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Unsuccessful linguistic validation of the Symptom Questionnaire for assessing quality of life in Polish patients with pelvic vein disorders

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Abstract: Pelvic venous disorder (PeVD) is a prevalent chronic condition characterized by the presence of varicose veins in the pelvis, leading to the development of chronic pelvic pain. Despite the growing interest in assessing quality of life in PeVD, well-designed and validated disease-specific questionnaires are missing. The objective of this study was a linguistic and clinical validation of the Symptom Questionnaire (SQ) in a cohort of Polish females with pelvic vein incompetence.

The Polish version of SQ was developed using a standardized validation process that involved a back-and-forth translation protocol.

A total of 58 female patients diagnosed with pelvic varicose veins, representing diverse educational backgrounds, participated in the study. Multiple issues were observed during linguistic validation, primarily originating from disparities between the Polish and British healthcare systems, as well as differing levels of sexual health education of those two populations. Cronbach α was calculated separately for each part of the questionnaire with results exceeded 0.6 for each section. Test-retest analysis indicated most Pearson correlation coefficients surpassing 0.70. The absolute agreement consistency between pretest and post-test measures, evaluated using the Intra Class Correlation (ICC), exceeded 0.8 in three sections and 0.7 in the remaining three sections.

However, the clinical validation failed due to the lack of standardized score calculation proposed by the authors of the questionnaire and inaccurately assigned values in the answer key for five questions.

Consequently, the practical utility of SQ in daily clinical settings remains uncertain, highlighting the urgent need for the development of a new, user-friendly questionnaire specifically tailored to assess the quality of life in individuals with PeVD.



Keywords: pelvic venous disorder, pelvic varicose veins, chronic pelvic pain, validation of quality of life.

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Introduction

Chronic pelvic pain (CPP) is a widely spread symptom with prevalence ranging from 6.4% up to 25.4% of adult women [1]. CPP was defined by The Royal College of Obstetricians and Gynecologists as intermittent or constant pain in the lower abdomen or pelvis, persisting at least six months, but not occurring exclusively with menstruation or sexual, also is not associated with pregnancy [2]. While CPP is associated with interstitial cystitis, endometriosis and irritable bowel syndrome, its leading cause is pelvic venous disorder (PeVD), including pelvic vein incompetence [3]. Although PeVD, historically named as “pelvic congestion syndrome”, was first described as long ago as in the 19th century, the link between this underlying condition and pelvic pain was described in 1949 by Taylor *et al.* [4]. It is a chronic medical condition characterized by chronic pelvic pain and discomfort, dyspareunia, and other associated symptoms caused by the presence of dilated and tortuous veins in the pelvis [5]. It is an illness complex in its nature, with an unconventional diagnostic path. Identifying the condition is carried out through a combination of several methods: pelvic and transvaginal ultrasound (TVUS) [6], pelvic venography with intravascular ultrasound (IVUS) [7], magnetic resonance imaging (MRI) or computed tomography angiography of the veins (CT venography) [8]. Reflux pelvic venography and coil embolization combined with foam sclerotherapy delivered simultaneously is commonly considered the gold standard and preferred diagnosis and treatment method [9].

Estimations of PeVD prevalence vary considerably across different studies. Some studies suggest that PeVD affects approximately 10–15% of women of reproductive age, while others propose a more comprehensive prevalence range from 6% to 27% worldwide [10].

However, it is worth noting that the exact prevalence of pelvic congestion syndrome remains uncertain due to several factors, including the absence of standardized diagnostic criteria and potential underdiagnosis, as its primary symptom, chronic pelvic pain (CPP), can be associated with other conditions, such as endometriosis and irritable bowel syndrome. Additionally, some women with pelvic congestion syndrome may not seek medical attention or may be misdiagnosed, leading to under-reporting.

Symptoms-Varices-Pathophysiology classification by the American Vein & Lymphatic Society International Working Group on Pelvic Venous Disorders provided physicians with a well-designed classification system for venous disorders of the pelvis but is still not commonly used [11].

Assessing quality of life is crucial in managing PeVD, considering its multidimensional nature encompassing physical, psychological, and social well-being. By understanding the impact of PeVD on overall health and well-being, quality of life assessments inform the development of effective treatment strategies to enhance physical and emotional health.

Despite the increasing interest in quality of life in PeVD, limited research has focused on this aspect. Only a handful of studies have examined the influence of PeVD on quality of life, revealing significant impairment in affected individuals' overall well-being [12, 13].

