Quality of life and symptom measurement in Chinese women with pelvic floor disorders: validation study of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire

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KEY MESSAGES

1. Chinese women with pelvic floor disorders, namely pelvic organ prolapse, urinary incontinence, and faecal incontinence, have an impaired quality of life, similar to Caucasian women.
2. The Chinese version of the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire are reliable and valid condition-specific health-related quality-of-life questionnaires for women with pelvic floor disorders.

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Introduction

The prevalence of pelvic floor disorders, namely pelvic organ prolapse, urinary incontinence, and faecal incontinence in women has been reported to be 11.4-39.7%, 25-52%, and 1.4-22% respectively. Caucasian women with pelvic floor disorders have been reported to have significantly impaired quality of life (QOL).[1]

The Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) are reliable, valid, and condition-specific symptom and QOL instruments to assess symptoms, their severity, and the impact of different types of pelvic floor disorder on a woman's activities and well-being.[2] Nonetheless, a Chinese version is not available.

This study aimed to investigate the reliability and validity of a Chinese version of the PFDI and PFIQ in Chinese women with pelvic floor disorders.

Methods

Study design

Approval to use the PFDI and PFIQ was obtained from the original authors. Ethics approval was granted by the local institute. Standard forward translation and back-translation was performed. The back-translated version was sent to the original English speaking authors for review and confirmed no major discrepancy. The Chinese version of the PFDI and PFIQ were finalised.

From July to September 2008, 36 Chinese women who attended the urogynaecology clinic with a pelvic floor disorder were invited to complete and comment on the Chinese version of the PFDI and PFIQ. They considered the questionnaires comprehensive.

From April 2009 to May 2010, all Chinese women who attended the urogynaecology clinic with a pelvic floor disorder were invited to participate. Exclusion criteria were women aged <18 years or those who were mentally incapacitated. Written consent was obtained. Women completed the Chinese version PFDI and PFIQ and Short Form Health Survey (SF-36).

They were then assessed by a gynaecologist. Both women and gynaecologist graded the overall severity of symptoms on a visual analogue scale (VAS) with a higher score indicating more severe symptoms.

Women then kept a 3-day urinary and faecal diary to quantify the severity of their urinary and bowel symptoms such as urinary frequency and number of incontinence episodes.

Four weeks later, the women recruited in the first 6 months repeated the questionnaires. None had been offered any treatment during this interval; data of those who had stable symptoms were used for analysis in test-retest reliability.

Women who had urinary symptoms were followed up with urodynamic studies. Those who had faecal incontinence underwent anal manometry and anal ultrasonography. The investigators were blinded to PFDI and PFIQ data.

Sample size

The subject-to-item ratio of a given measurement scale should be 5:1 or above, so a sample size >465 (93 items x 5) was needed. A sample size >100 was

required to establish the test-retest reliability.

Study instruments

The PFDI assesses lower urinary tract dysfunction, colorectal-anal dysfunction and pelvic organ prolapse symptom distress. It comprises 46 items in three scales: the Urinary Distress Inventory (UDI), the Pelvic Organ Prolapse Distress Inventory (POPDI), and the Colorectal-anal Distress Inventory (CRADI). Responses range from 1 (not at all) to 4 (quite a bit).

The PFIQ assesses life impact on women with a pelvic floor disorder. It contains three scales: the Urinary Impact Questionnaire (UIQ), the Pelvic Organ Prolapse Impact Questionnaire (POPIQ), and the Colo-Rectal-Anal Impact Questionnaire (CRAIQ), each with 31 items. Women were asked how symptoms affected their activities and emotions. Responses range from 1 (not at all) to 4 (quite a bit).

The validated Hong Kong Chinese version of the SF-36[3] was used to assess the validity of the PFDI and PFIQ.

Results

A total of 597 women (mean age, 55.0±11.3 years; mean parity, 2.7±1.5) completed the study. Among them, 54.4% had urinary incontinence only, 32.2% had both urinary incontinence and pelvic organ prolapse, 10.9% had pelvic organ prolapse only, 2.2% had urinary and faecal incontinence, and 0.3% had urinary and faecal incontinence and pelvic organ prolapse.

