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Peyronie's disease questionnaire: translation into Danish and cultural adaptation

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Abstract

Background: Peyronie's disease has an impact on men's mental and physical health.

Aim: We sought to translate the Peyronie's Disease Questionnaire into Danish, adapt it to the Danish cultural setting, and test it in a Danish population.

Methods: Translation of the Peyronie's Disease Questionnaire was performed according to the guidelines for adapting health status measures for use in languages other than the source language by Beaton et al. The validated American Peyronie's Disease Questionnaire was developed to monitor patient symptoms after an intervention and to inspire a subsequent dialogue about physical and psychological symptoms with a healthcare provider, thereby allowing the patient and the healthcare professional to choose the best treatment. The expert committee agreed on a Danish version after cross-cultural adaptation. The Danish Peyronie's Disease Questionnaire was sent by electronic mail to a preselected group of 41 men with Peyronie's disease.

Outcomes: After completing the questionnaire, 32 men participated in a video interview regarding the questionnaire and were asked to identify any problematic fields or areas open to misunderstanding.

Results: The Peyronie's Disease Questionnaire underwent major modifications in light of the comments of the first 10 respondents. Thereafter, only minor changes were made until data saturation was reached after 27 of the 32 respondents had been interviewed. In 87% of respondents Peyronie's disease bothered from the last time they had intercourse, and 93% of the men experienced being bothered by having intercourse less often. Peyronie's disease made 73% of respondents feel bodily discomfort, and 88% had intercourse less often than they used to have due to Peyronie's disease.

Clinical Implications: The Peyronie's Disease Questionnaire is a valuable tool in the crucial task of addressing Peyronie's disease, providing insight into the mental and sexual health problems as well as physical challenges faced by patients.

Strengths and Limitations: The interviewer's modest experience in conducting interviews is believed to have been duly compensated for by continuous and accumulating learning-while-doing process because the same interviewer conducted all of the interviews and did so consecutively.

Conclusions: Danish men expressed satisfaction with the questionnaire and found it valuable as a tool when visiting the doctor for the first time.

Keywords: penile induration; PD; PDQ; cultural adaptation; descriptive statistics.

Introduction

Peyronie's disease (PD) is an acquired fibrotic disorder of the penis. The pathophysiology of PD is not fully understood, but the underlying mechanism is generally thought to be multiple microtraumas to the tunica albuginea (TA), resulting in inflammation and later fibrosis.¹

The shortage of efficient treatments for PD with few side effects generates a strong need for alternative treatment modalities that recreate the anatomy of the penis while causing as few side effects as possible.

The psychological aspect of PD should also be addressed as PD has a substantial impact on the quality of life of the affected and their partners quality of life. Patients are burdened with bother, distress, and impaired sexual performance due to the deformity resulting from this disease.^{2,3}

An American Peyronie's Disease Questionnaire (PDQ) that measures the impact and severity of PD was validated by Hellstrom et al.² in 2013 (**Supplementary material**). Two studies testing the responsiveness of the PDQ and test-retest reliability were performed in 2015.^{3,4} The PDQ was highly responsive to change in men with PD⁴ and is a reproducible measure of PD that has been shown to be an effective end point patient-reported outcome measure in clinical trials.⁵

The PDQ has 3 subscale domains: physical and psychological symptoms, penile pain and symptom bother. It can be applied as an individual baseline score, can assess symptom improvement or worsening over time and can facilitate addressing psychological aspects of PD in patient-physician encounters. Undoubtedly, the PDQ would also be a helpful instrument in a Danish setting. The purpose of the present

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study was therefore to translate and cross-culturally adapt the PDQ to a Danish setting and explore whether Danish men with PD experience bother and distress because of PD.

