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Dorey G[1], Glazener C[2], Boachie C[2], Hagen S[3], Cochran C[2], Moore K[4]
1. *Department of Health and Applied Social Sciences, University of the West of England, Bristol,* ***2.*** *Health Services Research Unit, University of Aberdeen,* ***3.*** *Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian University,* ***4.*** *Faculty of Nursing, University of Alberta, Canada*

RESULTS FOR THE INTERVENTION GROUP OF A LARGE RCT FOR MEN WITH URINARY INCONTINENCE AFTER PROSTATE SURGERY

Hypothesis / aims of study

A large multi-centred randomised trial explored the use of pelvic floor muscle training as a treatment for urinary incontinence following radical prostatectomy (RP) and transurethral resection of prostate (TURP)[1]. The intervention was provided for 205 men who had urinary incontinence at 6 weeks after RP and 220 men after TURP, who were randomised into the intervention group in 34 UK centres. The control group received standard care. This paper explores the results of the men who were in the intervention group for both conditions and compares the data between the RP and TURP men.

Study design, materials and methods

A pelvic floor exercise intervention was provided by continence physiotherapists and continence nurses, who had received standardised training. The treatment consisted of a programme of therapy sessions with instruction for the men to perform: daily maximal strength pelvic floor muscle exercises (PFMEs), tightening during activities which increased intra-abdominal pressure such as sneezing, coughing, lifting and rising from sitting, a slight lift while walking and urge suppression techniques. Men were asked to perform three strong pelvic floor muscle contractions twice a day in each of the lying, sitting and standing positions. Men were taught to perform a strong PFM contraction after urination while still poised over the toilet to eliminate urine from the bulbar urethra and prevent post-micturition dribble. Urge suppression was aimed at waiting a minute while experiencing the 'urge' to void urine and then walking calmly to the toilet or continuing activities when the 'urge' had disappeared. Fluid advice was also given. During therapy sessions a detailed assessment was undertaken of incontinence, grade of pelvic floor muscle strength (0-6) ('no contraction' to 'very strong') by digital anal assessment, neurological problems, bowel disorders and sexual dysfunction. Men received up to four therapy sessions in three months from the therapists. Incontinence outcomes were recorded using the International Consultation on Incontinence urinary incontinence short-form questionnaire (ICIQ-UI SF, www.iciq.net).

Results

Men were on average younger in the RP intervention group (62 years, SD 5.7) compared to the TURP intervention group (68 years, SD 7.7). In the RP group, 92% attended at least one visit and 85% attended all four therapy appointments. In the TURP group, 86% attended at least one visit and 72% attended all four appointments.

Pelvic floor muscle assessment

One man in each group (RP and TURP) was unable to contract his pelvic floor at all at the first visit (Oxford Scale 0), while 4 and 8 men respectively achieved only 'a flicker' (Oxford Scale 1). By the end of the 3-month intervention, all men could perform a pelvic floor contraction, although one man in each group still had a very weak contraction (Oxford Scale 1).

In the RP group, 39.5% of men had a grade 4 to 6 (moderate to very strong) anal sphincter contraction strength at the first visit, and this increased to 82% of men after 3 months intervention. In the TURP group, 37% of men had moderate to very strong anal sphincter muscle contraction strength (grade 4 to 6) at the first visit, and this increased to 80% of men after 3 months intervention.

The corresponding data from the puborectalis muscle, showed that in the RP group, 43% of men were able to produce a moderate to very strong (grade 4 to 6) contraction at the first visit and this increased to 82% after 3 months intervention. In the TURP group, the corresponding figures were 35% increasing to 83%.

