

Development and psychometric evaluation of ICIQ-PadPROM: A quality of life questionnaire to assess the treatment effect of absorbent continence products

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Short Title: PadPROM Continence Product Quality of Life Questionnaire

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Abstract

Aim: To describe the development and evaluation of the ICIQ-PadPROM, the first self-reported quality of life questionnaire to assess the treatment effect of absorbent continence products, a new addition to the set of ICIQ modules providing international standardised assessment of lower pelvic dysfunction.

Methods: Developed in four phases, question items semi-structured interviews were conducted with pad using men (n=19), women (n=6), with secondary analysis undertaken on transcripts (n=15 women) from a previous study. Validity of a draft 67 item questionnaire was tested through cognitive debriefing interviews (n=34) and postal survey (n=239). Reliability was evaluated by 65 users with a three week interval between completions. Expert opinion and factor analysis were used to reduce the final questionnaire to 17 scored and 3 unscored items.

Results: The questionnaire comprises four scored domains: Pad design and Physical Effects (7 items), Psychological Effects (4 items), Social Effects and Pad Leakage (3 items) and Burden of Pad Use (3 items), plus 3 unscored items. Levels of missing data ranged from 0–7.6%, with fair-to-moderate agreement. The Cronbach's alpha coefficient for all question items was 0.91 and factor analysis was undertaken to reduce redundancy.

Conclusion: Existing incontinence-related outcome tools measure change in symptoms and quality of life impact. The ICIQ PadPROM questionnaire is the first to measure the impact of absorbent continence products on quality of life in the absence of any change in symptoms and will help policy-makers, clinicians, industry and researchers to evaluate different products designs and materials for different patient populations.

Introduction:

This paper describes the development and evaluation of a Patient Reported Outcome Measure (PROM) to assess the treatment effect of absorbent products used to manage urinary incontinence (UI) on the quality of life (QoL) of adults living in the community: the International Consultation on Incontinence Modular Questionnaire (ICIQ) PadPROM.

It is widely acknowledged UI is common, and that all forms adversely affect QoL ^(1,2,3). UI has manifold implications for sufferers, including increased risk of depression and anxiety and poorer life satisfaction ⁽²⁾. Although UI can often be improved, a substantial number of people who seek help for their UI will continue to experience episodes of urine leakage following treatment. Since these individuals are least amenable to treatment they will generally rely on appropriate containment products to manage their symptoms and the selection of suitable containment products is crucial to contain and conceal the problem of incontinence ⁽⁴⁾. Even though these products do not reduce bladder leakage, it is recognized that successful containment may bring substantial benefits by minimizing the impact of incontinence on QoL ⁽⁴⁾. Pad users are a heterogeneous group, and pads vary in design and absorbency and research suggests that the most commonly use pads are not necessarily the most cost-effective or most appropriate for an individual patients' requirements ^(5,6).

Treatments for UI are commonly directed towards decreasing symptoms and most existing health-related QoL measures are designed to evaluate change in symptoms and the impact of any symptom change on QoL. However, the main aim of using absorbent pads is to contain leakage that will likely remain unchanged. Changes in treatment (i.e. the design, use or provision of pads) would not directly affect incontinence symptoms, but could impact on the effective containment of leakage. Currently, it is unclear how absorbent pads influence QoL and a psychometrically robust patient-centered questionnaire, which reflects issues of importance to patients, is lacking ⁽⁴⁾. Without such a tool it is difficult for clinicians, policy-makers, healthcare providers and manufacturers to make systematic evaluations of the treatment effect of absorbent products.

Prior to the development of the ICIQ-PadPROM, little was known about how the key characteristics of absorbent pad designs used for UI affect QoL and there are no published questionnaires specific enough to examine the effectiveness of absorbent product designs. The impetus for this questionnaire comes from recommendations of consecutive editions of the International Consultation on Incontinence (ICI) which determined that a questionnaire specifically designed to examine pad users' perceptions of the key characteristics of absorbent products that affect their QoL was needed ^(4,7). The tool described in this paper will form part of the ICIQ which aims to provide fully validated international standardised questionnaires for lower urinary tract dysfunction, vaginal symptoms and

lower bowel dysfunction and has been developed with the following principles: high quality, validated questionnaires, to promote wider use, to standardize the assessment of the symptoms and impact on QoL of lower pelvic dysfunction.

The tool described in this paper will facilitate the evaluation of both the advantages of pad use and any associated side-effects. It will help to identify products that effectively maintain or improve QoL for the purposes of clinical practice, clinical research, product development and health service delivery.

