], a systematic evaluation is necessary if optimal clinical outcome is to be achieved. As only affected women can objectively report on their symptoms and QoL, developing a practical and reliable tool is of value in their appropriate management [7].

Sinhala and Tamil are the two main languages spoken in Sri Lanka, with ~75% of people speaking Sinhala and the rest Tamil. However, demographically, Tamil is spoken almost exclusively in northern parts of Sri Lanka. Even in the southern parts, people are conversant in only one of these languages. To our knowledge, there is no validated questionnaire in either Sinhala or Tamil for vaginal or sexual symptoms of pelvic floor dysfunction. The availability of a validated, simple, practical questionnaire would be valuable in overcoming time constraints in the often overcrowded gynecology clinics of a developing country.

The International Consultation on Incontinence Modular Questionnaire on Vaginal Symptoms (ICIQ-VS) is a self-administered method for assessing a comprehensive range of vaginal and sexual symptoms and their impact on QoL, particularly in those with POP. It is a useful tool for patient evaluation, to monitor symptoms over time, and to assess treatment effectiveness. The ICIQ-VS questionnaire is a practical, low-cost tool that is widely applicable to adult women both in primary and secondary care settings, with high levels of validity, reliability, and sensitivity when using standard psychometric methods [2]. Therefore, our objective was to translate and validate the questionnaire into Sinhala and Tamil.

Materials and methods

The ICIQ-VS questionnaire translation and validation was done according to the protocol provided by the International Consultation on Incontinence (ICI) (http://www.iciq.net/validationprotocol.htm). The English ICIQ-VS was translated in to Sinhala and Tamil according to standard guidelines before undergoing validation [8]. The translation process involved the following steps:

1. Literal translation and adaptation of the English ICIQ-VS questionnaire into Sinhala and Tamil was undertaken by bilingual native-language speakers.
2. Discussions were undertaken with gynecologists and patients (conversant in Sinhala and Tamil) in terms of the questionaire's acceptability, whether it measured what it

was designed to measure, and ensure clinically meaningful aspects were included.
3. Back-translation was carried out by another set of bilingual native-language speakers.
4. Back-translations were reviewed by the ICI.
5. Final translations were produced after modifications, and retranslation of was necessary to resolve problems and identify further discrepancies.

Validation was then undertaken to confirm that psychometrics were retained throughout the adaptation process.

Design, setting, and participants

The Sinhala validation was done in the professorial gynecology unit of the North Colombo Teaching Hospital, Ragama; Tamil validation was done in the gynecology units of district general hospitals Mannar and Vavuniya from February 2016 to September 2016. All women attending the clinics were included in the study, and those presenting with POP were considered as patients; women without POP were controls. Women who were <18 years, pregnant, or puerperal were excluded.

The ICIQ-VS questionnaire has four domains: vaginal, prolapse, and sexual symptoms and QoL. A patients-to-variables ratio of 10:1 was considered as adequate sample size. Therefore, a minimum of 40 patients with vaginal, sexual, and/or prolapse symptoms were required for each language.

Description of procedure

The questionnaire was given to each patient in the appropriate language. Women were provided with a private setting in which to complete the questionnaire, and a staff member was available to give nondirective assistance, as visual problems were encountered in the target population. The questionnaire was administered again 4 weeks after the first visit. A pelvic examination was done by the consultant in charge of the gynecology clinic, and a POP-Q form was completed by each participant prior to surgery [9]. Patients who underwent surgery were again assessed with the questionnaire 2 months after treatment.

Statistical analysis

Basic demographic characteristics of patients and controls were assessed for comparability between groups. Content/face validity was evaluated by analyzing missing data. Construct validity was evaluated using two methods: The first was whether the questionnaire could differentiate between patients and controls using the Mann–Whitney U test by comparing vaginal symptoms score (VSS), sexual symptoms score

(SSS), and QoL against the clinical diagnosis. Second, VSS, SSS, and QoL scores were compared against the POP-Q using Spearman's correlation coefficient. Internal consistency was evaluated using Cronbach's coefficient alpha. Stability (test–retest reliability) was assessed by a test–retest analysis performed 4 weeks after initial presentation. Agreement was further analyzed using the weighted Kappa (κ) statistic [10]. Sensitivity to change/responsiveness was assessed by comparing pre- and postsurgical difference in VSS, SSS, and QoL. Ethical approval was obtained by the Ethical Review Committee (ERC) of the Faculty of Medicine, University of Kelaniya (13 January 2016).

