

Validation of the Polish version of P-QoL questionnaire

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ABSTRACT

Objective: Pelvic organ prolapse (POP) is a common morbidity that affects many women and significantly decreases quality of life. The severity and the impact of the prolapse on the quality of life are important parameters in the management and follow-up of affected patients. The aim of this validation study was to validate the Polish version of the Prolapse Quality of Life questionnaire (P-QoL).

Material and methods: The P-QOL questionnaire was translated into Polish and administered to women recruited from two gynecological outpatient clinics (n = 231). Both symptomatic and asymptomatic women were included in the study and examined in supine position using the Pelvic Organ Prolapse Quantification System (POP-Q). The validity was assessed by comparing symptom scores and quality-of-life scores between symptomatic and asymptomatic women.

Results: A total number of 154 symptomatic and 77 asymptomatic women were included. There was a strong correlation between severity of the disease based on physical findings (POP-Q scale) and the P-QoL scores in main prolapse quality-of-life domains. The overall scores for each life domain were significantly different between symptomatic and asymptomatic women (p < 0.001). All the questions regarding symptoms showed significant differences (p < 0.001) between both groups.

Conclusions: The Polish version of P-QoL is a valid, reliable, and easily comprehensible instrument to assess quality of life and symptoms in Polish-speaking women suffering from urogenital prolapse.

Key words: pelvic organ prolapse, quality of life, P-QoL, prolapse symptoms, validation study

Ginekologia Polska 2016; 87, 7: 477–483

INTRODUCTION

Pelvic organ prolapse (POP) is a common female disorder. The number of the affected women is expected to increase by 45% in the next 30 years as a result of a steadily growing longevity among women aged 50 years and more [1]. POP carries very little morbidity but has a great influence on patient quality of life. Thus, evaluation of the impact of the occurrence and severity of the condition is best-done using disease-specific quality of life tools. The Prolapse Quality of Life questionnaire (P-QoL) is a disease-specific quality of life questionnaire that proved to be a valid and reliable instrument of assessing symptom severity, quality of life, and treatment outcomes in women with POP [2].

In terms of worldwide implementation, the crucial aspect of questionnaires assessing life quality is their applicability in many different settings and countries. This requires their translation into several languages and validation. To date, the P-QoL questionnaire has been validated for Italian-speaking patients and published by Digesu et al., in 2003. Then, it was translated into several languages including English, German, Dutch, Slovakian, Persian, Portuguese, Thai, Japanese, and Turkish [2–9].

OBJECTIVES

The aim of our study was to translate and validate the P-QoL questionnaire into the Polish language.

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MATERIAL AND METHODS

The P-QoL questionnaire was translated and validated in several languages [2–9]. The steps of translation and validation were similar in each language. Therefore, we decided to perform the Polish translation and validation in the same manner.

Local Ethics Committee approved of the study. Two independent English-Polish translators, unfamiliar with P-QoL, created the Polish version of the questionnaire. All linguistic and merit-related controversies were resolved with physicians fluent in English (J.R. and K.Z.) and the final version of the Polish questionnaire was accepted. The questionnaire was then back translated into English to prevent any misunderstandings in the Polish version. Both, the original English questionnaire and its Polish equivalent consisted of 38 questions, with 20 questions representing nine quality of life domains (general health perception, prolapse impact, role and physical limitations, social limitations, personal relationships, emotional problems, sleep/energy disturbances and symptoms severity) and 18 questions about prolapse symptoms. The responses ranged from „none/not at all” through „slightly/a little” and „moderately” to „a lot”. A four-point scoring system for each item was used for severity measurement of urogenital prolapse symptoms. The questionnaire does not form the combined score. If a woman has only one domain affected and another woman has all domains affected, both will be considered symptomatic but in different aspects of life quality.

The questionnaire was printed in a large font (16 point) and in a horizontal format in order to improve readability, especially for elderly women.

Study design

Respondents were recruited among consecutive women referred to the urogynecological outpatient clinic at the University Teaching Hospital in Warsaw. An informed consent was obtained from each subject.

The P-QoL questionnaire was distributed among women who agreed to participate in the study. The responses were reviewed and any unanswered questions were completed. Subsequently, all the women were examined in the supine position using the Pelvic Organ Prolapse Quantification System (POP-Q) [10]. Baseline demographic and clinical data were collected.

