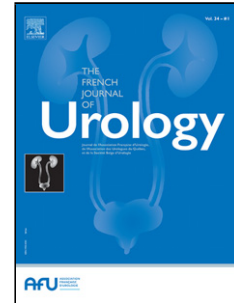


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French translation of the Peyronie's Disease Questionnaire: a pilot study

Traduction française du Peyronie's Disease Questionnaire : étude pilote

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Abstract

Background: The Peyronie's Disease Questionnaire (PDQ) was designed to quantitatively assess the symptoms and psychosexual consequences of Peyronie's disease but has only been validated in four languages. The aim of the study was to provide a French translation of the PDQ, to make it available to the French-speaking urology community.

Methods: After a double translation of the PDQ from English into French, followed by a back translation by four expert translators, a conciliation process enabled the creation of the final French version. For each item, participants were asked to answer two sub-questions. The percentage of responses "I fully understood the question" to sub-question a) constituted the validation criterion for the translation.

Results: The final French version was submitted to a series of 30 men with Peyronie's disease whose average age was 59 (± 12) years. For each question, the comprehension rate was over 95%, and for 12/15 items it was 100%. For the remaining 3 items, men declared that they did not feel disturbed or bothered by the questions and none of the questions were misunderstood.

Conclusion: This pilot study shows that our translation of the PDQ is valid and comprehensible by all participants, regardless of the age or level of education. This French version should be validated further in other French-speaking populations before final validation.

Résumé

Introduction : Le Peyronie's Disease Questionnaire (PDQ) a été conçu pour évaluer quantitativement les symptômes et les conséquences psychosexuelles de la maladie de La Peyronie, mais il n'a été validé qu'en quatre langues. L'objectif de cette étude était de fournir une traduction française du PDQ, afin de le mettre à la disposition de la communauté urologique francophone.

Matériel et méthodes : Après une double traduction du PDQ de l'anglais vers le français, suivie d'une contre-traduction par quatre traducteurs experts, un processus de conciliation a permis de créer la version française finale. Pour chaque item, les participants étaient invités à répondre à deux sous-questions. Le pourcentage de réponses "J'ai bien compris la question" à la sous-question a) constituait le critère de validation de la traduction.

Résultats : La version française finale a été soumise à une série de 30 hommes atteints de la maladie de la Peyronie, dont l'âge moyen était de 59 (± 12) ans. Pour chaque question, le taux de compréhension a été supérieur à 95%, et pour 12/15 items il a été de 100%. Pour les 3 items restants, les hommes ont déclaré qu'ils ne se sentaient pas perturbés ou gênés par les questions et qu'aucune des questions n'avait été mal comprise.

Conclusion : Cette étude pilote montre que notre traduction du PDQ est valide et compréhensible par tous les participants, quel que soit leur âge ou leur niveau d'éducation.

Cette version française devrait être validée auprès d'autres populations francophones avant d'être validée définitivement.

Mots-clés : Induration pénienne ; PD ; PDQ ; statistiques descriptives.

Keywords: Penile induration; PD; PDQ; descriptive statistics.

Introduction

Peyronie's disease (PD) is a benign condition characterized by fibrosis of the tunica albuginea of the corpora cavernosa, resulting in fibrous plaque and abnormalities of the erect penis (penile curvature, hourglass effect, penile shortening). It can also be accompanied by other signs and symptoms such as erectile dysfunction or, in the acute phase of the disease, penile pain, all of which may have a considerable impact on men's quality of life. Although methods for measuring penile curvature have become standardized in recent years, for subjects and their partners there is not necessarily a correlation between improvement in this symptom and other functional aspects of the disease (1).

The Peyronie's Disease Questionnaire (PDQ) was developed between 2004 and 2012 in collaboration with PD and sexual health experts and with guidance from the Food and Drug Administration (FDA) (2). This questionnaire was designed to quantitatively assess the symptoms and psychosexual consequences of Peyronie's disease by providing scores for three domain subscales; psychological and physical symptoms, penile pain, and discomfort related to PD symptoms. Although its use as a primary end point tends to be developing internationally (3), so far, it has been validated in English (4,5), Spanish (6), and recently in Danish (7) and Italian (8).

