

## **PREOPERATIVE BIOFEEDBACK-ASSISTED BEHAVIORAL TRAINING TO REDUCE POST-PROSTATECTOMY INCONTINENCE: A RANDOMIZED CONTROLLED TRIAL**

### Hypothesis / aims of study

Previous research on post-prostatectomy incontinence has demonstrated that behavioural intervention is effective for many men, but it has not been established whether it is a useful strategy if initiated preoperatively. The purpose of this study was to test the effectiveness of a behavioural intervention (pre-operative biofeedback-assisted behavioural training) for reducing duration and severity of incontinence and improving quality of life in the 6 months following radical prostatectomy.

### Study design, materials and methods

The study was a prospective randomized controlled trial comparing preoperative behavioral training to usual care. Patients in the study were a volunteer sample of 125 men aged 53 to 68 years who chose to undergo radical prostatectomy for treatment of prostate cancer. Eligible patients were stratified according to age and tumor differentiation and randomized to a single pre-operative session of biofeedback-assisted behavioural training plus daily pelvic floor muscle exercise or to a "usual care" control condition consisting of simple postoperative instructions to interrupt the urinary stream. Patients completed a one-day bladder diary each week following surgery and a 7-day bladder diary immediately post catheter removal and at six weeks, three months, and six months following surgery. Diaries were used to measure the primary outcomes: duration of incontinence (time to continence) and severity of incontinence (proportion with severe/continual leakage). Secondary outcome measures were also completed at each follow-up time point, and included a Patient Questionnaire about bladder control and life style issues, the Hopkins Symptom Checklist (SCL-90-R) to measure psychological distress, the Medical Outcomes Study Short Form Health Survey (SF-36) to assess health-related quality of life, and the Incontinence Impact Questionnaire (modified for men). The study was reviewed and approved by the University and VA Medical Center Institutional Review Boards for Human Use. Using a two-sided Log Rank Test, this study had 80% power to detect a difference of .28 in the proportion of patients remaining incontinent at 6 months assuming a total sample size of 106 and type I error rate of .05.

### Results

Preoperative behavioural training significantly reduced the time to continence ( $p = .03$ ; see Figure 1) and the proportion of patients with severe/continual leakage at the 6-month end point (5.9% vs. 19.6%;  $p = .04$ ). At 6 months, patients in the intervention group also had a higher proportion of dry days ( $p = .04$ ), a lower proportion of men using pads ( $< .05$ ), and a lower proportion of men reporting urine loss with coughing (22.0% vs. 51.1%;  $p = .003$ ), sneezing (26.0% vs. 48.9%;  $p = .02$ ), and getting up from a lying down position (14.0% vs. 31.9%;  $p = .04$ ). No differences were found on return to work and usual activities, impact of incontinence ( $p = .36$ ), psychological distress ( $p = .69$ ), or general health-related quality of life ( $p$  values = .31-.89).

### Interpretation of results

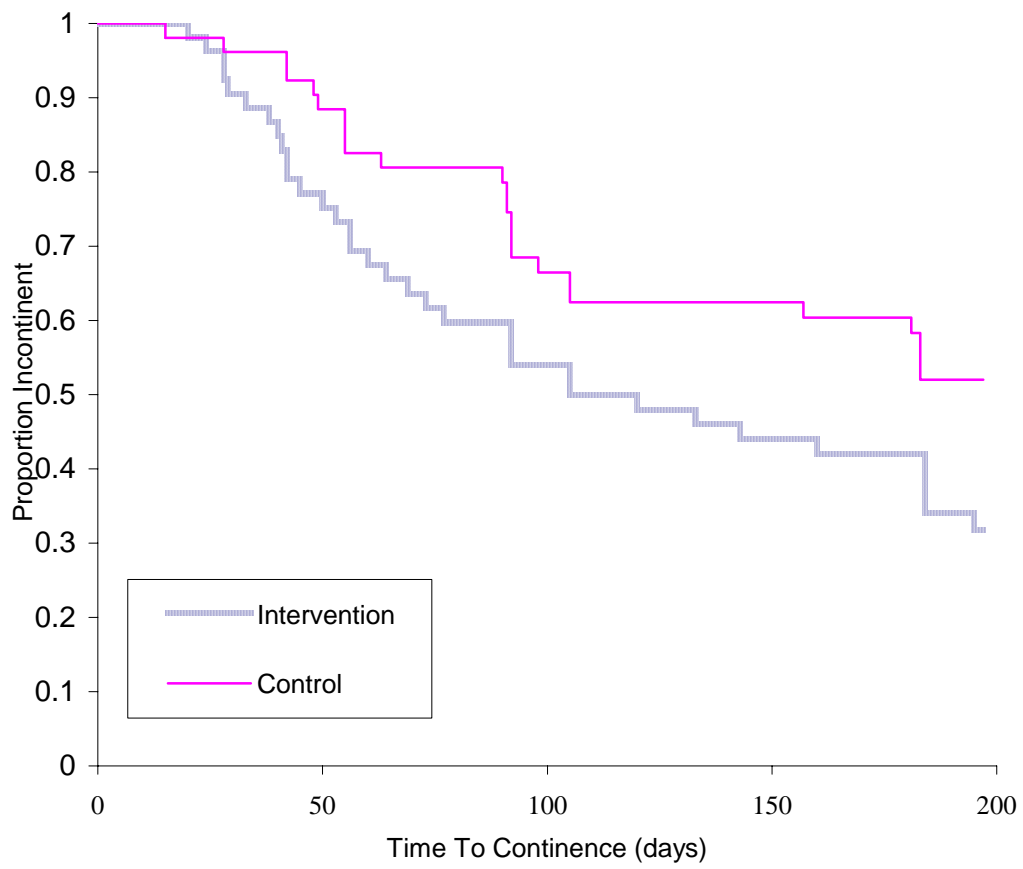
Pre-operative behavioural training can hasten the recovery of urine control and reduce the severity of incontinence following radical prostatectomy.

### Concluding message

Urologists and primary care providers could consider referring their patients who decide on prostatectomy for prostate cancer treatment to a continence center for preoperative pelvic floor muscle training.

Figure 1

### Survival Curves Comparing Time To Continenence



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