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Cultural adaptation of the female pelvic floor questionnaire (FPFQ) into French

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Abstract

Aims: The Female pelvic floor questionnaire (FPFQ) is a self-administered tool on pelvic floor function. Our aim was to carry out a cultural adaptation of the FPFQ into French and to assess its psychometric properties.

Methods: After cross-cultural adaptation into French, acceptability and reliability of the questionnaire were assessed through a sample of 56 women in a test-retest. Discriminative construct validity was evaluated by comparing the results obtained by the FPFQ to those of other validated questionnaires. Longitudinal follow-up of the 282 pregnant women included in the PreNatal Pelvic floor Prevention trial (3PN) was used to analyze responsiveness.

Results: The proportion of missing data did not exceed 4% for questions about bladder function, bowel function and pelvic organ prolapse; 10% for issues related to sexual function. Question 9 was considered difficult to understand by 14% of women. After rewriting, this issue was retested in a new sample of 52 women and presented no further problems. The intra-class correlation coefficient was greater than or equal to 0.7 for all domains during the test-retest. The FPFQ was strongly and significantly correlated (Spearman $r>0.5$) with the other validated questionnaires. The French version of FPFQ recorded changes in urinary and sexual symptoms for the women involved in 3PN trial with a standardized response mean equal to 0.83 and 0.44, respectively.

Conclusion: The French version of the FPFQ is self-administered, reliable, valid, and can detect a change in symptoms during follow-up.

Key Words: Pelvic floor – Symptoms – Questionnaire – Validation studies – French

Introduction

Pelvic floor disorders (PFD) in women are common and debilitating (1). It is estimated that 10-20% of women will be operated upon during their lifetime for these disorders (2). They can result in different pelvic-perineal symptoms affecting all areas of the anatomy such as voiding and anorectal difficulties, incontinence, prolapse and sexual disorders. These symptoms are often associated; 25% of patients consulting for genitourinary prolapse also suffer terminal constipation, and 33% from anal incontinence (3). They can cause functional difficulties beyond the organ concerned, for example urinary incontinence affects sexual satisfaction (4). Studies have demonstrated that treatment for one symptom can improve, worsen or even predispose another (5). Epidemiologists as clinicians need tools to assess the prevalence of symptoms associated with functional PFD and the severity of these symptoms. Many questionnaires have been developed to assess urinary incontinence (6) and urinary obstruction (7). Questionnaires investigating the symptoms of prolapse (8), sexual symptoms, anal incontinence or anorectal obstruction exist but are slightly less common (9). The Female Pelvic Floor Questionnaire (FPFQ) developed by Kaven Baessler explores all aspects of pelvic floor dysfunction: bladder, bowel, prolapse and sexual symptoms. This questionnaire was designed for the "Longitudinal Assessment of Woman" study conducted by the Betty Byrne Henderson research center in Brisbane, to collect longitudinal data on the incidence and prevalence of PFD in community-dwelling women (10). The reliability, validity and responsiveness of the tool were developed during two different studies (11,12). This questionnaire was originally in English and adapted into German (13). Translating and culturally adapting a questionnaire into another language is more interesting than creating a new instrument. This method makes it possible to compare

results across studies, despite different languages and cultures because the data comes from the same instrument. It also allows the study to be carried out on a larger scale with international participation. After translating and cultural adaptation, it is necessary to ensure the equivalence of the concept measured by the questionnaire through the analysis of its psychometric properties. The questionnaire must be acceptable to make data collection possible. It must be reliable and valid to properly discriminate between subjects, establish a profile or identify determining factors. To detect a change in the symptomatology of an individual in a longitudinal comparison, this tool must be sensitive to changes (14).

The aim of our study was to carry out the cultural adaptation of the FPFQ into French in two stages: translation and validation of the questionnaire to ensure cross-cultural relevance and conceptual equivalence with the original questionnaire.

Method

The FPFQ is a self-administered questionnaire with 37 questions. Thirty-three of them assess symptoms in 4 areas (bladder, bowel, prolapse and sexual function section) and 4 questions investigate the inconvenience caused by these symptoms in each area (11). Each question has four possible answers of increasing severity (usually *never*, *occasionally*, *frequently* or *daily)*. It is possible to calculate a 10 point subscore for each area. Each sub-score is the sum of the marks obtained in each section of questions divided by the maximum number of points, multiplied by 10. The addition of these four subscores provides a total score out of 40. The higher this score, the more the woman suffers from PFD.