Methods

To best achieve the purpose of the study, we used qualitative methodology, because this method is able to capture aspects in relation to patient experiences and the culture they live in. Here, we report the results of the translation process and the findings of semi-structured cognitive video interviews. The article follows the guidelines of the Consolidated Criteria for Reporting Qualitative Research checklist.⁶

Translation

We performed a translation of the already validated US questionnaire. The translation process was performed according to the guidelines of Beaton et al.⁷ (Figure 1). Two native Danish persons translated the original PDQ into Danish. One male translator (T1) was naive to the subject, and 1 female translator (T2) was a urologist familiar with the condition. After translating the PDQ into Danish, the translators met with the investigator to synthesize the 2 translations. Several words differed between the 2 versions. After going through the questionnaire, everyone agreed on a single version (T-12) that all thought best represented the US version. Two native English speakers received the Danish T-12 translation. Both were naive to the original version of the PDQ, ignorant of the concepts explored, and without a medical background. Each of the native English speakers produced a back-translation version (BT-1 and BT-2) and also met with the investigator and agreed on a combination of their translations (version BT-12).

Cultural adaptation

An expert committee consisting of 4 translators, 3 healthcare professionals, and a language methodologist was gathered. One translator was also a health professional, and the investigator was counted as 1 of the 3 healthcare professionals. The original questionnaire and the T-12 and BT-12 versions were compared. The expert committee addressed the versions in 4 areas: semantic, idiomatic, experiential, and conceptual, and the committee sought to achieve equivalence between the source and the target versions. By not limiting participation solely to heterosexual men or men sexually active within the past 3 months, the Danish PDQ differed from the original. The committee agreed that such limitations were not in accordance with Danish values, and from a patient perspective, they could be experienced as heteronormative. In addition, relevant information may have been excluded by such limitations.

PDQ and subject recruitment

The investigator produced an electronic version of the version on which the expert committee had reached an agreement. Subjects recruited to test the Danish PDQ were purposive samples primarily chosen from sexual clinics from a provincial and a university hospital. Inclusion criteria were patients diagnosed with PD in the acute or chronic phase at a urological department who were older than 18 years and could understand and speak Danish. Exclusion criteria were patients without verified PD or acquired penile deviation and those with no Danish language skills. Four participants were self-referrals after having read about the study in the local paper

or after they had heard about the project in a national TV show. The researchers recruited 12 men. The remaining 25 participants were referred by colleagues who were involved in the treatment of the patients. The participants were informed that the purpose was to test a newly translated questionnaire to discover inconsistencies and potential errors. The recruited men gave oral consent to participate. Five colleagues pilot tested the electronic version before sending it to the participants. All PDQs were sent to a secure online email box. If the questionnaire was not completed within 1 week, prospective participants received a reminder. In total, they received 2 reminders. Nonresponders were not contacted in any other way.

Interviews

The first author conducted all 32 semistructured cognitive video interviews. The interviews were designed to explore how the participants experienced the questions in the PDQ and the meanings they attributed to them. The interviewer was a female PhD student, a specialist in urology with a Master's degree in sexology. She had been a medical doctor for 17 years and a specialist for 7 years. She had no prior experience conducting cognitive interviews but had participated in a course on interviewing beforehand and had an experienced supervisor. The tested questionnaire was also later utilized in a clinical study conducted by the PhD student.

The investigator completed the interviews by video call. In this way, the participants could choose to be in a safe environment. The background of the researcher was blurred, and no one else was present during the interviews. Recording of the interviews took place after oral permission from the participants was obtained and stored in NVivo (Alfasoft Sweden, release 1.4.1). Prior to the interview, participants were contacted by email or telephone to arrange the best-suited time for the interview. At the beginning of the interview, the interviewer again briefed the interviewees on the purpose of the interview and asked whether they had any questions. The interview followed a self-constructed interview guide. To get the participants to elaborate on their answers, the interviewer was either passive or used paraphrasing. The audio was recorded and field notes were taken during the interviews. Participants did not receive transcripts for correction or comments, and no repeat interviews were conducted. Furthermore, the participants were not given the opportunity to provide feedback on the findings. In advance, it was decided that 30 men were needed to test the questionnaire. This number was in accordance with the guidelines of Beaton et al.⁷ After 10 interviews, input from the participants led to modifications of the PDQ and the interview guide. Some of the alterations were that question 2 (Q2) contained a double question, Q3 used the word penetration, which men did not quite understand or felt awkward about, and Q8 and Q10 were too similar, and the focus words were underlined in order for the men to perceive them as 2 different issues. The expert committee approved the modifications. We chose to continue with the same cohort because the changes were linguistic, and we assessed that it would not affect the outcome as the changes were minor. After 27 interviews, data saturation was obtained. An additional 5 interviews were conducted, in which all participants agreed that all questions were easy to understand and could be answered clearly. Minor design modifications were made throughout the period.