In those with urinary symptoms, 66.2%, 50.7%, 43.9%, and 25.5% had stress urinary incontinence, urinary urgency, urge urinary incontinence, and urinary retention, respectively. In all, 56.6%, 9.4%, 23.5%, and 10.5% had stage 0, I, II, and III/IV prolapse, respectively. Overall, 71.3% of women completed the 3-day urinary and faecal diary.

A total of 510 (85.4%) women underwent urodynamic studies; 37.0%, 33.2%, 8.9%, 1.8%, and 3.9% were diagnosed with no abnormality, urodynamic stress incontinence (USI), detrusor overactivity (DO), USI and DO, and voiding dysfunction, respectively. In those who complained of faecal incontinence, no pathology was identified after anal manometry or anal ultrasonography.

Of the 270 scheduled for retest, 253 completed the re-test and indicated no change in symptoms or severity of their pelvic floor disorders.

Reliability

Respectively for PFDI and PFIQ, the Cronbach's alpha was 0.92 and 0.98 indicating high internal consistency, and the intraclass correlation coefficient was 0.77 and 0.79 indicating acceptable test-retest reliability (Table 1).[4]

TABLE 1. Internal consistency and test-retest reliability of Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) and their subscales (Reproduced from: Chan SS, Cheung RY, Yiu AK, et al. Chinese validation of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. Int Urogynecol J 2011;22:1305-12.)

PFDI	Internal consistency (Cronbach's α)%	Test-retest reliability (intraclass correlation coefficient) [%]	PFIQ	Internal consistency (Cronbach's α)%	Test-retest reliability (intraclass correlation coefficient) [%]
PFDI	0.93	0.77	PFIQ	0.98	0.79
Pelvic organ prolapse distress inventory	0.87	0.79	Pelvic organ prolapse impact questionnaire	0.97	0.66
General	0.81	0.72	Physical activity	0.93	0.69
Anterior	0.82	0.81	Social relationships	0.92	0.61
Posterior	0.76	0.80	Travel	0.92	0.60
			Emotional health	0.93	0.46
Colo-rectal-anal distress inventory	0.86	0.80	Colo-rectal-anal impact questionnaire	0.98	0.72
Obstructive	0.76	0.80	Physical activity	0.92	0.68
Incontinence	0.77	0.71	Social relationships	0.95	0.66
Pain/irritative	0.76	0.75	Travel	0.92	0.70
Rectal prolapse	0.45	0.68	Emotional health	0.95	0.68
Urinary distress inventory	0.89	0.83	Urinary impact questionnaire	0.97	0.88
Irritative	0.72	0.80	Physical activity	0.83	0.77
Obstructive/discomfort	0.86	0.76	Social relationships	0.91	0.86
Stress	0.80	0.83	Travel	0.84	0.85

Convergent validity

Subscales of PFDI and PFIQ negatively correlated with each subscale of SF-36 (Table 2).[4] This indicated that the higher the score of PFDI or PFIQ, the greater the negative impact on general health.

The staging of pelvic organ prolapse was positively correlated with POPDI General subscale (r=0.20, P<0.05), POPIQ (r=0.24, P<0.05), and three subscales. POPDI General subscale score was higher in the stage II or III/IV prolapse group than in the no prolapse group. Anterior subscale was also higher in the stage III/IV group than in the stage II group. The POPIQ score was higher in the stage III/IV group.

The daytime voiding frequency was positively correlated with UDI (r=0.36, P<0.001) and UIQ (r=0.40, P<0.001). When comparing the UDI score, the no abnormality group scored lower than the USI or DO group. Women diagnosed with USI scored lower than the DO group on the irritative symptom subscale score. The stress symptom subscale score was higher in the USI group than in the no abnormality or voiding dysfunction group. The UIQ score was lower in the no abnormality group than the USI or DO group.

The frequency of faecal incontinence episodes was positively correlated with CRADI (r=0.27, P<0.001) and CRAIQ (r=0.23, P<0.001). The VAS scores of both women and the gynaecologist were positively correlated with PFDI and PFIQ.