Assessing the quality of life (QoL) in PeVD is complex, and requires the use of standardized dedicated tools that measure the impact of this condition on physical, psychological, and social domains. Currently, there is limited availability of dedicated tools for assessing QoL in PeVD. Studies primarily rely on generic questionnaires like SF-36. However, disease-specific instruments are more appropriate for in-depth analysis of QoL changes. Unfortunately, there is a notable absence of well-designed and validated QoL questionnaires specifically developed for PeVD. The Symptom Questionnaire, created at the University of Manchester, has not yet undergone validation or gained widespread recognition [14].

This study aimed to perform linguistic and clinical validation of The Symptom Questionnaire in Polish females undergoing endovascular treatment or IVUS diagnostics due to pelvic vein incompetence.

Material and Methods

Study design

This prospective observational study was conducted in the vascular medicine department. Female adult patients diagnosed previously with PeVD based on trans-vaginal ultrasound Doppler examination, admitted for IVUS combined with phlebography or embolization of pelvic varicose veins were enrolled. The exclusion criteria encompassed individuals who were pregnant or had given birth within the past 12 months, those with medical conditions that contraindicate endovascular treatment (such as severe heart or kidney failure or a strong allergic reaction to contrast agents), and individuals who declined participation in the study.

The Symptom Questionnaire (SQ)

SQ was acquired through mutual agreement with the University of Manchester. It was created selecting questions from the following validated scores: the International Pelvic Pain Society assessment form, the Endometriosis Health Profile (EHP-30),

the British Society of Gynaecological Endoscopy (BSGE) pelvic pain questionnaire, the heavy menstrual bleeding national audit questionnaire, and the VEINES symptom questionnaire. It also included questions from EQ-5D-3L and visual analog scores (VAS) for general health assessment [14].

Translation process

The Polish version of The Symptoms Questionnaire was created using a standardized linguistic validation process developed by Mapi Institute [15]. The translated Polish version was obtained in the process starting with forward translation, involving a minimum of two translators translating the material into Polish. Both translated versions were reconciled to generate accurate output. Subsequently, back translation was conducted by a separate group of translators (native English speakers not aware of the original questionnaire content, to ensure clarity and accuracy). Back translation was aligned with the original text, and the final draft underwent a review by the process coordinator before proceeding to the finalization stage. To assess the understanding of the translated questionnaire, face-to-face interviews were conducted with ten patients diagnosed with PeVD who did not participate in the next clinical validation stage. The EQ-5D part of the questionnaire was not translated, but an already-validated translation was used [16]. The sample was monogender due to the examined disorder specifics but included a balanced representation of mixed educational backgrounds. During the interviews, patients were asked to complete the Polish version of SQ and provide feedback on their understanding of the instructions, items, and response scales. The suggestions were considered and introduced in the final version of the translated questionnaire.

Ethical Aspects

All of the participants have given written informed consent to participate in this study. All participants were treated according to the standard of care dedicated to patients with PeVD in the study centre. Local Jagiellonian University Medical College Bioethics Committee approval was obtained before the study began. The whole study followed The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans.

Statistical analysis

Descriptive statistics was used. The χ^2 test was used for statistical significance assessment, while the Mann–Whitney test was used for numerical data. For The Symptoms Questionnaire internal reliability assessment, Cronbach α coefficients were calculated

for each of the parts, but the total score was not calculated. Intraclass correlations (ICC) were calculated for the test–retest analysis. To interpret effect size, the Cohen criteria were employed, with a small effect size defined as ≥ 0.2 and < 0.5 , a moderate effect size as ≥ 0.5 and < 0.8 , and a large effect size as ≥ 0.8 [17]. Statistical analysis was performed using IBM SPSS Statistics 29 [18].

Results

Population

The study involved 58 consecutive female patients, administered to the Angiology Department for IVUS and phlebography diagnostics ($n = 15$) or endovascular embolization of pelvic varicose veins ($n = 43$). The participants’ characteristics is presented in detail in Table 1.

Table 1. Demography and characteristics of patients.

	Number of participants ($n = 58$)
Mean age (range, SD)	44.17 (27–62 \pm 9.13)
Mean BMI (range, SD)	24 (18–36 \pm 3.88)
Smoking history, number (percentage)	former smokers, $n = 14$ (24%) current smokers, $n = 4$ (5%) never smoker, $n = 40$ (48%)
Median gravidity	2.76
Median parity	2.53
History of Deep Venous Trombosis (DVT), number (percentage)	3 (5.2%)

Overall, pelvic vein reflux was diagnosed in pelvic venography in 55 patients (94.8%). In 8 women, it coexisted with significant functional pelvic vein obstruction, and 3 patients were diagnosed with both pelvic vein reflux and chronic pelvic vein obstruction.