Cross-cultural adaptation

After obtaining the agreement from the author (Kaven Baessler) to perform the cultural adaptation of the FPFQ into French, three translations of the English version were performed independently by a urogynaecologist (XF), a rehabilitation doctor (MM) and a female non-doctor, whose native language were French and who had a good knowledge of English. A summary of these three translations was revised several times by the translators until a consensus was reached (15). The back-translation was deemed unnecessary to emphasize the meaning rather than the literal translation. This version was then pre-tested with 4 French women (none of whom were doctors or caregivers), in individual interviews.

- ***Validation***
- *Reference measurements*

Construct validity examines the ability of a questionnaire to measure what it is supposed to measure. It studies the correlations between the questionnaire scores and other reference measurements at a particular point in time (14). Five other questionnaires already validated

in French were chosen as reference measurement in this analysis: The ICIQ-UI-SF (International Consultation on Incontinence Questionnaire - Urinary Incontinence Short-Form) assesses urinary incontinence four questions; The IPSS (International Prostate Symptom Score) evaluates voiding difficulties via 8 questions; Contilife, a quality of life questionnaire adapted for women with urinary incontinence, comprises 28 questions divided into six sections; The PFDI-20 (Pelvic Floor Distress Inventory) assesses symptoms of prolapse and the inconvenience caused by these symptoms and is composed of 20 questions dealing with bladder (UDI-6), bowel (CRADI-8) and to prolapse symptoms (POPDI-6); The PFIQ-7 (Pelvic Floor Impact Questionnaire) is a questionnaire on the social impact of prolapse, it examines the severity of bladder (UIQ-7), bowel (CRAIQ-7) and specific prolapse symptoms (POPIQ- 7) (6-9).

- *Populations*

Three populations were used to evaluate the questionnaire. Two convenience samples, composed of easily queryable women in the investigators' entourage, were set up with 56 women in the first sample (No.1) and 52 women in the second (No. 2). Sample No. 1 tested understanding of the issues (acceptability) and the reliability of the questionnaire through a test-retest and the construct validity of the bladder section of the FPFQ. The issues deemed difficult to understand by sample No.1 were reformulated and then re-tested by sample No.2. Inclusion criteria for these samples were voluntary adult women in the authors' entourage (regardless of age or occupation) or an adult women consulting for reasons other than PFD. Women likely to benefit from PFD treatment or intervention were excluded, as were minors and those with neurological impairment.

The 282 pregnant women included in the Prenatal Perineal Prevention (3PN) study also received the questionnaire. 3PN is a multicenter, randomized study whose main objective was to compare the effect on urinary incontinence at one year postpartum of prenatal rehabilitation compared to receiving written information only (16). The data collected helped analyze the construct validity of specific questions on prolapse and bowel symptoms but also to explore sensitivity to changes through longitudinal monitoring of these women.

- *Administration of the questionnaire*

Sample No. 1 - Women completed the self-administered questionnaire twice, one month apart (test-retest). The first time, they were instructed to report difficulties in understanding and possibly propose a reformulation of the question. They also completed the aforementioned reference questionnaires.

Sample No. 2 - Issues considered difficult to understand by the women in sample No. 1 were reformulated and tested in sample No. 2.

3PN women were included in the testing during pregnancy and monitored for one year after childbirth (16). They completed the French version of FPFQ, the ICIQ-IUSF and Contilife questionnaires four separate times during monitoring. The 71 women enrolled in the 3PN study in Nîmes University Hospital completed two additional questionnaires covering prolapse symptoms (PFDI-20 and PFIQ-7).

- ***Statistical Analysis***

Acceptability - The incidence of difficulty understanding questions and the number of unanswered questions were indicators of acceptability. The non-response rate per question was calculated from sample No. 1 and from all 3PN patients on the data collected during the first completion of the FPFQ.

