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Imperial College Healthcare NHS Trust

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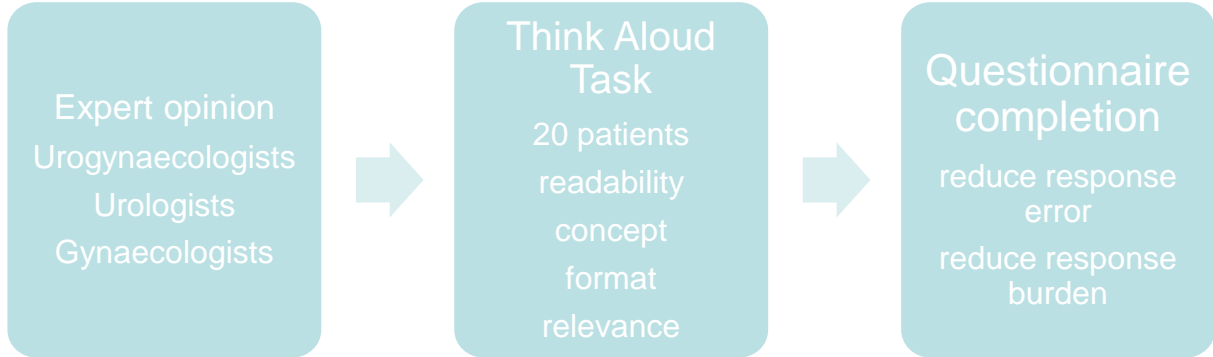2. Khullar, Vikram, Imperial College Healthcare NHS Trust

Hypothesis / aims of study

This study aims to create the first validated tool for the objective assessment of urological chronic pelvic pain using the ICS terminology which can be used in conjunction with history taking and examination.

Study design, materials and methods

Pain and lifestyle questions were devised with the use of ICS standards, literature review of established pain assessment questionnaires currently in use, expert opinion, and patient focus group for content and face validity.

Women reporting Chronic Pelvic Pain (CPP) which is pelvic pain for more than 6 months, over 18 years of age, and with a good understanding of the English language were recruited to answer the newly devised questionnaire alongside the McGill's pain questionnaire, which is a widely used validated pain questionnaire in Gynaecology. Pain location was assessed using body maps. Pain triggers such as bladder habits, menstruation, and sexual intercourse were assessed using frequency and severity scales.

Expert opinion
Urogynaecologists
Urologists
Gynaecologists
→
Think Aloud Task
20 patients
readability
concept
format
relevance
→
Questionnaire completion
reduce response error
reduce response burden

The questionnaire was devised with key themes of pain location and characteristics, exacerbating and relieving factors, impact on sexual function, mood, work, and lifestyle. Each symptom asked about had a severity of impact on quality of life (QoL) scale. Overall, a question-based questionnaire was selected.

Sample size power calculation of 310, for power of 0.8, SD 0.34, statistical significance 0.05. Sample size for construct validity of 50.

All data were transformed to numerical form and statistical analysis was performed using SPSS.

Validation:

✓ Pearson's Correlation (test-retest reproducibility for each item)
　0= no association, <0 = negative association, 0-1 indicates a positive association
✓ Intraclass correlation coefficient (ICC, assess the association between symptom and severity with subscores)
　ICC > 0.9 = excellent, ICC > 0.75 = good, ICC >0.5 =moderate and ICC < 0.5 = poor correlation

✓ Cronbach's alpha (internal consistency for each subscale) for each subscale separately.
　0= no correlation, 1= high correlations among the items on a scale.

✓ Cohen's Kappa (Interrater reliability)
　<0 = no agreement, 0.01-0.20 = none to slight, 0.21-0.40 = fair, 0.41- 0.60 = moderate, 0.61-0.80 = substantial and 0.81-1.00 = almost perfect agreement.

Results and interpretation

A total of 360 questionnaires were completed, including 50 which were repeated within 2 weeks for test-retest assessment. The method of completion was 293 and 17 questionnaires completed in paper form and electronically consecutively.

