

## 15 YEAR FOLLOW-UP OF A RANDOMIZED CONTROLLED TRIAL OF PELVIC FLOOR MUSCLE TRAINING TO TREAT FEMALE URODYNAMIC STRESS INCONTINENCE

### Hypothesis / aims of study

Several randomized controlled trials (RCTs) and systematic reviews have shown that pelvic floor muscle training (PFMT) is an effective treatment for female stress urinary incontinence (SUI) (1). However, according to a Cochrane review, long-term follow-up data of PFMT is sparse and difficult to interpret (1). Some studies followed up only one of the comparison groups, reported results for the whole cohort rather than by group allocation, or had difficulty tracing an adequate proportion of the original sample. The aims of the present study were to:

1. Evaluate the long term effectiveness of PFMT in women that participated in a RCT comparing two training protocols of PFMT for urodynamic stress incontinence 15 years ago
2. Compare amount of urinary leakage and satisfaction in those who later had surgery to those that did not.

### Study design, materials and methods

Originally 52 women (mean age 45.9 years (24-64)) with clinical and urodynamic SUI were randomized to either home exercise (HE) with 8-12 contractions 3 times a day, or home training + a weekly PFM exercise class (intensive exercise; IE). Both groups had vaginal palpation to ensure correct contraction, and individual assessment with a physical therapist once a month during the 6-month exercise period. Short-term results after 6 months showed significant improvement in favour of the IE group in muscle strength and urinary leakage. All women were encouraged to continue to exercise the PFM after cessation of the trial, but there was no offer of organized training or reminders during the follow-up period. Fifteen years after cessation of the trial all women in the two groups were asked to complete a postal questionnaire with demographic characteristics, general health status, interval surgical history, lower urinary tract symptoms (LUTS), satisfaction, and current status of PFM training. The questionnaire contained the Leakage index, a 13-item reproducible instrument that measures reported leakage during daily activities. The degree of SUI for each item queried is reported on a five point scale, and an overall mean score generated (1= never, 5 is always) (2). The study was approved by the Regional Ethics Committee, and the women gave written consent to participate.

### Results

Response rate was 91.3% in the IE and 89.7% in the HE group. There were no significant differences in demographic characteristics between the groups. Characteristics for the IE and HE groups, respectively, were: mean age 61.6 ( $\pm$  7.9) and 61.2 ( $\pm$  6.8) years, mean body mass index 24.6 ( $\pm$ 3.4) and 26.1 ( $\pm$ 4.2) kg/m<sup>2</sup>, mean parity 2.5 ( $\pm$  1.0) and 2.5 ( $\pm$  0.8), and hormone therapy 10 and 8 women. 47.6% of the IE and 50% in the HE group were operated for SUI. Nine of the 13 operated women in the HE group had their surgery within 5 years of cessation of training, while only three of the 10 had surgery within the first 5 years in the IE group. Two women had two surgeries and one had three surgeries.

Of the 10 non-operated women in the IE group, 5 and 8 reported urinary leakage during the last month during physical activity and coughing and sneezing, respectively: of the 13 non-operated women in the HE group, 4 reported leakage with physical activity and 7 with coughing/sneezing. There was no significant difference in reported frequency or amount of leakage between the IE and HE non-operated groups, nor was there any difference in the Leakage index total score (2.0  $\pm$ 0.5 versus 1.96  $\pm$  0.9,  $p=0.9$ ). There was no difference in the number of non-operated women reporting to be satisfied or almost satisfied (80 % in the IE versus 76.9 in the HE group). Significantly more women in the non-operated IE group were training the PFM  $\geq$  1 time/week compared to women in the non-operated HE group ( $p= 0.03$ ).

Table 1 shows differences between the surgery and non-surgery groups; the only statistically significant difference was found in impact of SUI on activities of daily life, with more women in the non-operated group reporting no such impact.

Table 1: Present status of Lower Urinary Tract Function (LUTS) in non-operated (n=23) and operated (n=24) SUI women 15 years after cessation of pelvic floor muscle training

	Non-operated (n=23)	Operated (n=24)	p-value
SUI last month (n)			
Cough/sneeze	15	9	0.06
Physical activity (PA)	9	7	0.47
UI > once a week (n)	7	12	0.10
Leakage index	2.0 (± 0.8)	2.1 (± 1.1)	0.60
Pad use (n)			
Never/only during PA	12	9	0.31
Always	3	7	0.18
No effect of SUI on daily living (score 0-1) (n)	15	7	0.04*
Fecal incontinence (n)	7	13	0.09
Problems with bladder emptying (n)	2	6	0.14
Urge incontinence (n)	8	5	0.28
Satisfied/almost satisfied (n)	18	18	Ns

Of those who were satisfied after completing PFMT 15 years ago 39.4% had had surgery. Of those not satisfied 78.6% had had surgery (OR 0.117 (95% CI: 0.041-0.760, p= 0.02). Of those that underwent surgery, 21% reported adverse effects, bladder emptying being the most common complaint. At present significantly more women in the non-surgical group performed PFM exercise  $\geq$  once a week (34.7%) and periodically (52.2%) than those who had had surgery (20.8%) and (20.8%), respectively.

### **Interpretation of results**

Forty-nine % of women who had participated in two different PFMT programs had not undergone surgery for SUI 15 years after cessation of the training period. The significantly improved results after intensive training seen on short-term follow-up was not maintained 15 years later. Twenty-one % of operated women reported adverse events after surgery. The rates of LUTS, including SUI, were similar in the operated and non-operated groups. The strength of this long-term follow-up study is the high response rate. However, the results should be interpreted with some caution since the power to detect differences is limited because of small numbers.

### **Concluding message**

More than 90% of SUI women participating in a RCT comparing two different programs for PFMT to treat SUI answered a questionnaire on LUTS 15 years after cessation of training. Seventy-eight % of non-operated women and 75% of operated women were satisfied with their condition. There were no differences in frequency and amount of leakage between operated or non-operated women. Surgery was associated with a higher rate of adverse events. PFMT should be first line treatment for SUI. Further work is needed to better understand factors associated with long-term effectiveness of both PFMT and surgery for SUI.

### **References**

1. Pelvic floor muscle training for urinary incontinence in women. Cochrane review. Oxford: The Cochrane Library. 2001
2. Reproducibility of instruments designed to measure subjective evaluation of female stress urinary incontinence. Scand J Urol Nephrol, 28: 97-100. 1994.