Aim: To develop and evaluate a self-report QoL questionnaire to assess the treatment effect of absorbent continence products for use by men or women over the age of 18

Methods:

This questionnaire was developed as a module of the ICIQ project using an internationally recognised protocol, by a team comprising researchers with expertise in questionnaire development and continence technology, expert patients and specialist continence nurses. The development involved four stages: exploratory interviews, cognitive debriefing, postal survey and item reduction. Ethics approval was gained from UK National Health Service (NHS) Health Research Authority Committee South Central (10/H0501/26). In all phases the sample comprised patients who manage their urinary incontinence symptoms with absorbent products regardless of other previous or current surgical or pharmacological interventions.

Phase 1: - Exploratory Interviews and item generation

Secondary Analysis was undertaken on interviews with female pad users (n=15) from Getliffe et al's (2007)⁽⁵⁾ earlier study to ascertain their views and perspectives on the treatment effects of absorbent products used to manage light UI. This work formed the basis for further interviews required to establish saturation, and to ensure that the content of the developing questionnaire was relevant to both male (n=19) and female (n=6) pad users with all levels of incontinence. A purposive sampling strategy was used to capture the views of a heterogeneous population from two NHS trusts in England. Interviews were recorded and transcribed. Thematic analysis was used to interpret the data⁽⁸⁾.

Phase 2: – Cognitive debriefing

From Phase 1 findings, a questionnaire comprising 67 items was drafted with the support of an expert panel (n=6, including continence advisors, a questionnaire design expert, and academic researchers) who participated in three rounds of a modified Delphi process to reach consensus on the key QoL concepts on absorbent pad use to be included in the tool. Face-to-face structured cognitive debriefing

interviews (n=34) were undertaken to reduce the number of items (n=47), evaluate ease of use, interpretation, acceptability of terminology, length and format of the questionnaire^(9,10). Participants were recruited from a single English NHS Trust continence service.

Phase 3: – Postal Survey

The final developmental version of the ICIQ-PADPROM was administered as a postal survey to pad users (n=600) on databases of continence services in four English NHS Trusts.

Content validity - The postal survey data was analysed for missing data in order to identify questions that could be irrelevant or difficult to answer.

Reliability:

Stability - The stability of the ICIQ-PADPROM was initially evaluated using test-retest assessment to ensure that the tool was capable of ongoing monitoring of the QoL status of pad users. Sixty-five pad users with a mean age of 70.3 years (age range between 35 to 97 years old) completed the developing ICIQ-PADPROM on two separate occasions within a three-week time interval to evaluate the stability of the instrument. The three week interval was considered to be adequate, as the pad users' level of leakage was anticipated to remain stable over that period.

Internal Consistency - The instrument's internal consistency was estimated by Cronbach's alpha coefficient using the baseline data (n=239). The Cronbach's alpha coefficient for all question items was found to be 0.91 suggesting that some items within the instrument were redundant⁽¹¹⁾. Given the length of the questionnaire, some redundancy was anticipated and this result supported item reduction.

Phase 4: – Item Reduction and factor analysis

The draft questionnaire contained 47 question items following revisions from the cognitive debriefing process (including four demographic items). This was considered to be lengthy and it was judged that further reduction was likely to yield a brief yet comprehensive measurement with increased acceptability in both clinical and research settings and reduced redundancy. Further exploration of the dataset was undertaken to identify which items correlated highly with each other using a correlation matrix and exploring paired items with correlation values greater than 0.7, indicating redundancy. An exploratory factor analysis was used to investigate the underlying structure of the questionnaire, identify possible domains and assist item reduction. Expert opinion and a review of the qualitative evidence was undertaken to identify the important items for inclusion to ensure the resulting questionnaire retained clinimetric relevance.

Results

Phase 1: Male pad users (n=19) (i.e. 8 men with light UI and 11 men with heavy UI), and female pad users (n=6) with heavy UI took part in semi-structured interviews, which were analysed with the transcripts (n=15) of interviews with women with light leakage from a previous study⁽⁵⁾ to generate

the items for the draft questionnaire. Thematic analysis identified 67 items with key themes of containment, planning ahead, physical impact, psychological impact and social impact. There were some differences between men and women regarding the key issues found to affect their QoL, with male pad users describing some previously unreported QoL issues. These concepts included: modification of the pads (e.g., cutting them in half) to meet their anatomical needs, and spouse support (e.g., their partners purchasing supplementary products such as perfumed waste bags, or carrying pads in their handbags). Male pad users also reported some tension in their relationships with their partners associated with the disposal of used absorbent products (e.g., not wrapping the used pads in the perfumed bags, or not disposing of them in a timely fashion). Similarly almost all male pad users reporting difficulties changing their pads outside of their homes, as many public toilets have replaced cubicles and waste bins with urinals and hand dryers compromising their privacy and ability of discreetly dispose of their used pads. Male pad users more often reported that they were in a relationship compared to female pad users, and this could (partly) explain the gender differences mentioned above.