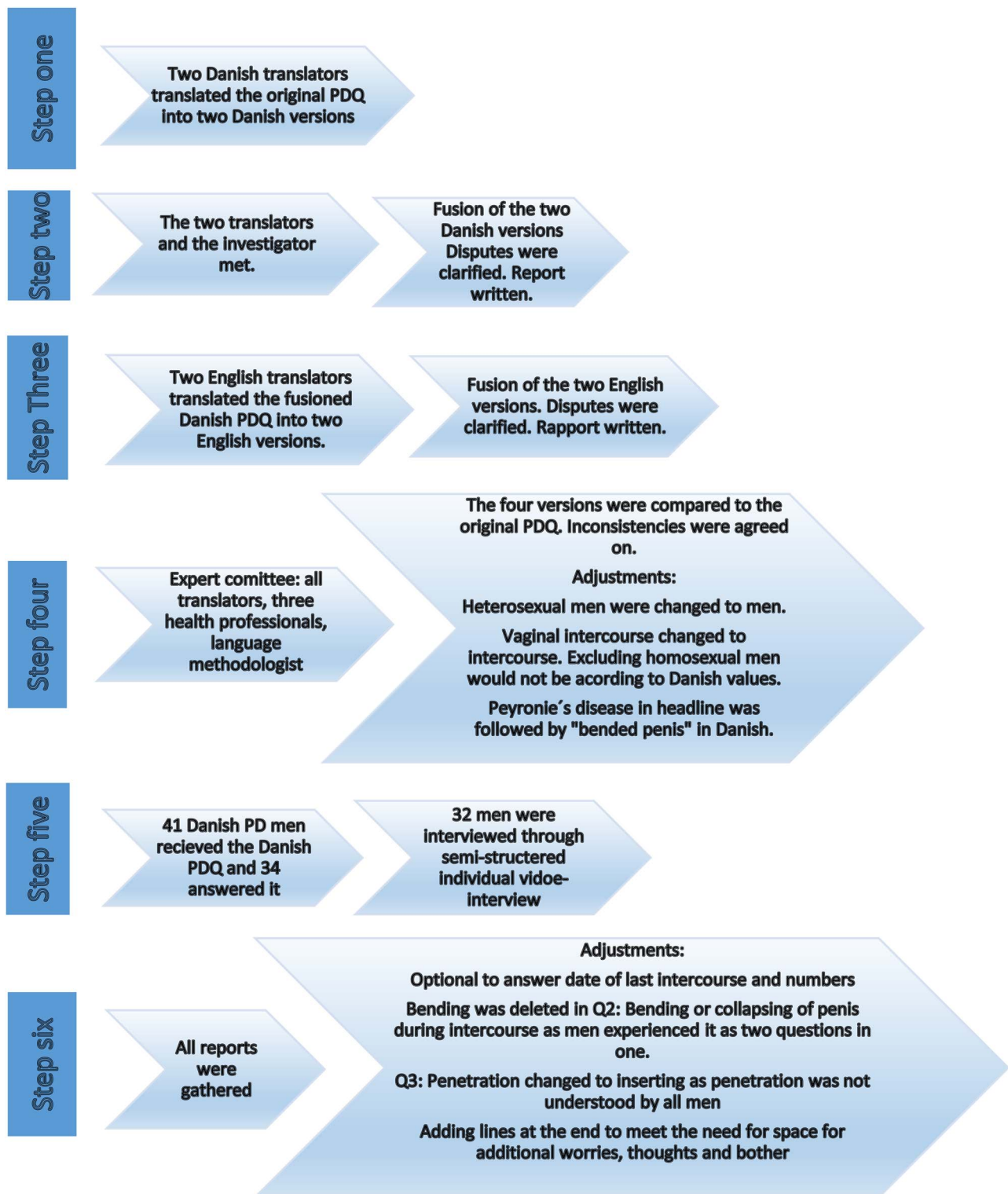


Figure 1. The 6 steps from the guidelines by Beaton et al.⁷

Participants

A total of 32 participants took part in the interviews, which were conducted from February 11 to June 21, 2021. On average, the delay from answering the questionnaire online until the interview was completed was 6.6 days (range 1–20 days). The interview, on average, lasted 32.23 minutes (range 10.13–58.36 minutes). All interviewees understood

and spoke Danish and took the interview alone. Two interviewees chose not to have the video turned on during the interview, and 1 interview was conducted over the phone due to technical failure.

Authors 1 and 2 coded the interview data. We mainly used inductive coding as the codes were not identified in advance, but 2 themes were formulated in the research questions.

Face validity

The majority of participants thought the length of the questionnaire was adequate. Some wished it to be longer and to have more questions about how PD potentially affected them mentally.

Content validity

The PDQ construct measures the impact and severity of PD at a specific time point and evaluates potential changes in symptoms over time. When the interviews were analyzed, the following themes were selected: relevance, understanding, content, and construct.

In the interview, 82% of the men stated that they felt the questionnaire was relevant to them and their condition. They felt that it could be a helpful tool and a good starting point when talking to their physicians. On the contrary, some men in relationships felt that the questionnaire was faulty and missed the inclusion of their partners' influence. These men also explained that their own experience of the situation highly depended on how their partners experienced or accepted the challenges. One man stated that sexual activity should also include whether or not men could masturbate as he experienced this as an additional, valuable way to be sexually active. Another man wished that the problems addressed concerned more topics and not just sexual activity because he had had problems urinating as his penis had become shorter.

Other participants mentioned that because it had been a long time ago since had intercourse, Q1 to Q6 were difficult to answer. Some men felt the questions were just right and highly relevant to ask in this setup; meanwhile, 2 men felt some of the questions crossed their personal boundaries, especially the question about the last date they had sexual intercourse. One wished that he did not have to answer that question.

