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ORIGINAL ARTICLE

Italian validation of the Pelvic Floor Distress Inventory (PFDI-20) questionnaire

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Abstract

Introduction and hypothesis The use of validated Quality of Life (QoL) questionnaires is useful in the standardization and interpretation process of pelvic floor patient symptoms, due to their functional nature and high prevalence. The Pelvic Floor Distress Inventory QoL questionnaire (PFDI-20) serves both as a symptom inventory and a measure of the degree of bother and distress caused by pelvic floor symptoms. It includes items related to pelvic organ prolapse and lower gastrointestinal and bladder dysfunction.

Methods After consensus translation and a comprehension test, the Italian version of the questionnaire was submitted to patients reporting bowel, bladder, or pelvic disorders (cases) and to asymptomatic women (controls). Cases received the questionnaire once again 2 weeks later by email.

Results A total of 254 patients answered the questionnaire. Construct validity was demonstrated by discriminating between cases and controls. Convergent validity was demonstrated for each domain ($F < 0.001$). In-ernal consistency reliability showed a satisfactory range (0.816–0.860).

Conclusions The PFDI-20 allows a comprehensive assessment of the effect of pelvic floor disorders on the quality of life of women. Moreover, the PFDI-20 represents a very solid QoL tool, since it has been extensively used in literature, and its use is highly recommended by the International Consultation on Incontinence. The present study demonstrated good features for the Italian version of the PFDI-20 questionnaire.

Keywords Pelvic floor disorders · Quality of life · Questionnaire · Pelvic organ prolapse distress · Urinary distress · Colorectal–anal distress

Introduction

Pelvic floor disorders (PFDs) represent a series of conditions — including prolapse, bowel, and bladder dysfunction — related to pelvic floor weakening and/or tears, usually related to obstetric trauma [1, 2]. Pelvic floor disorders share the same factors and may frequently coexist or recur [3, 4]. These may involve age, menopausal status, and obesity [1, 5]. Also, changes in the composition of connective tissue and metalloproteinases can be observed in patients with pelvic floor disorders [6]. Moreover, pelvic floor disorders can occur and/ or persist as a consequence of pelvic floor surgery [7, 8]. Symptoms can be

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multiple, including urinary incontinence, fecal incontinence, pelvic organ prolapse symptoms, voiding dysfunction, and defecatory dysfunction [9]. These conditions may negatively affect social, occupational, domestic, and psychophysical well-being [10]. Conservative management includes lifestyle modification, pelvic floor muscle training, biofeedback/electrical stimulation, vaginal laser, magnetic stimulation, pessaries, and pharmacological treatments [11–13]. Surgical treatment is indicated when conservative management fails and may involve native tissue repair, mesh surgery, and injection of various agents including stem cells [14–18]. Due to the functional nature of PFDs, the use of validated outcome measures, involving the impact on quality of life, is of the utmost importance in evaluating the efficacy of the treatments. Quality of life (QoL) assessment is a milestone of clinical practice in gynecology. In particular, the use of validated QoL questionnaires is of the utmost importance for the evaluation of pelvic floor disorders, due to their functional nature and high prevalence [19]. Validated QoL questionnaires allow the assessment of pelvic floor symptoms' frequency and severity, their impact on quality of life, and trends over time. Moreover, self-completed questionnaires are preferable to clinical interviews since they minimize bias related to caregiver interpretation. Lastly, a structured questionnaire that covers most aspects of pelvic floor disorders would be a useful tool to screen the population. Although several sexual life QoL questionnaires are available for the general population, there are very few questionnaires specifically designed for the simultaneous evaluation of bladder, prolapse, and bowel dysfunction domains [20]. One of them is represented by the PFDI-20, a 5-point Likert scale self-reported questionnaire with 20 items covering three domains of pelvic floor function [21]. In brief, the PFDI-20 serves the role of both a symptom inventory and a measure of the degree of bother and distress caused by the broad array of pelvic floor symptoms. It includes items related to pelvic organ prolapse, lower gastrointestinal, and bladder dysfunction. Unfortunately, this questionnaire has not been validated in the Italian language yet.

Consequently, the aim of this study was to translate and validate the Italian language version of the Pelvic Floor Distress Inventory (PFDI-20) questionnaire evaluating the validity, internal consistency, and test–retest reliability. That ensures that the questionnaire will make sense to patients, that it is able to differentiate between symptomatic patients and controls, that it is able to measure what it was intended to measure, and that the answer to each question will not change substantially if the questionnaire is administered twice over a short period.

