Validation of the Italian Version of the Peyronie's Disease Questionnaire (PDQ)

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Abstract

Background/objectives:

Peyronie's disease (PD) is a connective tissue disorder characterized by the formation of fibrous plaques in the tunica albuginea of the penis, resulting in pain, deformity, and erectile dysfunction. The Peyronie's Disease Questionnaire (PDQ) assesses the severity of symptoms, including pain, penile curvature, and erectile dysfunction, as well as the impact on sexual function, emotional well-being, and overall quality of life. Previous studies validated the PDQ US version and confirmed its test–retest reliability and responsiveness. The aim is to translate and validate the Italian version of the PDQ to be used in clinical practice and in PD research studies in Italy.

Methods

A non-interventional, observational study with 80 PD patients was conducted in 6 Italian high-volume centers, completing the PDQ in two different study visits. Patients received no type of treatment.

Results

PDQ-I has excellent test-retest reliability in the Italian population (ICC were between 0.86 and 0.92). Moreover, PDQ-I provides strong internal consistency, with all three scale scores exceeding the objective Cronbach's alpha coefficient of ≥ 0.70

Conclusions

The translation and validation of the PDQ for the Italian population provides a valid, useful, and reliable tool to clinically evaluate the quality of life of PD patients and to improve studies on the subject.

INTRODUCTION

Peyronie's disease (PD) is an acquired condition characterized by the formation of fibrous plaques within the tunica albuginea of the corpora cavernosa of the penis. PD can lead to penile deformities during erection such as curvature, shortening, indentations or hour-glass deformity and may be complicated by a variable degree of erectile dysfunction (ED) or, if in the acute disease phase, painful erections [1].

The global incidence is reported around 25 per 100,000 men and it is somewhat unusual in younger adults, with those below 40 years representing only 10% of PD cases. However, most studies reported an average onset of the disease in the range of 45–60 years, often corresponding to the onset of ED [2].

In case of failure of conservative therapies [3], patients with severe, chronic curvature abnormality or intractable PD can be treated successfully with surgery, although not without risk [4].

Moreover, to improve patient satisfaction rates, is mandatory to consider the patient's perception of the deformity before surgery [5].

Several sexual health surveys have been validated in various contexts, but only a small number are suitable for men with PD. The Peyronie's Disease Questionnaire (PDQ) was developed between 2004 and 2012 with the collaboration of experts in PD and sexual health and Food and Drug Administration (FDA) guidance [6].

The Peyronie's Disease Questionnaire (PDQ) was validated to measure the psychosocial effects of PD treatment. Penile pain, psychological and physical symptoms, and symptom bother are among the outcomes that PDQ assesses. It represents a substantial advancement in PD psychometrics and is widely regarded as a required outcome for current PD intervention research.

The PDQ was implemented in the Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies (IMPRESS) clinical trials program, two identical phase 3, double-blind, randomized, placebo-controlled studies that measured the safety and efficacy of collagenase clostridium histolyticum as a potential treatment for PD [1].

The studies supported the PDQ scale's conceptual validity and internal consistency [6]. Many of the criteria for patient-reported outcomes that should be assessed in PD clinical trials are included in PDQ, but it has yet to be widely used in clinical practice maybe for the absence of adequate validation in languages other than English [4]. It took eight years to design and included the advice of professional consultants and FDA guidelines. With the use of PDQ, it is now possible to statistically evaluate the psychosexual effects of PD in both everyday therapeutic practice and for research reasons [7].

This study is aimed to develop the translation into Italian and perform the validation of the Italian version of the PDQ to be used in the clinical practice and for clinical research in Italy.

MATERIALS AND METHODS

The Peyronie's Disease Questionnaire (PDQ)

A 15-item, self-administered, illness-specific, multidimensional printed format instrument was created to measure the psychosexual symptoms of Peyronie's disease. The PDQ has three scales: the "psychological and physical symptoms" scale (6 items), the "penile pain" scale (3 items), and the "symptom bother" scale (4 scored items and 2 yes/no questions). The 5-level Likert scale for the "psychological and physical symptom" dimension ranges from "none" to "very severe." Patients are asked to answer questions on the "penile pain" topic while reflecting on the previous 24 hours. The severity of the pain is rated on a numeric scale from 0 to 10. A 5-level Likert scale (not at all bothered, slightly troubled, moderately bothered, very bothered, and very worried) is used for the "symptom bother" domain. The sum of all responses is calculated and given separately for each domain: higher domain scores, which range from 0 to 24 for "psychological and physical symptom," 0 to 30 for "penile discomfort," and 0 to 16 for "symptom bother," indicate a higher negative impact [6].

Study Design and Population

The validation process of the PDQ in Italian was structured in 8 steps.

