

THE IMPACT OF URINARY INCONTINENCE OR ERECTILE DYSFUNCTION ON PHYSICAL AND MENTAL HEALTH AFTER TREATMENT FOR LOCALISED PROSTATE CANCER

Hypothesis / aims of study

A recent randomized trial and many cohort studies have concluded that overall quality of life, in terms of physical, social or emotional wellbeing, is not affected by surgery, radiotherapy or active monitoring for localized prostate cancer. However, each treatment is associated with a particular set of side-effects which can affect specific aspects of quality of life. For example, erectile dysfunction is a relatively common side-effect of radical treatment (surgery or radiotherapy), and raised levels of bother are found when comparing randomized or treated groups. Urinary incontinence is a less common side-effect of surgery, but this is also associated with raised levels of specific bother.

The aim of this study was to investigate this seeming contradiction by examining levels of general quality of life (physical and mental health, anxiety and depression) amongst men reporting urinary incontinence or erectile dysfunction following treatment for localized prostate cancer, compared with those not reporting these symptoms.

Study design, materials and methods

In the randomized trial in which the study is based, 1643 men with clinically localised prostate cancer underwent randomisation: 545 to active monitoring, 553 radical prostatectomy, and 545 radiotherapy. Urinary incontinence (UI) was assessed by patient-reported outcome measures (PROMs) - specifically the Expanded Prostate Cancer Index Composite (EPIC) items on absorbent pad-use and the firmness of erections for intercourse.(1) Physical and mental health were assessed by two domains of the generic health measure, the SF-12.(2) Anxiety and depression were assessed by the Hospital Anxiety and Depression Scale (HADS).(3) 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. Means and standard deviations were calculated for the HADS and SF-12, with p values testing the null hypothesis of equal population means across groups without the symptom or with the symptom at six months, or with the symptom at six, 12 and 24 months – assessed over the duration of the study (six years).

Results

Response rates were higher than 85% for all measures and did not decline over time.

There were 133 (13%) men with urinary incontinence (UI) who needed to use pads at six months and 62 men (6%) who needed to use pads at six, 12 and 24 months, compared with 845 (81%) who did not use pads for UI. Men who needed to use pads for UI had higher depression scores compared with those who did not need to use pads at all time points, with scores highest of all for those who needed to use pads for longer. There was strong evidence that depression scores were worse in those using pads at six months and 12 months ($p < 0.001$). The pattern for anxiety scores was somewhat similar. The highest anxiety scores were evident among men needing to use pads for longer, with those using pads only at six months having scores more similar to those without needing pads. There was some evidence that anxiety scores were particularly worse for those using pads at six and 12 months ($p = 0.02$ at six months and $p = 0.03$ at 12 months).

SF-12 scores for physical health were different only at six months, when there was slightly worse physical health in those who needed pads compared with those who did not ($p < 0.001$). After this, physical health was similar between the groups. Reflecting the HADS scores above, SF-12 scores for mental health were worse among those needing pads at six months ($p = 0.005$), with some weaker evidence of worse mental health at 12 months among those needing pads longer-term ($p = 0.07$).

There were 278 (27%) men who had erectile dysfunction (ED) at six months, 454 (44%) who had ED at six, 12 and 24 months, compared with 289 (28%) who did not report ED. HADS depression and anxiety scores were much higher in men reporting longer-term ED than those with ED only at six months, or no ED. For depression, this evidence was very strong ($p < 0.001$ at each time point); it was slightly less strong for anxiety at $p = 0.001$ to 0.07). Depression and anxiety levels did not decline over time among those with long-term ED, but there was some evidence that those who recovered function after six months experienced less anxiety and depression. These patterns mirrored in the SF-12 mental health scores. Perhaps more surprisingly, the experience of ED at six months or longer term was associated with a small reduction in physical functioning, and this was maintained for six years ($p < 0.001$).

Interpretation of results

High levels of erectile dysfunction are experienced by men who undergo treatment for localized prostate cancer and it affects physical and mental health, including anxiety and depression. ED continues to have a small but measureable impact on these aspects of general quality of life for the duration of the time it is experienced. Urinary incontinence affects a smaller number of men, but has a clear impact on anxiety, depression, physical and mental health at six months. This impact on physical and overall mental health reduces after six months, but urinary incontinence continues to be associated with slightly higher levels of depression and anxiety over time.

Concluding message

While it is commonly found that treatments for localized prostate cancer do not affect overall quality of life on average across the treatment groups, men who experience side-effects of erectile dysfunction or urinary incontinence have higher levels of impact on physical and mental health, particularly anxiety and depression, than men without these side effects. Men undergoing treatment need to be aware of these symptoms and their potential impact, and may need additional support when they experience them.

References

1. Wei JT, Dunn RL, Litwin MS, Sandler HM, Sanda MG. Development and validation of the Expanded Prostate Cancer Index Composite (EPIC) for comprehensive assessment of health-related quality of life in men with prostate cancer. *Urology* 2000; 56: 899-905.
2. Gandek B, Ware JE, Aaronson NK, et al. Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. *International Quality of Life Assessment. J Clin Epidemiol* 1998; 51: 1171-8.
3. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand* 1983; 67: 361-70.

Disclosures

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RCT: Yes **Subjects:** HUMAN **Ethics Committee:** East Midlands (formerly Trent) Multicentre Research Ethics Committee (01/4/025) **Helsinki:** Yes **Informed Consent:** Yes