Phase 2:

Based on the feedback of 9 men and 9 women with light UI, and 6 men and 10 women with heavy UI (from a total of 34 cognitive debriefing interviews), fourteen iterations of the developmental ICIQ-PADPROM were undertaken. Versions of the developmental ICIQ-PADPROM were reviewed and revised iteratively following successive rounds of interviewing. Changes focused on clarification of the instructions, the wording of the question items and refining response categories and instructions to make them more intuitive. Modifications increased coherency as similar items were grouped. At the end of Phase 2 the draft tool contained 47 items covering demographic factors, pad design, psychological effect, physical effect, social effect and financial burden.

Phase 3:

Baseline data for the validation studies was collected from a total of 239 pad users (116 men and 123 women) with a mean age of 65.3 years (Table 1). The overall response rate of the postal survey was 39.8 percent. A low rate had been anticipated due to the frail and elderly patient population dominating this group.

Content validity - Missing data was generally low (0-5.0%) with the exception of questions on social impact, burden of use and sexual activities (5.9-7.6%) (Table 2). A small proportion of pad users found it difficult to separate issues of social functioning relating to pad use and those associated with factors of co-morbidities. The question item enablement also had a missing value of 7.6 percent, which could be linked to the effect of co-morbidities. Nevertheless, given the sensitive nature of pad use, a missing value of about 7.0 percent was considered acceptable.

Reliability:

Stability - Sixty-five pad users (34 women and 31 men) with a mean age of 70.3 years (age range 35-97 years old) completed the developing ICIQ-PADPROM on two separate occasions three weeks apart to evaluate the stability of the instrument (Table 1). As in the validation test sample, the respondents were diverse in terms of age, and level of incontinence. The weighted Kappa statistic provided evidence of “moderate” (K , 0.41-0.60) or “fair” (K , 0.21-0.40) agreement in 45 of the 47 items analysed, indicating their acceptability for measurement in a healthcare setting, and these findings were taken into account in the item reduction phase. Values for the items in the final tool are provided in Table 4.

Internal Consistency - The Cronbach’s alpha coefficient for all question items within the newly developed ICIQ-PADPROM was examined using the baseline dataset and found to be 0.91. Higher values (> 0.9) implied some items within the instrument were redundant. Given the length of the questionnaire, some redundancy within the developing ICIQ-PADPROM was anticipated. Thus the result of internal consistency was useful, as it supported the removal of some question items from the ICIQ-PADPROM.

Phase 4: Item Reduction and factor analysis

Factor loadings ranged from 0.41 to 0.88 across eight factors with little variability (Table 3). Between two and nine items loaded onto each factor as indicated. Ten items - design, disposal, smell, noise, leakage, pad modification, awareness, confidence, family and friends, and employment did not load (loadings < 0.39 for all) onto any factor in these models. However, these items were identified as essential items for inclusion on the instrument from the pad users’ and experts’ perspectives, and were retained at this stage.

A varimax rotation technique was applied to each round of the factor analysis to make the output interpretable. The data was also interrogated using models composed of three to four factors to help determine clusters of the items, and if there were any remaining redundant items. On this basis a critical review of the evidence from the qualitative development, content validation and reliability studies was undertaken to identify possible redundant items and those considered necessary for inclusion. A process of critical thinking was used to reduce the length of the final questionnaire without compromising the assessment provided to ensure its clinimetric and psychometric robustness. Table 4 shows the psychometric properties of the final items.

Scoring: Items on the ICIQ-PadPROM were coded from 0 “never” to 4 “All the time” or in a reverse order where required to reflect the nature of the relationship. In addition, question three items (“Is your pad

easy to change?”, “Is your pad the right shape?”, and “What is your overall opinion of your pad?”) in the pad design and physical effects domain were coded from 0 indicating “very easy” or “very good” to 4 “very poor” or “very difficult”. Simple scores were then inferred by adding the frequency of the responses in each domain. A further dataset will be required to validate the scoring system.

Discussion

This paper describes the development of the ICIQ-PADPROM questionnaire and its psychometric properties. The questionnaire provides a robust tool to examine how absorbent continence products used to manage UI influence QoL. The ICIQ-PADPROM has been developed primarily from the perspectives of the pad users, and in collaboration with experts working in the field of continence care and the development of absorbent products.

