The recurrent urinary tract infection health and functional impact questionnaire (RUHFI-Q): design and feasibility assessment of a new evaluation scale

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Introduction: We aim to design a tool to assess the impact of recurrent urinary tract infection (rUTI) on quality of life (QoL) in adult women, given the notable absence of an established instrument for this purpose.
Materials and methods: Best practice guidelines in health-related survey design were reviewed. A literature review informed creation of an interview guide. Following ethical approval, 10 female patients (23-38 years) with rUTI were invited to participate in phase 1 of questionnaire design; all agreed. Individual semi-structured interviews were conducted exploring the impact of rUTI on patients' QoL. Interviews were repeated with 5 staff members (3 urology nurses and 2 consultant urologists). Responses were recorded and thematic analysis performed, to inform the design of a new questionnaire. A further 10 patients were recruited to assess feasibility of completion.

Results: All participants found available questionnaires unfit for assessment of rUTI-related QoL. Multiple themes emerged as integral to an rUTI questionnaire, including: frequency of UTIs, duration of symptoms, time to full recovery, specific symptoms of UTI, constitutional symptoms, impact on work/education, impact on leisure activities, impact on interpersonal relationships, impact on sexual relationships, psychological aspects and implications of treatment. Data saturation was reached. Based on responses, the Recurrent Urinary tract infection Health and Functional Impact Questionnaire (RUHFI-Q) was drafted, comprising 10 domains and 16 items.
Conclusions: We propose a novel self-administered questionnaire, the RUHFI-Q, as an instrument to standardize evaluation of the QoL impact of rUTI in a population of premenopausal women. Further validation studies are in progress.

Key Words: UTI, rUTI, recurrent urinary tract infection, quality of life, female urology

Introduction

Recurrent urinary tract infection (rUTI) is defined by European Association of Urology (EAU) guidelines as "recurrences of uncomplicated and/or complicated UTIs, with a frequency of at least three UTIs/year or two UTIs in the last 6 months."[1] UTI affects many adult women; US figures describe a frequency of uncomplicated cystitis in young sexually active women of approximately 0.5 episodes per person per year, with a 27% recurrence rate of UTI within 6 months following a first episode.[2,3] Recurrent urinary tract infection has been shown in recent large European studies to have a significant negative impact on patients' quality of life, as well as a significant societal and economic burden.[4,5]

To our knowledge, there is currently no established instrument to assess symptom severity or quality of life (QoL) in patients suffering from rUTI. A number of questionnaires for the evaluation of lower urinary tract symptoms in adult females exist. These include

the King's Health Questionnaire[6] and the International Consultation on Incontinence Modular Questionnaire[7] which capture a variety of incontinence-related symptoms, and the UTI Symptom Assessment Questionnaire[8] for individual episodes of acute urinary tract infection, amongst others. None of these, however, quantifies the patient reported functional impact of rUTI. We aimed to design such a tool, using qualitative research methodology.

Materials and methods

Best practice guidelines in health-related survey design were reviewed.[9] A literature review was performed by the first author, using the MEDLINE, SCOPUS and Cochrane databases. The themes identified throughout the literature were recorded, and used to create an interview guide.

Following institutional ethical approval, 10 female patients (age range 23-38 years) with rUTI were recruited by convenience sampling during routine clinical activities to participate in phase one of questionnaire design. All patients invited to participate agreed to do so. Inclusion criteria were a diagnosis of rUTI (two infections over a 6 month period or three infections over a 12 month period, with at least one urine sample whilst symptomatic culturing a pure growth of a known uropathogen with a colony count of $\geq 10^3$ cfu/mL[1]), ability to comfortably converse in English, and willingness to participate. Patients with possible UTI in the absence of microbiological verification on at least one occasion, and those with structural or functional abnormalities of the lower urinary tract were excluded.

Individual semi-structured interviews were conducted one-on-one with each of the 10 patients recruited, exploring the subjective impact of rUTI on the patient's life. Interviews were repeated with five members of staff (three urology specialist nurses and two consultant urologists). A pilot interview, as described by other authors, was conducted with a control volunteer prior to the research interviews, to ensure coherence of questions.[10] All interviews involved the same interviewer (the first author) to minimize potential bias secondary to varied interview style, and took place in a quiet location within the hospital.

A visual guide, consisting of the main points of the interview guide typed on an A4 page, was provided to participants. All participants were aware of the general topic to be discussed in advance of the interview, allowing time for personal reflection. Participants' responses were typed, and an anonymized compiled written transcript was created.

The compiled data in transcript form was reviewed and thematically analyzed.[11] The consolidated criteria for reporting qualitative studies (COREQ) guidelines[12] were used to guide analysis and reporting.

Results of thematic analysis were used to create a new questionnaire comprising a series of questions related to the impact of recurrent urinary tract infection on QoL. A scoring system was then proposed.

