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Original Article

Treatment of Female Urinary Incontinence with EMG-Controlled Biofeedback Home Training

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Abstract: The aim of the study was to evaluate the efficacy of pelvic floor training with EMG-controlled home biofeedback in the treatment of stress and mixed incontinence in women. Subjects were recruited from the urodynamic outpatient clinic and performed pelvic muscle training with an EMG-controlled biofeedback device for 20 minutes daily for 6 months. The number of pads used per day, the number of incontinence and urgency episodes, voiding frequency, maximum urethral closure pressure, functional urethral length and pressure/transmission ratio during stress were assessed before and after treatment. Thirty-three patients (13 with stress and 20 with mixed incontinence) completed the study. There was a significant decrease in the number of pads used per day, the number of incontinence and urgency episodes, and the voiding frequency. Twenty-eight patients (85%) reported that they were cured or improved. Urodynamic parameters did not change significantly. It was concluded that home pelvic floor training with EMG-controlled biofeedback is efficient in 85% of patients in alleviating the symptoms of genuine stress and mixed incontinence without causing side effects.

Keywords: Biofeedback; Conservative treatment; Urinary incontinence

Introduction

It is widely accepted that pelvic floor training with exercises, vaginal cones and electrical stimulation is an efficient way to improve or cure urinary incontinence in women [1–4]. The use of biofeedback in pelvic floor re-education programs offers the possibility on the one hand to control the correct contraction of the pelvic floor muscles, and on the other to visualize the strength and duration of any contraction. The aim of this study was to evaluate the efficacy of EMG-controlled biofeedback in the treatment of female urinary incontinence and to evaluate whether certain parameters can predict treatment outcome.

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Patients and Methods

All patients who were diagnosed with either stress or mixed incontinence in the Urogynecologic Outpatient Clinic of the Department of Obstetrics and Gynecology were offered the chance to participate in the study. Exclusion criteria were genital prolapse below the hymenal ring and inability to perform a levator ani contraction.

Evaluation before treatment included urodynamic testing (Dantec DU 5500 MK2, Dantec Co., Denmark) with retrograde cystometry with 50 ml/min and urethral pressure profilometry both at rest and during stress and uroflowmetry. Pressure/transmission ratio during stress was calculated using the formula PTR = Δ_p urethra/Δ_p bladder $\times$ 100 [%] [5]. A cough stress test and perineal ultrasound were performed. The diagnosis of stress urinary incontinence was based on a positive history and a positive stress test. The number of pads used per day, the number of incontinence episodes, frequency of micturition and the subjective severity of the incontinence problem, using a four-point scale (4 = very severe problem, 3 = major problem, 2 = minor problem, 1 = no problem) were assessed. Pelvic muscles strength

was evaluated by palpation, grading the contractions into 0 = nil, 1 = weak, 2 = medium and 3 = strong. The same protocol was repeated after completion of the study.

Women were carefully instructed to perform a correct pelvic muscle contraction by a specially trained resident. The initial instruction session took about 30 minutes, depending on the patient's ability to contract. The training program included short and sustained levator ani contractions with biofeedback control. Patients performed two 10-minute training sessions per day at home for 6 months. For biofeedback an EMG-controlled device with a vaginal electrode (Myostaeb KT, Staeb Medical, Eppstein, Germany) was used. The probe has two ring electrodes that record the electrical signals produced by muscle contractions. The signal intensity is visualized on a light scale. The device was designed only for biofeedback, not for electrical stimulation. Patients presented for follow-up visits every 4 weeks. After 6 months the initial examination was repeated.

To assess variables that might predict treatment outcome we evaluated age, menopausal status, pelvic muscle strength and maximum urethral closure pressure.

Statistical evaluation was made using the program SPSS for Windows Version 6.1.3 (Statistical Package for the Social Sciences, SPSS Corp.) [6]. Wilcoxon's signed rank test and Student's *t*-test for paired samples were used as appropriate. To study pretest variables for treatment outcome we applied a Wilcoxon test for several unrelated samples for non-parametric data and an analysis of variance for parametric data. $P < 0.05$ was defined as significant.

Results

Of the 67 women to whom bifeedback treatment was offered 17 did not wish to participate in the study. Ten patients had had plans for genital surgery unrelated to incontinence, and opted for a combined procedure to simultaneously treat incontinence on the same occasion. Four women wished to try a course of biofeedback but lived far away from the study center and could therefore not attend for regular check-ups. Three patients did not want to do physiotherapy at all and opted for surgery. Fifty women were included in the study. Thirty-three women completed the whole protocol, 6 patients completed the training program but refused the final examination, and 11 women dropped out. Thus results are presented for 33 patients. Reasons for dropping out included pregnancy (n = 2), moving away from the area (n = 4), diagnosis of myosthenia (n = 1), hysterectomy for fibromas with irregular bleeding (n = 1) and insufficient motivation (n = 3). The 6 patients who refused to undergo final examinations stated that they were improved (n = 6), but no objective data were assessed for them.

