

PELVIC FLOOR MUSCLE TRAINING OR BLADDER TRAINING TO TREAT STRESS URINARY INCONTINENCE IN ELDERLY WOMEN: A SINGLE BLIND RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study

The Third Consultation on Incontinence states that pelvic floor muscle training (PFMT) is an effective treatment for women with stress and mixed incontinence and should be offered as the first choice of treatment for stress urinary incontinence (SUI) (1). The Consultation noted that with regard to the elderly, randomised controlled trials are sparse and that there is still no strong evidence for the effectiveness of PFMT in elderly women. Two research groups (2, 3) have suggested that bladder training (BT) is effective in older women with SUI, as well as for urge and mixed incontinence. However, in both these studies the bladder training intervention included PFM contractions for urgency control. The question could then be posed as to whether pelvic floor muscle training was the effective component of bladder training for the stress and mixed urinary incontinent participants. It is important to distinguish the relative effectiveness of these two interventions to ensure that stress urinary incontinence is managed in the most effective and efficient way. The aim of the present study was to compare the effect of PFMT with BT, without pelvic floor muscle training, in women over 65 years with urodynamically proven SUI.

Study design, materials and methods

A two centre, single blind randomised controlled trial of 20 weeks duration, with two active intervention arms of pelvic floor muscle training and behavioural (bladder) training was conducted. Participants were community dwelling women over 65 years of age with urodynamic SUI, perceived by them as bothersome. Women with >10cmH₂O detrusor pressure rise on cystometry, incontinence due to neurological causes, PFMT intervention within the last 6 months, or unable to give informed consent were excluded. After initial assessment by a blinded assessor, participants were randomly assigned, stratified by treatment location using a computer generated random number table to either a PFMT or BT group. Concealment and assignment were undertaken by a researcher not involved in any outcome assessment. Participants attended weekly hour long exercise and education classes for 20 weeks and undertook a home program of either PFMT or BT. They were assessed at baseline, 4, 12 and at 20 weeks, the primary endpoint.

A clinically relevant 'medium' effect size (0.6) was used to calculate sample size. With a two-sided alpha of 0.05 and a power of 0.8, a sample size of 45 per treatment group was required. Primary outcome measures were urinary leakage during a cough stress test (with and without a pre-contraction of the pelvic floor muscles (PFM), quality of life (ICIQ-UI SF) and participant global perception of change. Secondary outcome measures included leakage episodes (7-day accident diary), degree of 'bother' (VAS) and health related quality of life (AQoL). All data analysis was by intention to treat. 'Last value carried forward' method was used where there were missing data. Mann-Whitney U (non-normally distributed data), independent t-tests (normally distributed data) and Chi-square tests were used to compare the two groups. Alpha was set at 0.05.

Results

Eighty-four women of mean age 72 (65-89) years were enrolled in the study. There were no differences between groups at baseline on any measures. At the primary endpoint, the PFMT group reported significantly greater improvement than the BT group (Table 1).

When the results were examined for participants who had zero leakage (0.0gm) on the cough stress test, 19 (47.5%) subjects in the PFMT group had no leakage (with no pre-contraction of the PFM) compared to nine (25.7%) in the BT group ($p=0.039$). With a pre-contraction of the PFM, 23 (57.5%) subjects in the PFMT group had no leakage compared to eight (22.9%) in the BT group ($p=0.004$).

Overall the PFMT group reported a greater perception of change in symptoms ($p=0.004$), though there was no significant difference between groups in satisfaction with treatment received ($p=0.102$).

Table 1. Scores on primary and secondary outcome measures at primary endpoint (20 weeks), and comparisons between PFMT and BT groups.

	PFMT (n=43)	BT (n=41)	p value
Primary outcomes			
Stress Test - cough (gm)			
Median gm, IQR (Mean Rank) #	0.1, 1.5 (36.18)	0.5, 2.4 (47.09)	0.034
Stress Test - brace/cough (gm)			
Median gm, IQR (Mean Rank) #	0.0, 0.4 (32.51)	0.3, 0.7 (44.27)	0.008
ICIQ-UI SF score scorescores#			
Median, IQR (Mean Rank) #	5, 4, (34.55)	8, 7, (50.01)	0.003
Secondary outcomes			
Accident Diary (leaks)			
Median, IQR (Mean Rank) #	4.5, 11, (36.47)	8.0, 27, (47.95)	0.030
AQoL total score			
Mean (SD) SEM*	14.44 (9.14) 1.394	11.88 (9.27) 1.519	0.217

Bother score (VAS)				
Mean (SD) SEM*	2.26 (2.139) 0.326	3.68 (2.654) 0.420		0.009

Mann-Whitney U

*Independent t-test

Interpretation of results

This study showed that older women with urodynamic stress urinary incontinence who undertook a 20 week intensive PFMT program, demonstrated a greater improvement in incontinence symptoms compared to those who undertook a behavioural BT program. Both groups received supervised interventions with the same amount of attention, and both groups were equally satisfied with their treatment. However the PFMT group demonstrated and perceived a larger degree of change in symptoms than the BT group. Further strengths of the study were the blinded design and use of reliable and valid outcome measures. While it is tempting to state that zero leakage in the cough/stress test represents a 'cure', this measure is of a moment in time only. The participant's perception of the nature of her symptoms must be considered. The ICIQ-UI SF scores also revealed a significant difference between the two groups in favour of the PFMT group, although the generic health related QoL scores (AQoL) did not. While zero leakage was not the only measure of cure in this study, zero leakage rates of 47.5% and 57.5% in the stress tests do compare favourably with cure rates in other studies.

Concluding message

Intensive pelvic floor muscle training is more effective than behavioural (bladder) training in treating stress urinary incontinence in a cohort of community dwelling older women. Increasing age should not be a barrier to prescribing exercise for older women with stress urinary incontinence.

References

1. Incontinence (2005) Health Publication, United Kingdom
2. J Urology (2004) 171(3):1165-1171
3. Am J Obstet Gynecol (1998) 179:999-1007

FUNDING: National Health and Medical Research Council of Australia competitive grant

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov NCT00222248

HUMAN SUBJECTS: This study was approved by the Human Research Ethics Committees of Austin Health and Royal Women's Hospital and followed the Declaration of Helsinki Informed consent was obtained from the patients.