The majority of the interviewees found the questions relevant and unproblematic to understand. However, some would have liked more focus on the mental impact of the disease and the possibility of disclosing causes other than PD for not being sexually active. Other participants remarked that it was difficult to remember the exact date of last intercourse and the number of times, as very few kept records of such activity. These participants suggested that if the time intervals were too long for convenient memory that it would make sense to skip certain questions when not relevant.

Ethics

The study was approved by the Danish Data Protection Agency (number 20/44103) and was conducted in accordance with the ethics of the Helsinki Declaration. We documented the oral informed consent in the patient file.

Data analysis

We used NVivo software to manage the qualitative interview data. In the early stages of the analysis, a word-frequency query was performed to help identify possible additional themes. Interviews were analyzed using thematic analysis, mainly adopting an inductive approach⁸ where the first step was obtaining an overview of all the interviews focusing on patient perspectives, experiences, and thoughts. Then, more structured and analytically meaningful themes and patterns were identified, defined, and named. In the final phase, the

themes were interpreted and discussed with regard to other research and theories in the explored field. To analyze the additional results from the PDQ, we used descriptive statistics (Table 1).

Interviewees

A total of 41 men with PD received the Danish PDQ, and 34 (83%) answered the questionnaire; their mean age was 59.5 (8) years. The average bending of the penis was 54° (range 0°–85°); the participants had had the condition for an average of 3.3 years (range 1 month–30 years). Thirty-seven participants (90%) were in the chronic phase and 4 (10%) in the acute phase. Two men (5%) answered the questionnaire but did not want to participate in the interviews. One of these men stated that he had no time, and the other said he saw no point in it anyway. Among the nonresponders, one forgot to fill out the questionnaire and did not respond until after the study had finished. It is unknown why the remaining 6 men did not wish to participate.

