PRIZE AWARD: Best Clinical Abstract

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A RANDOMISED CONTROLLED TRIAL OF CONSERVATIVE TREATMENT (PELVIC FLOOR MUSCLE TRAINING AND BLADDER TRAINING) FOR URINARY INCONTINENCE IN MEN AFTER PROSTATE SURGERY (MAPS)

Hypothesis / aims of study

What is the effectiveness and cost-effectiveness of active conservative treatment delivered by a specialist continence physiotherapist or a specialist continence nurse compared with standard management, primarily in terms of regaining urinary continence at 12 months after recruitment, in two groups: men with urinary incontinence at six weeks after a radical prostatectomy or a transurethral resection of prostate (TURP)? The hypothesis tested in each group of men (in two parallel but separate trials, one amongst men having a radical prostatectomy and the other amongst those having a TURP) was that active conservative management would result in an absolute difference of 15% between the groups in the proportion of incontinent men at one year after recruitment.

Study design, materials and methods

Men having prostate surgery were identified in 34 centres and invited to receive a screening questionnaire at three weeks after operation. Those men who had urinary incontinence (UI) were randomised. Men in the intervention group were randomised to attending four sessions with a Therapist over a period of three months. Instruction included pelvic floor muscle training and bladder training / urge suppression. The Control group continued with standard management. Both groups received a Lifestyle Advice Leaflet. Randomisation was by computer allocation using a remote randomisation service. Allocation was stratified by type of operation (radical prostatectomy or transurethral resection of prostate, TURP), and minimised using centre, age and pre-existing urinary incontinence. The process was independent of all clinical collaborators. Outcome measures were UI, performance of pelvic floor muscle exercises, bowel and sexual dysfunction and quality-adjusted life years (QALYs). UI was assessed using the ICI-UI Short Form survey instrument (www.iciq.net) by postal questionnaires.

Analysis was by intention to treat adjusting for age and pre-existing UI. Further sensitivity analyses were carried out using the 'adjusted treatment received' method described by Nagelkerke and colleagues (2000).

Results

Of those eligible, 95% (742/780) in the radical prostatectomy group, and 91% (2590/2836) in the TURP group were screened: 411 and 442 respectively were randomised. After a radical prostatectomy, but before randomisation, 98% of men had already received some information about pelvic floor muscle training from a wide variety of sources including continence advisors, leaflets or books, doctors, friends or family, the internet or a physiotherapist; as had around 80% of men after a TURP.

Radical prostatectomy trial: Amongst men who had a radical prostatectomy, follow-up rates were over 97% in each arm. Ninety-two percent of the men in the intervention group attended at least one therapy visit and these men were more likely to be carrying out any pelvic floor muscle training at 12 months (67%) compared with those in the control group (20%, adjusted risk ratio RR 1.30; [95% CI 1.09 to 1.53]). In the radical trial, the absolute risk difference in urinary incontinence rates at 12 months between the intervention (75.5%) and control (77.4%) groups was -1.9% [-10% to 6%], which rules out the likelihood that the prespecified target difference of 15% was missed. Adjusting for minimisation factors or performing a 'treatment received' analysis did not change these results. Although there was a trend towards higher NHS costs in the intervention group and higher societal costs in the control group, differences were not statistically significant. On average, QALYs were virtually identical in both the intervention and control group (MD 0.002 [95%CI -0.023 to 0.027]). When the perspective was the NHS there was only a 20% chance that pelvic floor muscle training would be cost-effective.

TURP trial: Amongst men who had a TURP, follow up was 97% in both arms. Over 85% of men in the intervention group attended at least one therapy visit and these men were more likely to be carrying out any pelvic floor muscle training at 12 months after randomisation (65%) than those in the control group (20%, adjusted RR 3.20 [2.37 to 4.32]). Following a TURP, the absolute risk difference in urinary incontinence rates at 12 months between the intervention (64.9%) and control (61.5%) groups for the unadjusted intention to treat analysis was 3.4% [95% CI -6% to 13%], which rules out the likelihood that the prespecified target difference of 15% was missed. NHS costs and societal costs were statistically significantly higher in the intervention group but QALYs were virtually identical. From both a societal and an NHS perspective there was little chance that pelvic floor muscle training would be considered cost-effective.

Interpretation of results

The provision of one-to-one conservative physical therapy for men with urinary incontinence after prostate surgery is unlikely to be effective or cost-effective compared with the extensive provision of information about conducting pelvic floor muscle training that is available in the medical and the public domain.

Concluding message

Any resources currently allocated to providing pelvic floor muscle training by a trained therapist in one-to-one consultations for men with incontinence after prostate surgery could be better used elsewhere.

References

1. Nagelkerke N, Fidler V, Bernsen R, Borgdorff M. Estimating treatment effects in randomized clinical trials in the presence of non-compliance. Statistics in Medicine 19 (14):1849-1864, 2000

Specify source of funding or grant	**National Institute for Health Research Co-ordinating Centre for Health Technology Assessment (NETSCC, HTA), UK**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ISRCTN87696430**
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	**MultiCentre Research Ethics Committee, Edinburgh, Scotland**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**