Reliability - The test-retest performed by sample No. 1 was used to analyze the reproducibility of the tool in clinically stable women. To compare the scores between the two evaluations, an intra-class correlation coefficient for sub-scores of each section and the total score was calculated. A value greater than 0.7 was considered acceptable (17). Concordance was measured for each FPFQ question component through a weighted Cohen Kappa coefficient. A Kappa coefficient up to 0.20 is classically poor, from 0.21 to 0.40 mediocre, from 0.41 to 0.60 moderate, from 0.61 to 0.80 good and beyond 0.80 excellent (18). The Bland-Altman method explored the correlation based on the score obtained (19).

Internal consistency - This analysis was carried out using data collected from sample No. 1 and 3PN women during the first FPFQ questionnaire. Cronbach's alpha was considered acceptable from 0.7.

Construct validity – Data from the FPFQ were compared with reference data collected for inclusion in sample No. 1 and 71 3PN women at the Nîmes CHU. Longitudinal follow-up of 3PN women allowed the change measured by the FPFQ questionnaire to be compared to those recorded by the reference measurements between the different assessments. Calculation of correlations from score differences allows data to be matched. Four statistical correlation levels were established: strong r> 0.5; moderate r = 0.36 to 0.5; poor r = 0.35 to 0.2; absent r <0.2 (20). To assess association strength, the Pearson and Spearman correlation coefficient was used.

Construct validity is far more robust if the investigators establish prior hypotheses about probable correlations between the test questionnaire and the reference measurements (14). Seventy-five prior assumptions (using 4 levels of correlation defined in the previous paragraph) were established on data collected at baseline.

Responsiveness - Pregnancy and postpartum periods are characterized by a risk of pelvic floor disorders that are often transient (21). Longitudinal follow-up of 3PN patients was used to assess changes in pelvic-floor symptoms associated with pregnancy and childbirth. The degree of variation was assessed by the Standardized Response Mean (RMS) (22).

- ***Ethics***

All women gave consent before participating. For samples No. 1 and No. 2, women included did not undergone any intervention or modification of their support related to their participation. Thus our work complied with French statutes and regulations, which authorise observational surveys without approval of an ethics committee. Collected data were processed according to the recommendations of the CNIL (Commission Informatique et Libertés, French Data Protection Authority- http://www.cnil.fr/english/). Questionnaires used in samples No. 1 and No. 2 were strictly anonymous.

The 3PN study received an institutional review board approval by the Comité de Protection des Personnes Sud-Ouest-et-Outre-Mer in September 2007 (#2007-A00641-52).

Results

For the translation and cultural adaptation, 6 intermediate versions were needed before obtaining a version judged to be suitable and consistent with the original questionnaire. The pre-test did not lead to any changes.

The average age of women was 42 years in sample No. 1, 44 years in the second and 29 in 3PN. 3PN women were all nulliparous and the mean parity was 2.0 and 1.3 in samples 1 and 2 respectively. These women had a low symptomatology with an FPFQ total score of less than 10 out of 40 (Table I-II).

Acceptability - Of the 56 women in sample No. 1, the proportion of missing data did not exceed 4% for questions about bladder, bowel and prolapse symptoms; this figure was 10% for sexuality-related issues. For the 3PN women, the missing data did not exceed 4% regardless of the type of question. Significantly less information was given in questions about sexuality than the others, in both samples ($p < 0.0001$). Question 9 "Votre jet urinaire est-il faible ou prolongé?" was considered difficult to understand by 14% (n = 8) of the women in sample No. 1. According to them, the terms "faible" and "prolongé" had opposite meanings. This was the literal translation of the original question: "Is your urinary stream / flow weak or prolonged?". This question was changed as follows: "Votre jet urinaire est-il faible ou ralenti?" and was retested with sample No. 2. In this new sample, the reformulated question 9 posed no further problem.

Reliability - In sample No. 1, 56 women completed the FPFQ once and 51 twice. The concordance of responses between the two assessments ranged from 58.3% [95% CI 43.2-72.4] to 94.1% [83.8-98.8] depending on the issues, with a median of 80.0%. Average kappa was equal to 0.6 ± 0.1 with a minimum of 0.3 [95% CI 0.1-0.4] and a maximum of 0.8 [95% CI

0.6-1.0]. The intraclass correlation coefficient was greater than or equal to 0.7 for the overall score and each sub-domain (Table I). On average, the change in the FPFQ total score and subscores was less than 10% between the two assessments (Table I). The Bland-Altman test was able to identify a lower response concordance among the most symptomatic women with a marked increase in the difference in overall score in women with a score higher than 6 out of 40 (Figure 1).

