Conservative treatment for urinary incontinence in Men After Prostate Surgery (MAPS): two parallel randomised controlled trials

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Executive summary

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Executive summary

Background

Successive Cochrane reviews have shown that, although conservative treatment based on pelvic floor muscle training (PFMT) may be offered to men with urinary incontinence after prostate surgery, there is insufficient evidence to evaluate its effectiveness and cost-effectiveness. Men After Prostate Surgery (MAPS) was a multicentre, UK, randomised controlled trial (RCT), the aim of which was to supply that evidence for men undergoing radical prostatectomy or transurethral resection of the prostate (TURP).

Radical prostatectomy is carried out for men suffering from early prostate cancer. The operation is usually carried out through an open incision in the abdomen, which may damage the urinary bladder sphincter, or its nerve supply, and other pelvic structures. Urinary incontinence occurs in around 90% of men initially but the long-term prognosis varies from 2% to 60%, depending on how incontinence is measured and time after surgery. TURP is carried out using an endoscope through the urethra: the aim is to remove enlarged prostate tissue from the lumen of the urethra. Damage to the distal urinary bladder sphincter or its nerve supply is less common than with radical surgery, and fewer men remain incontinent (an estimated 11% of men wear pads 3 months after surgery).

The two types of surgery were considered in two parallel but separate trials because the rates of incontinence and the chance of regaining continence were expected to differ between the two clinical populations.

Objectives

The following question was addressed, primarily in terms of regaining urinary continence at 12 months after recruitments for both types of surgery: what are the clinical effectiveness and cost-effectiveness of active conservative treatment delivered by a specialist continence physiotherapist or a specialist continence nurse compared with standard management?

The hypothesis tested in each group of men was that active conservative management would result in a difference of 15% between the groups in the proportion of incontinent men at 1 year after recruitment.

Methods

Men having prostate surgery were identified in 34 centres across the UK. Men were invited to receive a screening questionnaire after their operation. Those who reported at screening that they were incontinent were invited to enrol in MAPS.

Inclusion criteria were full informed consent; ability to comply with intervention; and urinary incontinence at 6 weeks after prostate surgery. Incontinence was defined as a 'positive' response to either of two questions in the screening questionnaire: ('how often do you leak urine?' and 'how much urine do you leak?').

Exclusion criteria were formal referral for physiotherapy or teaching of PFMT related to prostate surgery; radiotherapy planned or given during the first 3 months after surgery for men with prostate cancer; resection of prostate as palliation for outflow obstruction in advanced prostate cancer (known as 'channel TURP'); and inability to complete study questionnaires.

Men completed a questionnaire at 6 weeks after surgery and signed a consent form. Baseline information included sociodemographic and clinical characteristics including type of operation. Eligible men were randomised to attending four sessions with a therapist over a period of 3 months (intervention group). The therapists were either specialist continence physiotherapists or specialist continence or urology nurses. All therapists were provided with standardised training in the management of male urinary incontinence and erectile dysfunction. The control group received standard management. Both groups received a lifestyle advice leaflet.

Randomisation was by remote computer allocation using the randomisation service of the Centre for Healthcare Randomised Trials (CHaRT, Health Services Research Unit, University of Aberdeen). Allocation was stratified by type of operation (radical prostatectomy or TURP), and minimised using centre, age and pre-existing urinary incontinence. The process was independent of all clinical collaborators.

The primary clinical effectiveness outcome was urinary incontinence at 12 months after randomisation, and the primary cost-effectiveness outcome was incremental cost per QALY. Outcome data were collected by postal questionnaires at 3, 6, 9 and 12 months. At each time point, men also completed a urinary diary for 3 days. Data collected included: urinary outcomes (presence, frequency and severity of incontinence, effect of incontinence on quality of life, use of pads and catheters, type of incontinence, urinary frequency and nocturia); bowel outcomes (faecal incontinence, constipation, bowel urgency); sexual function (erectile function, ejaculation, change in sexual function); quality of life (EQ-5D and SF-12); use of health services (contact with community, hospital and private staff, use of alternative treatments such as pads, catheters, surgery, drugs or mechanical devices, and their costs); participants' costs (self-purchased health care, costs of accessing health care, cost of time away from usual activities); QALYs derived from responses to the EQ-5D and SF-12; and effect of the intervention in changing health-related behaviour and practice of PFMT and bladder training or urge suppression.

