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ORIGINAL ARTICLE

Translation and validation of the International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS): the Danish version

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Abstract

Introduction In the clinical evaluation of women with pelvic organ prolapse (POP), it is important to evaluate both objective and subjective presentations. The objective evaluation is done by gynecological examination, but the subjective presentation is more complex. The International Consultation on Incontinence Questionnaire–Vaginal Symptoms (ICIQ-VS) is an important tool for subjective evaluation, and a Danish version was developed.

Materials and methods The English version was translated into Danish in accordance with guidelines. Eight women underwent a semistructured interview showing no misunderstandings. Women with and without prolapse completed the questionnaire and underwent a Pelvic Organ Prolapse Quantification (POP-Q) examination. Three weeks later a retest was done. Women undergoing prolapse surgery completed the questionnaire 3 months postoperatively.

Results Ninety-four women with and 98 without prolapse were included; 52 underwent surgery. Retest response rate was 88–95%. Mean time between test and retest was 24.5 and 92.2 days, respectively. Missing data ranged between 0 and 1%. Test–retest reliability was good to excellent (ICC 0.61–0.88) and internal consistency was acceptable (Cronbach's alpha 0.79–0.84). The questionnaire was excellent when distinguishing between women with and without prolapse ($p < 0.001$). Criterion validity (correlation between POP-Q stage and the questionnaire) was perfect ($p < 0.001$). Sensitivity to change was excellent for vaginal symptom score and quality of life ($p < 0.001$) but not for sexual matters ($p = 0.059$).

Conclusions The Danish version of ICIQ-VS was successfully translated and can be a valuable tool for prolapse research and daily evaluation of patients.

Keywords Prolapse · Vaginal questionnaire · ICIQ-VS · Validation

Abbreviations

ICIQ-VS	International Consultation on Incontinence Questionnaire—Vaginal Symptoms
POP	Pelvic organ prolapse
VSS	Vaginal Symptom Score
SMS	Sexual Matter Score
QoL	Quality of Life Score
PGI-I	Patient Global Impression of Improvement scale

Introduction

Pelvic organ prolapse (POP) is a common condition affecting women of all ages [1]. POP is characterized by an objective

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bulge into or out of the vagina. Subjective feelings vary in intensity, as does the impact on quality of life (QoL). By using standardized measurements such as the Pelvic Organ Prolapse Quantification (POP-Q) system, objective prolapse is easily quantified [2]. Degree and subjective sensation of prolapse is strongly correlated, but bother and impact on QoL is highly subjective [3]. Since the objective degree of prolapse does not always reflect the degree of subjective symptoms or impact on sexual life and QoL, there is a need for a robust and validated instrument to measure and quantify them. In 2006, a group appointed by the International Continence Society (ICS) developed a validated self-completion questionnaire—the International Consultation on Incontinence Questionnaire–Vaginal Symptoms (ICIQ-VS) with the aim of assessing vaginal symptoms related to POP and the impact on sex life and QoL [4]. The questionnaire is translated and validated in Portuguese, Sinhala, Tamil, Greek, and German, and it was important to translate and validate it in Danish [5–8]. The aim of this study was to translate the ICIQ-VS into Danish and test its reliability, validity, and sensitivity.

Materials and methods

The ICIQ-VS is composed of 14 items: nine regarding vaginal symptoms, four on sexual life, and one on QoL. Items 1–9, 11, and 12 are designed so that both information on the frequency of a given symptom and the subjective bother are registered, resulting in 25 items/questions. The Vaginal Symptom Score (VSS) (items 1–9) ranges between 0 and 53, the Sexual Matter Score (SMS) (items 10–13) between 0 and 58, and QoL score (item 14) between 0 and 10. The score 0 reflects no symptoms and no bother. Only sexually active women answer items in the SMS.