Internal consistency - Internal consistency was satisfactory with a Cronbach α-factor greater than 0.7 for all areas of the FPFQ in sample No. 1 (Table I) and in the 3PN sample (Table II).

Construct validaty - The FPFQ was strongly and significantly correlated (Spearman r> 0.5) with the ICIQ-UI-SF (r = 0.7), the IPSS (r = 0.7) and Contilife (r = -0.7) in sample No. 1. Strong and significant correlations were also found in 3PN women recruited in Nimes, between the FPFQ and other reference tests (Table III). The kinetics of the scores during the longitudinal study was similar between the various assessment tools (Figure 2). The differences in scores recorded by the FPFQ were highly correlated with those measured by ICIQ-UI-SF, Contilife and PFDI-20. Correlations were lower (r between 0.1 and 0.6 depending on the section) between the FPFQ and PFIQ-7 (details not shown).

Correlations between the FPFQ and the reference measurements were consistent with the assumptions in 15 cases (20%), higher in 56 cases (75%), and lower in 4 cases (5%).

Responsiveness - 3PN women showed a significant (p <.0001) decline in bladder symptoms between late pregnancy and two months postpartum (SMR = 0.83); increased sexual symptoms between late pregnancy and two months postpartum (RMS = -0.30; p = 0.001) with a significant decrease at 12 months postpartum (SMR = 0.44; p <0.0001). Bowel symptoms were stable over time with a standardized mean response of less than 0.2

between successive assessments. These women had a slight increase in prolapse symptoms between months 6 and 9 of pregnancy (-0.25; $p < 0.001$). These symptoms then remained stable during postpartum (SMR <0.2).

Discussion

The results of the FPFQ were significantly and strongly correlated with those found in the reference tests. Significant changes in bladder and sexual symptomatology were recorded during longitudinal monitoring of women in the 3PN study.

The lack of a specific reference test for sexual symptoms did not assess the construct validity of this section of the FPFQ. The significant increase in the sexual subscore at 2 months postpartum in 3PN women, however, is an argument for its validation. This increase is consistent with the increase in prevalence of sexual dysfunction observed after delivery (23). Despite this limitation, one advantage of our study is that it explores the main psychometric properties of the French FPFQ, including analysis of sensitivity to changes, which is rarely performed during the validation of a measurement tool.

The proportion of questions unanswered was satisfactory, not exceeding 10% despite the taboo nature of incontinence. This result obtained from both sample No. 1 and the 3PN study demonstrates the acceptability of the tool. The wording of questions in the final version posed no comprehension difficulties. We believe the combination of specialist translators and a naive translator yielded a translation retaining the meaning of the original concept in a language understood by the target population. A back-translation was not deemed necessary. This procedure tends to favor a literal translation that amplifies unclear language in translations (15). The comprehension difficulties regarding question 9 raised by sample No. 1 is an illustration of this problem. The literal translation of "weak or prolonged" into "faible ou prolongé" modified the meaning of the phrase. In French, the term "prolongé" (prolonged) can have two different meanings: temporally prolonged (lasting longer than usual) or spatially prolonged (extended in distance). This second interpretation

suggests a stronger, more effective urinary stream which was judged by women to contradict the term "weak". The term “ralenti” (“slowed” in English) was therefore chosen to remain faithful to the original meaning.

The questionnaire showed stable results over time, during the test-retest, with an acceptable intraclass correlation coefficient in all sections of the FPFQ. Average difference did not exceed 10% between the two assessments. Our hypothesis is that a variation of less than 10% is not clinically significant as the smallest significant variation in quality of life was estimated at 15% for other surveys on the same subject (8). Despite high response consistency during the test-retest, weighted kappa coefficients were poor for certain issues. This result is explained by a low prevalence of certain responses because overall, sample No. 1 was not particularly symptomatic. The kappa coefficient is very sensitive to frequency of response and the extreme modalities of certain questions were never indicated (24). Response consistency was lower among the most symptomatic women according to the Bland-Altman test. This result can be explained by the fact that bladder and bowel symptoms are closely related to lifestyle and therefore likely to change over a short period of time in the absence of medical or surgical intervention.

