

EFFECTIVE MEASUREMENT OF LOWER URINARY TRACT SYMPTOMS INCLUDING URINARY INCONTINENCE, AFTER SURGERY, RADIOTHERAPY OR ACTIVE MONITORING TREATMENT FOR LOCALISED PROSTATE CANCER

Hypothesis / aims of study

It is well known that many men undergoing surgery and radiotherapy for localised prostate cancer experience adverse effects on urinary function. Those undergoing active monitoring or surveillance may also experience some adverse effects related to ageing or the receipt of radical treatments after changing management. However, the precise levels of the effects and their impact on quality of life are poorly understood because most studies have been limited by using variable definitions of urinary function and outcome, not using validated patient-reported outcome measures (PROMs), and having mostly short-term follow-up. Few studies that have evaluated contemporary active surveillance or active monitoring programmes. Two older trials compared surgery and watchful waiting/observation: the Scandinavian Prostate Cancer Group-4 trial and Prostate Cancer Intervention versus Observation Trial but they did not use full or standardised measures. In contrast, the ProtecT trial included a comprehensive set of validated PROMs to compare active monitoring, external beam radiotherapy and radical prostatectomy over six years of follow-up. Included in the assessment were several validated measures of urinary function, including urinary incontinence, and their impact on specific and general aspects of quality of life. This study compares the measures of lower urinary tract symptoms and urinary incontinence, and their impact on quality of life to evaluate the comparative effectiveness of the instruments and the most suitable to be recommended for use in research and clinical practice in future.

Study design, materials and methods

Details of the recruitment methods of the ProtecT trial and the baseline data have been published previously. In brief, after population-based PSA testing, 1643 men with clinically localised prostate cancer underwent randomisation: 545 to active monitoring, 553 radical prostatectomy, and 545 radiotherapy. Patient-reported outcomes were pre-specified secondary outcomes. Urinary incontinence (UI) and its impact on quality of life (QoL) were assessed by the International Consultation on Incontinence Questionnaire (ICIQ) score and QoL item;(1) Expanded Prostate Cancer Index Composite (EPIC) 50-item UI sub-score and item on pad-use;(2) and International Continence Society Male Short-Form (ICSmaleSF) questionnaire UI score.(3) Lower urinary tract symptoms (LUTS) and their impact on QoL were assessed by the ICSmaleSF questionnaire voiding score and frequency, nocturia and QoL items, and the EPIC urinary summary, bother and obstruction/irritation sub-scores. Study questionnaires were completed at baseline before the diagnosis was known, at six and 12 months after randomisation, and annually thereafter. PROMs were scored and analysed as recommended by their authors. Analyses were performed according to the intention-to-treat principle, and summary statistics and 95% confidence intervals were reported according to randomisation group. Two-level random-effects models were used to accommodate the correlation between the repeated assessments. Two-level linear models were used for continuous measures and logistic models for binary measures. No meaningful differences across groups were observed at baseline. As UI and LUTS were not assessed directly through pad measurement or urodynamics, PROMs were compared with each other.

Results

Response rates were higher than 85% and did not decline over time. All measures of UI (ICIQ, ICSmaleSF UI and EPIC UI scores and EPIC item on pad-use) showed that surgery had the greatest negative effect at 6 months, and that UI remained worse in the surgery group compared with radiotherapy and active-monitoring at all time points over six years ($P < 0.001$ for each measure). There was little difference in UI between radiotherapy and active monitoring over six years. Only the ICIQ measure had a specific item assessing the QoL impact of UI. This showed that men in the surgery group experienced most impact at six and 12 months after randomization; after 24 months, the QoL impact of UI recovered and became similar to the other groups, although the profiles were different ($p < 0.001$).

The ICSmaleSF voiding score showed differences between the groups ($p < 0.001$), with worse voiding symptoms in the radiotherapy group at six months, returning to be similar to the other groups from 12 months onwards. The EPIC obstruction/irritative sub-score did not detect these differences ($p = 0.77$). The ICSmaleSF illustrated differences between the groups for nocturia ($p < 0.001$) with radiotherapy worse at six months, but no differences in daytime frequency ($p = 0.47$). The distinct effect of voiding difficulties on QoL was unclear, however, as the question in both measures - EPIC urinary bother and ICSmaleSF QoL score - referred to the impact of all urinary symptoms including UI. The profiles from these scores as well as the EPIC urinary summary score, were very similar to the profiles related to UI. The EPIC urinary bother sub-score was not clearly different between the groups (0.095).

Interpretation of results

The EPIC, ICIQ and ICSmaleSF measures produced very similar profiles for the effects of treatments on UI. While the magnitude of differences was a little different between the measures, they were equally effective at measuring the effects of treatments on levels of UI. The only measure that assessed the impact of UI on QoL was the ICIQ questionnaire. The ICSmaleSF and EPIC measures did not concur over the assessment of LUTS. The main EPIC scores (urinary summary and bother) included items on UI, and so their profiles conflated UI with other LUTS. EPIC also did not have a specific voiding score, as its sub-score assessed obstructive and irritative symptoms combined (dysuria, haematuria, weak stream and frequency). ICSmaleSF had separate voiding and incontinence scores, as well as specific items for nocturia and frequency, which it recommends reporting separately. ICSmaleSF did not include items on dysuria or haematuria in its assessment. EPIC and ICSmaleSF both conflated UI and LUTS in their QoL impact item/scores.

Concluding message

There are clear similarities between measures in their assessment of UI, and so any of these validated PROMs could be used: ICIQ, EPIC or ICSmaleSF. However, the assessment of QoL related to UI is only assessed by the ICIQ. For the assessment of LUTS, the measures have differences that need to be taken into account when interpreting the results. The EPIC and ICSmaleSF questionnaires include different LUTS in their assessments of voiding, UI and obstruction/irritation. It is essential to use validated and standardized PROMs in research and clinical practice to include the assessment of patient-reported symptoms, but care needs to be taken when using scores as different measures include different items within similar-sounding scores. Particular issues arise for the assessment of voiding or storage symptoms, and the assessment of the impact of all LUTS, including UI, on QoL.

References

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Disclosures

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