Discussion

PFDI and PFIQ enable a more in-depth assessment of specific concerns critical to different types of pelvic floor disorder and of their treatment outcomes.[5] Nonetheless, there may be cultural or language concerns, and items may need to be adjusted accordingly. Validating the Chinese version of PFDI and PFIQ is therefore important for their use in Chinese and in Hong Kong.

Our results showed that the Chinese version of PFDI and PFIQ are reliable for use in women with pelvic floor disorders that include urinary incontinence, pelvic organ prolapse, and faecal incontinence. There was high internal consistency for both PFDI and PFIQ, comparable with the original version.[2] The test-retest reliability was also acceptable.

The validity of the Chinese version of PFDI and PFIQ was supported by a positive correlation between the women's VAS and their PFDI and PFIQ scores and a negative correlation between SF-36 and PFDI and PFIQ scores, as well as the positive correlation between the UDI and UIQ with the number of urinary incontinence episodes and daytime voiding. This was approximately equal to those demonstrated in the original UDI and the IIQ; and the Chinese version of UDI-6 and IIQ-7.[6] POPDI and POPIQ also correlated with the staging of pelvic organ prolapse; a higher correlation was found in those with stage II or above. The CRADI and CRAIQ correlated with the number of faecal incontinence episodes.

The differences in the subscale score of POPDI and POPIQ could demonstrate a difference between women with different stages of pelvic organ prolapse. Higher general and anterior subscale scores of POPDI, and POPIQ and emotional and physical activity subscale scores were found in the stage III/IV prolapse group. UDI and UIQ differed in women with different urodynamic diagnoses, with higher UDI and UIQ scores in women diagnosed with USI or DO, a higher irritative symptom subscale score in those with DO, and a higher stress symptom subscale score in those with USI than those with no abnormality. Finally, CRADI and CRAIQ were

TABLE 2. Correlation between subscales of Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) and subscales of SF-36* (Reproduced from: Chan SS, Cheung RY, Yiu AK, et al. Chinese validation of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. Int Urogynecol J 2011;22:1305-12.)

Subscales of SF-36	Correlation with subscales of PFDI			Correlation with subscales of PFIQ		
	Pelvic organ prolapse distress inventory	Colo-rectal-anal distress inventory	Urinary distress inventory	Pelvic organ prolapse impact questionnaire	Colo-rectal-anal impact questionnaire	Urinary impact questionnaire
Physical functioning	-0.33	-0.33	-0.38	-0.39	-0.34	-0.46
Role-physical	-0.36	-0.33	-0.36	-0.36	-0.30	-0.43
Bodily pain	-0.39	-0.42	-0.39	-0.33	-0.33	-0.43
General health	-0.29	-0.32	-0.29	-0.24	-0.30	-0.38
Vitality	-0.29	-0.32	-0.35	-0.28	-0.25	-0.42
Social functioning	-0.30	-0.34	-0.37	-0.37	-0.35	-0.51
Role-emotional	-0.32	-0.32	-0.36	-0.32	-0.29	-0.46
Mental health	-0.32	-0.38	-0.39	-0.32	-0.34	-0.53

* P<0.001 for all

higher in women with faecal incontinence. All these findings confirm the validity of both PFDI and PFIQ.

The Chinese version of PFDI and PFIQ may help healthcare providers, especially gynaecologists, when exploring symptoms and their impact on QOL in women with pelvic floor disorders, especially urinary incontinence and pelvic organ prolapse. These instruments are comprehensive and should encompass most urinary and prolapse symptoms. Gynaecologists may also use them to assess treatment outcome, both conservative and surgical, after the responsiveness of these tools has also been assessed.

The Chinese version of PFDI and PFIQ can be downloaded from the website of the Department of Obstetrics and Gynaecology, The Chinese University of Hong Kong (http://www.obg.cuhk.edu.hk/urogynaecology/urogynaecology-resources/).

Conclusions

The Chinese version of PFDI and PFIQ are reliable and valid condition-specific health-related QOL questionnaires for women with pelvic floor disorders.

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