The results of the FPFQ were strongly correlated with those of other symptom questionnaires (ICIQ-UISF, IPSS and PFDI-20). This result was also observed with specific quality of life reference tests (Contilife and PFIQ-7). It demonstrates that the French version of the FPFQ measures the same concept as the reference tests. These correlations were much higher than we had predicted. We found strong correlations for different areas; for example, the bowel section of the FPFQ was strongly correlated with the prolapse section of the PFDI-20 ($r = 0.6$) and the bladder section PFIQ-7 ($r = 0.5$). This result highlights common

association of different symptoms for the same woman (3). The interdependence between sections highlights the importance of symptom assessment in general with multidisciplinary care in clinical practice.

Longitudinal follow-up of 3PN patients highlighted identical score kinetics for the FPFQ and most other reference tests (ICIQ-UI-SF, Contilife and PFDI-20). Changes in symptomatology recorded by the FPFQ (RMS significant) and correlations between score differences measured by the FPFQ and those measured by the ICIQ-UI-SF and the Contilife PFDI-20 reflect good responsiveness. These correlations were weaker between the FPFQ and PFIQ-7. There is a lower sensitivity to change for the PFIQ-7 for PFDI-20, which justifies this difference in outcome (25).

Conclusion

The FPFQ offers an extensive evaluation of bladder, bowel and sexual function, pelvic organ prolapse. It is self-administered, which makes it a good tool to gather information deemed embarrassing or taboo. Based on the analysis of its psychometric properties, it is acceptable, understandable and properly discriminates between topics. Designed, developed and validated for the community-dwelling women, the questionnaire is an attractive research tool in this context. Its responsiveness allows it to be used as an evaluative instrument in multicenter clinical trials or in the longitudinal monitoring of patients, or measuring physiological changes during the life of a woman. These studies can be undertaken internationally as the FPFQ exists in English, German and French.

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Tables and figures

Table I Reliability - Internal consistency: Scores obtained in the FPFQ by sample No. 1 women in the test-retest; intraclass correlation coefficient (ICC) and its confidence interval 95% (95% CI ICC); Cronbach alpha coefficient calculated on the data collected during the first assessment.

* In the test-retest, 56 women completed the FPFQ once and 51 completed the questionnaire twice (a month apart.)

** The sex score of the FPFQ was calculated twice for 34 women. Of these, 3 were not sexually active because of pelvic floor disorders in at least one of the two assessments; the maximum score of 10 was assigned to this section. Seventeen women were not sexually active for reasons not related to pelvic floor disorders in at least one of the two assessments. For these women, no mean difference for the sex subscore was calculate.

Table II Internal consistency: Scores obtained in the FPFQ by patients in the 3PN clinical trial and Cronbach alpha coefficients calculated at baseline (n = 272*).

Missing data higher than 2 for each sub-score did not allow the calculation of that sub-score. In the absence of a sub-score, the total score was not calculated.

*Ten women included in the trial did not complete the questionnaires.

** The sexsubscore could be calculated for 232 women. Of these, 4 were not sexually active because of pelvic floor disorders; the maximum score of 10 points was assigned to this section of the questionnaire. Nineteen women were not sexually active in the sample for reasons not related to pelvic floor disorders.

Table III Construct Validity: Correlations between FPFQ scores on inclusion from patients enrolled in the 3PN study at Nîmes CHU (n = 71); Spearman correlation coefficient.

Figure 1: Representation of the difference in Total score of the test-retest based on mean score, as calculated by the Bland-Altman method - Sample No. 1 (n = 51)

Figure 2: Evolution of scores and sub-scores obtained in the FPFQ, the ICIQ-UI-SF, Contilife, the PFDI-20 and PFIQ-7 during longitudinal monitoring of 3PN patients recruited at Nîmes CHU (n = 71).

*The PFDI-20 and PFIQ-7 sub-scores are out of 100 points (UDI-6 CRADI-8 POPDI-6, UIQ-7 CRAIQ-7 POPIQ-7), the ICIQ-UI-SF is out of 21 points. These scores were reduced 10 to facilitate comparison with FPFQ subscores.

**Contilife is given a score out of 10 points and is inversely proportional to the FPFQ Bladder subscore. The graph shows the difference between the maximum score (10) and the score obtained by the subject.

***The PFDI-20 and PFIQ -7 are scored out of 300 points. These scores were reduced 40 to facilitate comparison with the total FPFQ score.