

# Development and psychometric evaluation of the ICIQ Vaginal Symptoms Questionnaire: the ICIQ-VS

N Price,<sup>a</sup> SR Jackson,<sup>a</sup> K Avery,<sup>b</sup> ST Brookes,<sup>b</sup> P Abrams<sup>c</sup>

<sup>a</sup>Department of Obstetrics & Gynaecology, John Radcliffe Hospital, Oxford, UK <sup>b</sup>Department of Social Medicine, University of Bristol, Bristol, UK <sup>c</sup>Bristol Urological Institute, Southmead Hospital, Bristol, UK  
Correspondence: Dr N Price. Email price@clara.co.uk

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**Objectives** To develop and validate a self-completion questionnaire for comprehensive assessment of the severity and impact of vaginal symptoms and related sexual matters, particularly those attributed to pelvic organ prolapse. To provide an instrument that can characterise the severity of these symptoms, measure their impact and evaluate treatment outcome.

**Design** Prospective development of the content of the questionnaire and testing of its psychometric properties including validity.

**Setting** Two hospital-based urogynaecology clinics and one community general practice in the South of England.

**Population** One hundred and forty-one urogynaecology clinic attendees with varying degrees of pelvic organ prolapse and 77 randomly selected women registered with a general practice.

**Methods** The questionnaire was developed through a literature review, consultation with clinicians and health scientists and structured interviews with patients. Content validity, construct validity, stability, internal consistency and sensitivity to change were examined by comparing the responses from the urogynaecology clinic with responses from the general community. Sensitivity to change was assessed using responses from women undergoing surgical treatment for pelvic organ prolapse before and

3 months after surgery. A final version of the questionnaire was obtained after factor analysis to assist item reduction and refinement of the scoring system.

**Main outcome measures** Content validity, construct validity, stability (test–retest reliability), internal consistency and sensitivity to change.

**Results** The questionnaire exhibited good validity, reliability and sensitivity to change. Excellent internal consistency was demonstrated for vaginal (Cronbach's alpha 0.79) and sexual (Cronbach's alpha 0.84) symptoms. Reliability was good. The questionnaire was able to identify changes in symptoms following surgical treatment. The final ICIQ-VS questionnaire had 14 items and a simple scoring system.

**Conclusion** The ICIQ-VS self-completion questionnaire meets the need for a robust instrument for assessing a range of vaginal and sexual symptoms, in particular those of pelvic organ prolapse. It will be of use in both routine clinical practice and epidemiological research, particularly when there is a need to assess the severity of these symptoms or the efficacy of treatment.

**Keywords** Factor analysis, pelvic organ prolapse, psychometric analysis, questionnaire, scoring, sexual symptoms, vaginal symptoms.

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## Introduction

Many women are troubled by vaginal symptoms, and pelvic organ prolapse is frequently implicated. These symptoms can severely affect the quality of life of such women, causing physical, social, psychological, occupational and sexual limitations of their lifestyles.<sup>1–3</sup> Vaginal symptoms, particularly those attributed to pelvic organ prolapse, commonly coexist with other pelvic symptoms, including urinary incontinence, faecal incontinence, voiding dysfunction and defecatory dysfunction.

Many women hesitate to bring these symptoms to the attention of their doctors, resulting in the delay in presenting to physicians. Very little is known about the effect of pelvic organ prolapse and related pelvic floor dysfunction on the quality of life of these women, so systematic evaluation is required for their clinical management and follow-up treatment.<sup>4,5</sup>

Symptoms and the findings of objective examination often do not correlate with each other, and women may be unwilling to volunteer symptoms, particularly after surgical intervention. Consequently, despite the prevalence of this condition,

we have little idea on how interventions alter symptoms and their impact.<sup>6–8</sup>

A number of questionnaires have been developed to assess pelvic organ prolapse including the Pelvic Floor Distress Inventory Questionnaire and the Pelvic Floor Impact Questionnaire.<sup>2,9,10</sup> However, the validation of these is incomplete: their responsiveness and sensitivity to change following corrective surgery for prolapse have not yet been tested. There remains a need for a fully validated and widely applicable questionnaire, as emphasised during the Third International Consultation on Incontinence (ICI) in June 2004.<sup>2</sup>

The ICI is presently developing a comprehensive and universally applicable set of modular questionnaires (ICIQ) to provide an international standard for the assessment of a range of pelvic symptoms related to dysfunction of the lower urinary tract, bowel and vagina.<sup>2,11</sup> Under the programme of the ICI, a new module for assessing the symptoms and impact of pelvic organ prolapse, the ICIQ Vaginal Symptoms (ICIQ-VS) questionnaire, has been developed and evaluated. The ICIQ-VS is designed to be widely applicable to adult women older than 18 years both in the primary and the secondary care settings. This study reports on the development, psychometric analysis, validation and optimisation of the ICIQ-VS.

## Study design and methods

A number of studies were undertaken to develop the ICIQ-VS questionnaire, examine its psychometric properties and validate it using standard methods of psychometric testing.<sup>12,13</sup> Ethical approval was granted by the Local Research Ethics Committees.

