

SINGLE BLIND, RANDOMIZED TRIAL OF PELVIC FLOOR MUSCLE TRAINING (PFMT), BIOFEEDBACK ASSISTED PELVIC FLOOR MUSCLE TRAINING (BAPFMT) AND ELECTRICAL STIMULATION (ES) IN THE MANAGEMENT OF OVERACTIVE BLADDER (OAB)

Aims of Study

To compare the efficacy of PFMT, BAPFMT and ES in the management of OAB in women.

Methods

Eligible patients had clinically proven OAB, i.e., they had the symptoms of frequency, urgency, or nocturia, with or without urge incontinence.

Exclusion criteria included pregnancy, deafness, neurological disorders, diabetes mellitus, pacemaker or intrauterine device users, genital prolapse greater than stage? of the ICS grading system, residual urine \geq 100ml, and urinary tract infection. Inclusion criteria included ages between 16-75, symptoms/signs of OAB more than 6 months, frequency of voiding \geq 8 / day, and urgency of voiding \geq 1 / day.

After the calculation of sample size, which disclosed the total sample size should be at least 102 women, randomization of the eligible participants into the 3 treatment groups was performed.

Initial assessment included a detailed medical history, a pelvic exam in the dorsal lithotomy position, a 1-hour pad test and a filling and voiding cystometry, as well as a 4-day 24-hour frequency/volume chart. Other assessments were comprised of evaluation of pelvic floor muscle strength using internal digital assessment according to the Oxford grading system, and measurement of vaginal pressure with a balloon probe connected to a pressure transducer, as well as the King's Health Questionnaire.

The interventions included \leftarrow a PFMT program tailored according to the subject's PERFECT scheme, \uparrow an EMG BAPFMT program with an intra-vaginal probe accompanied with a home program tailored according to the subjects PERFECT scheme, and \rightarrow an ES program using a biphasic symmetrical probe current with a frequency of 10 Hz, a pulse width of 400 μ s, and a duty cycle of 10/5. The treatment period consisted of 12 weeks. The PFMT program utilized the PERFECT scheme to train the patients at home. These patients also returned twice a week to the physiotherapy unit for mentoring the progress. The treatment protocol for the BAPFMT and ES groups was conducted twice a week at the physiotherapy unit. The main outcome measures were post-treatment pelvic floor muscle strength, the record of frequency/volume chart and the King's Health Questionnaire.

Results

137 women with clinically proven OAB were recruited for the present study. 120 subjects were randomly allocated to the 3 different treatment groups after 17 women were excluded due to various reasons. Another 17 women dropped out during the treatment, thus leaving 34 women in the PFMT group, 34 in BAPFMT and 35 in ES to complete the present study. (Table1 to be presented)

In comparing of the characteristics of the 3 groups, significant differences were noted both between the BAPFMT and ES groups as well as between the ES and PFMT groups in gravity ($p=0.22$, $p=0.003$, respectively), and number in menopause ($p=0.025$, $p=0.001$, respectively). A significant difference in parity ($p=0.01$) was also noted between the ES and PFMT groups. (Table2 to be presented)

With regard to pelvic floor muscle strength, compared to the ES group, in both the BAPFMT and PFMT groups there were significant improvements in the differences between pre-and post-treatment scale of power ($p<0.001$, $p<0.001$, respectively), times of fast contraction ($p=0.007$, $p=0.012$, respectively), and degree of vaginal pressure ($p<0.001$, $p<0.001$, respectively). However, between the BAPFMT and PFMT groups there were no significant pre- and post-treatment differences of the 3 variables mentioned above. (Table3 to be presented).

The changes in Domains 7(emotions), 9(severity measures) and 10(total score) of the King's Health Questionnaire revealed significant differences between the BAPFMT and ES groups ($p=0.003$, $p=0.029$ and $p=0.025$, respectively). The changes in these domains when comparing the ES and PFMT groups revealed significant differences as well ($p=0.007$, $p=0.001$ and $p=0.001$, respectively). However, the changes in these same domains revealed no significant differences between the BAPFMT and PFMT groups. (Figure1 to be presented) Median (range) adherence, with treatment was 0.833 (0.25, 1.00) for the BAPFMT group, 0.791 (0.58, 1.00) for the ES group and 0.750 (0.54, 1.00) for the PFMT group ($p=0.356$, Kruskal-Wallis test).

Conclusions

Based on the comparison of the main outcome measures, either BAPFMT or PFMT resulted in significantly better pelvic floor muscle strength and better life quality than ES. Thus, either BAPFMT or PFMT is more effective than ES in the management of OAB in women.