Best Clinical Abstract

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DO PELVIC FLOOR MUSCLE EXERCISES REDUCE POSTPARTUM ANAL INCONTINENCE? A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

To evaluate the treatment effect of pelvic floor muscle exercises (PFME) for postpartum anal incontinence (AI).

Study design, materials and methods

A parallel two-armed randomized controlled trial stratified on obstetrical anal sphincter injury with primary sphincter repair and hospital affinity was conducted in the period 2010-2013 in two ano-rectal specialist out-patients clinics. The randomization was performed using an internet-based computerized procedure and the intervention group (n=54) received six months of individual physiotherapy-led PFME. The control group received written information on PFME only. Changes in the main outcome measure, the St. Mark's score from baseline to post-intervention, was assessed by independent samples t-tests. Secondary outcome measures included manometry measures of anal sphincter length and strength, endoanal ultrasound defect score and voluntary pelvic floor muscle contraction (VPFMC). Predictors of post-intervention AI were assessed by multiple linear regression analyses. The study was not blinded. Adherence to treatment protocol was in the preset study defined as performing PFME more than once a week.

Results

One-hundred-and-nine postpartum women were included in the study. No significant differences were found between groups with regards to delivery-related variables. There was a significant difference in the reduction of St. Mark's scores from baseline to post-intervention in favor of the PFME group (-2.1 points (3.5) vs. -0.8 points (2.7), p=.040) (Table 1). No differences between groups were found in VPFMC, mean anal sphincter strength or length. Baseline St. Mark's score, PFME group affinity and endoanal ultrasound defect score predicted improvements in post-intervention St. Mark's score in the imputed intention-to-treat analyses (n=109). In addition, the analysis on the un-imputed data (n=81) indicated that women in the intervention group who performed PFME on a weekly basis, reduced their AI symptoms more than women in the control group, and also compared to women in the intervention group performing PFME less than weekly (Table 2).

Interpretation of results

In concurrence with previous studies (1,2), our results indicate that the efficacy of PFME in reducing postpartum AI symptoms may be associated with adherence to the treatment protocol. Further, our results show that women with lower baseline St. Mark's and anal sphincter defect scores had lower post-intervention St. Mark's scores than women with more severe AI symptoms and anal sphincter defects at baseline.

Concluding message

The present results indicate that performing individually adapted PFME on a regular basis may reduce postpartum AI, and that PFME may be offered as a first line treatment for postpartum AI. Further research of the optimal timing and frequency of PFME treatment is warranted.

Table 1. Maternal characteristics and pregnancy outcomes of the 109 participating women

Variables	**Intervention group (n=54)**	**Control group (n=55)**	Between group comparison
	n (%)	n (%)	p-value
Age (years), mean (SD) [range]	29.7 (4.3) [20-38]	30.6 (3.8) [23-40]	.241*
Inclusion (days postpartum), mean (SD)	389 (122)	375 (141)	.599*
Adherence –Weekly/daily PFME	32 (59.3)	-	
-Monthly PFME	6 (11.1)	-	
- No PFME/moved/withdrew/dna	16 (29.6)	8 (14.6)	
-Control group	-	47 (85.4)	
St. Mark's score baseline, mean (SD)	5.4 (3.6)*	5.0 (3.2)	.576*
St. Mark's score post-intervention,mean(SD)	3.3 (3.5)*	4.2 (3.4)	.188*
Change in St. Mark's score, mean (SD)	-2.1 (3.5)*	-0.8 (0.7)	**.040***

Data are presented as number (percentage) unless otherwise stated. Boldface numbers=p<.05; SD: Standard Deviation; PFME: pelvicf floor muscle exercises; dna: did not attend follow up appointment. *Independent sample's t-test,

Table 2. Results from the multiple linear regression models evaluating the association between post-intervention St. Mark's score and clinical measures at baseline;
Intention-to-treat analysis and analysis of un-imputed data

Model	Unstandardized Coefficients		Standarized Coefficients	Pearson r	p-value
Intention-to-treat analyses (n=109)	**B**	**SE-b**	**Beta**		
Constant	1.216	1.445			
2. Baseline St. Mark's score	.591	.094	.526	.591	**<.001**
3. Baseline sphincter length	-.089	.437	-.017	-.117	.840
4. Baseline sphincter strength	-.007	.010	-.064	-.170	.487
5. Baseline VPFMC score	-.092	.370	-.021	-.213	.803
6. PFME vs. control group	-.1748	.700	-.249	-.135	**.014**
7. EAUS defect score	.391	.151	.229	.386	**.011**
8. PFME frequency	.508	.311	.163	-.029	.106
Analyses of un-imputed data (n=81)	**B**	**SE-b**	**Beta**		
Constant	1.745	1.725			
2. Baseline St. Mark's score	.597	.112	.505	.572	**<.001**
3. Baseline sphincter length	-.389	.552	-.070	-127	.484
4. Baseline sphincter strength	-.008	.012	-.067	-.178	.529
5. Baseline VPFMC score	.032	.449	.007	-.237	.944
6. PFME vs. control group	-3.550	1.216	-.462	-.148	**.005**
7. EAUS defect score	.374	.178	.203	.390	**.039**
8. PFME frequency	1.608	.742	.344	.022	**.034**

The dependent variable was post-intervention St. Mark's score. Boldface numbers: p<.05
B=raw/unstandardized coefficient, SE-b=Standard error of the raw coefficient, Beta = standardized coefficient

References
1. 1) Boyle R, Hay-Smith EJ, Cody JD, Morkved S. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. The Cochrane database of systematic reviews. 2012;10:CD007471
2. 2) Hilde G, Staer-Jensen J, Siafarikas F, Ellstrom Engh M, Bo K. Postpartum pelvic floor muscle training and urinary incontinence: a randomized controlled trial. Obstet Gynecol. 2013;122(6):1231-8

Disclosures
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