Statistical analysis

Mann-Whitney U test was used to compare scores between symptomatic and asymptomatic women. Spearman's correlation was used to evaluate the relationship between P-QoL domain scores and vaginal examination findings in the symptomatic group. Internal consistency was tested using Cronbach's alpha coefficient. Alpha values of > 0.8 were considered as excellent [11]. All tests were 2-tailed and type-1 error was set at $\alpha < 0.05$. Sample size was calculated for power of 90% and 2:1 allocation of patients.

RESULTS

A total of 260 consecutive women were asked to participate in the study. Fifteen women declined, and 14 women (aged 24–30) with asymptomatic prolapse were rejected due to inability to match the groups for age. Thus, a total of 231 women were enrolled. One hundred and fifty-four women (66.7%) presented with complaints of pelvic organ prolapse and 61 (33.6%) had other GYN complaints and were considered asymptomatic for pelvic organ prolapse at the initial work-up. Basic demographics and the grade of uterovaginal prolapse are shown in Table 1. Both groups (symptomatic and asymptomatic) were matched for age. Mean age was 65.6 years (range 33–91) for symptomatic and 64.9 years (range 30–85) for asymptomatic women ($p = 0.8$). There were no differences in the weight between the two groups, mean weight was 70.57 kg (range 53–115) for symptomatic and 69.86 kg (range 49–97) for asymptomatic women ($p = 0.7$). There was an equal number of

Table 1. Basic characteristic of symptomatic and asymptomatic women with pelvic organ prolapse

	Symptomatic (n = 154)	Asymptomatic (n = 77)	P value
Age (mean, years)	65.6	64.9	0.8
Weight [kg]	70.57	69.86	0.7
Parity (mean)	1.9	2.6	0.6
POP-Q findings			
Grade 0	0 (0%)	43 (55.8%)	< 0.001
Grade 1	33 (21.5%)	27 (35.1%)	0.01
Grade 2	47 (30.5%)	4 (5.2%)	< 0.001
Grade 3	64 (41.5%)	3 (3.9%)	<0.001
Grade 4	10 (6.5%)	0 (0%)	<0.001

Table 2. Comparison of mean quality-of-life domain scores in symptomatic and asymptomatic women (SD values are provided in brackets. U Mann-Whitney test)

Prolapse quality of life domains	Symptomatic	Asymptomatic	P value
General health perception	46.11 (20.33)	19.67 (25.17)	< 0.001
Prolapse impact	74.38 (29.42)	20.55 (32.06)	< 0.001
Role limitations	53.17 (39.04)	9.62 (25.92)	< 0.001
Physical limitations	53.67 (38.92)	10.71 (25.85)	< 0.001
Social limitations	33.92 (34.28)	5.87 (18.41)	< 0.001
Personal relationships	40.69 (46.82)	4.76 (17.06)	< 0.001
Emotions	43.40 (35.01)	6.03 (15.01)	< 0.001
Sleep/Energy	40.12 (31.89)	9.39 (22.84)	< 0.001
Severity measures	41.88 (29.06)	4.88 (10.37)	< 0.001

Table 3. Internal consistency (Cronbach alpha coefficient) for prolapse quality of life domains

Prolapse quality of life domains	Cronbach Alpha
Role limitations	0.949
Physical limitations	0.931
Social limitations	0.930
Personal relationships	0.944
Emotions	0.932
Sleep/Energy	0.933
Severity measures	0.932

Table 4. Correlation between prolapse quality of life domains and vaginal examination findings (POP-Q stage) in symptomatic women

Prolapse quality of life domains	Spearman's rho coefficient	P value
General health perceptions	0.448	< 0.001
Prolapse impact	0.647	< 0.001
Role limitations	0.578	< 0.001
Physical limitations	0.566	< 0.001
Social limitations	0.506	< 0.001
Personal relationships	0.522	< 0.001
Emotions	0.593	< 0.001
Sleep/Energy	0.564	< 0.001
Severity measures	0.694	< 0.001

vaginal deliveries in both, asymptomatic and symptomatic women (2.6 and 1.9, respectively; $p = 0.67$).

