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PELVIC FLOOR MUSCLE TRAINING USING EXTRACORPOREAL BIOFEEDBACK DEVICE FOR THE TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Pelvic floor muscle training (PFMT) as a treatment for stress urinary incontinence (SUI) became widespread after the mid-1990s. However, discomfort or pain could be induced by inserting a vaginal sensor in order to perform pelvic floor biofeedback by a conventional method. Extracorporeal biofeedback device is a chair-shape which had the sensor on the center of chair, so there is no need to insert probe in the vagina, which can get rid of a sense of shame and the risk of outer contagion. We investigated the effects and safety of extracorporeal biofeedback in addition to the PFMT for the treatment of SUI.

Study design, materials and methods

This was a 12-week prospective, single arm study conducted at two university hospitals. Women with symptom of SUI, 2g or more than 2g of urine leakage on standard pad test with comfortable full bladder were enrolled for this trial. The patients with urge-predominant mixed incontinence or true or overflow incontinence were excluded. Primary endpoint was the cure rate of SUI at 12 weeks after PFMT with extracorporeal biofeedback. Objective cure was defined as less than 2g of urine leakage on the standard pad test. Assessments were done by incontinence visual analogue scale (VAS), Sandvik severity index, incontinence quality of life questionnaire (I-QoL), and benefit, satisfaction and willingness (BSW) questionnaire at baseline, 4 weeks and 12 weeks after the treatment. Standard pad test and pelvic floor muscle (PFM) strength measurement using perineometer and Oxford scale (0=nil; 1=flicker; 2=weak; 3=moderate; 4=good; 5=strong) as well as the cure rate of SUI were assessed at baseline and 12 weeks after treatment. Treatment adherence was evaluated at 4 weeks and 12 weeks after the treatment. “Good” adherence was defined as case that the patient can perform PFMT with biofeedback more than thirty sessions in a day during more than two thirds days of all days. “Poor” adherence was defined as case that the patient can perform PFMT with biofeedback more than thirty sessions in a day during less than one third days of all days. Resting cases of them were classified as “Reasonable” cases. The long-term effect of extracorporeal biofeedback device was investigated by interviewing the patients at 12 months after the treatment.

Results

Of a total of 106 patients who were enrolled this study, 71 (77%) patients completed the 12-week study. The average age of the patients was 52.2 years (range from 34 to 73 years). Mean number of vaginal delivery was 2.2 and mean symptom duration was 61.8 months. Sixty-three percent of patients had Stamey grade 1 symptom of SUI, 28.6% of grade 2 and 8.6% of grade 3. Objective cure rate was 52.1%. There was a significant reduction in the pad weight (from 20.6 ± 20.0g to 7.3 ± 13.6g). Twenty-three patients (32.4%) had no urine leakage on pad test at 12 week. Incontinence VAS, Sandvik severity index and I-QoL domains were significantly improved after the treatment ($p<0.0001$). The strength of PFM muscle measured by perineometer or Oxford scales was significantly increased after 12-week treatment. (Table) There was no different change of pelvic muscle strength measured by perineometer or Oxford scale before and after 12-week treatment according to whether SUI symptom was cured or not. (p-values : perineometer= 0.5017 ; Oxford scale= 0.2670) Fifty-nine percent of patients reported that they experienced “much benefit” from the BSW questionnaire. Ninety-four percent of the participants reported that they were “satisfied/very satisfied” with the treatment and 35.7% of patients were “very satisfied”. 65.7% of patients reported that their willingness to have retreatment. And 94.3% of patients reported that they would recommend the treatment to others. At 12-week treatment of PFMT, 64.3% of all patients noted good treatment adherence and 18.6% of patients had poor treatment adherence. Of 56 patients who answered to the telephone interview at 12 months after the treatment, 24 patients (42.9%) answered that they had done PFMT at home and 32 patients (57.1%) had not performed PFMT at all. There was no association between the current status of incontinence and the performing PFMT. When the multivariate analysis were performed, age (OR 0.017, 95% CI 0.001-0.330, p=0.0072) and pad weight (OR 0.005, 95% CI 0.000-0.263, p=0.0043) were predictive factors for cure of SUI after PFMT with extracorporeal biofeedback. No adverse event was related to the study treatment.

Interpretation of results

The results of the present study were that the efficacy of PFM exercises in combination with an extracorporeal biofeedback device showed in decreasing urine leakage and increasing muscle activity. Objective cure (2g or less of leakage) in this study was 52.1% in women training with biofeedback. This result was corresponded with the conclusion of randomized, controlled trials and meta-analysis comparing the effect of pelvic floor muscle training with and without biofeedback.[1,2] From our data, we can know that extracorporeal biofeedback assisted PFMT is an effective therapy in treating women with SUI even though we cannot determine which is most superior among PFMT with conventional biofeedback, PFMT alone, and PFMT with extracorporeal biofeedback because we could not perform this study with any control group.

Concluding message

PFMT using extracorporeal biofeedback can be an effective and safe conservative treatment option to treat female SUI without causing discomfort which may cased by vaginal sensor. Women aged over 60 years, or with a large amount of urine leakage have lower chance to improve the symptoms from the study treatment.

Table. The change of pad weight, subjective symptom, and pelvic muscle strength measured by perineometer and Oxford scale after 12 weeks after starting pelvic floor muscle training associated with extracorporeal biofeedback

	Baseline	12 weeks	p-value
Pad weight	20.6 ± 20.0	7.3 ± 13.6	<0.0001
0 - 1 g		52.1% (37)	
2 - 9 g	44.3% (31)	23.9% (17)	
10 - 19g	17.1% (12)	12.7% (9)	
20 - 29g	14.3% (10)	2.8% (2)	
30g -	24.3% (17)	8.5% (6)	
I-VAS†	6.5 ± 2.2	3.6 ± 2.4	<0.0001
Sandvik severity index*			<0.0001
no	5.7%	24.3%	
slight	10.0%	24.3%	
moderate	62.9%	45.7%	
severe	21.4%	5.7%	
I-QoL†			
avoidance/limiting behavior	56.4 ± 23.9	74.5 ± 16.2	<0.0001
psychosocial impact	57.7 ± 26.1	77.2 ± 17.3	<0.0001
social embarrassment	46.3 ± 26.3	66.9 ± 19.9	<0.0001
Perineometer †(cmH_2O)	19.6 ± 12.3	25.0 ± 13.5	<0.0001
Oxford scale*			<0.0001
1=flicker	10%	5.7%	
2=weak	24.3%	11.4%	
3=moderate	40%	28.6%	
4=good	24.3%	41.4%	
5=strong	1.4%	12.9%	

I-VAS ; Incontinence-Visual Analogue Scale, I-QoL; Incontinence-Quality of Life

† wilcoxon signed Rank test with Bonferroni's correction, *Analysis using GEE with Bonferroni's correction

References

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Specify source of funding or grant	**none**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**NCT00910338 clinicaltrials.gov**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Samsung Medical Center IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**