Among the 32 participants who were interviewed, 22 (69%) were in a relationship, 6 (19%) were single, and 4 (12%) did not answer. The interviewees were distributed in the same way in relation to the chronic and acute phases as the overall group.

Results

A total of 23 (67%) participants answered that they had intercourse within the past 3 months, and the mean number of intercourses occurring during the 3 months was 10 times. Whereas 24 men (71%) had no or little concern about damaging their penis during intercourse, 23 (68%) had moderate, severe, or very severe concern about losing the erection during intercourse, 30 (88%) had difficulties in some sexual positions that they used to enjoy, and 31 (91%) had problems penetrating their partners.

A few participants reported pain, with an average score of only 2 on the visual analogue scale (VAS) in the 3 pain questions.

In the last subdomain of the questionnaire, concerning bother, 23 (68%) participants found it difficult or impossible to have intercourse and 30 (88%) had intercourse less often than they used to have due to PD. Of the participating men, 25 (75%) were moderately, very, or extremely bothered when they looked at themselves. PD bothered 22 (87%) from the last time they had sexual intercourse and 30 (93%) of the men experienced bother by having intercourse less often than they used to have.

See Tables 2 and 3 for details on scores in the questions and 3 subdomains.

Discussion

In this article we describe the process of translating and adapting the previously developed and validated PDQ into Danish (Supplementary material). In this process, we affirmed that bother from PD and its negative impact on patient quality of life were outspokenly confirmed among the interviewed Danish patients with PD. General baseline demographic data concerning age, bother, and the frequency of intercourse within

Table 1. Part of evaluating the PROM PDQ using COSMIN box 2.^{a,9,10,11}

	Very good	Adequate
2a Asking about relevance design requirements (of 7 questions)	6	1
2b Asking about comprehensiveness (of 7 questions)	6	1
2c Asking about comprehensibility (of 7 questions)	5	2

PDQ, Peyronie's Disease Questionnaire; PROM, patient-reported outcome measure. COSMIN, COnsensus-based Standards for the selection of health Measurement INstruments. ^a2d and 2e cannot be answered, as professionals have not been asked about the Danish PDQ.

Table 2. Danish PDQ results compared to IMPRESS 1 and 2 results.

	Results, mean (SD)		
	Danish PDQ	IMPRESS 1	IMPRESS 2
Mean patient age, years	59.5 (8)	57.3 (8.6)	57 (8.6)
Mean curvature	54 (19.3)	41.9 (14.0)	50.5 (14.5)
Mean PDQ symptoms			
Physical and psychological	9.7 (4.5)	10.6 (5.1)	10.8 (4.9)
Pain	5.3 (5.9)	4.0 (5.0)	4.5 (5.2)
Bother	7.7 (3.4)	7.6 (3.6)	7.6 (3.6)
Duration of PD history, years	3.3 (6.1)	4.2 (4.9)	3.9 (3.7)
Mean intercourse frequency within previous 3 months	10	10.4	10.4

PD, Peyronie's Disease; PDQ, Peyronie's Disease Questionnaire.

Table 3. Distribution of answers to the Danish Peyronie's Disease Questionnaire.

Question no.	Answer distribution					Total
	None	Mild	Moderate	Severe	Very severe	
Q1	19	5	7	1	2	34
Q2	5	6	12	5	6	34
Q3	3	6	13	7	5	34
Q4	4	6	8	10	6	34
Q5	14	5	8	3	4	34
Q6	13	5	6	7	3	34
VAS pain score	0	1-5	>5			
Q7	26	6	2			34
Q8	17	12	5			34
Q9	17	10	7			34
Q10a	No pain 20	Pain: go to Q10b 14				34
Q10b	Not at all bothered 3	A little bit bothered 2	Moderately bothered 7	Very bothered 2	Extremely bothered 3	14
Q11	64	4	8	13		34
Q12	No: go to Q14 11	Yes: go to Q13 23				34
Q13	Not at all bothered 1	A little bit bothered 2	Moderately bothered 7	Very bothered 6	Extremely bothered 7	23
Q14	No: finish 4	Yes: go to Q15 30				34
Q15	Not at all bothered 0	A little bit bothered 2	Moderately bothered 10	Very bothered 9	Extremely bothered 9	30