There was a strong correlation between severity of the disease based on physical findings (POP-Q scale) and the P-QoL scores in main prolapse quality-of-life domains, as shown in Table 2.

The total scores for each of the P-QoL domains were found to be significantly higher for symptomatic women as compared to asymptomatic women ($p < 0.001$), as shown in Table 2.

Women with POP had significantly higher P-QoL scores indicating poorer QoL than those without prolapse. Significant differences were observed for each QoL domain between symptomatic and asymptomatic women ($p < 0.001$).

The P-QoL questionnaire demonstrated excellent internal consistency with an overall Cronbach alpha of 0.94. In all of the seven quality of life domains the Cronbach alpha values were greater than 0.9, demonstrating excellent internal consistency (Table 3). The internal consistency of the prolapse quality-of-life domains is shown in Table 4.

DISCUSSION

The issue that determination of the degree of prolapse before and after the treatment alone is insufficient for the assessment of the outcome has been raised by many authors [12–14]. Decisions about the management should also be based on the quality of life of the treated women. Since the prolapse may affect different aspects of a woman's life, by limiting psychological, physical, social and sexual domains of her life, the severity of these limitations and their impact on the quality of patient life becomes an important source of information for a surgeon while deciding whether a woman needs to be treated or what kind of therapy would be the most appropriate in her case. As it was shown by Digesu et al. [2], who developed the P-QoL questionnaire, and confirmed by many authors who proved its validity [4–6], the questionnaire is a reliable instrument in a routine clinical practice and treatment follow-up. Regardless of many quality-of-life questionnaires for women suffering from urinary incontinence, there is no validated questionnaire to assess QoL of Polish-speaking women with POP. In our study, we demonstrated that the Polish version of the P-QoL questionnaire is a valid and reliable tool. As in other translations, we achieved excellent data consistency with Cronbach's alpha, greater than 0.9 for each domain. In our opinion, the P-QoL questionnaire currently fills the role of a quality-of-life tool in establishing the degree of severity in subjects with POP. Our results demonstrated that the P-QoL questionnaire is a practical and self-administered instrument to be used in clinical practice and research in order to assess and document the severity and impact of POP in the affected women, thus aiding clinical decisions before treatment commencement.

CONCLUSIONS

Polish version of the P-QoL questionnaire is a validated tool for the assessment of POP in the Polish population. As in the case of the English version, the Polish version of the P-QoL questionnaire has proven to be a useful tool for

assessing symptom severity of urogenital prolapse and its impact on the quality of life among the affected women. It is easy to understand and may be administered and self-completed by the patient. Further multicenter comparison of the usefulness of this instrument would be beneficial for future reference.

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Wypadanie narządu rodneg Jakość życia (P-QoL)

Imię i nazwisko:

Wiek: lat

Data:

Wypadanie narządu rodneg polega na uwypuklaniu się go do pochwy, co często powoduje dyskomfort.

PROSZĘ WYPEŁNIĆ PONIŻSZĄ ANKIETĘ NAWET W PRZYPADKU NIEODCZUWANIA DOLEGLIWOŚCI ZWIĄZANYCH Z WYPADANIEM NARZĄDU RODNEGO!

Jak opisałaby Pani obecny stan swojego zdrowia?

(Proszę zaznaczyć jedną odpowiedź.)

- Bardzo dobry
 Dobry
 Średni
 Zły
 Bardzo zły

W jakim stopniu problem z wypadaniem narządu rodneg ma wpływ na Pani życie?

(Proszę zaznaczyć jedną odpowiedź.)

- Brak wpływu
 W małym stopniu
 W średnim stopniu
 W dużym stopniu

Proszę zaznaczyć, jeżeli występują u Pani podane symptomy oraz podać stopień ich uciążliwości.

	Nie występuje	Nieuciążliwy	Lekko uciążliwy	Umiarkowanie uciążliwy	Bardzo uciążliwy
Częste wizyty w toalecie w celu oddania moczu					
Nagła, bardzo silna potrzeba oddania moczu					
Wyciekanie moczu związane z silną potrzebą oddania moczu					
Wyciekanie moczu związane z kaszlem					
Wyczuwanie wybrzuszenia w pochwie					
Uczucie ciężkości lub ucisku w pochwie lub w dole brzucha pod koniec dnia					
Zgrubienie w pochwie utrudniające wypróżnianie					
Dyskomfort w pochwie, który jest większy podczas stania i zmniejsza się w trakcie leżenia					
Słaby strumień moczu					
Wysięk przy próbie opróżnienia pęcherza					
Kapanie moczu po opróżnieniu pęcherza					

Proszę zaznaczyć, jeżeli występują u Pani podane symptomy oraz podać stopień ich uciążliwości.

