

RESEARCH PAPER.**VALIDATION OF SINHALA AND TAMIL TRANSLATIONS OF AUSTRALIAN PELVIC FLOOR QUESTIONNAIRE**Suhajanan T¹¹Post Graduate Trainee obstetrics and Gynaecology Ministry of Health, Sri LankaCorresponding Author: suhajanan26@gmail.com**ABSTRACT**

Weakness of one or more groups of supporting elements of pelvis leads to pelvic floor dysfunctions and ultimately pelvic organ prolapse. Cross sectional validation study was conducted among 236 study participants at gynaecology unit Teaching Hospital Ragama. Patients with an age of 40 years or above who presented to the gynaecological unit for any reason were included. Sinhala and Tamil Translated versions of Australian Pelvic floor questionnaire was administered to participants to assess the pelvic floor dysfunction. The mean age of the study participant was 55.77 years (SD= 10.18 Years). Considerable number of study participants were not having experience of vaginal deliveries (N=65:27.5). 31.4% of study participants had undergone lower segment cesarean section (N=162). Tamil version of the study instrument Cronbach alpha value was determined as 0.632. The results of the reliability assessment of the Sinhala version of the study tool produced the satisfactorily accepted level (Cronbach alpha=0.610). According to the assessment of pelvic floor dysfunction tool, 56.33% (N=133) were diagnosed as a patient having pelvic floor dysfunction and 24%(N=57) were diagnosed by clinical assessment. Sensitivity of the Sinhala version of the study instrument is 100%. Specificity was calculated as 59.13%. positive predictive value was 41.53 and the negative predictive value was determined as 100%. Sensitivity of the Tamil version of the study instrument is 100%. Specificity was calculated as 55.3%. Positive predictive value was 44.11 and the negative predictive value was determined as 100%. The total statement score has significant predictability of pelvic floor dysfunction (AUC=0.743:95%CI=0.656-0.830). Bladder score alone showed the highest Predictability (AUC=0.888:95%CI=0.839-0.936). Prolapse of pelvic organ score also showed the significant predictability (AUC=0.648:95%CI=0.569-0.727). Reliability of the Sinhala and Tamil versions of the pelvic floor dysfunction assessment tools is at a satisfactory level. Sensitivity and negative predictive ability of the study tool are at a maximum level. Specificity and the positive predictive ability of the study tool are significantly low. Generation of false negative results by the study tool is minimum and tendency to generate false positives is relatively high. All the main components of the study tool have a significant ability to predict Pelvic floor dysfunction. Measures should be taken to publish the questionnaire used for the present study as a screening tool to detect pelvic floor dysfunction. Attention should be paid on developing more simple screening tools by using the identified predictive abilities of each component of the study tool.

Key words: Pelvic floor dysfunction, Validation, Reliability

INTRODUCTION

Weakness of one or more groups of these supporting elements leads to pelvic floor dysfunctions and ultimately pelvic organ prolapse³. Anal incontinence, Urinary Incontinence (UI) and Pelvic Organ Prolapse (POP) are together referred to as Pelvic Floor Dysfunction (PFD). The International continence society (ICS) has worked to standardise terminologies oriented by patient's history. Women who may have a prolapse by the lumpiness at vulva, lower back pain, dragging sensation, heaviness, or may need to replace the herniated part digitally in order to micturate or defecate⁴. Stress urinary incontinence is another sign of PFD that is defined as the observation of involuntary leakage from the urethra⁵, synchronous with exertion, or coughing or sneezing. Anal incontinence refers as Complaining of involuntary loss of flatus or feces⁶.

The world population prevalence of the PFD or POP is difficult to determine, anyhow relative risk of undergoing or requiring at least one surgery for correct incontinence or prolapse is estimated at approximately 11% in United States^{13,15}. Highest prevalence of PFD is found in Caucasian Americans and lowest were among Singaporean females^{14,16}, in Sri Lanka very high rate of the incidence of stress urinary incontinence was reported also very few of them seeking medical advice¹⁷.

According to the prevalence study in Sri Lanka, taking that UI is normal with aging and increasing parity, feeling embarrassed to consult a specialist, even not knowing that treatment is available or fear about surgery or being busy with their other

priorities of the family are the main causes for delaying the medical opinion¹⁷. Truly PFD, POP were giving greater impact on quality of life. Women who have POP are thinking that they more likely to have difficulty looking at them self-naked, complex about their sexual attractiveness and less likely to feel feminine¹⁸. According to a forecasting prevalence study in America, the prevalence of at least one PFD will be increased around 55% by 2050. It estimates incidence of faecal incontinence by 59% and UI by 55% and POP by 49%¹⁹.