Translation and cultural adaptation

Translation from English to Danish was done in four steps in accordance with international recommendations [9]. Every item was translated from English to Danish by the translation team (one bilingual doctor with no gynecological knowledge and three Danish gynecologists with good English skills), each of whom did the translation individually. A harmonization of individual translations was made, and the team agreed on one Danish version. Eight women filled out the Danish questionnaire and were individually interviewed using a semistructured scheme to detect misunderstandings. The questions were well comprehended, and no changes were necessary. Likewise, three health-care professionals familiar with diagnosing prolapse reviewed the questionnaire, found it complete, and made no changes. The Danish version was back-translated into English by a bilingual gynecologist unfamiliar with the original questionnaire and was then reviewed by the ICS group to guarantee the original content.

Study population

In this prospective study, women were recruited from the gynecological outpatient clinics at Aalborg University Hospital and the North Denmark Regional Hospital (February 2015–January 2016). Women both with and without POP, ≥18 years, and capable of reading and understanding the questionnaire were enrolled. One hundred women with POP and 100 women seen in the clinic for other gynecological problems were consecutively included. Based on other studies translating and validating the ICIQ-VS, a sample size of 200 was chosen [5–8]; 94 with and 98 without POP agreed to participate. At the primary visit (T1), women had a gynecological examination and a POP-Q score performed to diagnose whether POP was present or not, followed by patient-completion of the ICIQ-VS questionnaire. None of the women were scheduled for an intervention in relation to vaginal symptoms during the study period. Two to three weeks later (T2), the same questionnaire was sent to the participants by regular mail with a reply envelope. If the women did not reply within 1 week, a telephone call was made. This time frame was chosen on the assumption that 2–3 weeks was such a short a duration that subjective symptoms would not change but was long enough for women not to memorize their answers at T1.

Another 52 women scheduled for POP surgery were enrolled at the time of surgery (T3). They completed the ICIQ-VS questionnaire before surgery and POP-Q scoring was performed. Three months postoperatively (T4), they received the ICIQ-VS by mail and returned it in the reply envelope. They were also asked to fill out the validated Patient Global Impression of Improvement (PGI-I) questionnaire to evaluate surgical outcome [10].

Sociodemographic data (age, height, weight, parity, number of cesarian sections, previous POP surgery, and smoking status) were collected.

Statistical analysis

As suggested by the International Consultation of Incontinence Modular Questionnaire Validation Protocol, validation and reliability of the Danish ICIQ-VS questionnaire were tested in the following way [11].

1. Reliabillity
   Stability over time: measures whether questions are asked so the response from each woman is the same if they completed it twice (T1 and T2).
   Statistics: Intraclass Correlation Coefficient (ICC 2, 1A): evaluates every item in the questionnaire. ICC between 0.60 and 0.74 considered good and between 0.75 and

1.00 as excellent. Mean and median values of summed VSS, SMS, and QoL at the two timepoints compared and mean difference calculated. A Wilcoxon matched-pairs signed-rank test was performed.

Internal consistency: determines whether individual questions/items in the two combined scores (VSS and SMS) correlate with each other at time T1.

Statistics: Cronbach's alpha; a value of ≥0.7 is acceptable.

2. Validation

Content validity: examines whether questions are asked so women can answer based on the level of missing data.

Construct validity: examines whether questionnaire distinguish between women with and without POP. Compares scores between groups.

Statistics: mean/median values of summed scales and Mann–Whitney *U* test.

Criterion validity: measure any trend to a higher score with a higher degree of prolapse.

Statistics: Jonckheere-Terpstra trend test.

(3) Sensitivity

Sensitivity to change: measures whether questionnaire detects an intervention—in this case, POP surgery (T3 and T4).

Statistics: mean change and Wilcoxon matched-pairs signed-rank test.

(4) It was further examined whether mean score difference between before and after surgery correlated with the PGI-I, which measures satisfaction after surgery.

Statistics: Spearman's rho correlation coefficient.

Statistical analyses were performed using IBM SPSS statistics 22. The level of significance was set to a p value of 0.05. The local ethics committee (N-20150001) and the Danish Data Protection Agency (2008–58-0028) approved the study.