The final version of the ICIQ-PADPROM (Figure 1) comprises four scored domains: (1) pad design and physical effects, (2) psychological effects, (3) social effects and leakage and (4) burden of the pad use. A further three unscored items that provide evaluation of (a) pad modification, (b) sleep disturbance, and (c) ability to take part in work activities were also included.

The interviews with the pad users determined the key issues relating to absorbent pad use which affect QoL and evaluated the acceptability of the wording and terminologies used within the questionnaire. Analysis of the qualitative data indicated that, although many of the key issues were similar for male and female pad users and were consistent with concepts reported by Getliffe et al 2007⁽⁵⁾, there were also some important and notable differences between genders that have not previously been identified. These include the lack of anatomical coverage provided by unisex products, relationship difficulties often related to disposal of products and the re-engineering of products by cutting and altering to better suit men’s needs. These findings are important when considering the selection and provision of pads for men and the support they are given in managing their products.

The tool makes an important contribution to helping policy makers, service providers, clinicians, manufacturers and researchers evaluate and choose between different product designs, features and materials for different patient populations (e.g. men or women, heavy or light leakage). Using an absorbent product to contain leakage can be regarded as a treatment and, as such, the impact of the product should be evaluated. The treatment effect of pads (i.e. their potential for both advantageous and negative effects) has been given little consideration and to date there have been relatively few clinical trials of products ⁽⁴⁾. The ICIQ-PADPOM has been psychometrically tested and provides a standardised tool to examine how key characteristics of absorbent pads impact on quality of life.

Limitations

It is acknowledged that the majority of recruitment was conducted through the databases of the continence services in English NHS Community Trusts, which may have introduced bias. The response rate reflects the predominantly frail elderly population, who are disproportionately affected by multiple long-term conditions, including dementia. An assumption was made that the non-responders were the same as those who were recruited. However, the pad users who were recruited may have over-represented those whose QoL is most affected by pad use, and whose participation may have been motivated (in part) by the hope of accessing the best absorbent products to manage their urine loss.

No interviews were carried out among pad users who did not seek help for their UI symptoms and who may have represented either end of the severity spectrum with regard to the impact of pad use on their QoL. Further qualitative studies would be beneficial to provide more evidence of the applicability of the ICIQ-PADPROM to pad users in different settings such as residential and nursing homes, as well as its potential use in epidemiology studies. The wider applicability of the ICIQ-PADPROM to those pad users who were not well represented within this study also requires evaluation, including populations outside of the UK. The intention was to develop a tool relating to UI and it might not be suitable for providing a QoL assessment for patients using absorbent products to manage faecal incontinence. Further research will be needed to increase the knowledge of the ICIQ-PADPROM's clinical applicability, and its acceptability.

It is expected that the ICIQ-PADPROM will continue to evolve. Sensitivity to change/responsiveness testing is required and the tool will require further evaluation in different study populations with pad users. At present the ICIQ-PADPROM is the best available validated user reported assessment tool for examining the impact of absorbent pad designs on QoL of pad users.

Conclusion

Little research has been published on living with incontinence with regard to absorbent products. The ICIQ-PadPROM makes an important contribution to this limited body of work by providing the first self-report tool to evaluate the treatment effect of absorbent continence products. It encompasses the factors that are important to users and have the potential to affect their QoL, as well as being relevant to clinical experts. The development of this tool will allow the impact of future clinical or research interventions on patients' QoL to be measured.

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Table 1: Dataset used in the validation studies of the ICIQ-PADPROM

Datasets	Study Population	Mean Age (range)	Response Rate (%)
<u>Validation studies</u>	Total potential participants invited (N)=600		
	Respondents		239/600
	Female (n) = 123	63.4 (29-89)	(39.8)
	Male (n) = 116	67.1 (27-97)	
	Overall 65.3 years (27- 97)		
	Level of Incontinence (determined by disposable pad designs)		
	<u>Moderate/Heavy Urinary Incontinence</u>		
	Diaper (n) = 126 (52.3)		167/239 (69.6)
	Belted Diaper (n) = 14 (5.9)		
	Pull-ups (n) = 27 (11.4)		
	<u>Light Urinary Incontinence</u>		
	-Small Insert Pad (n) = 49 (20.7)		72/239 (30.4)
	- Pouch/Leaf (n) = 16 (6.8)		
	-Other products (n) = 7 (2.9)		
Study Population			
Mean Age (range)			
Respondents		65/239	
-Female (n)	68.6 (35-89)	(27.2)	
-Male (n)	72.0 (47-97)		
Overall 70.3 years (35-97)			
Level of incontinence (determined by disposable pad designs)			
<u>Moderate/heavy Urinary Incontinence</u>			
Diaper (n)=28 (43.1)		40/65 (61.5)	
Belted Diaper (n)=4 (6.15)			
Pull-ups (n)=8 (12.3)			
<u>Light Urinary Incontinence</u>			
Insert Pad (n)=15 (23.1)		25/65 (38.5)	
Pouch/Leaf (n)= 6 (9.2)			
Other products (n)= 2 (3.1)			
Missing data (n)= 2 (3.1)			
Second copy completed			
Test-retest reliability			