Results

Basic characteristics of the study population are shown in Table 1.

Validity

Content validity was assessed by the level of missing data, which was <4% for each item in Sinhala and <2% for each item in Tamil. Construct validity was assessed by the ability of the questionnaire to differentiate between patients and controls. Regarding VSS, the Sinhala questionnaire differentiated between patients ($n = 84$) and controls ($n = 134$) [mean 18.0, standard deviation (SD) 9.1 vs 5.0 (SD 6.0), respectively ($p < 0.001$)]; for SSS between patients ($n = 39$) and controls ($n = 103$) [mean 5.8 (SD 18.1) vs 7.67 (SD 13.0), respectively ($p < 0.01$); and for QoL between patients ($n = 83$) and controls ($n = 135$) [mean 5.1 (SD 3.3) vs 2.2 (SD 2.8), respectively ($p < 0.001$) (Fig. 1). There was a positive correlation between POP-Q scores and VSS ($r_s = 0.64$, $p < 0.001$, $n = 218$), SSS ($r_s = 0.27$, $p < 0.01$, $n = 142$), and QoL ($r_s = 0.49$, $p < 0.001$, $n = 218$) (Fig. 2).

The Tamil questionnaire also differentiated between patients and controls on VSS regarding prolapse ($n = 70$) and controls ($n = 94$), with mean scores of 18.1 (SD 9.2) and 5.4 (SD 6.0), respectively ($p < 0.001$). For SSS, it differentiated between patients ($n = 17$) and controls ($n = 54$) [mean 18.8 (SD 13.2) vs 10.01 (SD 16.1), respectively ($p < 0.01$)] and for QoL between patients ($n = 63$) and controls ($n = 84$) [mean 4.79 (SD 2.8) vs 1.8 (SD 2.6), respectively ($p < 0.001$)] (Fig. 1). There was a

positive correlation between POP-Q scores and VSS ($r_s = 0.65$, $p < 0.001$, $n = 164$), SSS ($r_s = 0.31$, $p < 0.01$, $n = 71$), and QoL ($r_s = 0.60$, $p < 0.001$, $n = 147$) (Fig. 2).

Reliability

Internal consistency was assessed using Cronbach's coefficient alpha scores: 0.78 (0.76 – 0.78) and 0.83 (0.80-0.84) in Sinhala and Tamil, respectively (Table 2).

Test–retest reliability of items for the Sinhala translation as assessed by weighted kappa values ranged from 0.58 to 0.88, except for item "vagina too tight," which demonstrated moderate reliability (kappa 0.47). Test–retest reliability for the Tamil translation ranged from 0.76 to 0.90 (Table 2).

Sensitivity to change

The Sinhala questionnaire was sensitive to change and showed that VSS ($n = 41$) improved from 11.31 to 5.46 following surgery (Wilcoxon matched-pairs signed-rank test $p < 0.001$). QoL ($n = 41$) also improved postoperatively, as scores decreased from 2.98 to 0.85 (Wilcoxon matched-pairs signed-rank test $p < 0.001$). However, SSS worsened from 8.86 to 9.25 following surgery ($p = 0.60$, $n = 8$; two patients who were not sexually active prior to surgery resumed sexual activity after surgery) (Fig. 3). The Tamil questionnaire was also sensitive to change and showed that VSS ($n = 44$) improved from 14.09 to 2.69 following surgery (Wilcoxon matched-pairs signed-rank test $p < 0.001$). QoL ($n = 42$) improved postoperatively, from 3.71 to 1.02, as did SSS—from 14.45 to 3.62 ($p < 0.05$, $n = 12$, including three patients who were not sexually active prior to surgery and resumed sexual after) (Fig. 3).

