

THE EFFECT OF EMG BIOFEEDBACK ASSISTED PELVIC FLOOR MUSCLE THERAPY ON SYMPTOMS OF THE OVERACTIVE BLADDER SYNDROME IN WOMEN: A RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study

The overactive bladder syndrome (OAB) is defined as urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence(1). The most commonly used approaches are behavioural therapy, pharmacotherapy and surgery. Although antimuscarinic drugs can cause a reduction in voiding symptoms, the effect is modest and many patients are intolerant of the side effects or do not experience sufficient relief(2). Literature indicates that pelvic floor physiotherapy is effective for incontinence, as well as for urgency, frequency and nocturia(3). The aim of this study was to determine the efficacy and effectiveness of EMG biofeedback assisted pelvic muscle therapy on symptoms of overactive bladder (OAB) after nine weeks of treatment.

Study design, materials and methods

Women with urgency/frequency and/or urge urinary incontinence were randomly divided into an intervention group that received biofeedback assisted pelvic floor muscle therapy (BAPFMT) or into a control group that received no treatment. Exclusion criteria were neurological disorders, a medical history with invasive perineal and/or rectal surgery or existing SUI. The Pelvic Floor Inventories (PeLFIs), the King's Health Questionnaire (KHQ), a voiding diary, a 24-hour pad test and vaginal EMG registration of the pelvic floor with an EMG probe (MAPLe) are used to determine the effect of BAPFMT on complaints of OAB and Quality of Life (QoL). Patients assigned to the intervention group received nine weekly 30-minute sessions of BAPFMT with the MAPLe using a standardized protocol. After nine weeks, both groups are requested to fill in the KHQ and the 24-hour voiding diary again and to conduct a 24-hour pad test. In addition, the PeLFIs is administered and the EMG registration of the pelvic floor is repeated. Group sample sizes of 26 and 26 achieve 81% power to detect a difference of 20.0 between the null hypothesis that both group means are 5.0 and the alternative hypothesis that the mean of group 2 is 25.0 with estimated group standard deviations of 25.0 and 25.0 and with a significance level (alpha) of 0.05000 using a two-sided two-sample t-test.

Results

Fifty –eight patients were included in this study. Six patients discontinued their cooperation in the study before completion of the nine weeks follow-up. Mean age was 56.13 years (range 16.24-72.96 years), Mean Body Mass Index (BMI) was 26.5 (range 16.7-44.14). The groups

were homogeneous for analysis. The PeLFIs showed significant improvement in the intervention group with respect to the control group in complaints of OAB in the domains micturition pattern ($p=0.001$), obstructive micturition ($p=0.02$) and urinary incontinence ($p=0.02$). For the KHQ the domains role limitation, physical limitation, social limitation sleep/energy and symptom severity improved significantly ($p<0.05$) in the intervention group, compared to the control group. The 24-hour voiding diary also showed significant improvement in the invention group in urgency ($p=0.006$), as did the 24 hour padtest (gram) ($p=0.01$) and the daily use of pads ($p=0.03$). EMG registration of the pelvic floor showed significant improvement in pelvic floor muscle function for tone at rest and Maximum Voluntary Contraction (MVC) for the intervention group with respect to the control group ($p < 0.05$).

Interpretation of results

The results show significant improvements in complaints of OAB and QoL. Therefore BAPFMT should be considered as a non-invasive therapy for OAB. Long term efficacy with a one year follow-up is conducted at this moment.

Concluding message

This is the first study that shows that EMG biofeedback assisted pelvic floor muscle therapy with the MAPLe is effective in the OAB syndrome in women after nine weeks of treatment. It significantly reduces symptoms and complaints of OAB and increases Quality of Life for patients.

						95% confidence interval	
Domain	BAPFMT	Mean	Standard error	df	P	Lower bound	Upper bound
General Health	Yes	33.513	3.286	88.926	0.29	26.984	40.042
	No	26.067	3.738	79.832			
Role limitation	Yes	37.468	5.467	91.441	0.06	26.610	48.326
	No	54.687	6.207	83.557			
Physical limitation	Yes	24.157	4.636	85.861	0.03	14.941	33.373
	No	41.246	5.328	77.310			
Social limitation	Yes	3.644	4.549	88.626	0.01	-5.395	12.683
	No	17.211	5.193	80.031			
Personal	Yes	2.938	4.628	61.988	0.20	-6.313	12.188
	No	8.806	4.991	61.502			

Emotional	Yes	13.038	4.244	79.495	0.15	4.591	21.484
	No	12.518	4.920	70.762		2.707	22.330
Sleep/ energy disturbance	Yes	20.758	4.885	77.396	0.01	11.030	30.485
	No	23.937	5.681	68.830		12.603	35.270
Symptom severity	Yes	29.750	3.730	79.148	0.03	22.327	37.174
	No	38.646	4.380	72.936		29.916	47.376

Table: KHQ: EMG assisted biofeedback versus no treatment

References

1. Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Neurourol Urodyn* 2010;29(1):4-20.
2. Haab F. Chapter 1: The conditions of neurogenic detrusor overactivity and overactive bladder. *Neurourol Urodyn* 2014 Jul;33 Suppl 3:S2-S5
3. Wyman JF, Burgio KL, Newman DK. Practical aspects of lifestyle modifications and behavioural interventions in the treatment of overactive bladder and urgency urinary incontinence. *Int J Clin Pract* 2009 Aug;63(8):1177-91.

Disclosures

Funding: Unrestricted grant of Novuqare **Clinical Trial:** Yes **Registration Number:** NL1799705808 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Medical Ethical Committee of the Leiden University Medical Center **Helsinki:** Yes **Informed Consent:** Yes