The primary objective of this work was to provide a French translation of the Peyronie's disease questionnaire (PDQ), to make it available to the French-speaking urology community. In accordance with the recommended translation procedure, we have endeavored to remain faithful to the original version while maintaining comprehensibility for all patients regardless of their level of education and being mindful not to be offensive (9).

Methods

1. Assumptions

Our French translation had to be comprehensible to people of all educational levels. This had to be reflected in a high percentage of participants ticking "I understood the question" in sub-question a) following each item tested.

Similarly, we expected that no participant, or only a small percentage of participants would tick one of the following boxes in sub-question a): "I had trouble understanding the question", "I didn't understand some of the words", "I didn't understand the meaning of the question".

Finally, our French translation was not intended to be offensive. We assumed that no participant would tick the following box in sub-question a) following each item tested: "The question hurt my feelings".

2. Reference system and work team

The original authors of the PDQ were contacted by e-mail, and their agreement to carry out this translation was obtained. During our translation, we requested the raw data from their study so that we could compare our results to theirs. Unfortunately, they were unable to provide this data. The results were therefore compared with those reported in previous validation studies (4,5).

3. Protocol sequence

To achieve our objective, we successively:

1. Asked two French urologists fluent in English to produce a separate French translation of the English PDQ questionnaire.
2. Compared the French translations provided and highlighted points of divergence.
3. Developed an initial version of the French translation of the PDQ.
4. Asked two professional English-speaking scientific translators to carry out a back translation from French into English.
5. Compared the original version of the scale, its translation, and the back translation with the translators to identify any inconsistencies.
6. Developed a final version of the PDQ translation in French.
7. Assessed the comprehension of the questions by French patients with Peyronie's disease during the pilot study.

8. Assessed whether any patient felt embarrassed or offended by certain questions, and whether they misunderstood them, had any difficulty answering them or felt disturbed by them.
9. Compared the response patterns of participants in our pilot study to those of participants in the original study to validate the translation conceptually.

4. Pilot study participants

According to the methodological guide for translating quality-of-life questionnaires (2017 edition), our pilot sample had to include 10 to 15 participants from the questionnaire's target population (9). However, the INRS (French National Research and Safety Institute) research report on the design, translation and validation of a questionnaire mentions a test with a panel of approximately forty participants (10). For our study, we planned to follow the example of the pilot study carried out for the Spanish translation (6) and to include approximately thirty patients corresponding to the target population. We recruited PD patients from the *Centre Hospitalo-Universitaire de Toulouse*, who presented for consultation between March 2023 and May 2023. Inclusion criteria were men ≥ 18 years of age with a diagnosis of PD, who did not object to data collection. Non-inclusion criteria were men with an inadequate level of French to write and/or understand the questionnaire methodology or to follow the instructions.

5. Ethics

The study protocol was approved beforehand by the Ethics Committee Ouest III (N°ID-RCB: 2023-A00219-36) on March 1st, 2023, and was conducted in accordance with the ethics of the Helsinki Declaration. All the patients received a written information leaflet prior to inclusion in the protocol. The study was registered on clinicaltrials.gov under the acronym FRAPEYQUEST (NCT05768867; <https://clinicaltrials.gov/study/NCT05768867>)(11).

6. Materials

Our final version of the PDQ was administered during a consultation to patients participating in the pilot study. The questionnaire was either in paper format, or via an internet link to Sphinx Déclit, a recognized site for the creation and distribution of online surveys. The PDQ is a self-administered, PD-specific questionnaire comprising 15 items, developed to quantify the psychosexual symptoms of PD. The PDQ comprises three scales: "psychological and physical symptoms" (6 items), "penile pain" (3 items) and "symptom discomfort" (4 scored items and 2 yes/no questions). The "psychological and physical symptoms" domain has a 5-level scale ranging from "none" to "very severe". Patients were asked to complete items in the "penile pain" domain in relation to the past 24 hours, and a numerical scale ranging from 0 to 10 was used to assess severity from "none" to "extreme". The "symptom discomfort" domain has a 5-level scale ("not at all bothered", "a little bit bothered", "moderately bothered", "very bothered", "and extremely bothered"). The sum of all responses is calculated and can be given separately for each domain. Higher domain scores indicate a greater negative impact, with the score ranging from 0 to 24 for "psychological and physical symptom", 0 to 30 for "penile pain" and 0 to 16 for "symptom discomfort"(5). For each item, participants were asked to answer two sub-questions a) "Concerning the previous question, please select the answer