### Developing the ICIQ-VS questionnaire

A developmental version of the ICIQ-VS questionnaire was produced following the combination of a systematic literature review,<sup>9,14–22</sup> consideration by an expert consensus committee and in-depth interviews with 14 urogynaecology clinic attendees with vaginal symptoms. The developmental version of the questionnaire included items covering three main areas. Some 14 items related to vaginal symptoms, of which 13 had a subquestion concerning the degree of problem caused; there was also one filter question (Appendix 1). In addition, there were ten items relating to sexual matters; nine with a degree-of-problem subquestion and one filter question. In general, vaginal symptom and sexual matter items used 4- or 5-point response frames and the problem subquestions an 11-point scale. Following consultation with public health scientists, the impact of vaginal symptoms on quality of life was considered with the single question: 'Overall, how much do vaginal symptoms interfere with your every-day life?'. This should provide an adequate understanding of the impact and should further evaluation be necessary, a separate, full quality-of-life questionnaire such as 'The Short Form-12

or Short Form-36 Health Survey Questionnaire' could be administered.<sup>2,23–25</sup> Some 14 women were observed while completing the questionnaire and subsequently interviewed to establish their comprehension of individual items. This developmental version of the ICIQ-VS was then psychometrically tested as described below.

### Testing the ICIQ-VS questionnaire

Various sampling methods were employed to test and evaluate the ICIQ-VS questionnaire in individuals who represented as potential respondents. A sample of urogynaecology clinic attendees with varying degrees of pelvic organ prolapse and a second randomly selected community-based sample of women of varying ages were selected. All statistical analyses were interpreted taking into account that multiple significance tests were performed. For example, for 14 symptoms, the Bonferroni correction<sup>26</sup> indicates that test-wise *P* values should only be considered as providing reasonable evidence of an effect if they are <0.0036. The following psychometric properties of the ICIQ-VS questionnaire were assessed.

#### Validity

A valid questionnaire has a content that reflects the medical conditions underlying the symptoms. It adequately represents the content domains and reflects the underlying theories of the constructs that it claims to measure.<sup>27</sup>

*Content validity.* Content validity is the assessment of whether the questionnaire makes sense to those being measured and to experts in the clinical area. Response rates and missing data indicate the acceptability of items.<sup>13</sup> Some 141 consecutive UK urogynaecology clinic attendees (median age 58.8 years, range 28.9–87.5 years) with symptomatic pelvic organ prolapse and varying levels of vaginal symptoms and 77 randomly selected women (median age 55.0 years, range 25.5–78.4 years) registered with a UK community general practice completed the questionnaire in a postal survey. The response rate and percent levels of missing data were calculated.

*Construct validity.* The ability of the questionnaire to reflect theories and traits underlying vaginal symptoms was examined. Chi-square tests were used to determine if the questionnaire could detect a difference in the prevalence of symptoms between a sample of community-based women (*n* = 77) and the sample of women attending urogynaecology clinics (*n* = 141).<sup>13</sup>

#### Reliability

*Stability.* The stability of individuals' responses to questionnaire items over a period in which their symptom status would not be expected to change was assessed in 37 women (median age 62.5 years, range 38.2–81.6 years) randomly selected from the clinic sample, who completed a second ICIQ-VS within 2–4 weeks of the first questionnaire. Agreement

between test and retest responses to individual items was analysed by graphical interpretation of the paired differences and the calculation of weighted kappa statistics for ordered categorical data.<sup>12,13</sup>

**Internal consistency.** If questionnaire items address similar issues, their scores will correlate with one another. On the other hand, if the correlations are too high, this will suggest redundancy or overlap between items. Correlation between the ICIQ-VS questionnaire items was assessed by the calculation of Cronbach's alpha coefficient using data provided by the clinic sample ( $n = 141$ ). An average Cronbach's alpha coefficient of 0.7–0.8 is generally considered acceptable for the demonstration of internal consistency. However, a very high alpha much above 0.9 suggests highly related items and therefore redundancy.<sup>12,13</sup>

**Sensitivity.** A sensitive questionnaire can detect the change in item responses following intervention. This was investigated in a sample of 66 women (median age 59.1 years, range 36.8–82.1 years) of 141 urogynaecology clinic attendees undergoing surgical treatment for pelvic organ prolapse. Surgical interventions included vaginal hysterectomy (VH), anterior vaginal repair (AR), posterior vaginal repair (PR), sacrospinous fixation (SSF), sacrocolpopexy (SCP) and various combinations of these procedures (VH + AR, 11; VH + PR, 9; VH + AR + PR, 12; VH + PR + SSF, 8; SSF + PR, 5; SCP, 2; AR + PR, 9). The percent change in the presence of symptoms between baseline and follow up approximately 12 weeks later was calculated. Wilcoxon matched pairs signed rank tests were used to determine whether symptom levels differed significantly.

