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PELVIC FLOOR MUSCLE TRAINING ADDED TO BLADDER TRAINING VERSUS BLADDER TRAINING ALONE FOR FEMALE URINARY INCONTINENCE: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

Urinary incontinence is one of the most common and distressing health problems in women. Although many conservative treatments are available for women with urinary incontinence, pelvic floor muscle training (PFMT) and bladder training (BT) are the most popular. PFMT is also recommended as the first-line therapy for female urinary incontinence. The new Cochrane review showed that there is insufficient evidence to state whether or not there were additional effects of adding PFMT to BT when compared with BT alone for urinary incontinence in women (1). Wyman et al. (2) reported greater improvement with combination therapy (BT+PFMT) immediately after treatment, but the long-term effect was similar. Therefore, additional research is needed to conclude whether combination therapy is superior to BT alone. The aim of the present study was to compare the effect of combination therapy with BT alone in women with urinary incontinence.

Study design, materials and methods

This was a prospective, non-blinded randomized controlled trial (RCT) of 6 weeks duration, with two active intervention arms (BT+PFMT vs. BT alone). Inclusion criteria were the following: female subjects with symptoms of stress urinary incontinence (SUI), urgency urinary incontinence (UUI) or mixed urinary incontinence (MUI), age> 18 years, drug free interval at least 4 weeks before start of study for the drugs for urinary incontinence, being literate to fill out forms and urinary diaries. Antenatal or postnatal women (up to three months after delivery), women who were unable to voluntarily contract their pelvic floor muscles and subjects who had persistent urinary tract infection, impaired mental state, pelvic organ prolapse past the vaginal introitus, neurological disorder, concurrent or recent physiotherapy intervention (within the last year) were excluded. After comprehensive clinical evaluation, participants were stratified on the basis of their symptomatic diagnosis and assigned randomly to 6 weeks of BT+PFMT or BT alone treatment arm. Using a computer generated random number table, stratified block randomization procedure was used with blocks of four. A standardized treatment protocol was implemented for both groups by a physical therapist in 4 visits (baseline and week 2,4,6) during a period of 6 weeks. Both treatments were home-based. Exercise and bladder diaries were used to facilitate adherence. All patients were assessed at baseline and at the end of 6 weeks.

Primary outcome measure was participant's global perception of change by 4-point Likert scale (worse, unchanged, improved and cured). Secondary outcome measures included incontinence severity by Incontinence Severity Index (ISI), life impact by Incontinence Impact Questionnaire-7 (IIQ-7), symptom distress by Urogenital Distress Inventory-6 (UDI-6), number of daily incontinent episodes from urinary diaries and pelvic floor muscle strength via vaginal perineometer (PFMS). Treatment adherence was also assessed with a 100 mm visual analogue scale. Differences between groups were analysed with t-tests (normally distributed data), Mann-Whitney U test (non-normally distributed data) and Chi-Square tests (for categorical variables). All analyses were performed for each of the three subgroups (SUI, UUI and MUI) and for all patients. Alpha was set at 0.05.

Results

108 women of mean age 49.8 (SD 9.3) years were enrolled in the study. Of these patients, 56 (SUI:26, UUI:8, MUI:22) were in BT+PFMT group, 52 (SUI:24, UUI:8, MUI:20) were in BT alone group. There were no significant differences between two study groups at baseline in demographic characteristics or outcome measures. Adherence to treatment protocols was also similar between groups.

According to chi-square test for the primary outcome, a total sample size of 108 achieves 99% power to detect an effect size of 0.4800 with a significance level of 0.05. Significantly more patients in BT+PFMT group reported cured and improved symptoms than in BT alone group (100% (41.1% cured, 58.9% improved) in BT+PFMT vs. 82.7% (5.8 cured, 76.9 improved), p= 0.001 in BT alone group). There was also significant difference between groups in favour of combined therapy for SUI (p=0.001) and MUI (p=0.038) but not for UUI (0.352).