Discussion

For content and construct validity and reliability in terms of internal consistency, test–retest reliability and sensitivity to change were acceptable for both Sinhala and Tamil questionnaires. There was good internal consistency, with Cronbach's coefficient alpha scores being 0.78 (0.76–0.78) and 0.83 (0.80–0.84) in Sinhala and Tamil, respectively. Test–retest

Table 1 Basic characteristics of recruited women

	ICIQ-VS Sinhala ($n = 234$)		ICIQ-VS Tamil ($n = 169$)	
	Prolapse ($n = 99$)	Controls ($n = 135$)	Prolapse ($n = 72$)	Controls ($n = 97$)
Age [mean, (SD)]	56.2 (12.6)	42.6 (11.3)	60.4 (11.4)	41.4 (12.8)
Median parity (IQ1–IQ3)	2 (2–4)	2 (1–3)	3.5 (3–4.5)	2 (1–3)
BMI [kg/m^2 (SD)]	23.9 (3.3)	23.2 (2.9)	24.0 (3.2)	25.5 (4.7)

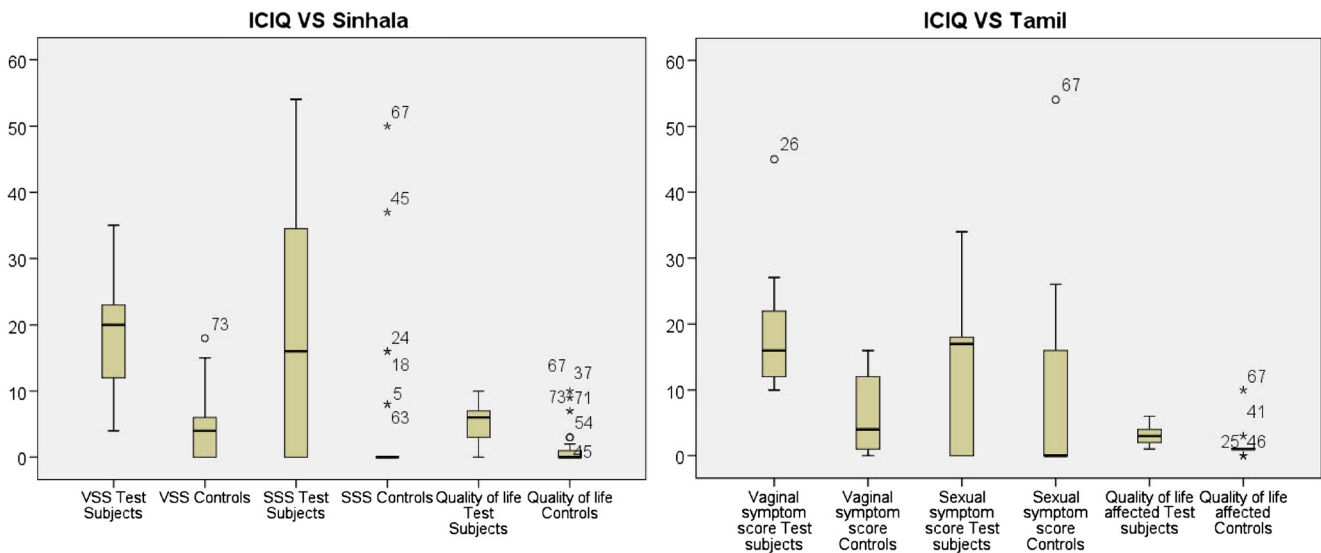*SD* standard deviation, *IQ* interquartile range

Fig. 1 Construct validity. Sinhala and Tamil questionnaires using vaginal symptoms (VSS), sexual symptoms (SSS), and quality of life (QoL) scores versus clinical diagnosis

reliability was exceptional: weighted kappa scores ranged from 0.76 to 0.90 for Tamil and from 0.58 to 0.88 for Sinhala. Only the item "vagina too tight' on the Sinhala version demonstrated moderate reliability (weighted kappa 0.47). This item, which is not used for scoring, demonstrated poor reliability in the article by Price et al. [2].