### Short form and scoring of the ICIQ-VS questionnaire

The final optimised version of the questionnaire with a reduced number of items was obtained through an iterative process of factor analysis, further psychometric tests and an assessment of the clinical importance of individual items by two experienced urogynaecologists. Factor analysis was also employed to investigate whether a scoring system for the final questionnaire was appropriate.<sup>28</sup> Models were considered for various numbers of factors using Varimax rotation to aid interpretation. Cronbach's alpha was calculated for each resulting domain to assess internal consistency. The distributions of scores in the different study samples were examined in order to investigate the validity of the final scoring system.

## Results

### Psychometric properties

#### Validity

**Content validity.** Patient's interviews and review by clinical and social science experts indicated that ICIQ-VS items were

well interpreted and covered all important issues relating to vaginal symptoms. The postal response rate was good (community group 59%, clinic group 89% and 74% overall). Vaginal symptom items demonstrated low levels of missing data: less than 3% for all items, with the exception of the item relating to tampon use, which was missing for 56% of women who reported that they no longer had periods. In terms of items relating to sexual matters, between 10 and 13% of items had missing data, except 'sex life spoilt' for which 25% was missing. Problem subquestions also demonstrated low levels of missing data (less than 4% missing for all items, with the exception of 'sex impossible' for which 4.9% was missing).

**Construct validity.** The prevalence of vaginal symptoms and sexual items reported by the clinical and community populations is shown in Table 1. The ICIQ-VS distinguishes well between clinic attendees and community-based women. Women in the clinic sample reported much higher prevalence of vaginal symptoms and impact on sexual matters than those in the community for the majority of vaginal symptoms (chi-square test,  $P < 0.001$ ). Differences between the populations in response to the questions 'use of a pessary' and 'urinary evacuation' demonstrated weaker evidence ( $P < 0.005$ ). There was no difference between the clinic and the community samples in response to the question that the 'vagina is too tight'. All sexual items demonstrated high levels of construct validity ( $P < 0.0001$ ), with the exception of 'leakage during intercourse'.

#### Reliability

**Stability.** Test–retest reliability was good for the majority of items. For items using 4- or 5-point Likert response frames, the percentage of women reporting identical ratings or moving only one category between the time points (e.g. from 'occasionally' to 'sometimes') ranged from 79 to 100%. About 0–17% of women moved two categories. For items using the wider 11-point visual analogue scales, 78–100% of women reported identical ratings or moved three categories or less. Kappa values exhibited good to very good stability (between 0.58 and 1.0,  $P < 0.0001$ ) for the majority of symptoms and sexual items. The items 'vagina too loose', 'dry vagina' and 'difficulty using tampons', 'leakage during intercourse', 'partner avoids' and 'relationship affected' demonstrated fair to moderate stability (kappa values between 0.23 and 0.54). The item 'vagina too tight' demonstrated poor reliability (kappa 0.18,  $P > 0.05$ ). The test–retest stability of the most common symptoms is shown in Figure 1.

**Internal consistency.** Cronbach's alpha coefficients for items assessing symptoms and sexual matters were high at 0.81 and 0.88, respectively. This coefficient excluded the item relating to 'tampon use' since it was only relevant to 56% of the women and among those, only 44% responded.

**Table 1.** Percentages of women reporting symptoms in the clinic and community samples

	Clinic sample (n = 141)		Community sample (n = 77),* prevalence (%)	P value**
	Prevalence (%)	Bothersomeness median (IQR)		
<b>Vaginal symptoms</b>				
Dragging pain	82.3	5 (3–7)	41.6	<0.0001
Soreness	74.5	5 (3–8)	42.9	<0.0001
Reduced sensation	47.9	4 (3–6)	2.6	<0.0001
Pessary	15.0	N/A	2.6	0.005
Dropping down feeling	89.9	7 (4–9)	6.6	<0.0001
Loose vagina	84.7	7 (4–8)	9.2	<0.0001
Lump felt inside	89.3	8 (6–10)	2.6	<0.0001
Lump seen outside	75.0	8.5 (7–10)	1.3	<0.0001
Urinary evacuation	17.3	6 (5–8.5)	0.0	<0.001
Faecal evacuation	39.8	8 (6–9)	1.3	<0.0001
Painful dryness	62.6	6 (3–8)	19.7	<0.0001
Dry vagina	66.7	5 (3–8)	35.5	<0.0001
Tight vagina	10.7	4 (2–5)	5.3	0.215
Difficulty using tampons	62.9	5.5 (4–8)	2.7	<0.0001
<b>Sexual matters***</b>				
Sex dangerous	43.9	5 (3–8)	2.7	<0.0001
Sex impossible	51.6	5 (3–8)	6.6	<0.0001
Sex life spoilt	85.9	N/A	19.0	<0.0001
Pain during intercourse	72.6	5 (3–8)	30.4	<0.0001
Leakage during intercourse	17.7	7.5 (7–10)	1.8	0.005
Worries	79.0	6.5 (3–9)	14.3	<0.0001
Relationship affected	67.7	6 (4–8)	7.2	<0.0001
You avoid	79.0	6 (4–8)	12.5	<0.0001
Partner avoids	39.3	6 (4–8)	5.4	<0.0001
Worse	58.1	6.5 (3.5–8)	5.4	<0.0001

IQR, interquartile range; N/A, not applicable.