So, the need of improving the quality of life of our women with PFD can be achieved by early detection and management, for this purpose a self-patient oriented questionnaire is needed, to this purpose an already validated Australian pelvic floor questionnaire²⁰ to be validated in their own mother tongue.

METHODS

Cross Sectional Validation Study was conducted at Teaching Hospital Ragama. Period of one year starting from August 2017. Data collection was carried out for a period of 06 months starting from October 2017 to March 2018. Patients above 40 years of age who got admitted to the gynaecological ward for any reason and patients who were attending the gynaecological clinic for any reason were selected. Patients were asked to re attend the clinic for further clarifications if they needed further treatment, as they agreed to follow up in the Gynaecological clinic. Patients who underwent any surgery for Pelvic Floor Dysfunction, Patients who underwent spinal surgery, Patients who

have any spinal cord problems were excluded. Translated Tamil and Sinhala versions of Australian pelvic floor questionnaire was used with a self-administered questionnaire to ascertain socio-demographic features of study participants was used as study instrument.

Translation-Forward and backward translation method was adopted to develop the Sinhala and Tamil translations of Australian pelvic floor questionnaire with the assistance of two independent language experts. Assessment of Judgmental Validity-For content and consensual validity of the translated version of Australian pelvic floor questionnaire was assessed by a Multidisciplinary panel of experts comprising of a VOG, VP and Community Medicine Experts. Each of the questionnaires was evaluated by using a rating system.

The developed Sinhala version of Australian pelvic floor questionnaire was

administered to the eligible study participants upon their informed written consent by the principal investigator.

Tamil translation was administered by a Tamil Medical Officer who was trained by the principal investigator. The clinical diagnosis of Pelvic Floor Dysfunction was made by the VOG after administration of the questionnaire.

RESULTS

Age of the study participants ranged between 40years to 81 years. Mean age of the study participants was 55.77 years (SD= 10.18 Years). Majority of the study participants belonged to the age group below 60 years(N=163:69.1%). Body Mass

Index of the study participants ranged between 15.1 kg/m² to 36.3 kg/m². Mean value of the Body mass index was 26.92 kg/m² (SD=4.67 kg/m²). Body mass Index of the majority of the study participants was above 25 kg/m².

Table 1 : Distribution of the reliability assessment of the Pelvic Floor Dysfunction questionnaire for all the study participants

Parameter	Pearson's r	Mean	SD
Bladder Score	.723	11.15	9.54
Bowel Score	.402	6.07	5.60
Pelvic organ prolapses	.423	2.83	3.774
Sex Score	0.051	3.31	7.52

Mean bladder score is 11.15 (SD=9.54). Bladder score showed the highest correlation with the total score of the statement responses. Sex score showed the least correlation with the item total

correlation. The item total correlation assessment of the reliability can be confirmed as in the accepted level (Cronbach alpha=0.623)(Table 1).

Table 2 : Distribution of the reliability assessment of the PFD questionnaire Tamil Version for study participants

Parameter	Pearson's r	Mean	SD
Bladder Score	.726	11.40	10.161
Bowel Score	.385	6.75	6.863
Pelvic organ prolapses	.418	3.11	3.92
Sex Score	.023	2.98	6.944

Bladder score showed the highest correlation with the total item correlation. Mean bladder score was 11.40 (SD=10.161). Pelvic organ prolapses showed the second highest positive correlation with the total item correlation. Sex score of the correlation showed a

minimum positive correlation with the total item correlation. According to the calculated assessment of the tool, satisfactorily accepted level of reliability was determined (Cronbach Alpha=0.632)(Table 2).

Table 3 : Distribution of the reliability assessment of the Pelvic Floor Dysfunction questionnaire Sinhala Version for study participants

Parameter	Pearson's r	Mean	SD
Bladder Score	0.719	10.91	8.92
Bowel Score	0.446	5.39	3.97
Pelvic organ prolapses	0.424	2.55	3.62
Sex Score	0.085	3.64	8.061

The scores of all the individual parameters of the study instrument positively correlated with the total score of the study tool. Bladder score contributes to the highest degree of correlation and sex score contributes to the least degree of correlation. All the parameters except

bladder score showed a correlation of less than 0.5. According to the complete reliability assessment of the study instrument, reliability can be determined as in the satisfactorily accepted level (Cronbach alpha=0.610)(Table 3).

