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Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: a multicenter, placebo-controlled trial.

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OBJECTIVE: Our purpose was to determine the efficacy of transvaginal electrical stimulation in treating genuine stress incontinence. **STUDY DESIGN:** This was a multicenter, prospective, randomized, double-blind, placebo-controlled 15-week trial comparing the use of an active pelvic floor stimulator with a sham device. Thirty-five women used an active unit and 17 control subjects used sham devices.

Weekly and daily voiding diaries were recorded throughout the trial. Urodynamic testing, including pad test and subtracted cystometry, was done before and at the end of device use. Pelvic muscle strength was measured at baseline and at the end of the trial. Patients scored their symptoms on visual analog scales and completed quality-of-life questionnaires before and after therapy. **RESULTS:** Significant improvements from baseline were found in patients using active devices but not in controls.

Comparisons of changes from baseline between active-device and control patients showed that active-device patients had significantly greater improvement in weekly ($p = 0.009$) and daily ($p = 0.04$) leakage episodes, pad testing ($p = 0.005$), and vaginal muscle strength ($p = 0.02$) when compared with control subjects. Significantly greater improvement was also found for both visual analog scores of urinary incontinence ($p = 0.007$) and stress incontinence ($p = 0.02$), as well as for subjective reporting of frequency of urine loss ($p = 0.002$), and urine loss with sneezing, coughing, or laughing ($p = 0.02$), when compared with controls. Pad testing showed that stress incontinence was improved by at least 50% in 62% of patients using an active device compared with only 19% of patients using sham devices ($p = 0.01$). Voiding diaries showed at least 50% improvement in 48% of active-device patients compared with 13% of women using the sham device ($p = 0.02$). No irreversible adverse effects were noted in either group. **CONCLUSIONS:** Transvaginal pelvic floor electrical stimulation was found to be a safe and effective therapy for genuine stress incontinence.