Mean blank rate was 11.48% 90-46.7%) vs 22.19% 90-49.3%) for McGill's pain questionnaire. Usability and patient acceptance was also assessed.

The relevance was rate as 'yes' in 100% of participants with bladder pain and 98% of overall CPP group. The overall usability was rated as 'acceptable' by 99% of participants (307/310 participants) and 'somewhat acceptable' by 0.7% (2/310 participants) and 'unacceptable' by 0.3% (1/310 participants). This was explained by the participant feeling that an electronic version would be more environmentally friendly. The length was felt to be 'too long' by 43% (133/310) and 'just right/acceptable' by 57% (177/310).

Pearson's correlation (test-retest was > 0.5 for all items but one (0.383), which was the description of pain type. For long term reliability, good to excellent values were found for all subitems but three. The questions on being sexually active and pain characteristic of relation with bladder filling and pain distribution scored ICC of 0.61, 0.71 and 0.56 respectively.

Cronbach's alpha coefficient results (Table 1) were above 0.9 (Excellent) for all 14 relevant question items. McGill's questionnaire showed the variance of 0.63 (strong). Criterion Validity When compared to the McGill's questionnaire for items on pain location, type and severity, strong correlation was found r^2 =0.63. Interrater reliability Cohen's kappa (inter-rater reliability) of 0.64-0.76.

Figure 1: An example of the questionnaire

➤ Validated patient reported questionnaire which encompasses the quality of pain, patient symptomology, and it's impact of quality of life including sexual function and relationships.

➤ High patient acceptance and relevance

➤ Subscale scores – identify key symptoms

➤ Likert scales with corresponding visual analogue scores for bother. This allows measurement of minimal important differences; these are patient derived scores that reflect changes in a clinical intervention that are meaningful to the patient.

➤ A 'substantial' inter-rater and intra-rater reliability for the qualitative items of the questionnaire. All items of the questionnaire good or excellent internal consistency suggesting that the items are worded appropriately and asked of an appropriate sample.

Table 1 : unfilled items and internal consistency of individual key aspects of the questionnaire.

Item		Cronbach's alpha	Unfilled items
Pain location	4 locations inc. combination	N/A complex clinical phenomenon that do not have to be correlated.	0
Pain type	4 subtypes	N/A	0
Pain description	7 options	N/A	0
Radiation	6 locations	N/A	0
Pain duration	6 month- over a year (3)	N/A	0
Pain -bladder	Categories (5)	0.956	2.06% (32/1550)
	scale	0.980	34.3% (3531/1550)
Periods	Y/N	n/a	10% (31/310)
Period Pain	Categories	0.995	1.77% (11/620)
	Numerical Scale	0.991	8.54% (53/620)
Sexually active?	Y/N	n/a	10% (23/310)
Pain during/after SI	Categories	0.930	2.26% (7/310)
	Numerical scale	0.975	8.39% (26/310)
Bowel related	Categories (3)	0.943	3.66% (34/930)
	Numerical scale (3)	0.976	39% (363/930)
ADL related pain	Categories (4)	0.939	3.3% (41/1240)
	Numerical scale (4)	0.980	42.82% (531/1240)
Food/drink related	Categories (4)	0.947	30.1% (280/930)
	Numerical scale (4)	0.973	46.7% (434/930)
Pain time	Under 1 min-ATT (7)	n/a	1.6% (5/310)
Relieving factors	4 factors	0.922	4.52% (56/1240)
Associated Features	10 symptoms	0.983	8.71% (270/3100)
Lifestyle	12 features	0.971	6.39% (198/3100)

Conclusions

The aims of this study were to develop a validated instrument for assessing chronic bladder pain, it's associated symptoms and impact on lifestyle. The data indicates that this is a validated and reliable questionnaire with a high content validity and internal consistency. At the time of writing, we believe that this is the only validated questionnaire focusing on urologic chronic pelvic pain.

References

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