	Nie występuje	Nieuciążliwy	Lekko uciążliwy	Umiarkowanie uciążliwy	Bardzo uciążliwy
Uczucie nie w pełni opróżnionych jelit po wypróżnieniu					
Zaparcia, trudności w wypróżnieniu					
Wysięk towarzyszący wypróżnieniu					
Wybrzuszenie w pochwie przeszkadzające we współżyciu					
Ból pleców występujący razem z dyskomfortem w pochwie					
Pomoc palcami przy wypróżnianiu					

	Więcej niż raz dziennie	Raz dziennie	Raz na dwa dni	Raz na trzy dni	Raz na tydzień lub rzadziej
Jak często ma Pani wypróżnienie?					

Poniżej znajduje się opis codziennych czynności, które mogą być zakłócone dolegliwościami związanymi z wypadaniem narządu rodnego.

W jakim stopniu owe dolegliwości wpływają na codzienne czynności u Pani?

Proszę odpowiedzieć na wszystkie pytania.

Proszę zaznaczyć odpowiednią odpowiedź.

OGRANICZENIA W CODZIENNEJ AKTYWNOŚCI

	Wcale	Rzadko	Czasem	Bardzo
W jakim stopniu wypadanie narządu rodnego ogranicza Pani zajęcia domowe (sprząatanie, zakupy)				
Czy wypadanie narządu rodnego wpływa na Pani pracę lub normalne zajęcia poza domem w ciągu dnia?				

OGRANICZENIA FIZYCZNE/SPOŁECZNE

	Wcale	Rzadko	Czasem	Bardzo
Czy wypadanie narządu rodnego ma wpływ na Pani czynności fizyczne (spacer, bieganie, sport, gimnastyka, itp.)				
Czy wypadanie narządu rodnego ma wpływ na Pani zdolność podróżowania?				
Czy wypadanie narządu rodnego ogranicza Pani życie towarzyskie?				
Czy wypadanie narządu rodnego ogranicza Pani możliwości odwiedzania znajomych?				

RELACJE OSOBISTE

	Wcale	Rzadko	Czasem	Bardzo
Czy wypadanie narządu rodnoego ma wpływ na Pani relacje z partnerem?				
Czy wypadanie narządu rodnoego ma wpływ na Pani życie seksualne?				
Czy wypadanie narządu rodnoego ma wpływ na Pani życie rodzinne?				

EMOCJE

	Wcale	Rzadko	Czasem	Bardzo
Czy wypadanie narządu rodnoego wywołuje u Pani przygnębienie?				
Czy wypadanie narządu rodnoego powoduje, że czuje się Pani nerwowa i zaniepokojona?				
Czy wypadanie narządu rodnoego powoduje, że czuje się Pani niepełnowartościową kobietą?				

SEN/ENERGIA

	Wcale	Rzadko	Czasem	Bardzo
Czy wypadanie narządu rodnoego ma wpływ na Pani sen?				
Czy czuje się Pani zmęczona/wykończona?				

Czy wykonuje Pani którąś z niżej opisanych czynności, aby pomóc sobie w problemie z wypadaniem narządu rodnoego?

Proszę podać odpowiedź nawet w przypadku, gdy uważa Pani, że nie ma problemu z wypadaniem narządu rodnoego.

	Nigdy	Czasem	Często	Cały czas
Czy używa Pani tamponów/wkładek/ciasnej bielizny, by sobie pomóc?				
Czy odprowadza Pani wypadający narząd rodny z powrotem?				
Czy odczuwa Pani ból lub dyskomfort z powodu wypadania narządu rodnoego?				
Czy wypadanie narządu rodnoego uniemożliwia Pani stanie?				

Dziękujemy.

Proszę sprawdzić, czy udzieliła Pani odpowiedzi na wszystkie pytania.