\*Within the community sample, the numbers reporting the presence of the majority of symptoms were very small, such that summary statistics of the bothersome subquestions were uninformative.

\*\*P values obtained by chi-square tests. Data are significant if  $P < 0.0036$ .

\*\*\*Data for sexually active women only.

### Sensitivity to change

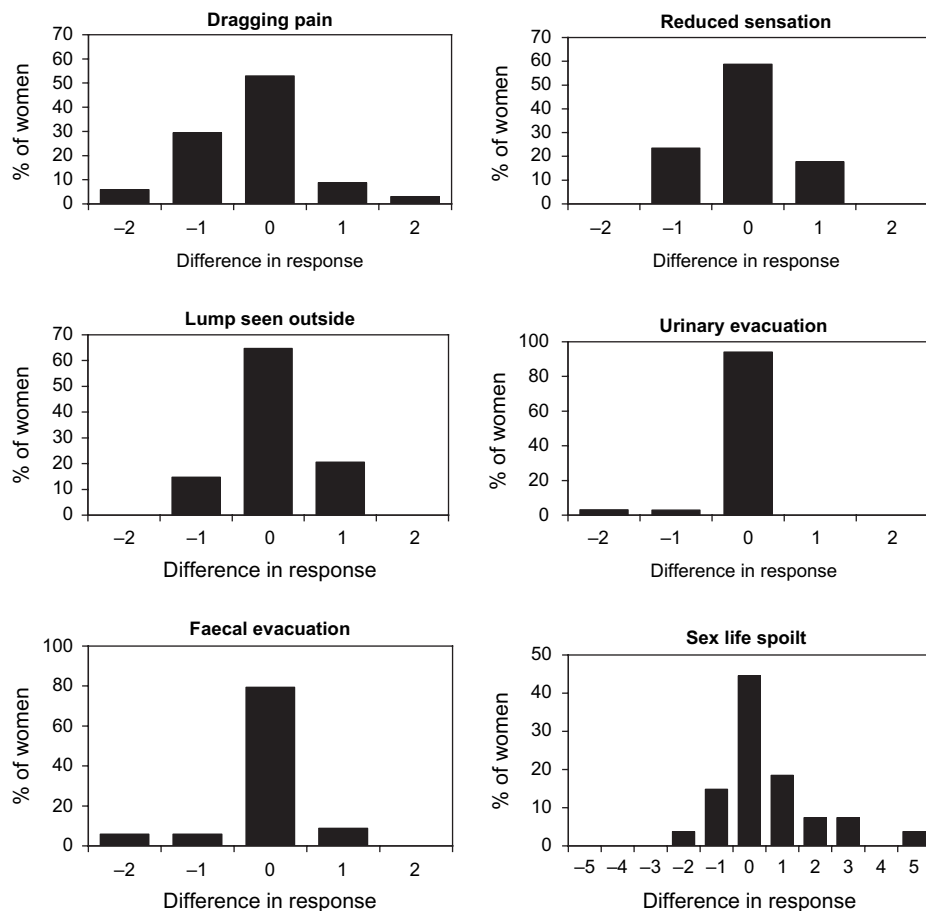
Among the 66 women undergoing surgical treatment for prolapse, the percentage of women reporting 13 of the 14 vaginal symptoms decreased after treatment, between 7.4 and 83.1%. The symptom 'vagina too tight' did not demonstrate change. There was significant improvement following surgery in 11 of the 14 symptoms ( $P < 0.0001$ ), less change for the item relating to 'faecal evacuation' ( $P = 0.0014$ ) and little sign of any improvement in terms of 'vagina too tight' and 'difficulty using tampons' ( $P > 0.05$ ) (Wilcoxon matched pairs signed rank test). For sexual matters, decreases ranging from 3.1 to 49.8% were observed in the percentages of women reporting problems on each of the 11 items following treatment, although only the improvement in items relating to the view that sexual intercourse was 'dangerous' or 'impossible' was

significant ( $P = 0.0004$  and  $P < 0.0001$ , respectively) (Wilcoxon matched pairs signed rank test). Figure 2 demonstrates that the questionnaire is sensitive to change and can be used to compare the level of individual symptoms for patients before and after surgery.

### Short form and scoring of the ICIQ-VS questionnaire

#### Vaginal symptoms

All the 14 vaginal symptoms were initially included in the factor analysis (filter question and bother subquestions were not included). Models containing between one and five factors were examined to identify clusters of symptoms and indicate any redundant items. Items that did not load particularly



**Figure 1.** Stability of key symptoms, showing percentage of women moving zero to two response categories between test and retest.