Six Italian high-volume centers for andrological diseases on the Italian territory were involved. 80 adult patients (aged ≥ 18 years) with a diagnosis of PD, who come to the andrology outpatient clinic, were enrolled in the study. Each patient must have had penetrating intercourse within the previous three months and be in a committed relationship with a partner for at least three months; patients with any history of a neuropsychiatric condition that could have affected how respondents answered the questionnaire were excluded from the study. Adherents signed a specially created informed consent with the approval of the ethics committee. A demographic registry was created. Completion took place independently at T1 and T2 and an ID code was assigned. At T1, participants completed questions on their demographic characteristics and health status information related to PD, the Italian translation of PDQ (Fig. 1) and the International Index of Erectile Function (IIEF-5 – Fig. 2). At T2, participants completed the PDQ again.

Step 1) Two Italian mother tongue translators translated independently of each other.

Step 2) Meeting between the two translators with a group of Italian experts to analyze the two versions produced with an evaluation of similarities, inconsistencies, and the production of a third translation.

Step 3) Randomization of two privileged groups, one composed of patients who had not had treatment and one composed of healthy volunteers. Both groups were administered the two versions: one at T1 time and one at T2 time, 15 days apart.

Step 4) Drawing up of the fourth draft of the PDQ-I considering the modifications and suggestions of the group of experts.

Step 5) A third English mother-tongue translator, retranslated the Italian version into English verifying the equivalence between the two versions.

Step 6) Approval by the University Hospital's ethics committee of the original English version and the Italian translation.

Step 7) administration at time T1 and the second administration at time T2 at a distance of 6 months and with the same time frame and compilation of the International Index of Erectile Function (IIEF-5) test for the evaluation of erectile disfunction (ED).

Step 8) processing of the data collected.

Analyses

The test-retest reliability of the PDQ and the internal consistency of the PDQ-I subscales were assessed. Intraclass correlation coefficients (ICC) were calculated to assess the degree of association between the three PDQ subscale scores at T1 and T2 [8]. Paired t-tests were used to assess whether there was statistically significant score changes between T1 and T2. Test-retest reliability and reproducibility is a

measure of the concordance of scores based on two separate administrations of the same instrument under stable conditions. To assess the reproducibility of a measuring instrument, a stable study population is required. Internal consistency reliability was assessed by calculating Cronbach's alpha for each of the three PDQ subscales. Coefficients of ≥ 0.70 were considered indicative of good internal consistency. $P < 0.05$ was considered significant [9]. All data were analyzed using the Statistical Package for Social Science SPSS, Chicago, USA for Mac IBM version 25.

RESULTS

Eighty men were enrolled in the study, but 79 of them completed both T1 and T2 questionnaires. The sample mean age was 56.95 (± 11.055 SD) years. All patients were Caucasian, and all reported having vaginal intercourse in the last 3 months at T1. The mean (± SD) number of times was 12.38 (± 5.578). The mean score on the erectile function domain of the IIEF-5 was 19.04 (± 5.578), which indicated the sample had mild ED.

In Table 1 are reported the sociodemographic characteristics of the sample. 38 patients (47,5%) developed the disease in the last 12 months, while 13 (16,3%) patients had a degree of curvature greater than 60°. In 21 cases (26,3%) the onset of the disease was associated with a penile trauma.

Table 2. describes the internal consistency of the PDQ subscales; the ICC was 0.86 for the Psychological and Physical Symptom Subscale, 0.78 for the Peyronie's Symptom Bother Subscale and 0.92 for Penile Pain Subscale. Cronbach's alpha estimates for all subscales were acceptable at all time points at the > 0.70 level (Table 3).

Table n.1
Sociodemographic characteristics of the patients

Sociodemographic characteristics	**N = 80**
Age Mean ± SD	56,95 ± 11,055
Employment status n (%)	
Employee work	40 – (50%)
Self-employment	8 – (10%)
Freelancer	7 – (8.8%)
Unreported	24 – (30%)
Education level, n (%)	
Primary school diploma	5 – (6.3%)
Secondary school diploma	13 – (16.3%)
High school diploma	40 – (50%)
Professional qualifications	5 – (6.3%)
Bachelor's degree	10 – (12.5%)
Old university degree and/or Master's degree	5 – (6.3%)
PhD degree	1– (1.3%)
PD duration, n 79 (%)	
6–12 months	38 – (47.5%)
13–18 months	19 – (23.8%)
18–24 months	7 – (8.8%)
> 24 months	15 – (8.8%)
Penile bending n 79 (%)	
< 30°	33 – (41.3%)
30°> and < 60°	33 – (41.3%)
> 60°	13 – (16.3%)
Penile trauma n 79 (%)	
No	58 – (72.5%)
Yes	21 – (26 – 3%)
Total IIEF-5 n. 79 Mean ± SD	

Sociodemographic characteristics	N = 80
IIEF-5 score	19.4 ± 5.578

Table n.2
Reproducibility of PDQ-I subscale scores at T 1 and T 2 (n = 79)