Results

We approached 1158 men having a radical prostatectomy and 5986 having TURP in 34 centres. The response rate for the screening questionnaire was 95% (742/780) of the eligible men in the radical prostatectomy group and 91% (2590/2838) in the TURP group.

Amongst the radical prostatectomy group, of 472 eligible men who returned a questionnaire after surgery, 411 entered the radical prostatectomy RCT: 205 in the intervention group and 206 in the control group. Follow-up rates were high (95% of all men in each arm, 97% and 98% respectively after accounting for withdrawals and deaths).

Ninety-two per cent of the men allocated to the intervention group attended at least one therapy visit. Men in the intervention group were more likely to be carrying out any PFMT at 12 months (67%) than those in the control group (50%, adjusted risk ratio (RR) 1.30, 95% confidence interval (CI) 1.09 to 1.53).

Among the men who had a radical prostatectomy, the difference in urinary incontinence rates at 12 months between the intervention and control groups (148/196, 75.5%, vs 151/195, 77.4%)

was not statistically significant: the absolute risk difference for the unadjusted intention-to-treat analysis was –1.9% (95% CI –10% to 6%), which ruled out the prespecified target difference of 15%. Adjusting for minimisation factors or performing a 'treatment received' analysis did not change these results.

NHS costs were higher in the intervention group (£181, 95% CI £107 to £255), but costs to the NHS and the participant were on average lower (–£588, 95% CI –£1330 to £153). On average, QALYs were virtually identical in both the intervention and the control groups (–0.002, 95% CI –0.027 to 0.023). When the perspective was the NHS there was only a 20% chance that PFMT would be cost-effective. However, from a societal perspective, there was an 80% chance that it would be cost-effective. The findings from the societal perspective were driven by a trend towards more time away from usual activities in the control group. These data are counter-intuitive when considered alongside the rest of the trial data and so should be treated cautiously.

Amongst those who had TURP, of 512 eligible men who returned a questionnaire at 6 weeks after surgery, 442 entered the TURP RCT: 220 in the intervention group and 222 in the control group. Follow-up rates were high (88% and 92% respectively of all men, 97% in both arms after accounting for withdrawals and deaths).

Over 85% of the men allocated to the intervention group attended at least one therapy visit. Men in the intervention group were more likely to be carrying out any PFMT at 12 months after randomisation (65%) than those in the control group (20%, adjusted RR 3.20, 95% CI 2.37 to 4.32).

Following a TURP, the difference between the intervention and control groups in the proportion of men who had urinary incontinence at 12 months (126/194, 64.9% vs 125/203, 61.5%) was not statistically significantly different: the absolute risk difference for the unadjusted intention-to-treat analysis was 3.4% (95% CI –6% to 13%), which rules out the prespecified target difference of 15%. Adjusting for minimisation factors or performing a 'treatment received' analysis did not change these results.

The differences in NHS costs (£209, 95% CI £147 to £271) and NHS and participant costs (£420, 95% CI £54 to £785) were higher in the intervention group. On average, QALYs were virtually identical in the intervention and control groups (–0.00003, 95% CI –0.026 to 0.026). From both a societal and an NHS perspective there was little chance that physical therapy would be considered cost-effective.

Conclusions

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 standard care (which includes the provision of information about conducting PFMT).

Implications for research

- Physical therapy of the type used in this trial is not worthwhile, but the continuing burden of incontinence suggests that research into other treatments is worthwhile, for example research on the value of surgery in controlling symptoms. Specifically, an RCT comparing different surgical options for men with severe persistent urinary incontinence is needed.

- MAPS has not tested whether the provision of any PFMT advice is an effective and efficient way of reducing incontinence. Further research into the effectiveness of any other method of delivery of PFMT would be worthwhile.
- Of the men in the radical prostatectomy trial, 80% still had erectile dysfunction at the 12-month follow-up, and over 60% had tried various treatments. As PFMT was of no value to these men, research into effective and efficient treatments for this condition would be worthwhile. Such a study should also include a wider population of men following radical surgery and not just those with urinary incontinence.
- The MAPS data set can be used to improve the quality of further research and to improve other aspects of management. Specifically, MAPS data can be used to further validate the outcome measures for use in future research and clinical settings. The further analysis of the epidemiological data will inform the debate about different methods of prostatectomy and provide prognostic information for counselling men.

Trial registration

This trial is registered as ISRCTN87696430.

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Publication

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NIHR Health Technology Assessment programme

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 03/14/03. The contractual start date was in December 2004. The draft report began editorial review in March 2010 and was accepted for publication in August 2010. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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