corresponding to your feeling” and b) “If you have selected an answer other than the first (“I understood the question”), please explain why, or tell us what you didn't understand”. These responses enabled us to determine whether the wording of the items was comprehensible to everyone, or if not, to identify the difficulties it created and their causes.

7. Data analysis

We used Excel to structure our results according to the responses received, to facilitate analysis and interpretation. We used the statistical software R Version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria) for descriptive and statistical data analysis. The main aim was to determine the percentage of “I understood the question” responses to sub-question a) of each item. A high rate of this response to each questionnaire item for all patients enabled validation of the translation.

Results

1. French version and study population

Once the translation and back translation stages were completed, we obtained the French version of the PDQ (**Supplementary material**), which was administered to the pilot study participants. **Table 1** summarizes the characteristics of the population. A total of 30 men with PD completed the questionnaire. All reported having had sexual intercourse in the past three months. The mean age was 59 (SD \pm 12) years; the majority of the men were cohabiting (n = 22, 73%). Nearly half (43%) were retired. The men's disease status at the time of answering the questionnaire was very heterogeneous, with almost a third in standard follow-

up (n = 8, 31%), a third in treatment (n = 8, 31%) and a third in post-treatment follow-up (n = 14, 38%).

2. Answers to the questionnaire

The mean scores obtained by calculating the sum of the responses to the questions in the three PDQ subcategories are shown in **Table 2**. The results were compared to the studies that validated the questionnaire in other languages (5–8). Overall, scores were fairly similar for psychological and physical symptoms compared to the English-speaking population (10.9, SD \pm 5.1 vs. 10.6, SD \pm 5.1) and for symptoms of discomfort compared to the Spanish and Italian-speaking people (6.2, SD \pm 4.1 vs. 6.0, SD \pm 4.6 vs. 6.3, SD \pm 6.3). In contrast, the men in our study had a high penile pain score compared to English, Spanish and Danish-speaking populations but a lower penile pain score compared to Italian-speaking population (6.4, SD \pm 6.3 vs. 9.0, SD \pm 5.1).

Answers to the sub-questions of each PDQ item were recorded. For each question, the comprehension rate was over 95%, with 100% comprehension for 12/15 items. For the 3 remaining items, all men declared that they did not feel disturbed or bothered (hurt or embarrassed) by the questions. None of the questions translated from English into French was misunderstood (understanding of the sentence, specific words, or the meaning of the question) (**Table 3**).

Discussion

Peyronie's disease is not a life-threatening condition, but it can have significant psychosocial repercussions for patients. Whereas penile curvature is an available objective endpoint to monitor the progression of the disease, so far, there is no validated tool in French enabling to assess the impact on the quality of life. Many studies have described the psychological impact of PD on patients' daily lives, but the means of assessment are very heterogeneous (12,13). This assessment requires a validated tool that would provide measurable and reproducible endpoints. Hellstrom et al. developed and validated the PDQ questionnaire which assesses the impact of Peyronie's disease in three areas: psychological and physical symptoms, penile pain and discomfort (5). This questionnaire was subsequently validated on a larger scale in a population of men with PD and is the only validated questionnaire that assesses the psychosocial impact of the disease (4). Subsequently, a Spanish version has been validated (6), but so far, even if a French version has ever been used in IMPRESS 1 (5) and a study of the efficacy of platelet-rich plasma injections in PD (3), the French version had not been validated.