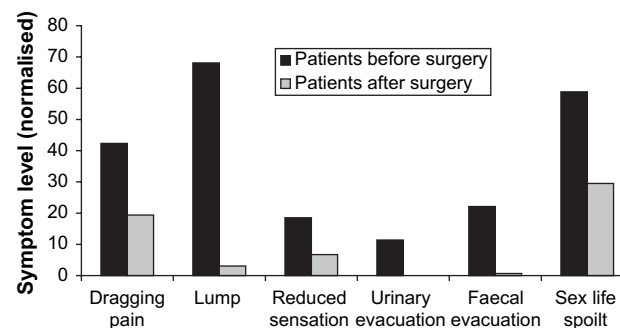
heavily on any factors in any model included 'pessary use', 'urinary evacuation problems' and 'vagina too tight'. 'Pessary use' and 'urinary evacuation problems' were not commonly reported and were less bothersome than other items, so they were removed from the questionnaire at this stage. The item 'vagina too tight' was relatively uncommon and less of a problem presurgery. However, it is important for the detection of over-narrowing of vagina following surgical intervention and was retained in the questionnaire as a separate factor but excluded from the scoring system.

There were also some overlapping items, which considered very similar symptoms. For example, 'dropping down feeling', 'lump felt inside' and 'lump seen outside' all loaded well onto the same factor. The item 'dropping down feeling' loaded the least well of these three items, and in addition, it was highly correlated with both 'lump felt inside' and 'lump seen outside' (0.70 and 0.78, respectively,  $P < 0.0001$  for both). This item was omitted from the questionnaire.

Although the item 'difficulty using tampons' loaded well, the question did not relate to many women because 56% reported that they no longer had periods. Within the remain-

ing women, there was also a high level of missing data for this item, and it was not sensitive to change and not reliable. It was removed from the final questionnaire.

The remaining eight vaginal symptoms ('dragging pain', 'soreness in vagina', 'reduced sensation around vagina',



**Figure 2.** Sensitivity to change. Comparison of the mean levels of key individual symptoms for symptomatic clinic group before and after surgery, with results normalised as a percentage of the maximum possible level for each symptom.

'vagina too loose', 'lump felt inside', 'lump seen outside', 'faecal evacuation' and 'vagina too dry') were entered into a further factor analysis, which yielded one major factor. Cronbach's alpha of 0.79 demonstrated good internal consistency for these eight symptoms. The standard deviation for each of the items was similar. The factor score coefficients suggested the following simple scoring scheme, each item being measured on a 4-/5-point scale:

$$\begin{aligned} \text{Vaginal-symptom score} &= 2 \times (\text{dragging pain}) \\ &+ 2 \times (\text{soreness in vagina}) + (\text{reduced sensation}) \\ &+ 2 \times (\text{vagina too loose}) + 2 \times (\text{lump felt inside}) \\ &+ 2 \times (\text{lump seen outside}) + 2 \times (\text{vagina too dry}) \\ &+ (\text{faecal evacuation}) \end{aligned}$$

### Sexual matters

All ten items relating to sexual matters were included in an initial factor analysis (filter question not included). Two eigenvalues were in excess of 1; hence, models containing one and two factors were examined. Items that did not load heavily in either model were 'leakage during intercourse' and 'partner avoids' (<0.5 for both). The prevalence of both these is relatively uncommon (Table 1). 'Leakage during intercourse' did not perform as well as other items in terms of construct validity, and 'partner avoids' demonstrated poor test-retest reliability. Both items were removed from the questionnaire.

The remaining eight items yielded one major factor, with all items loading reasonably well (>0.55). Cronbach's alpha of 0.90, however, demonstrated further redundancy and all remaining items were highly correlated with one another ( $P < 0.0001$  for the majority). The items 'sex perceived dangerous' and 'sex impossible' loaded least well onto the single factor (0.55 and 0.61, respectively) and were relatively uncommon (Table 1).

While the item 'sex life spoiled by vaginal symptoms' demonstrated the highest level of missing data, it had the highest prevalence, good test-retest reliability and stability and good construct validity. From a clinical perspective, 'sex life spoiled', 'worries about vagina interfere with sex life' and 'relationship

affected' were felt to encompass the main issues and therefore retained for the final questionnaire. While 'sex life spoiled' loaded less well than the other two items, all loadings were greater than 0.62. The internal consistency of these three items remained high (Cronbach's alpha 0.84). The factor score coefficient for 'sex life spoiled' was approximately 3/8 of the magnitude of the other two items. Taking into account that this item was measured on an 11-point rather than 4-point scale, the following simple scoring scheme was adopted:

$$\begin{aligned} \text{Sexual matters score} &= (\text{sex life spoiled}) \\ &+ 8 \times (\text{worries about vagina interfere with sex life}) \\ &+ 8 \times (\text{relationship affected}) \end{aligned}$$

### Validating the scoring system

Descriptive statistics were calculated for the factor scores of the community sample (77 women), the urogynaecology clinic sample before surgery (141 women) and the clinic sample 3 months after surgery (66 women). The vaginal symptom score had a possible minimum of 0 and maximum of 53 and the sexual matters score had a possible minimum of 0 and maximum of 58. These statistical results, shown in Table 2, indicate that the scoring system can clearly differentiate between the different samples. Figure 3 illustrates the scoring system by comparing the mean vaginal symptom score and the mean sexual matters scores for the community group, the urogynaecology clinic group before surgery and the clinic group 3 months after surgery.