Linguistic validation issues

During linguistic validation, we faced multiple major and minor issues. Firstly, 80% of the participants who tested the translated questionnaire (8 out of 10 patients) expressed that the questionnaire was excessively lengthy, leading to a sense of overwhelm due to the high number of questions. Additionally, the accurate translation of

the “Use of Healthcare Resources” section raised issues due to notable differences between the British and Polish healthcare systems.

Specifically, we encountered difficulties with Question 42, which inquired about the healthcare professionals consulted in the past year (“Over the last year, who have you seen regarding your health?”). The provided answer options included: GP, Specialist Nurse, Practice (GP) Nurse, Pharmacist/Chemist, Consultant/Hospital Doctor, Other. While the range of competencies of a GP Nurse is different, the Specialist Nurse does not function as an independent healthcare practitioner and does not consult patients. It was translated into “Hospital Nurse” (Pol. “Pielęgniarka Szpitalna”), as the nurse specialization itself does not give additional permissions regarding consultations. The institution of “Consultant” is also not present in the Polish healthcare system, it is rather “Specialist Physician” (Pol. “Lekarz specjalista”) and it has been translated this way. Most of the patients needing specialist consultation or medical care are referred to specialist outpatient, not hospital, which is why “Hospital Doctor” was also changed into “Specialist Physician” in translation.

Moreover, patients did not understand question 46 (“Over the last year, how many times have you been to see a hospital doctor?”): it was unclear if their answers should regard all specialists or only the doctors who treat vein conditions.

In question 35, it was reported by patients that they are unfamiliar with the term “restless leg syndrome” and needed additional explanation of the issue.

What was unexpected, multiple patients mistook the menstrual cycle for menstruation itself (i.e. Question 16) and initially reported the length of menstruation as 28 days, which turned out to be the length of a cycle when discussed. Another misunderstood issue was the question about the menstrual cycle in the cases of the patients after menopause — they did not know if it concerned the last cycle, the average from previous cycles or if they should skip it as it is not related to them, as there is no option “Not applicable”.

Questionnaire reliability

As The Symptoms Questionnaire does not have a summary score, the calculation of Cronbach α for the entire questionnaire was impossible. It was calculated separately for every part of the questionnaire and results exceeded 0.6 in every case (Table 2).

Test-retest reliability

All of the Pearson correlation coefficients obtained from the test-retest analysis of The Symptoms Questionnaire (except Use of Healthcare Resources) exceeded 0.70, as indicated in Table 3.

Table 2. The values of Cronbach α for the parts of The Symptoms Questionnaire.

Part	Pre-test (n = 58)	Post-test (n = 58)
About You	0.91	0.95
Your Health Today	0.83	0.88
VAS	0.72	0.79
The Menstrual Cycle	0.66	0.77
Pain Symptoms	0.82	0.91
Varicose Veins	0.76	0.85
Use of Healthcare Resources	0.72	0.75

Table 3. Test-retest reliability (Pearson R correlations between The Symptom Questionnaire pretest and post-test).

Part	Pearson r correlations
About You	0.99*
Your Health Today	0.85*
VAS	0.71*
The Menstrual Cycle	0.70*
Pain Symptoms	0.78*
Varicose Veins	0.82*
Use of Healthcare Resources	0.68**

*p < 0.01, **p = 0.02

The intraclass correlation coefficient (ICC) assessing the absolute agreement consistency between the pretest and post-test measures, utilizing a 2-way mixed model, surpassed 0.8 in 3 parts (“About You”, “Your Health Today” and “Varicose Veins”) and 0.7 in 3 parts (“VAS”, “The Menstrual Cycle” and “Pain Symptoms”). “Use of Healthcare Resources” result was 0.69 (Table 4).

An attempt at clinical validation

The clinical validation of The Symptom Questionnaire failed. The first obstacle to performing such an analysis was the lack of any standardized score calculation proposed by the authors of the questionnaire. There is only scoring for every question. What is more, the values assigned to the answers were incorrect, especially in questions 38, 39, 40, 45 and 46, where the answers are arranged in ascending order, but the numbers dedicated to them are not.

Table 4. Intraclass correlation of The Symptoms Questionnaire.