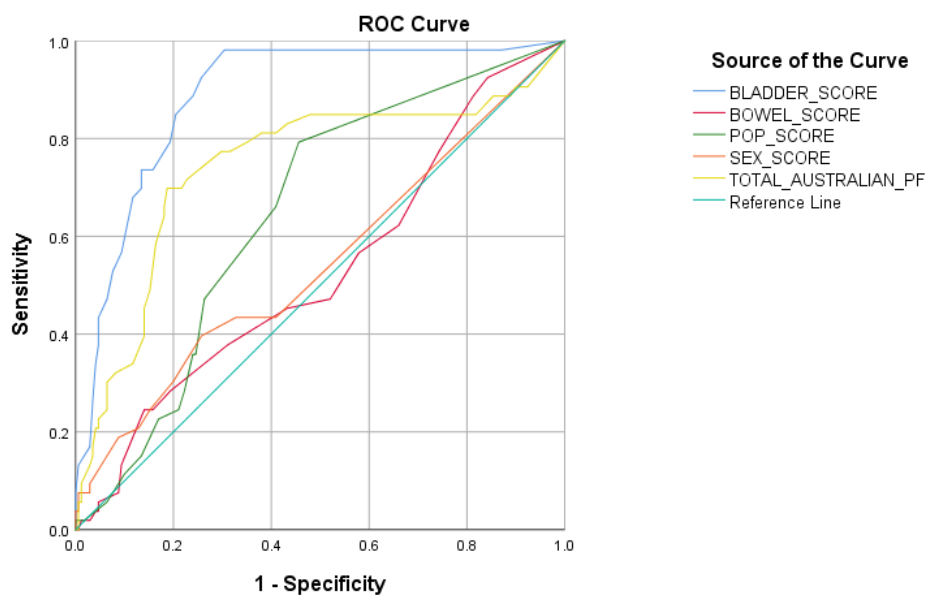
Table 4 : Criterion validity assessment of the Study instrument Sinhala version

	Disease Positive	Disease Negative	Total
Sinhala Version			
Test Positive	27	38	65
Test negative	0	55	55
Total	27	93	120
Tamil Version			
Test Positive	30	38	68
Test negative	0	45	45
Total	30	83	113

Sensitivity of the Sinhala version of the study instrument is 100%. Specificity was calculated as 59.13%. Positive predictive value was 41.53 and the negative predictive value was determined as 100%(Table 4).

Sensitivity of the Tamil version of the study instrument is 100%. Specificity was calculated as 55.3%. Positive predictive value was 44.11 and the negative predictive value was determined as 100%(Table 4).

Figure 1: Graphical illustration of the predictive ability of the different component of the study instrument



All receiver operator characteristic curves cover the area more than 0.5 in the predictability graph. Score of all the parameters showed the accepted

predictability of pelvic floor dysfunction. The area covered by the bladder score is higher than the area covered by the total score (Figure 1).

Table 5 : Distribution of predictability values of separate parameters of the study instrument

Variable(s)	AUC	Std Error	P value	95% Confidence Interval	
Bladder_score	.888	.025	.000	.839	.936
Bowel_score	.530	.046	.515	.440	.620
POP_score	.648	.040	.001	.569	.727
Sex_score	.545	.048	.322	.451	.639
Total Score	.743	.044	.000	.656	.830

AUC=Area under the curve, POP=Pelvic Organ Prolapse

The total statement score has a significant predictability of Pelvic Floor Dysfunction (AUC=0.743: 95%CI=0.656-0.830). Bowel score (AUC=0.530: 95% CI = 0.440-0.620) and the sex score (AUC=0.545: 95%CI=0.451-0.639) showed the least predictability. Bladder score alone showed the highest predictability (AUC =0.888: 95%CI=0.839-0.936). Prolapse of pelvic organ score also showed a significant predictability (AUC=0.648: 95%CI=0.569-0.727) (Table 5).

