

THE EFFECT OF URINARY INCONTINENCE ON HEALTH UTILITY AND HEALTH RELATED QUALITY OF LIFE IN MEN FOLLOWING PROSTATE SURGERY.

Hypothesis / aims of study

The impact of urinary incontinence on health related quality of life (HRQoL) has been less well researched in men than in women and the general population.

While some observational research has identified an association between urinary incontinence and reduced quality of life in men following prostate surgery (1), other research has suggested that it is often regarded as a relatively minor problem (2,3).

The aim of this study was to assess the association between urinary incontinence and HRQoL in men at one year after prostate surgery using high quality data from a large randomized controlled trial.

Study design, materials and methods

Secondary analysis was conducted of outcome data from a large study that comprised two parallel randomised controlled trials of active conservative treatment of urinary incontinence (UI) in 853 men following prostate surgery. Men were recruited January 2005 to September 2008, with follow up one year after surgery. Men of any age scheduled for RP or TURP were recruited at 34 centres in the United Kingdom. Each was asked to consent to randomisation should they experience incontinence postoperatively. Exclusions: radiotherapy planned or given within 3 months of surgery; TURP as palliation for outflow obstruction in advanced prostate cancer; multiple sclerosis or Parkinson's disease. One trial included 411 men following radical (RP) prostatectomy and the other trial 442 men following transurethral resection of the prostate (TURP). The primary outcome in both trials was self-reported UI. Data were also collected on faecal incontinence (FI) and on health status and HRQoL using SF-12 and EQ-5D questionnaires.

Analysis focused on the association between UI and health utility and health related quality of life. Chi-squared tests and t-tests were used to consider the distribution of categorical or continuous data between groups. In addition to univariate analysis, multivariate linear regression was used to control for confounding factors (age, obesity, concomitant UI or FI).

To allow the detection of a difference equivalent to 0.30 of a standard deviation for continuous measures, such as quality of life, with 80% power at the 5% level, 174 men per arm of each trial would be needed. Allowing for dropout after enrolment, it was planned to recruit 200 men per arm of each trial.

Results

Mean age 62.3 years (SD 5.7) in the RP trial and 68.0 (SD 7.9) in the TURP trial. Of men with UI at 6 weeks after surgery, 76.7% in the RP group and 63.2% in the TURP group still had UI at 12 months. Any level of UI persisting at 12 months was significantly associated with reduced HRQoL in the RP group and lower EQ-5D and SF12 Mental Component Scores in the TURP group. (See tables 1 and 2)

Interpretation of results

Even after controlling for age, BMI and the presence of concomitant faecal incontinence, any degree of urinary incontinence was significantly associated with reductions in health utility as measured by EQ5D and both physical and mental aspects of health related quality of life as measured by SF-12, particularly in the younger group of men who had undergone radical prostatectomy.

Concluding message

Any UI is a significant factor in reduced HRQoL in men following prostate surgery, particularly younger men who undergo RP. Its importance to patients as an adverse outcome should not be underestimated.

Table 1: Mean EQ-5D and SF12 Physical (PCS) and Mental (MCS) Component Scores (t tests) by surgery group and continence status at 12 months.

	Mean EQ-5D (95% CI)	p	Mean SF12 PCS (95% CI)	p	Mean SF12 MCS (95% CI)	p
All	0.88		51.3		53.2	

		(0.86 - 0.90)		(50.5 - 52.1)		(52.4 - 54.1)	
	Any UI	0.87 (0.85 - 0.89)	0.034	50.7 (49.7 - 51.8)	0.016	52.7 (51.7 - 53.7)	0.034
	No UI	0.92 (0.89 - 0.95)		53.2 (51.9 - 54.5)		54.9 (53.3 - 56.6)	
	All	0.78 (0.76 - 0.81)		44.3 (43.1 - 45.5)		52.2 (51.2 - 53.2)	
TURP	Any UI	0.76 (0.73 - 0.80)	0.014	43.5 (41.9 - 45.1)	0.097	51.1 (49.7 - 52.4)	0.004
	No UI	0.83 (0.79 - 0.87)		45.6 (43.7 - 47.6)		54.1 (52.6 - 55.6)	

Table 2: Multivariate linear regression – association of urinary incontinence and EQ-5D index, SF12 Physical Component Score and Mental Component Score (adjusting for faecal incontinence, obesity and age)

		EQ-5D	SF12 PCS	SF12 MCS
	Adjusted R ²	0.030	0.023	0.017
Radical		β (95% CI)	β (95% CI)	β (95% CI)
	Any urinary incontinence	-0.06 (-0.10 to -0.01)*	-2.72 (-4.76 to -0.68)**	-2.41 (-4.50 to -0.32)*
	Adjusted R ²	0.039	0.100	0.035
TURP		β (95% CI)	β (95% CI)	β (95% CI)
	Any urinary incontinence	-0.06 (-0.11 to -0.03)*	-1.35 (-3.85 to 1.14)	-2.43 (-4.52 to 0.34)*

* p<0.05 ** p<0.01

References

1. Penson DF, Feng Z, Kuniyuki A, McClerran D, Albertsen PC, Deapen D, et al. General quality of life 2 years following treatment for prostate cancer: what influences outcomes? Results from the Prostate Cancer Outcomes Study. J Clin Oncol. 2003;21:1147-54.
2. Smith DP, King MT, Egger S, Berry MP, Stricker PD, Cozzi P, et al. Quality of life three years after diagnosis of localised prostate cancer: population based cohort study. BMJ. 2009;339:b4817.
3. Sanda MG, Dunn RL, Michalski J, Sandler HM, Northouse L, Hembroff L, et al. Quality of life and satisfaction with outcome among prostate-cancer survivors. N Eng J Med. 2008;358:1250-61.

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Approval for the study (of whose data this abstract reports secondary analysis) was obtained from the Scottish Multicentre Research Ethics Committee (Reference Number MREC/04/10/01) and confirmed by each centre's local Research Ethics Committee and R&D department.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes