

Comparison of a bladder neck effective pelvic floor rehabilitation program and EMG-Biofeedback augmented pelvic floor muscle training: a randomized controlled trial – Results at 3 months



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AIMS of Study

The aim of this prospective randomized controlled trial was to compare subjective improvement and cure rates of a specific bladder neck (BN) effective pelvic floor muscle (PFM) rehabilitation program with pelvic floor muscle training (PFMT) augmented with biofeedback (BF) in women with stress urinary incontinence with or without overactive bladder symptoms.

Subjects

64 women were randomly allocated to undergo BN effective PFM rehabilitation program (group 1), n= 36 or biofeedback-augmented PFMT (group 2), n=31. Women with previous pelvic floor (PF) surgery, neurological diseases, dementia or those currently in treatment for PF disorders were excluded. Power calculation: 50% improvement/cure rate of PFMT and biofeedback, 29 women were required in each group to demonstrate a clinically significant difference of 25% with a power of 80% and alpha=0.05. PC-generated randomization with allocation concealed in opaque envelopes

Background

Efficacy of pelvic floor muscle training (PFMT) programs for women with stress and/or urge incontinence vary with regards to patient centered outcomes, long-term efficacy, adherence and effect on pelvic floor muscle (PFM) changes. In a prospective trial, BN-effective PFM rehabilitation with integration into daily life showed excellent success rates (1).

Materials

- Validated PF questionnaire before and after treatment (2).
- After PF rehabilitation, an additional post-treatment module (3) was applied to assess improvement and satisfaction with treatment success and with care.
- Follow-up was scheduled at 4 weeks, 3, 6 and 12 months.
- All women were offered to switch groups after three months if they were not satisfied with treatment success.

Intervention group 1: PF coordination program and daily life integration



Perineal ultrasound for pelvic floor

Abdominal ultrasound for lower TrA (transverse abdominal muscle)

In group 1, perineal ultrasound was performed to evaluate, teach and practice BN-supporting or BN-elevating PFMC. Co-contraction of TrA was also instructed and visually controlled by ultrasound. In three sessions 1-4 weeks apart, women were taught to maintain submaximal PFMC and co-contractions during increases in IAP and to integrate PFMC before coughing e.g. ("Knack") into daily life (1).

Intervention group 2: PF strength training program



EMG-biofeedback and vaginal probe for daily home strength training

In group 2, women received an EMG-Biofeedback device (Sine Bravo, MTR, Germany) with a vaginal probe (Periform). They were instructed to perform a strength training program by a specialized physiotherapist and at home. They were also seen three times.

Parameters of this 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.

Results

	Specific PFMT n=30	PFMT with biofeedback 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	10 (28%)	12 (46%)	0.365
Great improvement	15 (42%)	8 (31%)	

- 6 women in group 1 and 7 in group 2 were lost to follow up.
- Baseline characteristics did not differ significantly between groups.
- Both groups reported significant improvement without significant differences in bladder function scores and satisfaction with treatment success and with care.
- 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.

Conclusions

The specific BN-effective PF rehabilitation program, which avoided maximum PFMC, proved to be similarly effective as the biofeedback-augmented strength training program. Increase in PFM-strength as the only biological explanation for success in physical therapy for the treatment of urinary incontinence has to be reconsidered. Further follow up is underway to assess long-term efficacy.

References

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