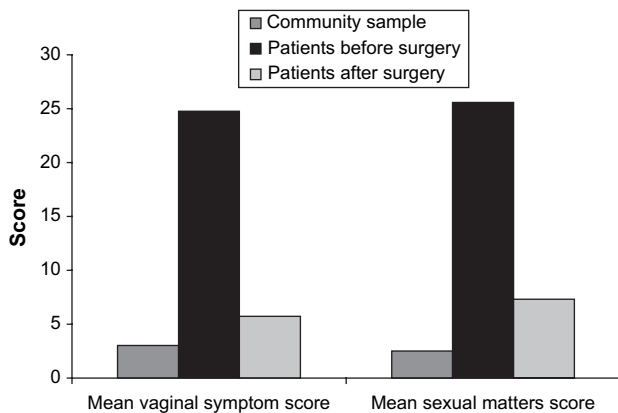
## Discussion

Throughout this project, our aim has been to develop a robust self-completion questionnaire for evaluating the frequency, severity and impact of vaginal symptoms and related sexual matters. Although originally aimed at the assessment of pelvic organ prolapse, the questionnaire was subsequently broadened to cover symptoms pertaining to female lower genital tract dysfunction and its effect on sexual life. Clinicians

**Table 2.** Verification of the scoring system: statistical results comparing the mean vaginal symptoms score and the mean sexual matters score for different samples

	Community sample (n = 77)	Clinic sample before surgery (n = 141)	Clinic sample after surgery (n = 66)
<b>Vaginal symptoms score (maximum = 53)</b>			
Mean score (SD)	3.0 (3.1)	24.8 (10.4)	5.7 (4.4)
Median score (range)	4 (0–16)	24 (4–46)	5 (0–21)
<b>Sexual matters score (maximum = 58)*</b>			
Mean score (SD)	2.5 (6.5)	25.6 (16.6)	7.3 (14.9)
Median score (range)	0 (0–31)	21 (0–58)	0 (0–58)

\*Sexually active women only.



**Figure 3.** Verification of the scoring system. Comparison of the mean vaginal symptoms score and mean sexual matters score for the community sample, symptomatic clinic sample before surgery and clinic sample after surgery.

involved in the development of the instrument consider that this wider aim has been achieved with a high level of content validity.

The variable relationship between the level and the impact of symptoms of pelvic organ prolapse has been widely acknowledged.<sup>1,3,6,7</sup> While vaginal symptoms, particularly those attributed to pelvic organ prolapse, are prevalent among the general population, they are not always bothersome, even to those reporting severe symptoms.<sup>1,10</sup> To assess the impact of vaginal symptoms comprehensively, it is therefore necessary to measure both the level of an individual's symptoms and the extent to which they impair their life. This is particularly important when making a decision as to whether an individual is likely to require or benefit from treatment, and in evaluating the effectiveness of such treatment. The ICIQ-VS questionnaire is designed to do this.

The studies reported here indicate that the ICIQ-VS questionnaire exhibits high criteria of validity, reliability and sensitivity to change. In-depth interviewing indicated that most items were easily understood, although some ambiguous items were identified and subsequently modified. Most women happily completed the questionnaire (developmental version) within 10–15 minutes, with a low level of missing data. The ICIQ-VS questionnaire is also clearly able to differentiate between community and clinical populations, indicating good construct validity. Although piloting of the questionnaire showed that some symptoms, e.g. dragging pain, dry vagina, vaginal soreness and pain on intercourse, were found to be quite common (30–42%) in the general community group, this is consistent with the level (10–30%) of prolapse reported for the general population.<sup>3,29</sup> This draws attention to the need to relate questionnaire responses to the other clinical and objective factors found in patients.

In addition to being valid and reliable, a questionnaire that is intended for use in measuring the outcome of treatments must be sensitive to change. We have shown that the ICIQ-VS questionnaire is sensitive to changes in patients' symptoms following surgical intervention for pelvic organ prolapse. This provides evidence of the suitability of the questionnaire for use both in routine clinical practice to monitor the status of individual patients or assess clinically important changes following treatment, and in health services research to assess the efficacy of intervention.

The developmental version of the ICIQ-VS questionnaire originally included 27 items organised under three headings: vaginal symptoms (14 items plus 1 filter question), sexual matters (ten items plus one filter question) and quality of life (one item). However, while internal consistency for the two subsets of items was excellent, some redundancy was indicated and these items were removed from the final version of the questionnaire.

