

🏆 PRIZE AWARD: Conservative Management Award

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EFFECT OF POSTPARTUM PELVIC FLOOR MUSCLE TRAINING ON URINARY INCONTINENCE IN PRIMIPAROUS WOMEN WITH AND WITHOUT MAJOR PELVIC FLOOR MUSCLE DEFECTS. AN ASSESSOR BLINDED RANDOMISED CONTROLLED TRIAL.

Hypothesis / aims of study

To date, only few randomised controlled trials (RCTs) have investigated the effect of postpartum pelvic floor muscle training (PFMT) in a mixed group of women with and without urinary incontinence (preventive studies), and the effect is ambiguous and unclear (1). Recent research using ultrasound and MRI have demonstrated that 13-36% of women may present with major defects to the levator ani (LA) muscles after normal vaginal deliveries. So far, none of the published former trials on postpartum PFMT have assessed to which extent the participating women had pelvic floor muscle defects or not. The main aim of the present study was to evaluate the effect of postpartum (PFMT) on urinary incontinence (UI) in primiparous women stratified on major LA defects verified by transperineal 3D/4D ultrasound.

Study design, materials and methods

This was an assessor blinded RCT, conducted at a university hospital from February 2010 to May 2012. The participants were included six weeks after delivery, stratified on major LA defects being present or not, and then randomised into two groups in blocks of ten. The randomisation sequence was computer generated using opaque sealed envelopes. Inclusion criteria were singleton primiparous women delivering vaginally after more than 32 weeks of gestation and ability to understand the native language. Women, having a prior abortion/still birth after gestational week 16 or severe perineal tearing (>3b) during delivery, were excluded. Major defects of the LA muscle were diagnosed six weeks postpartum and defined as present when a complete loss of visible muscle attachment toward the pubic bone was seen either unilaterally or bilaterally using tomographic imaging (2). Power calculation was based on a former study performed within a similar setting (3). With a power of 0.90 and significance level of 5% 31 participants were required in each group. As the effect of PFMT in women with major LA defects is unknown, the statistical advice was to aim for 80 women with- and 80 women without major LA defects. Both comparison groups received thorough instruction, feedback and practice on how to contract the pelvic floor muscles (PFM) correctly. After randomisation, the training group (TG) attended an exercise class with supervised PFMT once a week led by an experienced physiotherapist over a period of 16 weeks (3). In addition, the TG was prescribed to perform daily PFMT at home consisting of 3 sets of 8-12 intensive PFM contractions. Exercise adherence was recorded in a training diary. Beyond the instruction on how to contract correctly the control group (CG) received no further intervention. Baseline- and post intervention assessment were performed six weeks- and six months postpartum respectively. The primary outcome was UI assessed by ICIQ-UI SF questionnaire and by pad test (3). Secondary outcomes were vaginal resting pressure (VRP), PFM strength and endurance measured by a vaginal balloon connected to a high precision pressure transducer. Data were analysed by Logistic regression and Independent sample t-test. The principal analysis was done on an intention to treat basis (ITT). Missing categorical data were imputed by "last observation carried forward", continuous data by using the baseline value plus added change observed in the corresponding control group. In addition a "per protocol analysis" was performed, including those completing the trial, having exercise adherence $\geq 80\%$, and no new pregnancy at the clinical visit six months postpartum. P-values < 0.05 were considered significant.

Results

One hundred and seventy-five primiparous women delivering vaginally were included six weeks post partum. The mean age was 29.8 years (SD 4.1). Fifty-five women were diagnosed with major LA defects and 120 with no major defects. Fifteen women (8.6%) were lost to follow up: Four from the "major defect stratum" (3 from the TG; 1 from the CG) and 11 from the "no major defect stratum" (9 from the TG and 2 from the CG). For women with major LA defects the odds ratio (OR) of UI six months postpartum was 20% lower in the TG than in the CG, but the finding was not statistically significant ($p=0.680$). The pad test for women with major LA defects showed increased leakage from six weeks- to six months postpartum in both groups. This increase was higher in the CG, but the group differences were non significant (Table 1). Between group comparisons on UI and Pad test in the stratum of women without major defects were non-significant (Table 1). For both strata, the between group differences for VRP, PFM strength and endurance at six months postpartum were not significant. Per protocol analysis did not alter any findings.

Table 1. Effect of postpartum pelvic floor muscle training on urinary incontinence (UI) in primiparous women either with or without major levator ani (LA) muscle defects. Six weeks postpartum is baseline and six months postpartum is post intervention.

	Major LA muscle defects (n=55)				No major LA muscle defects (n=120)			
	ITT analysis				ITT analysis			
	TG (n=27)	CG (n=28)	OR ^a (95% CI) MD ^b (95% CI)	P	TG (n=60)	CG (n=60)	OR ^a (95% CI) MD ^b (95% CI)	P
UI (yes) ^a	13/27	14/28	0.929	0.929	21/60	30/60	0,538	0.098
6 weeks pp	(48.1%)	(50.0%)	(0.322-2.674)		(35.0%)	(50.0%)	(0.259 -1.121)	

UI (yes) ^a 6 months pp	12/27 (44.4%)	14/28 (50.0%)	0.800 (0.277-2.311)	0.680	18/60 (30.0%)	20/60 (33.3%)	0.857 (0.397-1.851)	0.695
Pad test (gr.) ^b 6 weeks pp	4.3 (± 8.6)	6.1 (± 11.1)	-1.8 (-7.2 to 3.5)	0.494	3.5 (± 8.8)	6.2 (± 14.5)	-2.7 (-7.0 to 1.7)	0.228
Pad test (gr.) ^b 6 months pp	6.0 (± 16.4)	9.8 (± 27.5)	-3.7 (-16.0 to 8.6)	0.546	1.6 (± 6.6)	2.3 (± 9.4)	-0.7 (-3.6 to 2.2)	0.637

ITT=intention to treat; TG=Training group; CG=Control group; pp=postpartum. Categorical data expressed as numbers with percentage (%); Continuous data as mean with standard deviation (SD); Odds ratios (OR^a) and mean differences (MD^b) reported with 95% confidence intervals (CI) and corresponding P values (P).

Interpretation of results

To our knowledge, this is the first RCT evaluating the effect of postpartum PFMT in women with major defects of the LA muscle. Results on self reported UI and a pad test at six months showed no significant difference between the PFMT and the control group in either stratum. The strength of the present study is the randomised controlled design, blinding of assessors, high adherence and the use of reliable and valid outcome measures. We aimed at 80 women with major LA defects, but managed to recruit only 55, which may have resulted in lack of statistical power.

Concluding message

No effect of postpartum PFMT was found for UI in this assessor blinded RCT neither in the strata with major LA defects nor in the strata with no major LA defects.

References

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Disclosures

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