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Title: MAGNETIC STIMULATION OF THE SACRAL ROOTS IN THE TREATMENT OF URGE INCONTINENCE AND URINARY FREQUENCY: AN INVESTIGATIONAL STUDY AND A PLACEBO-CONTROLLED TRIAL

Aims of Study:

Pelvic floor electrical stimulation has been reported to be effective for urge incontinence and urinary frequency. However, this treatment remains infrequently used mainly due to discomfort or pain induced by high intensity of percutaneous electrical currents. Magnetic stimulation is a novel technique for stimulating nervous system non-invasively. It can extracorporeally stimulate the nerves deep from skin surface by high intensity of the electrical currents induced in the magnetic field. Therefore, we expected that the magnetic stimulation could directly activate the sacral roots without a pain and insertion of anal or vaginal plug, subsequently be more efficient and comfortable than the conventional electrical stimulation. We recently demonstrated the short-term effect of magnetic stimulation of the sacral roots for stress incontinence in a placebo-controlled study (J Urol, 164: 1277-1279, 2000). We designed an investigational study and a placebo-controlled trial to evaluate the potential efficacy of magnetic stimulation of the sacral roots in the treatment of urge incontinence and urinary frequency.

Methods:

A total of 48 female patients with urge incontinence and/or frequency (43 to 75 years, mean age 62 years) were studied. The inclusion criteria were the followings; 1) one or more episode of urge incontinence, and/or 8 or more of mean number of voids/day on 3-day voiding diary, 2) less than 250ml of mean urine volume/void on 3-day voiding diary, 3) no disorders possibly causing any lower urinary tract symptoms, such as urinary infection, interstitial cystitis and large uterine myoma, 4) no ongoing treatments for urge incontinence and frequency, including pelvic floor exercises, medical treatment and electrical stimulation. Ethics committee of the hospital approved for this study and informed consent was obtained from each patient. Magnetic stimulation was performed in prone position using a rapid-rate stimulator with a 90 mm circular coil (Magstim rapid, Magstim Company Ltd., UK). Referring to an X-ray photograph of pelvis, we fixed the coil over the sacrum to cover the bilateral third sacral foramina. 15Hz repetitive magnetic stimulation with the intensity of 50 % of the maximum output and the duration of 5 sec./min. was applied. The stimulation was continued for 30 minutes, namely, 2,250(15×5×30) stimuli were given. Urodynamic investigations under the magnetic stimulation were performed in 11 patients to evaluate the acute effects to the lower urinary tract function. Thirty-seven women were enrolled in a placebo-controlled study to investigate the short-term efficacy of the magnetic stimulation. The patients were randomly divided into two groups. 22 women were treated by using the active device as an "active stimulation group" and other 15 women by using the sham device as a "sham stimulation group". Mean number of voids/day, mean urine volume/void, number of urge incontinence episode for 3 days, and quality of life (QOL) score were evaluated before and 1 week after the stimulation.

Results:

The urodynamic investigations revealed an apparent elevation of the urethral closure pressure induced by the stimulation (mean 8.2 ± 3.0 cmH₂O, $P<0.0001$) and a significant increase of bladder capacity after the stimulation (mean 40.0 ± 51.0 ml, $P=0.015$). [In the placebo-controlled study, no significant difference of patient](#)

characteristics before treatment was observed between the two groups. After the stimulation, the number of urge incontinence and mean number of voids/day in the active stimulation group, significantly decreased by 3.6 ± 4.1 ($p=0.01$) and 1.0 ± 2.0 ($p=0.03$), respectively. In contrast, no significant decrease of these two parameters was found in the sham stimulation group (0.6 ± 1.4 , $p=0.18$ and 0.5 ± 1.1 , $P=0.09$; respectively). The mean urine volume/void, and QOL score significantly more improved in the active stimulation than those in the sham stimulation group (23.5 ± 25.6 ml vs. 6.2 ± 22.5 ml, $p=0.04$; and 1.4 ± 1.3 vs. 0.4 ± 0.8 , $P=0.01$; respectively). No adverse effects were noted in any patients.

Conclusions:

The present placebo-controlled study first demonstrated that the magnetic stimulation of the sacral roots might be useful for the treatment of urge incontinence and urinary frequency. Further studies are needed to evaluate the long-term efficacy of this potential treatment.