Materials and methods

This was a multicenter study conducted in Italy. Ethical committee approval was obtained before starting the study (name of the protocol "ITA PFDI-20"). Investigators were experienced in the translation and validation of QoL tools [22, 23]. The questionnaire was based on the Pelvic Floor Distress Inventory (PFDI-20) questionnaire. This represents a validated questionnaire for bladder, bowel, and pelvic symptoms severity assessment in patients with pelvic floor disorders, which was developed in 2005 as the short form of the Pelvic Floor Distress Inventory (PFDI). The PFDI consists of 46 questions separated into three scales; the UDI, Pelvic Organ Prolapse Distress Inventory (POPDI), and the ColoRectal Anal Distress Inventory (CRADI) [21]. The PFDI-20 was then developed, since the relative length of the original version made the former somehow inefficient or impractical for most clinical and/or research situations. For the UDI scale, six items already existing as a separate tool (UDI-6) were incorporated in the PFDI short form. For the POPDI scale, six items were identified for the short form development due to the correlation between the combined score of these six questions (POPDI-6) and the total score deriving from the POPDI long form. For the CRADI scale, eight items (CRADI-8) that significantly correlated with the long-form version of the scale were identified [21]. To obtain the PFDI-20 score, the mean value of all of the answered items within the corresponding scale (possible value 0 to 4) should be obtained and then multiplied by 25 to obtain the scale score (range 0 to 100). Missing items are dealt with by using the mean from answered items only. Consequently, each of the three scales of the PFDI-20 is scored from 0 (least distress) to 100 (greatest distress) [21]. The sum of the scores of these three scales serves as the overall summary score of the PFDI-20 and ranges from 0 to 300.

Translation

The validation process of a linguistic translation must maintain conceptual and technical equivalence between the source and the target language [24]. The questionnaire was translated into Italian by the following procedural steps [25]. A preliminary translation from English into Italian was performed in parallel by two native Italian-speaking translators, with English as their first foreign language. Then, a consensus meeting among translators and the research group was held to compare the two Italian versions, which yielded the first consensus Italian version of the questionnaire. After that, a native English-speaking translator with Italian as his first foreign language back-translated the Italian consensus version. A second consensus meeting was held between the English mother-tongue translator and clinical investigators, during which the back-translated and the original questionnaires were compared and differences discussed. The process led to a revised version of the first consensus questionnaire.

The comprehension of the obtained Italian consensus version was therefore tested in a real-life population to assess questionnaire comprehension. The questionnaire was submitted to women during a gynecological medical interview, and they were asked to evaluate their perceived degree of difficulty in understanding each question item. After that, the final Italian version of the questionnaire was obtained.

Study participants

Recruitment was obtained by the pelvic floor unit outpatients in the recruitment centers. Women referred for genital prolapse or incontinence, aged 18 years and over were included. Exclusion criteria included: insufficient Italian language proficiency and psychiatric or neurological disorders. Study participants filled out the questionnaire during clinical interviews. The questionnaire was submitted to women reporting bowel, bladder, or pelvic disorders (cases) and to asymptomatic patients (controls). For the test–retest evaluation, cases received the questionnaire 2 weeks later by email. Questionnaire distribution and all interviews were undertaken by the authors.

Questionnaire validation

Construct validity was tested to guarantee that the questionnaire is able to discriminate between women with pelvic floor symptoms and controls [26]. In order to test validity, the questionnaire was administered to women with and without pelvic floor disorders (respectively defined as ‘cases' and ‘controls'). Cases and controls were defined, as done previously, with respect to bowel, bladder, or prolapse symptoms using the question: “How much do your symptoms bother you?” and the following choice of answers: “Not applicable – I do not have symptoms”, “not at all”, “a little”, “quite a lot” and “very much” [22]. Controls were identified as women answering “Not applicable — I do not have symptoms” or “not at all”; otherwise, patients were defined as cases. Total scores for women with and without significant symptoms were compared and tested for statistical differences in order to assess validity. Given the heterogeneity of variances, the Wilcoxon test (non-parametric) was used to assess differences between cases and controls. Convergent validity for each domain was tested using specific items (#17, #18, and #19) of the Italian Version of the Prolapse Quality of Life Questionnaire (PQOL) [27].

The internal consistency — the strength of association among items — was tested using Cronbach’s Alpha [28, 29]. Cases were given the questionnaire at baseline and 2 weeks later to evaluate the test–retest reliability. The test–retest reliability analysis was aimed to determine the questionnaire's reproducibility over time [26]. The degree of agreement of test–retest results of different individuals was tested with the intraclass correlation coefficient (ICC) [30, 31].