The mean age of the subjects was 50.8 years (range 29–75). Twenty-one women (64%) were postmenopausal, 14 (42%) had had a hysterectomy, 5 (15%) an anterior repair and 2 (5%) a colposuspension; 25 (76%) had had at least one vaginal delivery. Thirteen women were diagnosed with genuine stress urinary continence, and 20 with mixed stress–urge incontinence.

After 6 months of training the number of stress incontinence episodes was reduced significantly ($P < 0.001$, Wilcoxon signed rank test). Before therapy 14 women had weekly and 19 women daily stress incontinence: after treatment 8 women reported having no incontinence episodes, 17 had symptoms only weekly, and 8 complained of daily incontinence. The number of patients who had no urgency symptoms increased from 13 to 20 ($P < 0.05$, Wilcoxon signed rank test). There were no significant changes in patients with symptoms of motor urge incontinence (n = 5). One woman developed de novo detrusor instability during the treatment period. Voiding frequency during the daytime decreased significantly from 8.2, SD = 3.7 (range 4–20) before treatment to 6.8, SD = 3.2 (range 4–20) after treatment (P = 0.01, Student's *t*-test). Nocturia decreased from 1.2, SD = 1.4 (range 0–5) before treatment to 0.8, SD = 1.0 (range 0–3) after treatment ($P < 0.05$, *t*-test). Subjectively 6 women (18%) reported cure of any symptoms, 7 (21%) were much improved, 15 (45%) moderately improved, and 5 (15%) were unchanged.

Levator ani muscle strength improved significantly as evaluated by palpation, from 1.7, SD = 0.6, before treatment to 2.4, SD = 0.6, after treatment ($P < 0.001$, Wilcoxon signed rank test).

The number of pads used per day decreased from 1.9, SD = 1.9 (range 0–8) to 0.7, SD = 1.1 (range 0–4) ($P = 0.001$, *t*-test). After the completion of training 18 patients (55%) did not use any pads, compared to 7 (21%) before treatment. No difference in outcome could be detected between patients with genuine stress incontinence and those with mixed incontinence.

Urodynamic testing before and after treatment showed no significant changes in maximum urethral closure pressure and functional urethral length. Pressure/transmission ratio increased from 68%, SD = 16.3 to 78%, SD = 32.2, but these changes were not significant.

None of the pretest parameters evaluated showed any significant influence on treatment outcome.

Discussion

This study shows that home pelvic floor training with EMG-controlled biofeedback is efficient in alleviating the symptoms of genuine stress and mixed incontinence.

Pelvic muscle training is widely accepted as being a successful way to cure or to improve urinary incontinence in women [1,2]. Kegel, in 1948, was the first to describe the efficacy of levator ani muscle training to cure stress urinary incontinence [7]. Improvement rates of up to 80% have been reported [8,9]. EMG-controlled home biofeedback is a useful tool in conservative incontinence treatment. It offers the possibility of demonstrating the contraction strength to the patient and thereby improving their motivation to keep trying.

Bo and co-authors reported that up to 30% of women do not correctly perform a levator ani contraction when verbal instruction only is provided [10]. Careful instruction with palpation of the pelvic muscles is therefore necessary to ensure correct use of the pelvic floor muscles. In some studies biofeedback has been shown to significantly increase the success of Kegel exercise training for stress urinary incontinence [9,11], but other authors could not confirm this observation [12,13]. Susset [14] reported an 80% cure rate and an additional improvement rate of 12% following a home biofeedback regimen. The determination of the long-term effect using a questionnaire showed a higher motivation for training afterwards and better results on the biofeedback group [11].

Compliance was acceptable in this study, with a dropout rate of 25% in spite of a rather time-consuming treatment schedule of 20 minutes daily. A 6-month time frame was chosen because an increase in muscle strength was reported still to occur after up to 20 weeks of training [15]. However, other authors have described cure and improvement after 4–12 weeks [16]. Further study is needed to evaluate whether a shorter training period might lead to the same results. Interestingly the dropouts occurred mainly in the first 3 months of the study, when continuous care by the same provider was not available. In this study significant change in urodynamic parameters was not found. This is in agreement with other authors [8,17]. Meyer et al. showed excellent subjective results after conservative treatment with electrostimulation and biofeedback, while urodynamic parameters remained unchanged [8]. In contrast, Elia [18] described a significant increase in maximum urethral closure pressure and in pressure/transmission ratio after 3 months of pelvic muscle training.