Results

A total of 94 women with a prolapse grade >2 more filled out the questionnaire at T1; median age was 64 (range 25–86) years, median number of births two (range 0–5), median number of cesarean sections 0 (range 0–1), and median body mass index (BMI) 27.0 kg/m^2 (range 20.0–41.5). Grade 2 prolapse was found in 71 (75.5%) and grade 3 in 23 (24.5%) patients; no woman had grade 4 prolapse. Ninety-eight women with grade 0 [52 (53.1%)] or 1 [46 (46.9%)] prolapse filled out the questionnaire at T1; median age was 43 (range 18–82) years, median number of births twi (range 0–7), median number of cesarean sections 0 (range 0–4), and median BMI 25.1 (range 18.1–47.3). Of the women with POP, 89 (95%) participated in the retest. Mean time between T1 and T2 was 24.5 days (median 23, range 9–51). POP surgery was offered to 52 women [median age 61.5 (range 40–81) years] . Of them, 46 (88%) responded to the retest at T4; mean time between T3 and T4 was 92.2 (range 80–116) days; 46 postoperative women completed the PGI-I.

Stability over time The test–retest (between T1 and T2) showed excellent ICC >0.75 (range 0.75–0.88) for all items except 1a, 1b, 3a, 3b, 4a, 4b, and 5a, where ICC was found to be good (range 0.61–0.74). Mean values and confidence intervals (CI) for VSS, SMS, and QoL at T1 and T2 are shown in Fig. 1; there was no significant difference in median values for either VSS, SMS, or QoL (p value 0.125–0.935).

Internal consistency Evaluating Cronbach's alpha for items in VSS and SMS showed excellent values (0.79 and 0.84., respectively.)

Content validity Missing data for single items ranged between 0 and 1%. Two patients skipped a whole page of the questionnaire, one patient did not answer question 4b, and another skipped question 14.

Construct validity To test whether the questionnaire could distinguish between women with and without POP, mean and median values for the three scores were calculated for the two groups at T1 (Fig. 2). A Mann–Whitney *U* test showed significantly different scores between women with and without POP (Table 1).

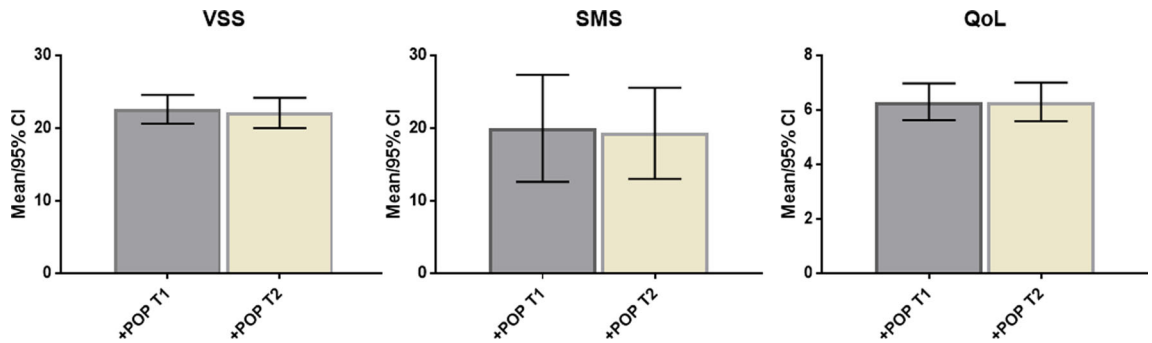

Fig. 1 Mean value [95% confidence interval (CI)] for VSS, SMS, and QoL for women with prolapse (+POP) at time T1 and T2. *VSS* Vaginal Symptom Score, *SMS* Sexual Matter Score, *QoL* Quality of Life Score, *POP* pelvic organ prolapse