Statistical analysis

The statistical analysis was performed with JMP 7.0 (SAS, Cary, NC, USA). Where ratings were missing, items were excluded from the analysis pool. Patients who did not complete the questionnaire both at baseline and at the test–retest visit were excluded from the analyses. Continuous data are presented as mean ± standard deviation, and non-continuous data as absolute (relative) frequency. Wilcoxon non-parametric test, Cronbach’s Alpha, and the intraclass correlation coefficient were evaluated to assess the characteristics of the tool. A $P < 0.05$ was considered significant.

Results

The comprehension test was used to evaluate the ease of use of the questionnaire in a real population. Ten patients were given a preliminary interview after completing the questionnaire. All women correctly understood questions and pre-coded answers; no item was therefore changed. Consequently, the final Italian version of the questionnaire was obtained. In total, 254 women answered the final version of the questionnaire. The population characteristics are shown in Table 1. Most of the patients (80.3%) were in menopausal status. There was no dropout, since all of them answered at least part of the questionnaire. The rate of missing items was 0.4%. Table 2 summarizes the prevalence of considered pelvic floor disorders in the population of the study. The prevalence of prolapse, bowel, and bladder bothersome symptoms was respectively 63.4%, 49.2%, and 84.3%. Construct validity was demonstrated, as the questionnaire discriminated between patients with and without symptoms. Convergent validity was tested with PQOL-specific items, and was demonstrated for each domain ($F < 0.001$; Table 3). Internal consistency reliability evaluated with Cronbach's Alpha showed a satisfactory range (0.816–0.860; Table 4). Test–retest reliability evaluation is reported in Table 5.

Table 1 Population characteristics

Age (years)	61.7 ± 13.9
Menopausal status	204 (80.3%)
Parity (*n*)	1.8 ± 1.0
BMI (kg/m^2)	25.2 ± 4.3

Continuous data are presented as mean ± standard deviation and non-continuous data as absolute (relative) frequency

Table 2 Construct validity assessment

Domain	Bothersome symptoms	*N* (%)	Score	*P* value
Prolapse	Yes	161 (63.4%)	9.9 ± 5.4	< 0.0001
	No	93 (36.6%)	1.6 ± 3.2	
Bowel	Yes	125 (49.2%)	9.6 ± 6.1	< 0.0001
	No	129 (50.8%)	1.6 ± 2.5	
Bladder	Yes	214 (84.3%)	10.2 ± 5.8	< 0.0001
	No	40 (15.7%)	1.7 ± 2.6	

Continuous data are presented as mean ± standard deviation and non-continuous data as absolute (relative) frequency

Intraclass correlation coefficients ranged between 0.792 and 0.933, indicating a very satisfactory overall agreement for each item. Specific ICC for each item is reported in Table 6.

Discussion

Pelvic floor disorders involve a wide variety of interrelated conditions, including urinary incontinence, fecal incontinence, pelvic organ prolapse symptoms, voiding dysfunction, and defecatory dysfunction, that can negatively impact the quality of life. Therefore, measuring quality of life is essential when evaluating symptoms at baseline and efficacy of treatments on the lives of women. According to a very recent systematic census of Italian-validated questionnaires on pelvic floor disorders, several questionnaires are available for evaluating different areas of pelvic floor disorders [20]. However, none of them completely evaluate pelvic floor disorders in three domains — namely prolapse, bowel, and bladder — like the PFDI-20. In the present study, we translated and tested the validity of the Italian version of this questionnaire. Translation and linguistic validation of a QOL tool are of the utmost importance, and should be implemented before the questionnaire is used in clinical practice [32]. A questionnaire that is valid and reliable for a particular language may not be valid and reliable when used in a different population and scenario [33]. In our study, no issues arose from the translation process, which was carried out following the method proposed by Guillemin, consisting of forward and backward translations with researchers–translators consensus meetings [25]. The obtained version of the questionnaire was tested for comprehension — according to the widely accepted process for linguistic validation — and no difficulties in understanding each question item and related precoded answers in a real-life population were found. Construct validity was confirmed, as the questionnaire was able to discriminate between patients with and without symptoms for all the domains of the questionnaire. Convergent validity was tested and demonstrated with specific items from the Italian version of the Prolapse Quality of Life Questionnaire (PQOL). A strong association of individual items in each domain was shown with the internal consistency reliability analysis using Cronbach's Alpha. Lastly, the longitudinal stability of the questionnaire was evaluated and confirmed with test–retest reliability through the intraclass correlation coefficients analysis.