Q, question.

the past 3 months are similar to those obtained in the Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies 1 and 2 (IMPRESS 1 and 2).² The duration of PD history was shorter in our small cohort. This may be because some men participating in our study could also have acute PD, whereas only men who had PD for more than 1 year (i.e. patients with chronic PD) took part in the IMPRESS 1 and 2 studies. This difference may not be clinically significant as, in 2008, Nelson et al.¹² showed that, for instance, depression scores did not significantly differ across time since diagnosis of PD. Hence, the questionnaire should be useful for men

in both the acute and stable phases of PD. We found the mean scores in the PDQ domain of physical and psychological symptoms of PD were lower than those in the IMPRESS 1 and 2 studies, even though we see men with greater curvature. These findings do not correlate with the findings of Gelbard et al.,¹³ who found that psychological symptoms were weakly correlated with greater penile curvature.

In the original PDQ, only men who had vaginal intercourse were included. During our cross-cultural adaptation process, the expert committee agreed that such a limitation was not in accordance with Danish values; whether you are heterosexual,

homosexual, or something other should not be a limitation to answer a questionnaire about PD symptoms that can affect all men.

The developers of the original PDQ thought that setting a limitation for the last intercourse at 3 months was to aid recall and data reliability.⁴ This seems wise; however, in this way, a large group of men, possibly those with the most bother, could be excluded. In our study, accepting this limit, we would have missed one-third of the men with PD, who all experienced bothering symptoms. We experienced, though, that those men who had not been sexually active within the past 3 months, or even within the past couple of years, *did* have problems answering questions 1 to 6 but still felt that the remainder of the PDQ was a good starting point in a conversation with the physician. The questionnaire, therefore, also made sense to them. We acknowledge that when the latest intercourse took place long before answering the questionnaire, a substantial risk of recall bias exists. On the other hand, men who have not been able to be sexually active for one or the other reason can still have pain or great bother, reflecting the negative impact PD has on their quality of life. A solution could be to differentiate the questionnaire so that non-sexually active men have the option to skip questions 1 to 6.

We believe the primary goal of this questionnaire is to ask questions that reflect the problems of PD, and response categories should capture real-life experiences and leave little room for guesswork. With the majority of men having sexual intercourse less often and being bothered from the last time they interacted, it is clear that PD does generate great bother and profoundly affects the quality of life of Danish men with PD.

In our results on psychological and physical symptoms, the respondents scored slightly lower than those in Hellstrom et al.²; yet, bother scores were similar in the 2 studies. The Danish men appear to have had higher scores in pain, probably due to the slightly higher rate of men in the acute phase in this study.

Several men in our study stated that their partners' involvement was missed in the questionnaire. To examine how partners of men with PD are affected, Farrell et al.¹⁴ compared male and female experiences of the disease. They used the nonvalidated Female Sexual Function Index (FSFI), a 12-item questionnaire adapted from the male PDQ. We have chosen to add some blank lines in the male PDQ for possible remarks about, for instance, partner influence. However, a partner PDQ would be a good adjunct to the male PDQ and relevant to translate for the Danish partners of PD patients as well.

Notably, the questionnaire does not discriminate men in terms of whether they have had intercourse recently or not or vaginal intercourse or not. That the questionnaire has value in everyday life is more important than that all questions have to be answered. Therefore, we have changed the text in the introduction of the questionnaire. If men have been sexually active within the past 3 months, they may write the number of times, but a date is not compulsory. If the man has not been sexually active within the past 3 months, he may skip questions 1 to 6 if they make no sense to him. In this way, all men with PD could fill in the relevant parts of the questionnaire without having to guess or estimate.