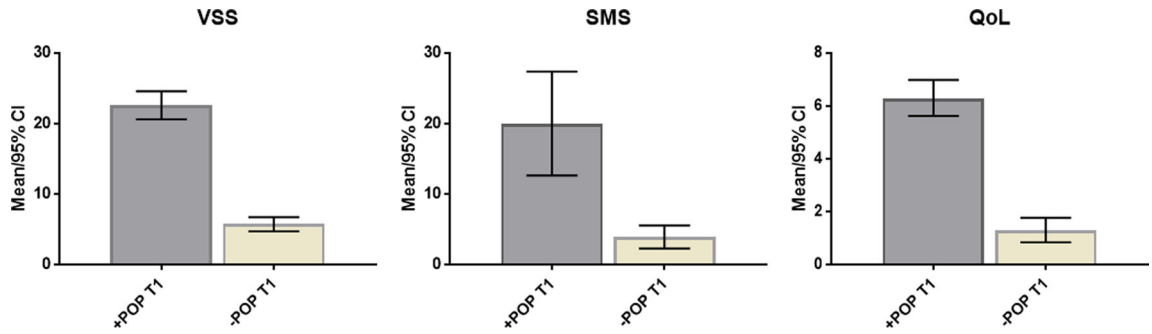

Fig. 2 Mean value for VSS, SMS, and QoL for women with (+POP) and without (-POP) pelvic organ prolapse at time T1. *VSS* Vaginal Symptom Score, *SMS* Sexual Matter Score, *QoL* Quality of Life Score

Criterion validity To test whether questionnaire scores tended to be higher in women with a higher degree of prolapse, mean and median values of the three individual scales were calculated for the four degrees of POP (grades 0–3) (Table 2). A Jonckheere-Terpstra trend test was performed showing a significant association between the degree of prolapse and the VSS, SMS, and QoL (all p <0.001).

Sensitivity to change Figure 3 displays mean scores before and after surgery, showing significant sensitivity to change for VSS ($p < 0.001$) and QoL ($p < 0.001$) but not for SMS (p 0.059). We also tested the ICIQ-VS questionnaire against the PGI-I questionnaire (satisfaction after surgery). Of the 46 women who underwent POP surgery, 27 felt very much better, nine much better, five a little better, and five the same. PGI-I score was correlated with mean change in each score and showed a Spearman's rho correlation coefficient for VSS at −0.272 (p 0.034), SMS at −0.733 (p 0.001), and QoL −0.007 (p 0.482), showing that VSS and SMS correlate with the PGI-I, whereas QoL does not.

Discussion

This study demonstrates a successful translation of the English version of the ICIQ-VS questionnaire into Danish. Test–retest reliability was good, and internal consistency was acceptable. Moreover, the questionnaire was excellent for distinguishing between women with and without prolapse. Finally, the criterion validity was perfect, and sensitivity to change was excellent for VSS and QoL but not for SMS.

Danish is spoken by only 6 million people in Denmark. There is a long tradition of research in all fields of medicine. Since 1968, all Danish residents have been registered by a unique social security number, and since 1976, every contact with a hospital has been reported to the National Patient Registry with information of diagnosis and surgical procedures [12]. In addition, numerous clinical databases, including a urogynecological database, have been established in the last 10–15 years. This provides a unique opportunity to conduct large-register studies and identify patients for follow-up studies. For the quality of such studies, there is a need for validated measurement instruments, such as questionnaires. In the urogynecological field, numerous validated questionnaires in the English language have been developed, and to compare results from research around the world, it is necessary to use such validated questionnaires rather than developing new ones. The ICIQ-VS questionnaire is widely used in the field of prolapse research [13, 14], covering a wide range of subjective symptoms and comprising questions regarding influence on QoL and sexual problems, and we found it an optimal tool by which to evaluate patients with prolapse.