The validation sample included patients and controls because, as the questionnaire is a new tool, it would cause greater harm if it were to have false positives versus false negatives. In other words: if only symptomatic patients were enrolled, it would only be a measure of scale sensitivity. By testing controls as well, we were able to assess scale specificity as well.
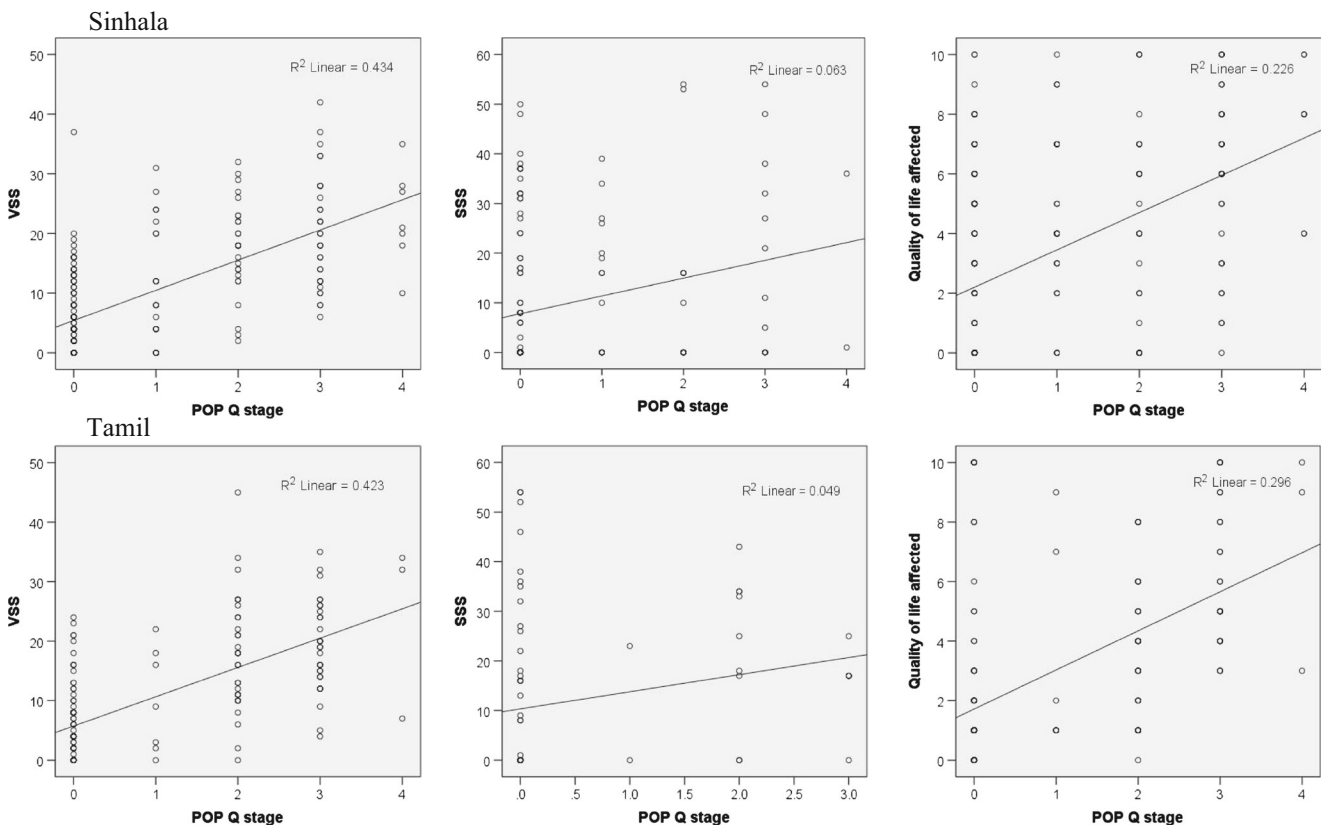

Fig. 2 Construct validity: Sinhala and Tamil questionnaires using vaginal symptoms (VSS), sexual symptoms (SSS), and quality of life (QoL) scores versus Pelvic Organ Prolapse Quantification (POP-Q) system classification