The PFDI-20 carries some theoretical advantages compared to other QoL tools. The main one is that it allows a comprehensive assessment of the effect of pelvic floor disorders on the quality of life of women, rather than assessing just one aspect of pelvic floor function such as constipation or urinary incontinence. This is particularly important, since disorders of the pelvic floor share the same factors and may frequently coexist [34, 35]. Moreover, the treatment of one of these disorders can improve, worsen, or even predispose to another [7, 36]. For example, prolapse repair has been shown to improve overactive bladder symptoms, but worsening has been demonstrated when a concomitant sling procedure is performed at the time of surgery [35]. Similarly, the anterior vaginal compartment prolapse repair may predispose to postoperative stress urinary incontinence in case of the presence of urodynamic risk factors [7]. Due to these complex relationships, tools that allow a comprehensive approach to the baseline evaluation and assessment of treatment efficacy should be preferred. Moreover, the PFDI-20 total score has been recently stratified into three classes of distress severity, which can be used

Table 3 Convergent validity was tested with PQOL-specific items (#17, #18, #19) and was demonstrated for each domain

Prolapse	Bowel	Bladder
< 0.001	< 0.001	< 0.001

F values are provided

Table 4 Internal consistency reliability

Prolapse	Bowel	Bladder
0.846	0.860	0.816

Cronbach's Alpha values of the domain. Overall Cronbach's Alpha for the questionnaire is 0.906

Table 5 Test–retest reliability

Prolapse	Bowel	Bladder
0.792–0.862	0.870–0.933	0.821–0.886

Intraclass correlation coefficient values range of the domain

Table 6 Test–retest reliability

Item	ICC
Pelvic Organ Prolapse Distress Inventory 6	
1. Do you usually experience pressure in the lower abdomen?	0.826
2. Do you usually experience heaviness or dullness in the pelvic area?	0.861
3. Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?	0.835
4. Do you ever have to push on the vagina or around the rectum to have or complete a bowel movement?	0.845
5. Do you usually experience a feeling of incomplete bladder emptying?	0.862
6. Do you ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?	0.792
Colorecta–Anal Distress Inventory 8	
7. Do you feel you need to strain too hard to have a bowel movement?	0.870
8. Do you feel you have not completely emptied your bowels at the end of a bowel movement?	0.913
9. Do you usually lose stool beyond your control if your stool is well formed?	0.893
10. Do you usually lose stool beyond your control if your stool is loose?	0.931
11. Do you usually lose gas from the rectum beyond your control?	0.911
12. Do you usually have pain when you pass your stool?	0.883
13. Do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?	0.933
14. Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?	0.931
Urinary Distress Inventory 6	
15. Do you usually experience frequent urination?	0.852
16. Do you usually experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom?	0.858
17. Do you usually experience urine leakage related to coughing, sneezing or laughing?	0.875
18. Do you usually experience small amounts of urine leakage (that is, drops)?	0.835
19. Do you usually experience difficulty emptying your bladder?	0.886
20. Do you usually experience pain or discomfort in the lower abdomen or genital region?	0.821

Intraclass correlation coefficient (ICC)values for each item

to facilitate the understanding of the patient's health status [37]. Using a partial credit model, the authors proposed the following classification of distress: absence of symptoms (score zero), symptoms with mild distress (1 to 15 points), symptoms with moderate distress (16 to 34 points), and symptoms with severe distress (35 to 40 points). Lastly, PFDI-20 represents a very solid QoL tool, since it has been extensively used in literature, and its use is highly recommended by the International Consultation on Incontinence. A systematic review of 25 studies evaluating the measurement properties confirmed the high quality of evidence for criterion validity, construct validity-hypothesis testing and responsiveness, moderate quality for test–retest reliability, and measurement errors for PFDI-20 [38].

Strengths of the study include standardized procedural steps for translation/validation, its originality — being that the questionnaire in question is the first one able to evaluate three domains of pelvic floor disorders in the general population in the Italian language — and the evaluation of test–retest reliability.

Conclusions

The present study demonstrated good features for the Italian version of the PFDI-20 questionnaire. A validated Italian questionnaire is now available for clinical use to investigate the incidence, severity, and impact on the quality of life of prolapse, bowel, and bladder symptoms in women with pelvic floor disorders.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00192-023-05572-8.

Author contributions Marta Barba: data collection, manuscript writing.
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Stefano Salvatore: data collection.

Marco Torella: data collection.

Matteo Frigerio: project development, data collection, manuscript writing.

Data Availability The datasets generated and/or analyzed during the current research are not publicly available as individual privacy could be compromised, but are available from the corresponding author on reasonable request.

Declarations

Conflicts of interest None.

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