Urinary incontinence

At each visit therapists asked the men in the RP group if they still had urinary incontinence using the two questions derived from the ICIQ-UI SF: 'How often have you leaked urine in the last week?' and 'How much did you leak?' The proportion of men with incontinence decreased during the three-month therapy period. At visit 1 (6 weeks after RP) 92% reported incontinence; at visit 2 (2 weeks later) 91%, at visit 3 (6 weeks later), 84% and at visit 4 (12 weeks later) it reduced to 73%. This trend was also exhibited in the ICIQ-UI SF mean scores which decreased from 7.9 to 6.8, 5.6 and 4.3 at each successive time point. Similarly, the proportion of men who reported incontinence in the TURP group decreased during the three-month therapy period from 82% to 69%, 60% and 52% respectively. ICIQ-UI SF mean scores decreased from 6.5, 4.8, 3.7 to 3.0 respectively. Similar results were found for the control group. This may be due to 97% of men after RP and 84% of men after TURP having prior knowledge of PFMEs. In addition, men could have received a leaflet describing PFMEs as part of standard care in their hospital.

Type of incontinence

In the RP group, men were most likely to report stress urinary incontinence (SUI). After 3 months of treatment, this fell from 84% to 72%, while urgency urinary incontinence (UUI) decreased from 20% to 15% and post-micturition leakage significantly reduced from 63% to 25% ($p<0.001$).

In the TURP group, men were more likely to have UUI than SUI. After 3 months of treatment, SUI reduced from 36% to 21%, UUI decreased from 57% to 20% and post-micturition leakage significantly reduced from 57% to 33% ($p<0.001$).

Bowel problems

Therapists asked men about their bowel problems at each visit. In the RP group, men reported faecal incontinence (2%), faecal urgency (7%) and constipation (12%) at the first visit. In the TURP group, men reported faecal incontinence (3%), faecal urgency (9%) and constipation (16%) at the first visit. After the three month intervention, there was little change in faecal incontinence or faecal urgency in either clinical group, but constipation fell to 8% in the RP group and to 6% in the TURP group.

Sexual problems
Before surgery 17/205 (8%) of men in the RP group and 67/214 (32%) of men in the TURP group were unable to achieve an erection. After RP, 89% of men reported difficulty gaining an erection. After TURP, 55% of men reported difficulty gaining an erection. After the 3 month intervention period, there was little change: 89% in the RP group and 52% in the TURP group reported difficulty in gaining an erection.

Interpretation of results
Men increased their pelvic floor muscle strength after 3 months of a supervised programme of daily PFMEs and incontinence was reduced in both the RP group and TURP group. However, there were no long term differences in terms of UI when measured 12 months later compared with UI rates in the men randomised to the control group, who did not receive the individual one-to-one therapy[1].
SUI was more prevalent after RP and UUI was more prevalent after TURP. These improved in both groups of men. It is possible that the urgency symptoms in men after TURP may have pre-dated the operation, as 36% reported urinary incontinence before surgery, the majority of whom would have had UUI. This compares with only 6% who had incontinence before RP, reflecting a younger age group in a population largely without obstructive prostate disease. Supervised pelvic floor muscle training was not effective, at least in the short term, in treating bowel problems and sexual problems in the 3 months after RP and TURP.

Concluding message
In the intervention group of this RCT, men increased their pelvic floor muscle strength and reduced their urinary leakage during four one-to-one appointments with a therapist over three months. However, this decrease in urinary leakage was also seen in the men in the control group, which was reported elsewhere[1] and therefore it may be taken to represent natural recovery after operation. Bowel problems and sexual problems were unchanged in the short term.

References
1. 1 Glazener C, Boachie C, Buckley B, Cochran C, Dorey G, Grant A, Hagen S, Kilonzo M, Moore K, N'Dow J, Ramsay C, Vale L. A randomized controlled trial of conservative treatment (pelvic floor muscle training and bladder training) for urinary incontinence in men after prostate surgery (MAPS). Abstract 200 International Continence Society Annual Meeting Toronto August 2010.

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Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**This trial was approved by the Multicentre Research Ethics Committee, Edinburgh, Scotland, and overseen by an independent trial steering committee and a separate independent data monitoring committee. All men gave signed informed consent to being screened, and separately to being randomised: the trial was conducted in accordance with the Declaration of Helsinki.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**