PDQ-I Sub Scale	T1 – N- Mean ± SD	T2 - N - Mean ± SD	Difference score	*t* value	*P* value	ICC
Psychological and Physical Symptoms	79 8.65 ± 5,70	79 8,79 ± 5,67	0.14	-0,423	0,74	0.86
Peyronie's Symptom Bother	79 6,29 ± 6,28	79 6,79 ± 6,33	0,50	-1.085	0,47	0.78
Penile Pain	79 8,97 ± 5,10	79 9,36 ± 5,15	0,39	-1.72	0,33	0.92

Table n.3
Internal consistency reliability of the PDQ-I at T1 and T 2 (n = 79)

PDQ-I Sub Scale	T1		T2	
	n	Cronbach's alpha	n	Cronbach's alpha
Psychological and Physical Symptoms	79	0,83	79	0.79
Penile Peyronie's Symptom Bother Pain	79	0.80	79	0.80
Penile Pain	79	0.70	79	0.83

DISCUSSION

The current study's objective was to validate the Italian translation of the PDQ in order to provide physicians with a helpful tool for the clinical diagnosis of PD. The findings show measurement characteristics (validity and reliability) that are comparable to those reported in the PDQ US version validation studies [1, 6, 10]. The results of this study show that the PDQ-I has excellent test-retest reliability in the Italian population, suggesting that it would be useful for use in patients with PD. The strength of the PDQ-I is that the reliability estimates of the scale scores based on ICC were very high, ranging between 0.86 and 0.92. In addition to test-retest reliability, the PDQ-I provides strong internal consistency, with all three scale scores exceeding the objective Cronbach's alpha coefficient of ≥ 0.70

(Table 3). Nelson et al. demonstrated in 2008, depression scores did not significantly change over time following PD diagnosis [11]. Consequently, the questionnaire should be helpful for males with both acute and stable PD.

Although cross-cultural questionnaire adaptation was difficult, Beaton et al.'s instructions provide a clear explanation of the procedure [12]. Borja García-Gómez et al. recently published a Spanish translation and validation with solid data that is comparable to the Italian cohort examined [13]. The Danish group of Majken H. Wiborg et al. also recently produced a study to translate and validate the PDQ questionnaire in the Danish language [14].

Moreover, in PD patients a complete psycho-sexological assessment must be performed. Smith et al. found that patients cited their sexual performance and function as key concerns even if they were able to engage in sexual activity [15]. Intercourse was described to PD patients as being different, more physically challenging and uncomfortable. They were also discovered to be worried about their appearance, their sexual identity and their lack of sexual confidence, which increased the psychological symptoms and the comorbidity of penile curvature [16]. In this way, it's critical to keep in mind that people with PD have not only a variety of physical abnormalities, but also significant psychological problems that should be accurately identified and assessed throughout the clinical assessment [17].

Aware of these variabilities, the presence of a validated tool translated into the native language of the patient seems more and more essential nowadays in order to make both the clinical evaluation and the organization of studies as homogeneous as possible.

Furthermore, our polycentric study involved 6 centers, uniformly distributed throughout Italy to ensure the heterogeneity of the study sample. The heterogeneity of the sample was also ensured regarding socio-economic and marital status.

Limitations

However, the condition that patients have engaged in penetrative vaginal intercourse within the last three months severely restricts the PDQ. Many individuals with PD do not meet these requirements because they do not currently have a sexual partner and/or because of the functional restrictions brought on by penile curvature, indentation and other sexual dysfunction. Moreover, the PDQ does not adequately account for various forms of sexual activity, such as oral and anal sex, which can occur between heterosexual and homosexual partners. This might lead to individuals who are asked to complete the PDQ feeling isolated [17]. Major deficiencies of this study are the small sample size and the fact that the PDQ changes were not followed over time, with no comparison with ED assessment with a validated tool, such as the International Index of Erectile Function.

CONCLUSIONS

In conclusion, the translation and validation of the PDQ for the Italian population provide a valid, useful, and reliable tool to clinically evaluate the quality of life of PD patients. The PDQ has proven a valid instrument to measure multidimensional aspects of sexual function in PD patients. This study also supports the usefulness of this questionnaire for both daily clinical practice and PD investigation purposes and will play an important role in assessing the correct diagnostic and therapeutic work-up of Italian PD patients.

Declarations

Funding: This research received no external funding.

Institutional Review Board Statement: This is a prospective non-interventional study conducted on patients treated by the law and the national and European ethical guidelines. All Authors ensured that their institutions and their clinical behavior are complying with the specific requirements of the Country. The informed consent as well as the use of personal data was regularly collected from all the subjects involved in the study. Signed informed consent forms are stored in an appropriate repository.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data are anonymized and stored at the Urology Clinic in the University of Trieste at the Department of Medical, Surgical and Health Sciences.

Conflicts of Interest: The authors declare no conflict of interest.

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