Overall, it proved possible to reduce the ICIQ-VS questionnaire in size from 27 items in the development version (Appendix 1) to 14 items in the final version (Appendix 2) without compromising validity, stability or sensitivity. The internal consistency of the final reduced version of the questionnaire remained high (Cronbach's alpha 0.79 and 0.84 for vaginal and sexual symptoms, respectively).

A simple scoring system, not including the 'bother' sub-questions, has been developed, which is suitable, scientifically justified and demonstrates adequate psychometric properties. The scoring system includes one simple score for the eight vaginal symptoms 'dragging pain', 'soreness in vagina', 'reduced sensation around vagina', 'lump felt inside', 'lump seen outside', 'vagina too dry', 'vagina too loose' and 'faecal evacuation' and the separate (unscored) symptom 'vagina too tight', and a similar simple score for the three sexual matter items 'sex life spoilt by vaginal symptoms', 'worries about vagina interfere with sex life' and 'relationship affected'.

It would be useful at some stage to test out this ICIQ-VS subjective questionnaire against an objective measurement of prolapse, for example, using the pelvic organ prolapse quantification system, although it might be difficult to think of an objective way of measuring, e.g. vaginal dryness or decreased vaginal sensation or soreness. Clearly, much of the symptomatology is subjective, underlining the importance of an unambiguous and reliable questionnaire in elucidating problems.

## Conclusion

The ICIQ-VS questionnaire meets the need for a simple, robust and widely applicable self-completion questionnaire to assess a comprehensive range of vaginal symptoms and sexual matters and their impact on quality of life, in particular those of pelvic organ prolapse. It will be of use in routine clinical practice for simple patient evaluation, to facilitate

patient–clinician encounters, to monitor patients' symptoms over time and to assess the effectiveness of treatment. Importantly, the questionnaire measures both the severity and the perceived impact of symptoms. In addition, the questionnaire may be of use in research as an outcome measure to assess the effectiveness of treatment interventions.

The ICIQ-VS questionnaire is quickly and easily completed and provides clinicians with a practical low-cost tool. The final shortened version of the questionnaire has been shown to have high levels of validity, reliability and sensitivity when evaluated using standard psychometric methods. The ICIQ-VS questionnaire has been exhaustively tested and is now ready for use. It is freely available to clinicians and researchers. Copies can be requested from the ICIQ office at [www.iciq.net](http://www.iciq.net) or by email to Ms Nikki Gardener at [nikki\\_gardener@bui.ac.uk](mailto:nikki_gardener@bui.ac.uk).

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Details of the ICIQ-VS questionnaire shown in Appendices 1 and 2 are reproduced with kind permission from the ICIQ Group. ■

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**Appendix 1.** Developmental version of the ICIQ-VS: main items**Vaginal symptoms**

- 1a. Are you aware of dragging pain in your abdomen?
- 1b. How much does this bother you?
- 2a. Are you aware of soreness in your vagina?
- 2b. How much does this bother you?
- 3a. Do you feel that you have reduced sensation or feeling in or around your vagina?
- 3b. How much does this bother you?
4. Do you currently have pessary or ring inside your vagina for treatment of prolapse?
- 5a. Do you feel that something is dropping down inside your lower abdomen or vagina?
- 5b. How much does this bother you?
- 6a. Do you feel that your vagina is too loose or lax?
- 6b. How much does this bother you?
- 7a. Are you aware of a lump or bulge coming down in your vagina?
- 7b. How much does this bother you?
- 8a. Do you feel a lump or bulge coming out of your vagina altogether, so that you can feel it or see it on the outside?
- 8b. How much does this bother you?
- 9a. Do you have to insert a finger into vagina to help empty your bladder?
- 9b. How much of a problem is this for you?
- 10a. Do you have to insert a finger into your vagina to help empty your bowels?
- 10b. How much of a problem is this for you?
- 11a. Do you have pain or discomfort because of a dry vagina?
- 11b. How much does this bother you?
- 12a. Do you feel that your vagina is too dry?
- 12b. How much does this bother you?
- 13a. Do you feel that your vagina is too tight?
- 13b. How much does this bother you?
14. (Filter question) Do you have periods?
- 15a. Do you have difficulty keeping tampons in your vagina?
- 15b. How much does this bother you?

**Sexual matters**

- 16a. Do you think that it is dangerous to have sexual intercourse because of your vaginal symptoms?
- 16b. How much does this bother you?
- 17a. Do you think it is impossible to have sexual intercourse because of your vaginal symptoms?
- 17b. How much does this bother you?
18. How much do you think that your sex life has been spoilt by vaginal symptoms?
19. (Filter question) Do you have sex life at present?
- 20a. Do you have pain when you have sexual intercourse?
- 20b. How much does this bother you?
- 21a. Do you leak urine during or after sexual intercourse?
- 21b. How much does this bother you?
- 22a. Do worries about your vagina interfere with your sex life?
- 22b. How much does this bother you?
- 23a. Do you feel that relationship with your partner is affected by vaginal symptoms?
- 23b. How much does this bother you?
- 24a. Do you avoid sexual intercourse because of vaginal symptoms?
- 24b. How much does this bother you?
- 25a. Do you feel that your partner avoids sexual intercourse with you because of your vaginal symptoms?
- 25b. How much does this bother you?
- 26a. Do you avoid sexual intercourse because you think it will make your vaginal symptoms worse?
- 26b. How much does this bother you?