In overall and SUI patients, the combined therapy group was also improved to significantly greater degree than the BT alone group in incontinence severity, symptom distress, daily incontinent episodes and life impact but not in PFMS. The only parameter showing more improvement in patients with MUI was incontinence severity, in patients with UUI was quality of life. There were no other significant differences between BT+PFMT and BT alone group (Table 1).

Table 1. Secondary outcome variables, comparisons between BT+PFMT and BT alone groups

		BT+PFMT	BT	
Variables	Type	Δ1 (median, IQR)	Δ2 (median, IQR)	p
Incontinence severity	Overall	4.0(2.0-5.7)	0.0(0.0-3.0)	**0.001***
	SUI	3.0(2.0-5.2)	0.0(0.0-2.0)	**0.001***
	UUI	4.0(2.0-5.5)	0.0(0.0-4.5)	0.098
	MUI	4.0(2.0-6.2)	2.5(0.0-4.0)	**0.039***
UDI-6 score	Overall	27.1(16.6-41.6)	8.3(-4.1-33.3)	**0.001***
	SUI	27.1(16.6-38.5)	4.1(-4.1-16.6)	**0.001***
	UUI	20.8(10.4-36.4)	10.4(-3.1-38.5)	0.563
	MUI	35.4(8.3-54.1)	16.6(-1.0-37.5)	0.108

IIQ-7 score	Overall	23.8(9.5-41.6)	7.1(-4.7-28.5)	**0.005***
	SUI	19.0(9.5-42.8)	7.1(0.0-28.5)	**0.040***
	UUI	28.5(-5.9-36.9)	-14.2(-26.1-5,9)	**0.045***
	MUI	23.8(4.7-44.0)	16.6(0.0-35.7)	0.283
Incontinent episodes (No./day)	Overall	0.6(0.0-1.3)	0.0(0.0-1.0)	**0.024***
	SUI	0.3(0.0-1.0)	0.0(0.0-0.6)	**0.047***
	UUI	0.3(0.0-1.5)	0.0(-0.2-2.6)	0.546
	MUI	1.0(0.0-1.6)	0.5(0.0-1.0)	0.231
PFMS	Overall	0.2(-0.2-0.7)	-0.1(-0.5-0.5)	0.072
	SUI	0.1(-0.2-1.0)	-0.3(-0.9-0.4)	0.054
	UUI	0.3(-0.4-0.7)	0.4(0.1-0.6)	0.916
	MUI	0.3(0.1-0.7)	-0.1(-0.4-0.4)	0.158

Δ1, Δ2: Differences between baseline and last visit, p: Comparison of changes (Δ1 and Δ2) between BT+PFMT and BT alone group, Mann-Whitney U test, * $p < 0.05$.

Interpretation of results

Although some controversial results were seen in subgroups of UUI and MUI, this study showed that women with symptom-based urinary or stress urinary incontinence who had a 6 week intensive PFMT combined with BT, demonstrated a greater improvement compared to those who had BT alone. In the study of Wyman et al. (2) treatment effect did not differ by urodynamic diagnosis. Compared with this study, the duration of PFMT in the present study may be thought relatively short but the daily number of contractions is quite high (from week 1 to week 6, from 100 to 600 contractions). The lack of differences for some outcome variables in UUI and MUI may be related to duration of present study, small number of patients in UUI subgroup and to the difficulty of treating MUI. Since MUI include both “stress incontinence” and “urgency incontinence”, it was reported more difficult to treat than pure SUI (3) . Therefore, the additional effect of PFMT may not have seen in MUI.

Concluding message

Intensive pelvic floor muscle training combined with bladder training seems to be more effective than bladder training alone in treating female urinary or stress urinary incontinence. It appears that the combination therapy may also lead to a greater long-term benefit in urgency and mixed urinary incontinence. Based on the results of the present study, further RCTs with larger sample size (for urgency urinary incontinence) and long-term follow up are needed.

References

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Disclosures

Funding: Hacettepe University, Scientific Research Projects Coordination Unit The Scientific and Technological Research Council of Turkey, National Scholarship Programme for PhD Students **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** The local ethics commitee of Hacettepe University (2012/06, LUT 12/36-24) **Helsinki:** Yes **Informed Consent:** Yes