Following questionnaire creation, the Flesch-Kincaid readability index[13] was applied using online software, and wording modified to ensure that the written questionnaire did not exceed a 'Grade 6' reading level. A further 10 participants were recruited to assess feasibility of completion.

Results

Domains
Ten interviews were successfully completed; data saturation was felt to have been reached by the seventh interview. Thematic analysis produced in excess of 100 verbatims, which were refined to a total of 26 codes by two of the researchers. These were categorized into 10 themes, with any differing of opinion of the researchers agreed by discourse.

The following themes emerged from the interviews as integral to a questionnaire exploring the impact of rUTI on a patient's QoL:

1. The frequency at which UTIs occur
2. The duration of symptoms, or time taken to recover from a UTI
3. The specific symptoms of UTIs when present, comprising both urinary and constitutional symptoms
4. The impact of rUTI on a person's work and/or education related pursuits
5. The impact of rUTI on a person's participation in usual leisure activities
6. The impact of rUTI on a person's non-sexual interpersonal relationships, for example with family or friends
7. The impact of rUTI on a person's sexual relationships
8. The impact of rUTI on a person's psychological well-being
9. The impact of necessary or recommended treatment or preventative strategies related to rUTI on the individual

All participants expressed the opinion that each of these themes was relevant.

Scoring and weighting
A scoring matrix was devised that resulted in each domain being assigned a broadly similar maximum total score.

Feasibility

A Flesch-Kincaid reading ease score of 68.8 with a grade level of 5.9 was ascribed to the completed questionnaire, meaning that the text should be comprehensible to patients with equivalent education to an American 11-12 year old in mainstream English language schooling. Feasibility of completion of the written questionnaire was confirmed with 10 further volunteers.

Discussion

Study design

A semi-structured interview approach was chosen as it was felt it would allow balance between optimizing the richness of qualitative data gathered and allowing the interviewer to provide prompts and impose structure where necessary, so that the research questions would be addressed. Semi-structured interviews are seen as unique in fostering balance between relevancy and responsiveness to the interviewee.[14] Face-to-face interviews were conducted, to allow non-verbal communication and to elicit more detailed and comprehensible points from respondents,[15] and a visual guide[15,16] was provided to prompt reflection and engage participants with different communication styles. Participants were engaged and forthcoming throughout the interviews.

Previous work has shown the potentially valuable contribution of healthcare workers to QoL questionnaire composition, with 35% of QoL items produced by healthcare workers in one study.[17] For this reason, five healthcare workers were interviewed in addition to patients.

A phenomenological approach to data analysis was applied, with concentration on participants' subjective experiences and opinions to minimize researcher bias.[18,19]

Scoring and weighting

Where appropriate, questions were phrased to address the patient's perceived bothersomeness of each item. The bothersomeness of symptoms has been shown in studies of lower urinary tract symptoms related to prostatic enlargement to have a greater impact on quality of life and health-seeking behavior than symptom prevalence.[8,20,21]

Scores were weighted such that each individual domain carried approximately the same weight. A higher overall potential maximum score (of 16) was given to Domain 4, the impact of rUTI on a patient's work or education, based on feedback during the patient interviews. A maximum potential score of

16 was also associated with Domain 10, the patient's global impression of how rUTI have affected her QoL, in acknowledgment of the importance of the patient's perceptions in this questionnaire. The decision to weight the other domains relatively evenly was based on the fact that no clear or reproducible discrimination between the domains according to QoL impact was made by patient participants in the semi-structured interviews. Staff impressions of importance were not explored, as it would be difficult to assume generalizability of such opinions to a patient population.

The questionnaire produces a maximum potential total score of 122. At present, we recommend the score being interpreted on a continuum from mild to severe QoL impact.

Limitations

The questionnaire in its current format has been designed based on interviews with female participants aged 23-38 years, who suffer from recurrent urinary tract infection in the absence of known additional lower urinary tract pathology. This was a deliberate study design, with the aim of limiting bias and producing a questionnaire suitable for use in a similar population. This does, however mean, that the current questionnaire is not necessarily suited to use in patients suffering complicated UTI, in post-menopausal females or in male patients.

In this paper we report phase 1 (design) and phase 2 (feasibility testing) of a new instrument. We acknowledge that further studies are required for validation and to confirm appropriate categorization of potential score groupings. Such research is ongoing.

Conclusions

This study used qualitative methodology, centered around semi-structured interviews with 10 patients and 5 urological staff members, to explore patient perceptions of the impact of rUTI on their QoL. Based on the findings, we have created a novel self-administered questionnaire, the Recurrent Urinary Tract Infection Health and Functional Impact Questionnaire (RUHFI-Q) and propose this as an instrument to standardize evaluation of the QoL impact of rUTI. We are currently working on psychometric validation of this questionnaire.   □

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