Single-Blind, Placebo Controlled, Randomized Controlled Study of the Efficacy of a High-Frequency Continuous Magnetic Stimulator for Urgency Incontinence

Introduction and Objective: To evaluate the efficacy and safety of a high-frequency continuous magnetic stimulator for urgency incontinence in a multicenter, single-blind, placebo controlled randomized controlled study in 13 institutions.
Materials and Methods: A total of 151 female patients with urgency incontinence were included in the study from January 2009 to July 2010. The 25-minute magnetic stimulation was applied using an armchair type high-frequency continuous magnetic stimulator (SMN-X, Nihon Kohden, Japan) twice a week. The intensiveness of active stimulation was set by the maximum stimulation method at 10 Hz. Sham stimulation was used at 1 Hz in 5-sec “on” - 5-sec “off” pulsing manner. The study period consisted of the baseline period for 1 week, treatment period for 6 weeks, and follow-up period for 6 weeks. The primary endpoint was the frequency of urgency incontinence (number of leaks/week) as recorded in the bladder diary. Secondary endpoints were the number of void and urgency/24hours, mean and maximum voided volume, and the quality of life (QOL) assessment.
Results: Changes from baseline in the number of leaks/week were –13.08±11.00 (mean±standard deviation) in the active group, and –8.68±13.49 in the sham group, showing that the number of leaks/week was significantly reduced in the active group (*P*=0.0377). Changes in the voided volume were 14.03±34.53 in the active group, –4.15±40.60 in the sham group (*P*=0.0056), changes in the number of urgency/24hours were –2.65 in the active group, and –1.53 in the sham group (*P*=0.0114). After the completion of the 12th stimulation, changes from baseline in the number of leaks/week were –13.50±12.06 in the active group, and –10.55±13.06 in the sham group at Week 3 of follow-up, and –14.88±13.05 and –11.64±13.88, respectively, at Week 6 of follow-up. These results indicated that this stimulation therapy was continuously more effective in the active group based on reduction of the number of leaks/week. As for safety, except for expected adverse events including diarrhea and constipation, no patients experienced any device-related adverse event of particular concern.
Conclusions: The magnetic stimulation was effective on urgency incontinence in comparison to sham stimulation in female overactive bladder patients.