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Glazener C[1], Boachie C[1], Hagen S[2], Kilonzo M[1], Cochran C[1], Buckley B[3], Dorey G[4], Moore K[5], McDonald A[1], McPherson G[1], N'Dow J[1], Grant A[1]

1. *University of Aberdeen,* ***2.*** *Glasgow Caledonian University,* ***3.*** *Bladder and Bowel Foundation,* ***4.*** *University of the West of England,* ***5.*** *University of Alberta*

CLINICAL OUTCOMES TWO YEARS AFTER A RANDOMISED CONTROLLED TRIAL OF PELVIC FLOOR MUSCLE TRAINING AFTER RADICAL PROSTATECTOMY OR TURP: MEN AFTER PROSTATE SURGERY TRIAL (MAPS)

Hypothesis / aims of study

The aim of the MAPS study (two parallel trials) was to identify the effectiveness and cost-effectiveness of a strategy of one-to-one pelvic floor muscle training (PFMT) compared to standard management, in men who had urinary incontinence (UI) after prostate surgery, either radical prostatectomy (RP) (trial 1) or transurethral resection of prostate (TURP) (trial 2). The primary outcome was UI at 12 months after randomisation. There were no differences between the randomised groups in either trial at one year.(1) This paper will present two year data for prevalence and type of urinary incontinence and other relevant clinical outcomes amongst the two groups of men.

Study design, materials and methods

Men having prostate surgery were identified in 34 centres and invited to receive a screening questionnaire. Those men who had UI at six weeks after operation and consented were randomised. Men randomised to the intervention group were invited to attend four one-to-one sessions with a therapist over a period of three months for pelvic floor muscle training and bladder training / urge suppression. The control group did not attend therapist sessions but received 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 (RP or TURP), and minimised using centre, age and pre-existing UI. The process was independent of all clinical collaborators.

Outcome measures were measured at one and two years: presence and severity of UI; performance of pelvic floor muscle exercises; bowel problems; and sexual dysfunction. Outcomes were assessed using International Consultation on Incontinence survey instruments (www.iciq.net) administered by postal questionnaire. Primary outcome analysis was by intention to treat (responders at two years) and adjusted for age and pre-existing UI.

Results

From the men having RP (742) and TURP (2590), 411 and 442 respectively were randomised; at one year, 391/411 (95%) and 397/413 (96%) men were followed up. Of the men still in the study at two years, 361/391 (92%) and 344/397 (87%) respectively responded. The prevalence of UI was still high in both clinical groups (Table 1). While there was little difference between the randomised groups in the RP trial (adjusted RR 1.03 [95% CI 0.92 to 1.17]; P=0.573), more men in the intervention group were incontinent after TURP (RR 1.18 [1.01 to 1.38]; P=0.0370) although the differences in severe UI and pad use were not significant (Table 1). While there were no significant differences between the randomised groups, the men were more likely to have stress urinary incontinence (SUI) after a RP (compared to after TURP), while urgency urinary incontinence (UUI) was more common after TURP (Table 1). Analysis including non-responders as dry were also not significantly different (Trial 1: UI 68% vs 63%; Trial 2: 53% vs 47%). Over a third of the original population of men screened after surgery were still wet after RP (270/742, 36%), as were 9% after TURP (221/2590).

In general, more men reported abnormal bowel function after TURP than after RP (Table 2), but TURP men were around 10 years older at the time of operation. In contrast sexual dysfunction was much higher after RP and men were much more likely to seek treatment (around 60% of men had tried either medical or vacuum devices, Table 2). Again, there were no statistically significant differences according to randomisation.

