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COMPARISON OF A BLADDER NECK EFFECTIVE PELVIC FLOOR REHABILITATION PROGRAM AND EMG-BIOFEEDBACK AUGMENTED PELVIC FLOOR MUSCLE TRAINING: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study
Efficacy of pelvic floor muscle training (PFMT) programs for women with stress and/or urge incontinence vary with regards to patient centred outcomes, long-term efficacy, adherence and effect on pelvic floor muscle (PFM) changes. The aim of this prospective randomized controlled trial was to compare subjective improvement and cure rates of a specific bladder neck (BN) effective PFM rehabilitation program with PFMT augmented with biofeedback (BF).

Study design, materials and methods
Sixty four women with stress urinary incontinence symptoms with or without overactive bladder symptoms were randomly allocated to undergo a bladder neck effective PFM rehabilitation program (group 1) or biofeedback-augmented PFMT (group 2). Women with previous pelvic floor (PF) surgery, neurological diseases, dementia or those currently in treatment for PF disorders were excluded.
Primary outcome measure was subjective improvement or cure outlined in a self-administered validated PF questionnaire that includes a posttherapeutic module with improvement and satisfaction scales. Based on a systematic review that calculated a 50% improvement/cure rate of PFMT and Biofeedback (1), 29 women were required in each group to demonstrate a clinically significant difference of 25% with a power of 80% and alpha=0.05. Secondary outcomes included changes in PF questionnaire scores and ability of BN-effective PFM contraction.
Randomization was PC-generated. Allocation was concealed in opaque envelopes that were stored by a secretary who was not involved in the study. Allocation blinding was not possible during the study but post- treatment data collection and analysis was performed by a third party.
All women completed a validated PF questionnaire that included bladder, bowel, prolapse and sexual symptoms. After PF rehabilitation, an additional posttreatment module was applied. This module assesses improvement by scales as well as bothersomeness and satisfaction with treatment success and with care.
Perineal ultrasound was performed before and after treatment to assess BN position and movements during pelvic floor muscle contractions (PFMC). In group 1 perineal ultrasound also belonged to the rehabilitation program to evaluate, teach and practice BN-supporting or BN-elevating PFMC. In three sessions 1-4 weeks apart, women were taught to maintain submaximal PFMC during increases in IAP and to integrate PFMC before coughing e.g. (“Knack”) into daily life. Women in group 2 received an EMG-Biofeedback device with a vaginal probe (Periform). Parameters of the strength training program: 80% of a maximal contraction with 8 s contraction time and 10 s rest between the contractions for 10 minutes. Women were .asked to practice for three months and adherence and handling were also checked three times. Women were offered to switch groups after three months if they were not satisfied with treatment success.
Follow-up was scheduled at 4 weeks, 3, 6 and 12 months. This report contains data on 3-months-follow up.

Results
Eighty eight women were invited to participate, 8 declined, 80 were randomized (group 1; n=36; group 2; n=31), 6 women in group 1 and 7 in group 2 were lost to follow.
Baseline characteristics did not differ significantly between groups (age, parity, BMI, bladder function score; Tab. 1).
Both groups reported significant improvement without significant differences in bladder function scores and satisfaction with treatment success and with care (Tab. 1). However, only group 1 demonstrated improvement in OAB symptoms.
In group 2, 14 women preferred to switch to group 1 after three months of biofeedback training.

	Group 1 N=30	**Group 2 N=24**	**P***
Age (years)	46 (27-84)	45 (29-75)	**0.886**
BMI	24 (19-32)	23 (19-37)	**0.424**
Vaginal parity	0.5 (0-3)	1 (0-2)	**0.822**
Bladder Score BEFORE treatment	2.9(1.1-6)	3.0 (1.6-6)	**0.353**
Bladder Score AFTER treatment	1.9 (0-5.6)	2.4 (0.2-4.9)	**0.197**
Satisfaction with treatment success	60 (20-100)	57 (10-100)	**0.421**
Satisfaction with care	100 (60-100)	97 (30-100)	**0.866**
Some improvement Great improvement	10 (28%) 15 (42%)	12 (46%) 8 (31%)	**0.365**

Tab. 1: Baseline characteristics and outcome measures
* Mann-Whitney- test

Interpretation of results
The bladder neck effective PF rehabilitation program yields similar short term results as an established PFMT with EMG-Biofeedback. However, only women in the biofeedback group desired to switch after 3 months.
Further follow up is necessary to assess long-term efficacy.

Concluding message

Strength training programs are not the only physical training programs that are successful. If increase is strength is the only goal that should be achieved in physiotherapy to treat incontinence is still unclear.

References

1. Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women. Cochrane Database Syst Rev. 2011

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