Table 2 Internal consistency and reliability validation

| Question	Internal consistency (Cronbach's coefficient alpha scores)		Reliability (weighted Kappa scores)	
	Sinhala ($n = 141$)	Tamil ($n = 61$ for each item)	Sinhala	Tamil
Are you aware of dragging pain in your lower abdomen?	0.78	0.82	0.64 ($n = 108$)	0.76 ($n = 107$)
Are you aware of soreness in your vagina?	0.77	0.81	0.64 ($n = 108$)	0.80 ($n = 108$)
Do you feel that you have reduced sensation or feeling in or around your vagina?	0.78	0.83	0.66 ($n = 108$)	0.80 ($n = 107$)
Do you feel that your vagina is too loose or lax?	0.78	0.81	0.71 ($n = 106$)	0.86 ($n = 106$)
Are you aware of a lump or bulge coming down in your vagina?	0.76	0.82	0.88 ($n = 108$)	0.87 ($n = 108$)
Do you feel a lump or bulge come out of your vagina, so that you can feel or see it on the outside?	0.76	0.82	0.86 ($n = 107$)	0.88 ($n = 108$)
Do you feel that your vagina is too dry?	0.77	0.83	0.69 ($n = 107$)	0.80 ($n = 108$)
Do you have to insert a finger into your vagina to help empty your bowels?	0.78	0.83	0.72 ($n = 107$)	0.85 ($n = 108$)
Do you feel that your vagina is too tight?	0.78	0.83	0.47 ($n = 101$)	0.79 ($n = 67$)
Do worries about your vagina interfere with your sex life?	0.76	0.81	0.68 ($n = 74$)	0.84 ($n = 32$)
Do you feel that your relationship with your partner is affected by vaginal symptoms?	0.77	0.80	0.58 ($n = 74$)	0.86 ($n = 32$)
How much do you feel that your sex life has been spoilt by vaginal symptoms?	0.76	0.81	0.65 ($n = 74$)	??? ($n = 32$)
Overall, how much do vaginal symptoms interfere with your everyday life?	0.77	0.81	0.66 ($n = 107$)	0.90 ($n = 94$)
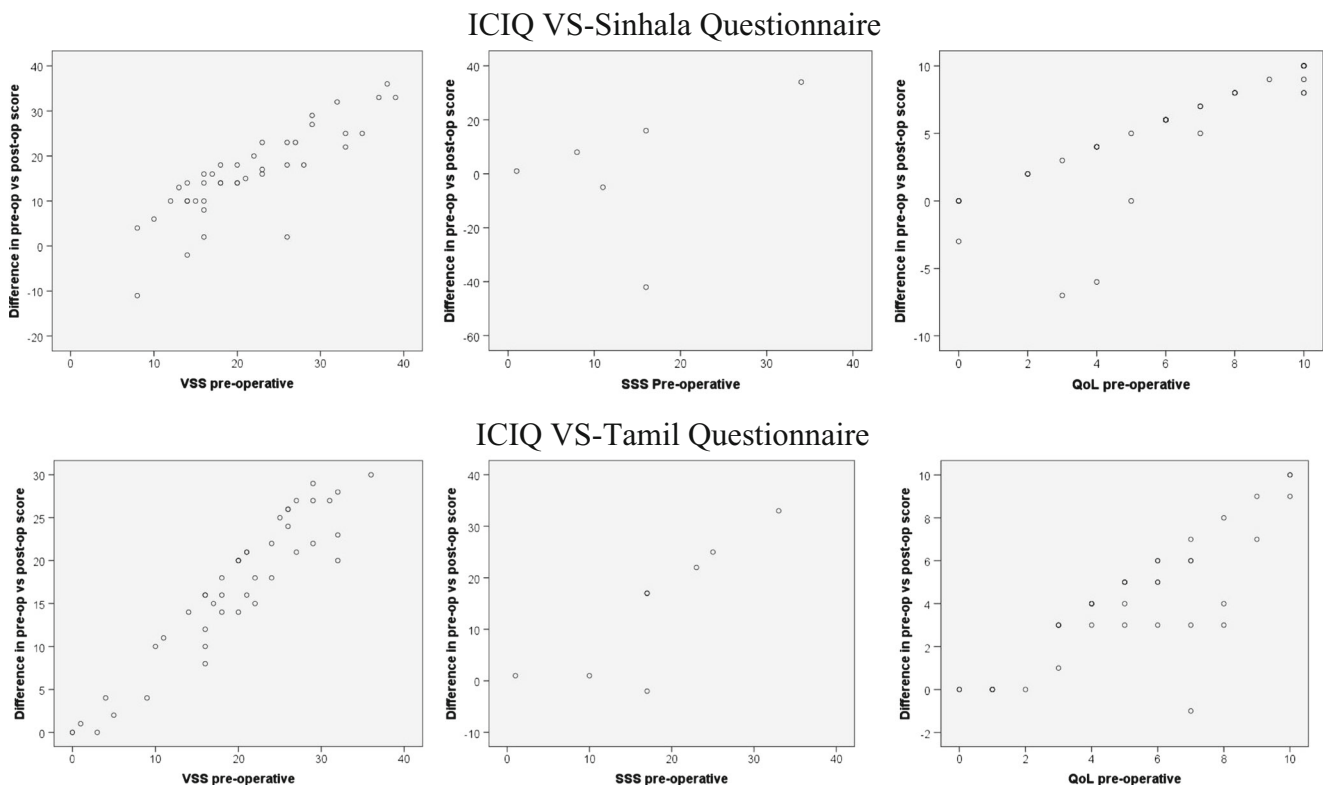
Fig. 3 Sensitivity to change: Sinhala and Tamil questionnaires comparing preoperative scores for VSS, SSS and QoL on the *X*-axis difference between pre- and postoperative scores on the *Y*-axis

Therefore, using both patients and controls was the optimal method.

