Original Article

Pelvic Floor Electrical Stimulation for Genuine Stress Incontinence: Who Will Benefit and When?

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Abstract: This study sought to determine the characteristics of women in whom pelvic floor electrical stimulation will reduce stress urinary incontinence. It also evaluates how long electrical stimulation should be used before significant improvements are seen in clinical outcomes. Subjects with genuine stress incontinence were enrolled into a multicenter non-randomized trial. They used electrical stimulation for 15 minutes twice daily or every other day for 20 weeks. At the end of 20 weeks, those with a 50% reduction in leakage episodes on voiding diary (‘responders’) were compared with those who did not show a 50% reduction (‘non-responders’). Thirty-one subjects were enrolled and 28 completed the study. After the treatment period, 19 subjects were defined as responders and 9 as non-responders. There were no significant differences between the two groups in baseline demographics (e.g. age, parity, largest birth weight etc.) other than body mass index (greater in nonresponders). Significant subjective and objective improvements were noted among responders by 10 and 14 weeks, respectively. Compliance was higher in responders during weeks 12–15 of the study (P=0.05). It was concluded that a minimum of 14 weeks of pelvic floor stimulation was necessary before significant objective improvements were seen. Body mass index and patient compliance may affect success.

Keywords: Electrical stimulation; Genuine stress urinary incontinence

Introduction

Pelvic floor stimulation is a behavioral therapy that has been used with clinical success in the treatment of urinary incontinence since the 1960s [1]. Pelvic floor electrical stimulation controls urinary incontinence through the micturition reflex system. Its effect in the treatment of genuine stress incontinence is attributed to contraction of the striated pelvic floor musculature, including the external urethral sphincter [2]. Numerous studies have shown that pelvic floor stimulation improves genuine stress incontinence in 60%–90% of patients [3–10]. However, the studies are difficult to compare as they vary in their treatment protocols, the equipment used, and measurements of success. Trials have been conducted lasting from 30 days to over 2 years [5,6,11,12]. Some investigators recommend long-term use of electrical stimulation [5,13,14]. Others propose that it should be used only to teach patients to perform a pelvic floor contraction, but there are very few data to support either statement [15]. Essentially no data are available on the interim improvement in those who were successfully treated versus those who failed treatment.

According to the Clinical Practice Guidelines on Urinary Incontinence, conservative therapies such as pelvic floor stimulation should be offered to patients prior to more invasive procedures [16]. For optimal allocation of healthcare resources, and for patient convenience and compliance, it is crucial to know how long and for whom to use this conservative modality. The duration of therapy needed to predict which patients will ultimately benefit from pelvic floor stimulation is unknown. Patient characteristics which increase the likelihood of a favorable response are also not known.
The purpose of this study was twofold: to determine the duration of pelvic floor stimulation necessary in evaluating response, and to determine patient characteristics that will predict successful outcomes.

Materials and Methods

Between November 1993 and March 1994, 31 ambulatory community-dwelling women with urinary incontinence were recruited by advertisement and referral. They were enrolled at study sites of urology, urogynecology and nurse practitioner practices. Institutional review board approval was obtained at each site. All subjects had urodynamically proven genuine stress incontinence without motor urgency, using provocative substracted cystometry according to International Continence Society criteria. The initial data comparing those subjects treated daily to those treated every other day, showed no significant difference between the two groups [12], therefore both were combined in this study to compare responders with nonresponders.

The Innova pelvic floor stimulation device used in this study (Empi Inc.; Fig. 1) has a symmetrical biphasic output waveform, and each phase has a pulse duration of 0.3ms and a constant current range of 1–100mA. To reduce the potential for muscle fatigue and maintain consistency with other studies of genuine stress incontinence [12], the device current range was limited to 60mA and a stimulus frequency of 50Hz was selected. At the end of 20 weeks subjects who required >60mA to produce a pelvic floor contraction were allowed to adjust the device parameters and increase the intensity. The second channel of stimulation (12.5Hz) was not utilized during this trial. The vaginal electrode is composed of silicone rubber with four carbon bands designed to match the electrical impedance of the vaginal wall to improve the efficiency of current delivery and eliminate the edge effect [17,18]. The device was equipped with a compliance meter which registered only during intracorporeal use. Subjects were taught how to use the device and monitored by study coordinators for intensity settings and appropriate pelvic floor contraction. Proper intensity settings were verified by the study coordinator on at least two subsequent visits. Compliance information recorded internally by the device was transmitted from the device to an external recorder at each follow-up visit. Subjects were aware of the compliance meter in each device.

Subjects were 18 years or older and had one or more episodes of involuntary urine loss on voiding diary during a 3-day period. After giving written informed consent, all underwent a history, physical examination, urinalysis and catheterized residual urine measurement. Urodynamic studies included standing, substracted retrograde water cystometry, direct visualization of fluid loss, and either urethral profilometry or simultaneous cystourethrography. Exclusion criteria included pregnancy, previous incontinence surgery, pelvic or abdominal surgery in the past 6 months, chronic or current urinary tract infection, current alternative incontinence treatments (e.g. incontinence medications, biofeedback and bladder training), cardiac pacemaker, neurologic abnormality, hypermenorrhea, symptomatic atrophic vaginitis, active vaginal lesions, genitl prolapse beyond the introitus, residual urine >100 ml, and polyuria >4000 ml/day. Although there was no maximum number of leakage episodes which excluded subjects, an open bladder neck at rest on fluoroscopy and a resting urethral closure pressure of 20 cmH₂O or less were also exclusion criteria.

Enrolled subjects were assigned consecutively to one of two treatment regimens for 20 weeks. The first 16 were assigned to use stimulation 15 minutes twice a day, every other day. Subsequent enrollees were assigned to use stimulation for 15 minutes twice daily. These regimens were chosen to compare efficacy as part of a related study which determined that treatment either daily or every other day with pelvic floor stimulation is effective in improving or curing urinary incontinence [12]. A modified perineal pad-weighing test [19] was performed at 75% of the subject's maximum bladder capacity at 0, 10 and 20 weeks. Also during these weeks subjects completed quality of life questionnaires, including the Incontinence Impact Questionnaire [20], an abbreviated American Urologic Association Symp-