Part	Intraclass correlations coefficient	95% CI		P-value
About You	0.96	0.94	0.99	<0.001
Your Health Today	0.87	0.83	0.91	<0.001
VAS	0.72	0.66	0.78	<0.01
The Menstrual Cycle	0.76	0.7	0.82	<0.001
Pain Symptoms	0.86	0.83	0.9	<0.001
Varicose Veins	0.88	0.86	0.92	<0.001
Use of Healthcare Resources	0.69	0.61	0.78	0.02

As the “Your health today” section was directly implemented from the EQ-5D questionnaire, we were able to analyze the results using the original questionnaire guidelines (Table 5). We did not repeat such analysis as the EQ-5D questionnaire was previously clinically validated.

Table 5. The results of the “Your Health Today” section of The Symptoms Questionnaire.

MOBILITY			
	Cases (n)	Percentage (%)	Mean score
I have no problems in walking about	50	86.2	1.14
I have some problems in walking about	8	13.8	
I am confined to bed	0	0	
SELF-CARE			
	Cases (n)	Percentage (%)	Mean score
I have no problems with self-care	58	100.0	1.00
I have some problems washing or dressing myself	0	0	
I am unable to wash or dress myself	0	0	
USUAL ACTIVITIES			
	Cases (n)	Percentage (%)	Mean score
I have no problems with performing my usual activities	45	77.6	1.22
I have some problems with performing my usual activities	13	22.4	
I am unable to perform my usual activities	0	0	

Table 5. cont.

PAIN / DISCOMFORT			
	Cases (n)	Percentage (%)	Mean score
I have no pain or discomfort	11	19.0	1.84
I have moderate pain or discomfort	45	77.6	
I have extreme pain or discomfort	2	3.4	
ANXIETY / DEPRESSION			
	Cases (n)	Percentage (%)	Mean score
I am not anxious or depressed	30	51.7	1.48
I am moderately anxious or depressed	28	48.3	
I am extremely anxious or depressed	0	0	

Discussion

The Symptom Questionnaire was designed by a working group in the University of Manchester to assess the quality of life in women experiencing PeVD [14]. It was the first attempt to construct a PeVD disease-specific questionnaire. The translation and its validation revealed some major and minor concerns, but it was conducted successfully. The most important conclusion is that some questions require more details or footnotes. Although Poland is the country with one of the poorest sexual health education in the European Union, which could be the reason for the issues with answering menstruation-related questions [19], they need to be clear for the responders regardless of age or education level.

The overall assessment of The Symptoms Questionnaire suggests that it has been assembled from various existing questionnaires without a comprehensive methodological design. It appears that the authors attempted to encompass a wide range of complex symptoms by including numerous questions, resulting in an overwhelming length of the questionnaire. Finding the appropriate balance in the number of questions is crucial, as it should be detailed enough to elicit precise responses while remaining concise to maintain respondent focus [20, 21].

One of the most significant issues is the lack of any summarizing score and its interpretation. The results are uninterpretable and cannot be introduced into the diagnostic process. The proposed scoring system is inconsistent. Moreover, in five questions, it is simply incorrect.

However, it features many questions about various areas of this illness, its specificity may leave room for improvement.

A large part of this questionnaire was dedicated to leg varicosis. While pelvic vein incompetence and lower limb varicoses might coexist in patients, this coexistence is

not obligatory, and they should be considered as comorbid but not mutually exclusive conditions [22]. Moreover, the importance of pelvic origin lower extremity varicose veins arising from the pelvic area through the leak points and potentially extending into the femoral region should be emphasized.

Finally, some PeVD symptoms are not included in the SQ, such as haematuria or pain after sexual intercourse (which is more specific for pelvic vein incompetence rather than typical dyspareunia) [8].

Considering all of the abovementioned issues, a study involving the creation of a new and improved pelvic vein incompetence questionnaire with its validation is needed.

Conclusions

The linguistic validation of The Symptoms Questionnaire in the Polish language was partially successful. The differences in the organization of healthcare systems between Poland and the United Kingdom were significant and caused some difficulties. Due to the lack of standardized score formulas and answer-key errors, clinical validation was impossible. Even though The Symptom Questionnaire was a promising tool, its daily clinical use is questionable. There is still an urgent need to develop a new, easy-to-use and validated questionnaire that could reliably assess the changes in life quality of patients suffering from Pelvic Venous Disorders.

Disclosures

Authors' contribution: conceptualization, M.M., Ł.P., P.M.; methodology, Ł.P.; software, P.K, W.M., validation, Ł.P., P.M.; formal analysis, J.K., M.M.; investigation, P.K., M.M., E.G., G.T., K.K.; data curation, M.M., J.K.; writing — original draft preparation, P.K., M.M., J.K.; writing — review and editing, Ł.P., P.M.; supervision, P.M.; project administration, M.M.

Conflict of interest — none declared.

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