Table 1 Incontinence at 2 years after surgery (responder analysis)

	Radical Trial 1		**TURP Trial 2**	
	Intervent. N=184	**Control N=177**	**Intervent. N=168**	**Control N=176**
Any incontinence	140/184 (77)	130/177 (73)	117/168 (70)	104/176 (59)
Severe incontinence [a]	57/184 (31)	54/177 (31)	42/168 (25)	34/176 (19)
ICIQ Score [b]	4.58 (3.71) 184	4.72 (4.41) 177	4.17 (3.72) 168	3.58 (3.77) 176
Use of pads	50/184 (27)	54/177 (31)	21/168 (13)	14/176 (8)
Urinary frequency (per day)	6.47 (2.09) 173	6.65 (2.22), 165	7.37 (7.13) 160	6.44 (2.51) 160
Urinary frequency (per night)	1.16 (0.93) 172	1.33 (1.09) 166	1.60 (1.20) 159	1.75 (1.45) 165
Type of Incontinence				
SUI	106/184 (58)	99/177 (56)	29/168 (17)	30/176 (17)
UUI	20/184 (11)	26/177 (15)	36/168 (21)	40/176 (23)
MUI (both)	17/184 (9)	18/177 (10)	7/168 (4)	13/176 (7)
Post-micturition leak	80/184 (44)	77/177 (44)	16/168 (10)	15/176 (9)
Other incontinence	40/184 (22)	39/177 (22)	35/168 (21)	11/176 (6)

Data are presented as n/N (%) or mean (SD) n.
[a] Severe incontinence defined as at least once a day AND moderate or large amount of leakage
[b] Derived from ICIQ-UI SF (www.icig.net): combined measure of amount and bother from UI.

Table 2 Bowel and sexual function outcomes (responder analysis)

	Radical Trial 1		TURP Trial 2	
	Intervent. N=184	**Control N=175**	**Intervent. N=166**	**Control N=168**
Faecal incontinence	20/184 (11)	17/175 (10)	39/166 (23)	30/168 (18)
Faecal urgency	72/184 (39)	82/175 (47)	96/165 (58)	87/167 (52)
Constipation	11/184 (6)	15/175 (9)	35/165 (21)	33/168 (20)
Sexual function	**N=177**	**N=173**	**N=152**	**N=157**
Unable to achieve any erection [a]	93/177 (53)	84/173 (49)	40/152 (26)	47/157 (30)
Degree of bother due to abnormal erection [b]	5.60 (3.31) 150	5.50 (3.54) 154	4.27 (3.59) 122	4.54 (3.74) 115
Use of medication for sexual problems	81/175 (46)	91/171 (53)	19/148 (13)	12/157 (8)
Use of vacuum device for sexual problems	61/177 (34)	47/172 (27)	3/147 (2)	0/157 (0)
Using either medication or vacuum	104/177 (59)	107/173 (62)	20/148 (14)	12/157 (8)
Leaking urine during intercourse	27/118 (23)	35/129 (27)	1/111 (1)	4/117 (3)

Data are presented as n/N (%) or mean (SD) n.
[a] Defined as 'erection not possible'
[b] 'How much does this bother you?' rated from 0 (not at all) to 10 (a great deal)

Interpretation of results

The levels of urinary, bowel and sexual dysfunction after both RP and TURP indicate a high level of unmet need. These factors would be expected to have a significant effect on quality of life, and effective treatment might significantly improve the adverse effects of prostate surgery. However, it is clear that one-to-one PFMT does not improve two-year outcomes, probably because much information is already available in the public domain.

Concluding message

One-to-one PFMT was not effective compared to standard care, either at one or two years after surgery. However, there was a significant burden of unmet need in terms of urinary, bowel and sexual function problems which merit further research into their effect on men's quality of life and men's need for further treatment.

References

1. Glazener C, Boachie C, Buckley BS, Cochran C, Dorey G, Grant AM, Hagen S, Kilonzo M, Moore K, N'Dow J, Ramsay C, Vale L. A randomised controlled trial of conservative treatment (pelvic floor muscle training and bladder training) for urinary incontinence in men after prostate surgery (MAPS) abstract. Neurourol Urodyn 2010;29(6):1093-4.

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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	**Scotland A Research Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**