The primary translation of the questionnaire was successful was easily understood by women participating in the pretesting; no changes were necessary. For the main study, we initially mailed the questionnaire and study information, together with an appointment date for women referred to the gynecological outpatient clinic. They were asked to complete

Table 1 Descriptive analysis of Vaginal Symptom Score (VSS), Sexual Matter Score (SMS), and Quality of Life (QoL) Score between women with and without pelvic organ prolapse (+POP/-POP). *P* values compare women with and without POP

Group	ICIQ-VS scores	No.	Mean	SD	Median	Range	*P* value
+POP	*VSS*	*94*	*22.6*	*9.7*	*21.5*	0–46	*<0.001*
	SMS	*28*	*20.0*	*18.6*	*18*	0–58	*<0.001*
	QoL	*93*	*6.3*	*3.3*	*8*	0–10	*<0.001*
-POP	*VSS*	*98*	*5.7*	*5.0*	*4*	0–25	
	SMS	*68*	*3.9*	*6.8*	0	*0–24*	
	QoL	*98*	*1.3*	*2.3*	0	*0–9*	

ICIQ-VS International Consultation on Incontinence Questionnaire–Vaginal Symptoms, *SD* standard deviation

Table 2 Descriptive analysis of Vaginal Symptom Score (VSS), Sexual Matter Score (SMS), and Quality of Life (QoL) Score between women according to Pelvic Organ Prolapse Quantification (POP-Q) grade

POP-Q stage	ICIQ-VS scores	No.	Mean	SD	Median	Range
0	*VSS*	*52*	*5.6*	*4.7*	*4*	*0–17*
	SMS	*37*	*3.6*	*7.0*	*0*	*0–24*
	QoL	*52*	*1.2*	*2.3*	*0*	*0–8*
1	*VSS*	*46*	*5.9*	*5.4*	*5.5*	*0–25*
	SMS	*31*	*4.1*	*6.7*	*0*	*0–20*
	QoL	*46*	*1.4*	*2.3*	*0*	*0–9*
2	*VSS*	*71*	*22.0*	*9.8*	*21*	*0–42*
	SMS	*21*	*19.5*	*19.8*	*18*	*0–58*
	QoL	*70*	*6.3*	*3.3*	*8*	*0–10*
3	*VSS*	*23*	*24.6*	*9.0*	*22*	*0–46*
	SMS	*7*	*21.3*	*15.9*	*18*	*0–44*
	QoL	*23*	*6.2*	*3.2*	*8*	*0–10*

the questionnaire at once and bring it to their appointment 2–3 weeks later. Our intention was that the second questionnaire (T2) would be completed in the clinic. However, we found that women did not understand this time request and completed the questionnaire just before they came to the clinic, resulting the period between T1 and T2 being too short. The recruiting procedure was therefore changed to the one described in "Materials and methods", and all women in the main study were recruited in accordance with this. The response rate for the retest was extremely high (95%), and only a few women had to be contacted by telephone to return the questionnaire.

Reliability was evaluated by stability over time and internal consistency. Stability over time showed good to excellent values for all items, indicating that the interpretation of every single question was the same every time it was asked. The lowest values were 0.61 for question 5a, which asked how often the women was aware of a lump or bulge coming down in the vagina. From our clinical point of view, some women have problems with explaining whether the bulge is inside the vagina or comes outside; this might explain the lower values. There was no statistically significant difference in the three scores at T1 and T2. We chose not to include women without prolapse in the statistical evaluation of stability over time, which is converse to the German validation [7]. Not having symptoms, and therefore answering 0 in every item, probably results in more stable answers over time compared with symptomatic women.