**Quality of life**

27. Overall, how much do vaginal symptoms interfere with your everyday life?

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Appendix 2. Final version of the ICIQ-VS.

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Initial number

ICIQ-VS 10/05

**CONFIDENTIAL**

## VAGINAL SYMPTOMS QUESTIONNAIRE

Many people experience vaginal symptoms some of the time. We are trying to find out how many people experience vaginal symptoms, and how much they bother them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

Please write in today's date:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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DAY

MONTH

YEAR

Please write in your date of birth:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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DAY

MONTH

YEAR

### Vaginal symptoms

**1a. Are you aware of dragging pain in your lower abdomen?**

- never  0  
 occasionally  1  
 sometimes  2  
 most of the time  3  
 all of the time  4

**1b. How much does this bother you?**

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10  
 not at all a great deal

**2a. Are you aware of soreness in your vagina?**

- never  0  
 occasionally  1  
 sometimes  2  
 most of the time  3  
 all of the time  4

**2b. How much does this bother you?**

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10  
 not at all a great deal

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**3a. Do you feel that you have reduced sensation or feeling in or around your vagina?**

not at all  0

a little  1

somewhat  2

a lot  3

**3b. How much does this bother you?**

*Please ring a number between 0 (not at all) and 10 (a great deal)*

0 1 2 3 4 5 6 7 8 9 10  
not at all a great deal

Prolapse is a common condition affecting the normal support of the pelvic organs, which results in descent or 'dropping down' of the vaginal walls and/or the pelvic organs themselves. This can include the bladder, the bowel and the womb. Symptoms are usually worse on standing up and straining (e.g. lifting, coughing or exercising) and usually better when lying down and relaxing.

Prolapse may cause a variety of problems. We are trying to find out how many people experience prolapse, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

**4a. Do you feel that your vagina is too loose or lax?**

not at all  0

a little  1

somewhat  2

a lot  3

**4b. How much does this bother you?**

*Please ring a number between 0 (not at all) and 10 (a great deal)*

0 1 2 3 4 5 6 7 8 9 10  
not at all a great deal

**5a. Are you aware of a lump or bulge coming down in your vagina?**

never  0

occasionally  1

sometimes  2

most of the time  3

all of the time  4

**5b. How much does this bother you?**

*Please ring a number between 0 (not at all) and 10 (a great deal)*

0 1 2 3 4 5 6 7 8 9 10  
not at all a great deal

**6a. Do you feel a lump or bulge come out of your vagina, so that you can feel it on the outside or see it on the outside?**

- never  0  
 occasionally  1  
 sometimes  2  
 most of the time  3  
 all of the time  4

**6b. How much does this bother you?**

*Please ring a number between 0 (not at all) and 10 (a great deal)*

- 0 1 2 3 4 5 6 7 8 9 10  
 not at all a great deal

**7a. Do you feel that your vagina is too dry?**

- never  0  
 occasionally  1  
 sometimes  2  
 most of the time  3  
 all of the time  4

**7b. How much does this bother you?**

*Please ring a number between 0 (not at all) and 10 (a great deal)*

- 0 1 2 3 4 5 6 7 8 9 10  
 not at all a great deal

**8a. Do you have to insert a finger into your vagina to help empty your bowels?**

- never  0  
 occasionally  1  
 sometimes  2  
 most of the time  3  
 all of the time  4

**8b. How much does this bother you?**

*Please ring a number between 0 (not at all) and 10 (a great deal)*

- 0 1 2 3 4 5 6 7 8 9 10  
 not at all a great deal

**9a. Do you feel that your vagina is too tight?**

- never   
 occasionally   
 sometimes   
 most of the time   
 all of the time

**9b. How much does this bother you?**

*Please ring a number between 0 (not at all) and 10 (a great deal)*

- 0 1 2 3 4 5 6 7 8 9 10  
 not at all a great deal

## Sexual matters

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

**10. Do you have a sex life at present?**

yes  1

no, because of my vaginal symptoms  0

no, because of other reasons  2

**If NO, please go to question 14**

**11a. Do worries about your vagina interfere with your sex life?**

not at all  0

a little  1

somewhat  2

a lot  3

**11b. How much does this bother you?**  
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

not at all a great deal

**12a. Do you feel that your relationship with your partner is affected by vaginal symptoms?**

not at all  0

a little  1

somewhat  2

a lot  3

**12b. How much does this bother you?**  
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

not at all a great deal

**13. How much do you feel that your sex life has been spoilt by vaginal symptoms?**

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

not at all a great deal

## Quality of life

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

**14. Overall, how much do vaginal symptoms interfere with your everyday life?**  
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

not at all a great deal

**Thank you very much for answering these questions.**

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