The fact that urodynamic parameters remain unchanged might be related to the possible mechanism of how pelvic muscle training works. As stated by Kujansuu, pelvic muscle training leads to an increase in levator ani muscle strength and possibility to a coordinated activation of the levator ani muscle before the increase of intra-abdominal pressure during stress [19]. This so-called reflex contraction can be demonstrated qualitatively with EMG recordings: however, to our knowledge a quantitative change has not yet been demonstrated [20]. It could be concluded that the improvement of muscle strength and of coordination of muscle action does not lead to a change in maximum urethral closure pressure or functional urethral length. There might be an effect on pressure/transmission ratio, but the changes did not reach a significant level in this study.

One aim of this study was to find out whether pretreatment factors could help to predict treatment outcome, but none of the parameters analyzed in this study showed any significant relation to outcome. This might have been influenced by the small number of patients included. The severity of stress incontinence symptoms has been shown by several authors to have a negative correlation to treatment outcome [16,18,21], but Bo and co-authors [22] reported a positive correlation. Wilson et al. demonstrated that younger women were more likely to improve, whereas Bo and co-authors showed in their study that older women showed better results [16,22]. Pressure/transmission ratio [18] and menopausal status [21,23] have also been reported to be related to treatment outcome. Susset, in 1995, found compliance with treatment to be the most significant variable predictive of a good outcome [24].

Conclusion

Home pelvic floor training with EMG-controlled biofeedback is efficient in 85% of patients in alleviating the symptoms of genuine stress and mixed incontinence without causing side effects.

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EDITORIAL COMMENT: This is a nicely constructed and implemented study evaluating the home treatment of incontinent women with EMG biofeedback. It is a shame that 34% (17 of 50 enrolled) of patients were excluded from the final analysis because of a significant dropout rate. In this small group of patients (*n* = 33) there was a significant decrease in number of pads used per day and the frequency of incontinent episodes, as well as a decrease in voiding frequency. This study actually reflects reality, as similar dropout rates are experienced in the clinical setting. Conservative, non-surgical therapy of female incontinence requires patient motivation and determination in 'keeping with the program' for optimum success.

Reviews of Current Literature

Abdominal Sacral Colpoperineopexy: a New Approach for Correction of Posterior Compartment Defects and Perineal Descent Associated With Vault Prolapse

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Women with pelvic organ prolapse complicated by constipation, chronic pulmonary disease or recreational straining may require repair using other than native tissues. The proposed surgery provides the interposition of a synthetic suspensory bridge between the anterior sacrum and the prolapsed vagina. Anterior and posterior straps of mesh are secured to the sacral promontory separately. Perineal descent is an anatomic finding in anorectal disorders, including constipation, fecal incontinence, rectal pain and solitary rectal ulcer syndrome, rectocele and enterocele. Excessive perineal descent may elongate the pudendal nerve by 20%, and fecal incontinence resulting from anal sphincter weakness may result from pudendal nerve injury. Modification of the sacral colpopexy to included support of the perineum may prevent ongoing pudendal nerve compromise and recurrent prolapse. Nineteen of 97 women having surgical correction of pelvic organ prolapse had the new approach. The overlying peritoneum was not dissected unless it was necessary to mobilize the bladder. The rectovaginal space was dissected to the most superior posterior vaginal fascia connected to the perineal body. The anterior and posterior vaginal fasciae were reapproximated superiorly if required. The posterior mesh was attached to the posterior vaginal fascia, or to the perineal body if the fascia was attenuated. A Halban culdeplasty was performed and the sutures incorporated through the posterior mesh. The sacral sutures were brought through the posterior mesh and tied, and then brought through the anterior mesh and tied with less tension. Pelvic organ prolapse was much improved and perineal descent corrected. Eight of 12 women with bowel complaints had resolution of their symptoms.

Comment:

The premise of the more extensive surgery is that a damaged pelvic diaphragm needs a strong repair to compensate for damaged tissues, and that a purely anatomic repair may not be sufficiently strong or durable to be satisfactory. The study has small numbers and short follow-up, but the technique is new and worthy of report. Further reports in this area would be welcome in order to observe long-term outcome with objective measures. A comparison of standard technique with posterior repair versus the newly described procedure may be the best means of assessing comparative outcomes.