We found that some men were challenged in answering some of the questions because our respondents included men who had not been sexually active within the past 3 months. In the interview, they expressed that they missed additional blank lines to elaborate on their situation.

To comply with their wishes to improve the dissemination of information about PD and the potential problems PD creates, which may include problems with masturbation, mental health issues, partner influence, or if their withdrawal from sexual activity is for another reason than PD, we chose to add blank lines at the end of the questionnaire. For research purposes, this can be problematic, as elaboration on own experiences cannot be readily standardized; but then again, we find it important that the questionnaire captures relevant daily issues and makes sense to the users. Frustrations or feelings of not being heard are not beneficial to the communication and cooperation need for future treatment.

The present study is to our knowledge the first to translate and cross-culturally adapt the original PDQ into Danish. Previously, approaches to Danish patients with PD have differed between treatment centers. International studies have shown that PD has a significant negative psychological impact on the patient quality of life, with low self-esteem, depression, and relationship problems.^{12,15} Patients need to be treated with a thorough holistic approach, and we award these mental issues the same importance as the physical symptoms.

Limitations

It was not possible to calculate Cronbach's alpha because of the small sample size. To complete the adaptation of a questionnaire, it should be validated and evaluated with an appraisal of its test retest reliability and responsiveness. The original PDQ has been thoroughly tested, and because our small group of patients with PD lie within the same range for most subdomains, age and degrees of curvature, as the results from the original PDQ published by Hellstrom et al.,² we believe that the Danish PDQ is sufficiently tested for clinical use.

The interviewer's modest experience in conducting interviews is believed to have been duly compensated for by continuous and accumulating learning-while-doing as the same interviewer conducted all the interviews and did so consecutively. Some recall bias may have existed since the men answered the questionnaire at a mean delay of 6.6 days before participating in the video interview. We used purposive sampling, which implies a vulnerability to the error of judgment on the part of the researcher and a risk of personal bias. The investigator did not recruit the majority of men, hopefully limiting selection bias. Furthermore, it is not possible to generalize the research findings, as there may be a low level of reliability and high levels of bias.

On the contrary, there were potentially fewer biases and mistakes when using an electronic questionnaire. Hohwü et al.¹⁶ showed that using an electronic questionnaire instead of a paper-based version reduced bias and mistakes, and sending the PDQ to a secure online mailbox lowers missing values and is more cost-effective.

Conclusions

Cross-culturally adapting a questionnaire was cumbersome, but the process is well described in the guidelines of Beaton et al.⁷ The advantage of using a validated questionnaire is that it shortens the process and aids in taking advantage of the tremendous work of others. On the down side, this method also limits one's own possibility to make major changes and contribute with one's own preferences.

The majority of the interviewees felt the questionnaire was easy to understand, had an adequate length, and was a helpful tool that could be a good starting point when talking to the physician about PD. Some participants stated that it was a shortcoming that the partner point of view was not part of the questionnaire as their opinion highly affected whether men with PD experienced their situation as problematic.

The Danish men in this study were bothered mainly by the extent to which PD disturbs their ability to be sexually active to the extent they wish. They found it especially bothersome to be sexually active, resulting in a lower frequency of sex. The Danish-translated and cross-culturally adapted PDQ should be piloted in a future study.

Supplementary material

Supplementary material is available at *The Journal of Sexual Medicine* online.

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Author contributions

Conceptualization, M.H.W, B.S.L, and E.B.K; Methodology, M.H.W and B.S.L; Formal Analysis: R.K., E.B.K, B.S.L, L.L and M.H.W Investigation, M.H.W, B.S.L, E.B.K, and L.L Writing – Original Draft, M.H.W, B.S.L., RK; Writing –Review & Editing, M.H.W, B.S.L, E.B.K, R.K and L.L; Visualization: M.H.W; Supervision, E.B.K, B.S.L, R.K. and L.L; Funding Acquisition, M.H.W.

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