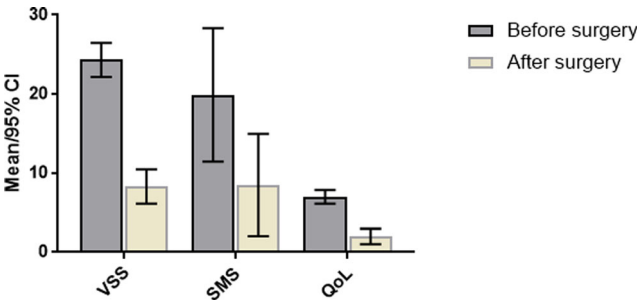

Fig. 3 Sensitivity to change. Mean value [95% confidence interval (CI)] for VSS, SMS, and QoL for women with pelvic organ prolapse (POP) before and 3 months after surgery. *VSS* Vaginal Symptom Score, *SMS* Sexual Matter Score, *QoL* Quality of Life Score

To evaluate whether the single items in the total score (VSS and SMS) correlate, Cronbach's alpha was calculated, showing excellent results though lowest for VSS. If question 8 in the VSS were deleted, Cronbach's alpha would be higher. The question asks whether the woman needs to insert a finger into the vagina to help empty the bowels, a symptom that often arises from a rectocele. Since the study population is a mix of women with prolapse in all three compartments (anterior, middle, and posterior), most will report symptoms in questions 1–7 but not always in question 8.

Construct, content, and criterion validity were used to evaluate overall questionnaire validity. Evaluating the reason for missing data revealed a good understanding of the questionnaire and a willingness to answer. Evaluating missing data seems to indicate that two women experienced adherent pages, which accounts for 11 of the 13 questions missed (84.6%). This indicates that misunderstanding the question was not the reason for missing data. There was a significant difference between scores among women with and without POP, revealing excellent construct validity. Evaluating demographic data showed a significant difference in the number of births and BMI among groups, but this is not surprising, since these are factors predispose to developing POP. Age was also significantly different between groups, and this could potentially explain some differences in total scores. However, we believe the presence of POP is the main reason. We also tested whether total score tended to be higher in women with a greater degree of prolapse. This was not only confirmed but showed that even some women with grade 0–1 prolapse had a high score. Some questionnaire items are not specific to prolapse; e.g., "Are you aware of soreness in your vagina?"; "Do you feel your vagina is too dry?" In both categories, even women with no prolapse can have a high score.

Responsiveness was evaluated by sensitivity to change and showed a significant difference in VSS and QoL scores before and after surgery but was only nearly significant for SMS. This is similar to results found with translation in Sinhala, Tamil, and German [5, 7, 8]. Sensitivity to change was not assessed in the Greek validation study [6]. Small sample size for the SMS could be an explanation for this result. The retest was performed 3 months postoperatively, and we believe some sexual problems take longer than 3 months to improve, which also might explain why we found no significant difference. Regarding subjective success of surgery, one may expect that women reporting the highest satisfaction on the PGI-

I would have the highest mean change in ICIQ-VS; this was true in our study for all components except QoL, where we found a borderline correlation only.

One limitation with our study is that women underwent a gynecological examination and knew they had prolapse before completing the questionnaire, which may have led to a falsely higher construct validity. Asking women to complete the questionnaire before presenting to the outpatient clinic would have been eliminated this potential bias. For the control group, we chose women referred to outpatient clinic for conditions other than POP, and those other symptoms may have influenced scoring; however, results indicate that the scales used was able to distinguish between conditions with and without POP.

In conclusion, the Danish version of the ICIQ-VS was successfully translated and is now ready to use as a strong and validated tool for assessing women with prolapse—both in daily clinical practice and in research. We strongly encourage researchers from countries not yet having a translated and validated version of the ICIQ-VS to do so in their language. This will make it possible for researchers to compare results.

Author's contribution LTS Arenholt: Project development, data collection, statistical calculations, manuscript writing.
M Glavind-Kristensen: Manuscript writing/editing.
H Bøggild: Statistical support, manuscript writing/editing.
K Glavind: Manuscript writing/editing.

Compliance with ethical standards

Conflict of interest L.T.S. Arenholt and K. Glavind have accepted travel grants from Pierre Fabre and Astellas; M. Glavind-Kristensen accepted a travel grant from Astellas. Henrik Bøgild has no conflict of interest.

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