Therefore, we decided to translate this questionnaire using a methodology designed to avoid ambiguities or misinterpretations: translation from English to French by two people, arbitration by a multidisciplinary reading committee, back translation from French to English by professional translators, arbitration by a multidisciplinary reading committee again, and, finally, qualitative evaluation by interviewing a representative pilot study sample of the target population.

General baseline characteristics of our population were fairly similar regarding age, discomfort and frequency of sexual intercourse in the past three months to those included in PD efficacy and safety studies (Hellstrom). Nevertheless, we found that mean scores for penile

pain were higher in our small cohort. This could be due to the fact that some men in our study might also have been in the acute phase of PD, whereas only men with PD for more than a year (the stabilized phase) participated in the IMPRESS 1 study. However, we reported a penile pain score lower compared to Di Grazia's study (6.4, SD \pm 6.3 vs. 9.0, SD \pm 5.1). In this study, men were younger (mean age of 57) and one third of the cohort had a low penile curvature (< 30°). A recent study by Cilio et al. aiming at determining whether patient age has an impact on the symptomatic burden of PD revealed that younger men tended to have a higher risk of penile pain despite a lower curvature (14). Therefore, the questionnaire should be useful for men in both the acute and stable phases of PD. The PDQ is an exhaustive questionnaire which may seem difficult to use in daily urology practice. However, it enables an accurate description of the patient's disease and could therefore allow optimal decision-making and precise follow-up.

Limitations of the current study include its unicentric nature and consequently, a lack of comparative data on certain populations. For example, unfortunately, there was a lack of men with PD with atypical symptoms such as the hourglass effects. Furthermore, use of the PDQ is currently limited to patients with regular vaginal intercourse in the three preceding months, which excludes from the analysis men who have avoided or ceased all sexual activity due to the severity of their disease, as well as homosexuals or men who have oral and anal intercourse with their partners. One solution to this problem would be to set up a committee of experts including more translators and healthcare professionals, to adapt the original questionnaire to French values, as Wiborg et al. did for the Danish translation of the PDQ (7). Finally, since our analysis was based on only one response to the questionnaire per patient, PDQ scores have not yet been correlated with changes in disease severity or treatment outcome, which raises the question of test-retest reliability in a future study.

Nevertheless, we hope that this first publication will provide a basis for the use of this questionnaire in future clinical studies, which will also be able to assess its discriminatory nature, consistency, and reproducibility. Such studies are bound to come to fruition, with the PDQ used as the main endpoint to improve the analysis of the full complexity of PD. While the urologist's role must include the management of physical symptoms, the patient as a whole and the psychosocial impact of his or her disease must also be considered. Indeed, Smith et al. showed a high prevalence of emotional (81%) and relationship problems (54%) in men suffering from PD (15). A recent study by Thach et al. assessed the impact of PD on couples, using the Hospital Anxiety and Depression (HAD) scale. They found a median HAD score of 20, suggesting significant psychological consequences in men with PD (16). While these results are interesting, this questionnaire is not specific to PD. We believe that the PDQ could be very useful, as its content is more focused on the symptoms of PD, and therefore urologists could finally have a tool to better assess the psychological impact of this disease. We have submitted a protocol for a multicenter clinical study on the use of the French version of the PDQ to the Ethics Committee, with a view to validating the translation in a larger population.

Conclusion

This work enabled us to validate the French translation of the PDQ questionnaire. We ensured that the wording of each item was comprehensible to all patients, regardless of their age or level of education, and that it accurately reflected patients' feelings, while preserving the meaning of the questions asked in the original questionnaire. To achieve this, we had the support of the authors of the original questionnaire who clarified what they wanted to question in their questionnaire. There were no comprehension problems with the wording of

the items, specific words, or the meaning of the questions. We hope to further increase the level of validation of our questionnaire by conducting a multicenter study in France.

Declarations

Funding (information that explains whether and by whom the research was supported)

Not applicable

Research involving Human Participants and/or Animals

The study protocol was approved beforehand by the Ethics Committee Ouest III (N°ID-RCB: 2023-A00219-36) on March 1st, 2023 and was registered on clinicaltrials.gov under the acronym FRAPEYQUEST (<https://clinicaltrials.gov/study/NCT05768867>).

