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Title: VALIDATION OF A NEW QUESTIONNAIRE FOR INCONTINENCE: THE INTERNATIONAL CONSULTATION ON INCONTINENCE QUESTIONNAIRE (ICI-Q)

Aims of Study

The primary objective is to assess the validity and reliability of the International Consultation on Incontinence Questionnaire Short Form (ICI-Q SF), a new self-completion questionnaire for use in research and clinical practice to quantify loss of urine and impact on quality of life (QoL). The questionnaire is being developed with the aim of being applicable to all adult men and women of all ages across all societies with symptoms of urine loss.

Methods

The ICI-Q is being assessed for validity, reliability, responsiveness to change and international applicability using standard methods of psychometric testing. Items for the questionnaire were devised following a combination of systematic reviewing of previous questionnaires, expert opinion from relevant clinicians and social scientists, and interviews with patients with incontinence. Many separate studies are underway to explore the psychometric properties of the questionnaire, including:

- (a) Content validity – interviews with, and observations of, 63 consecutive patients with incontinence; expert opinion by consensus committees; levels of missing data to assess the acceptability of the items.
- (b) Construct and criterion validity – surveys by post and in clinics of groups of individuals and patients to investigate whether the questionnaire measures what it is expected to measure – for example, differences between older and younger patients, clinic and community samples, men and women, patients with various diagnoses. Relationships between the ICI-Q and other questionnaires such as the BFLUTS, ICS*male* and King's Health questionnaires are also being assessed.
- (c) Test-retest reliability – 143 patients with incontinence (119 women, 24 men) are completing the ICI-Q at baseline and again approximately two weeks later.
- (d) Internal consistency/reliability – baseline data from a range of studies will be used to assess, by Cronbach's alpha statistic and factor analysis, the clustering and internal consistency of items, and thus their ability to be transformed into a score or range of scores.
- (e) Sensitivity to change – the ICI-Q is being included in a number of outcome studies of surgical and other therapies to assess its ability to detect change following treatment.
- (f) International validation – the ICI-Q has been professionally translated and back-translated into 7 languages.

Results

The developmental ICI-Q SF emerged from material produced by the 1998 ICI Symptom and Quality of Life Assessment Committee, following systematic review of the literature [1]. Items were included to quantify loss of urine and impact on QoL by addressing the type, frequency and severity of incontinence, the use of

protection for urine loss and the impact of incontinence on specific and general aspects of QoL. Review by clinical and social science experts indicated that the ICI-Q SF covered all important domains and symptoms.

Content validity was further evaluated in 63 consecutive patients (46 females, 17 males) aged 18 or over with UI and LUTS attending urology clinics at Southmead Hospital, UK, between October 1999 and January 2000. Small amendments to the content or format of the questionnaire/items were made via a repeating process of patient completion of the questionnaire during in-depth interview with a researcher, assessment of patients' comments and their understanding/completion of the questionnaire followed by researcher discussion. This process was repeated until a 'final' version of the ICI-Q SF was produced, comprising 10 items.

A study to assess the feasibility of self-completion of the ICI-Q SF in a clinical and a community sample was conducted. A total of 222 consecutive patients with UI (182 females, 40 males) aged 18 or over attending urology clinics at Southmead Hospital between May 2000 and March 2001 were recruited via a postal study to provide a clinic sample. A further 25 consecutive patients (16 females, 9 males) aged 18 or over attending a general practice in Bristol, UK in February 2001 were recruited as a community sample. Each patient self-completed the ICI-Q SF whilst at home.

The items in the questionnaire also demonstrate low levels of missing data on self-completion (1.2-2.4%, 1 item 3.2%).

Conclusions

The content validity of the ICI-Q SF has been established. 'Expert' evaluation indicates that the 10 items are representative of the content domain. In-depth interviews demonstrated that the majority of patients were able to complete the questionnaire unaided and the items and response categories were clearly interpreted and well understood by a wide range of patients with a variety of levels of urinary incontinence. A high level of content validity is further indicated by low levels of missing data on self-completion. The ICI-Q SF is currently undergoing further psychometric validation both in the UK and internationally and it will be launched in Paris at the Second International Consultation on Incontinence. Further data establishing the validity, reliability and responsiveness of the questionnaire are currently being analysed and will be available for presentation.

References

1. Incontinence: 1st International Consultation on Incontinence – June 28-July 1, 1998. Plymouth:Health Publication Ltd., 1999.

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