DISCUSSION

It was observed that several investments were used to evaluate pelvic flow dysfunction. For this purpose, pelvic flow incontinence symptoms were frequently used. Pelvic

flow disorder scale which consisted of three main sections with 28 items each, was mainly used to address pelvic organ prolapse and colorectal dysfunctions. Pelvic organ prolapse inventory which consisted of 16 items and colorectal anal impact questionnaire with 17 items were directed towards pelvic organ prolapse. But in the present study tool, both pelvic organs prolapse and incontinence are considered as the components of a single study tool. In the pelvic organ prolapse impact questionnaire which consisted of 31 items, a psychometric evaluation of the pelvic floor disorders was also done²⁸.

During the present study, minimum attention was paid on the quality of life related to psychological aspect. When

the present study instrument is compared with the findings of the analysis done in Germany mean scores obtained for all the parameters are less than the mean scores of the present study. But the mean score for the urogynaecology patients was observed to be significantly higher than the normal women. During the present study, a score comparisons was not done between the normal women and patients. However patient mean values approximately equal with the total mean values of the present study²⁹.

Reliability assessment values of the studies done in other countries were above 0.7. But in the present study, Cronbach alpha values for both Sinhala and Tamil versions were 0.6. But a validation was not done in Sri Lanka or in a neighbouring Asian country. Therefore, reliability comparison appears to be erroneous³⁰.

When considering the total analysis of applying the current study instrument to Sinhala and Tamil speaking individuals, reliability assessment was in a satisfactory level ($\alpha = 0.623$). Highest correlation with the total score was demonstrated by the bladder score ($r = 0.723$) and the minimum correlation was observed with the sex score ($r = 0.051$). The difference between the correlation value of the item with the highest correlation and the least correlation appeared relatively higher. Therefore, reliability of the whole study instrument was not increased up to the expected level.

This situation is equally demonstrated in both Sinhala and Tamil translated study instruments as well. It is possible to confirm the suitability of using this item total correlation reliability value for validating this study tool. Because in a diagnostic tool which reliability tool is not satisfactory, validation could appear more challengeable.

Comparison between the diagnostic results generated by the study instruments and the clinical diagnostic results was used for assessment of criterion validity. During this sensitivity value for Sinhala version was 100%. Specificity value was relatively low when compared with the sensitivity value. Same consistency was observed with the values of the Tamil version as well. Sensitivity of the Tamil version was 100% and specificity appeared 55.3%. Both versions of the study instrument showed a low positive predictability. But the negative predictability was at its maximum level. When scanning individuals by a diagnostic tool of this quality, all the disease positive patients are detected by the diagnostic tool.

But at the same time, it generates a significant number of false positives as well. Therefore, all the Pelvic Floor Dysfunction individuals who are detected with the study tool should be referred to the specialist gynaecologist for confirmatory diagnosis. In a clinical condition such as Pelvic Floor Dysfunction, there is less opportunity

for developing adverse effects with false positive diagnosis.

As invasive tests are not incorporated with confirmatory procedures, as patient is not subjected to special preparations for clinical evaluation and as diagnostic procedures with higher cost are not incorporated with diagnostic procedures, there are minimum socio-cultural effects for the patient due to false positive Pelvic Floor Dysfunction diagnosis.

On the other hand, negative predictive value of this test is at 100% levels. That is all the individuals detected as negatives by this test are truly disease-free individuals. Detection of false negative individuals is not done with this study tool. Therefore, individuals with Pelvic Floor Dysfunction will not be missed by this tool. Pelvic Floor Dysfunction is a complex clinical condition which is aggravated with increased age. Early identification of this clinical condition facilitates application of effective secondary prevention interventions. Cost effectiveness of these interventions will be higher. As disease free individuals are accurately detected, there will not be any false reassurances.

Due to the increased sensitivity and negative predictive ability of this tool, this test can be applied periodically. This leads to identification of Pelvic Floor Dysfunction at the early stages and post phone the complications by

providing necessary medical interventions.

CONCLUSIONS

Reliability of the Sinhala and Tamil versions of the pelvic floor dysfunction assessment tools is at a satisfactory level. Sensitivity and negative predictive ability of the study tool are at a maximum level. Specificity and the positive predictive ability of the study tool are significantly low. Generation of false negative results by the study tool is minimum and tendency to generate false positives is relatively high. All the main components of the study tool have a significant ability to predict Pelvic floor dysfunction

Further studying should be done regarding the questionable parameters which can be used to reduce the false positive detection and increase the tool validity. Attention should be paid on developing more simple screening tools by using the identified predictive abilities of each component of the study tool.

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