Informed consent

All the patients received a written information leaflet prior to inclusion in the protocol.

Code availability (software application or custom code)

Not applicable

Protocol/project development

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Data collection or management

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Data analysis

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Manuscript writing/editing

Dang VT, Delaunay B, Roumiguié M, Gamé, X, Soulié M, Huyghe E

Conflicts of interest/Competing interests (include appropriate disclosures)

The authors have nothing to disclose.

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Table 1 - Characteristics of the study population (n = 30).

Table 1 - Characteristics of the study population (n = 30).

	Study population (n = 30)
Age, years	59 [\pm 12] ^a
Marital status, n (%)	
Single	8 (27)
Cohabiting	22 (73)
Profession, n (%)	
Farmers	1 (3.3)
Craftsmen, shopkeepers, and business owners	2 (6.7)
Executives and higher intellectual professions	5 (17)
Employees	1 (3.3)
Workers	4 (13)
Intermediate professions	3 (10)
Retirees	13 (43)
Unemployed	1 (3.3)
Previous PD treatment, n (%)	
No	10 (33)
Verapamil injections,	1 (3.3)
PRP	3 (10)
LISWT	14 (47)
Surgery	2 (6.7)
Current situation, n (%)	
Standard monitoring	8 (31)
Currently being treated	8 (31)
Follow-up after treatment	14 (38)
Sexual intercourse in past 3 months, n (%)	30 (100)
Number of days since last intercourse	12 [\pm 13]
Number of sexual intercourses in the past 3 months	8 [\pm 5]

^a Mean values [standard deviation]
 PD indicates Peyronie's disease; LISWT, low-intensity shock wave therapy; PRP, platelet-rich plasma

Table 2 - Comparison of the Peyronie's Disease Questionnaire item scores with other studies.

Table 2 - Comparison of the Peyronie's Disease Questionnaire item scores with other studies.

	Our study	English study (Hellstrom, 2013)	Spanish study (García-Gómez, 2022)	Danish study (Wiborg, 2023)	Italian study (Di Grazia, 2023)
Psychological and physical symptoms (/24)	10.9 [±5.1] ^a	10.6 [±5.1]	8.5 [±6.5]	9.7 [±4.5]	8.7 [±5.7]
Penile pain (/30)	6.4 [±6.3]	4.0 [±5.0]	5.1 [±6.2]	5.3 [±5.9]	9.0 [±5.1]
Symptoms of discomfort (/16)	6.2 [±4.1]	7.6 [± 3.6]	6.0 [±4.6]	7.7 [±3.4]	6.3 [±6.3]

^a Mean values [standard deviation]

Table 3 - Question-by-question analysis of the feelings of men who completed the Peyronie's Disease Questionnaire (n= 30).**Table 3** – Question-by-question analysis of the feelings of men who completed the Peyronie's Disease Questionnaire (n= 30).

	Feelings about the question asked			
	Understood	Not understood	Disturbed	Not disturbed

Psychological and physical symptoms, n (%)				
Question 1	29 (97)	0	0	1 (3)
Question 2	30 (100)	0	0	0
Question 3	30 (100)	0	0	0
Question 4	30 (100)	0	0	0
Question 5	30 (100)	0	0	0
Question 6	30 (100)	0	0	0
Penile pain, n (%)				
Question 7	29 (97)	0	0	1 (3)
Question 8	30 (100)	0	0	0
Question 9	30 (100)	0	0	0
Discomfort, n (%)				
Question 10	30 (100)	0	0	0
Question 11	30 (100)	0	0	0
Question 12:	29 (97)	0	0	1 (3)
Yes → go to Q13				
No → go to Q14				
Question 13 (n = 14)	14 (100)	0	0	0
Question 14:	30 (100)	0	0	0
Yes → go to Q15				
No → end of questionnaire				
Question 15 (n = 20)	20 (100)	0	0	0

Annex 1 - French version of the Peyronie's Disease Questionnaire.