Construct validity was assessed by two methods; first the ability of the questionnaire to differentiate between patients and controls compared with clinical diagnosis by the doctor, and second, to assess the questionnaire against POP-Q stage. The latter was suggested in the original article by Price et al. [2] and has been used as a measure of criterion validity in the Portuguese validation of the ICIQ-VS; however, we feel that as POP-Q stage is derived from clinical assessment, and also as it is not a specific test, it has greater similarity with construct rather than criterion validity [11].

Although both questionnaires easily differentiated between patients and controls on VSS ($p < 0.001$) and QoL ($p < 0.001$), performance on SSS was less significant ($p < 0.01$). This may be because patients without prolapse who were considered as controls had sexual symptoms. Moreover, some studies found mild to moderate correlation between impaired sexual activity and worsening prolapse in all three compartments [3, 4]. In a similar vein, a strong positive correlation was found between POP-Q scores and VSS (Tamil $r_s = 0.65$, $p < 0.001$, Sinhala $r_s = 0.64$, $p < 0.001$), and QoL (Tamil $r_s = 0.60$, $p < 0.001$, Sinhala $r_s = 0.49$, $p < 0.001$); there was only a weak correlation for SSS (Tamil $r_s = 0.32$, $p < 0.01$, Sinhala $r_s = 0.27$, $p < 0.01$).

Sensitivity to change on the scale was significant for both languages in terms of vaginal symptoms and QoL ($p < 0.001$). Although both improved significantly following surgery on both questionnaires, there was no significant improvement in SSS on the Sinhala questionnaire. This nonsignificance may be because sexual satisfaction is multifactorial and does not depend solely on prolapse severity or because the time interval (2 months) of assessment following surgery may be too short for patients to resume sexual activity. We chose this time interval for reassessment because a longer follow-up would have led to higher dropout rates and loss to follow-up. It is customary in Sri Lanka to review patients 6 weeks following surgery for benign conditions to review histology with them. As this time period is short, we extended it to 2 months for this study.

Our study was hospital based, as finding a community sample for controls was not feasible. Community health services in Sri Lanka are not well-developed, as in a first-world country, and using a community sample as controls would likely have included patients with prolapse who were undiagnosed and not attending hospital. In addition, financial constraints was a barrier to selecting a community sample. Patient recruitment was therefore done in gynecology clinics serving urogynecology patients, as there are no such specialized clinics.

Perhaps due to this problem, we found a difference in age and parity between study and control groups. This was expected, as the chance of prolapse is higher with increasing age and parity [12]. Demographically, the mean age in prolapse patients was postmenopausal, while that of controls was perimenopausal. As menopausal status was not available, this variable may have acted as a confounder for construct validity. However, it is unlikely that validation results were materially affected by this difference, as the questionnaire was validated on five aspects: content validity, internal consistency, stability, construct validity, and responsiveness—none of which depend on age.

Selecting controls from a unit such as the medical ward or outpatient department and comparing it with patients from the gynecology clinic would have created a more heterogeneous population, making it easier to derive a higher reliability. However, by selecting controls from clinic rather than the community, the questionnaire had to differentiate prolapse from other gynecological patients, some of whom may have had some undetected vaginal symptoms, whereas ideal controls from the community may be less likely to have symptoms. Therefore, it was more difficult to obtain a satisfactory reliability coefficient. If it were to be achieved, as in this case, reliability of the questionnaire in the community would be much higher than in our study [13]. In addition, the gynecology clinic is where we envision the questionnaire being used and as such is the most practical setting for testing. The translation and validation of both Sinhala and Tamil versions of the ICIQ-VS questionnaire demonstrate a high level of validity, reliability, and sensitivity when evaluated using standard psychometric methods. It will be useful as an objective tool to screen patients, recommend treatment, and to further research on this topic.

Compliance with ethical standards

Conflicts of interest None.

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