Table 2: Question item with missing data (in %) on the developmental ICIQ-PADPROM

Items	Missing Data (%)	Items	Missing Data (%)
Pad Design		Physical Effect	
Q7- Convenient - easy to use	0.4	Q29 - Skin irritation	2.9
Q10 - Shape	0.8	Social Impact	
Q11- Fixed - stay in place	0.0	Q33 - Take part in social activities	6.8
Q13 - Coverage - cover all the right places	0.0	Q34 - Socialise with close friends /family	6.4
Q14 - General Comfort	2.1	Sexual Relationship	
Q15 - Comfort when wet	5.0	Q40 - level of intimacy you are able to experience	7.1
Psychological Impact		Burden of Pad use	
Q16 - Worry ~ Smell	4.2	Q42 - Cost of leaks (Financial Impact)	5.9
Q18 - Pad leak (Absorbency)	2.9	Q44 - Get on with daily lives (Enablement)	7.6
Q21- Confidence in the pad	2.5	Q45 Overall Opinion	2.98
Q24 - Self-esteem	4.2		
Q27 - Discreteness	3.8		

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Table 3: Factor Loadings for the final ICIQ PadPROM domains

Factor	Number of items	Loading ranges
1	9	0.48 - 0.89 (Embarrassment, emotion, self-esteem, gender identity, gender ID, discreteness, limit drinks, personal relationship and acceptance)
2	7	0.42 - 0.82 (Ease of use, shape, fixed, fit, coverage, comfort and opinion)
3	3	0.70 - 0.80 (Sexual relationship, impact of pad use and intimacy)
4	3	0.46 - 0.70 (Social activities, socializing and travel)
5	3	0.47 - 0.63 (Pad leakage, skin health and wet comfort)
6	2	0.57 - 0.69 (Independence and enablement)
7	2	0.46 - 0.70 (Extra work and cost of leak)
8	3	0.46 - 0.60 (Pad size, thickness of pad and sleep disturbance)

Table 4: Characteristics and properties of the final ICIQ-PADPROM

Domain	Question Items	Missing Data (%)	Factor Loadings	Reliability (Kappa value)	Cronbach's alpha
Pad design and Physical effects	7a) Is your pad easy to change?	0.4	0.44	Moderate (0.49)	0.84
	8a) Is your pad the right shape?	0.8	0.64	Fair (0.40)	
	9a) Does your pad stay in place?	0.0	0.65	Fair (0.38)	
	10a) Is your pad comfortable when it is 'dry'?	2.1	0.61	Fair (0.26)	
	11a) Does your pad cover all the right places?	0.0	0.62	Fair (0.37)	
	12a) Does your pad cause skin irritation?	2.9	0.44	Moderate (0.43)	
	13a) What is your overall opinion of your pad?	2.9	0.59	Fair (0.41)	
Psychological effects	14a) Does your pad cause you to worry about smell?	4.2	0.43	Fair (0.40)	0.71
	15a) Do you worry that your pad might be visible under your clothes?	3.8	0.76	Moderate (0.50)	
	16a) Does your pad make you feel bad about yourself?	4.2	0.73	Fair (0.40)	
	17a) Does your pad affect the level of intimacy you are able to experience?	7.1	0.54	Moderate (0.56)	
Social effects	18a) Does your pad help you to socialise with close friends/family?	6.4	0.62	Moderate (0.41)	0.61
	19a) Does your pad help you to take part in social activities?	6.8	0.74	Fair (0.23)	
	20a) Does your pad help you to get on with your daily life?	7.6	0.54	Moderate (0.57)	
Leakage and burden of pad use	21a) Does your pad leak?	2.9	0.52	Moderate (0.46)	0.63
	22a) Is your pad comfortable when it is 'wet'?	5.0	0.52	Moderate (0.43)	
	23a) Does your pad affect you financially?	5.9	0.48	Fair (0.35)	
Unscored Items	Do you modify your pad?	3.0	N/A	Moderate (0.46)	N/A
	Does your pad disturb your sleep?	21.4	N/A	Fair (0.27)	N/A
	Does your pad help you to take part in work activities?	6.8	N/A	Fair (0.28)	N/A

