

ORIGINAL ARTICLE

Long-Term Sacral Magnetic Stimulation for Refractory Stress Urinary Incontinence



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Abstract

Objective: To evaluate the effects of sacral magnetic stimulation (SMS) on functional and urodynamic improvement in patients with refractory stress urinary incontinence (SUI).

Design: A sham-controlled, double-blind, parallel study design with a 4.5-month follow-up.

Setting: A tertiary hospital.

Participants: Women (age, 45–75y) with SUI refractory to first-line management (N=34) were allocated to either an experimental (n=20) group or a sham (n=14) group.

Interventions: The SMS protocol consisted of 5-Hz, 20-minute treatments administered over the bilateral third sacral roots, with the intensity set at approximately 70% of the maximal output, for 12 consecutive weekdays.

Main Outcome Measures: Urodynamic assessments and 2 life stress questionnaires, namely, the Urge-Urinary Distress Inventory (U-UDI) and the Overactive Bladder Questionnaire (OAB-q), were administered pre- and post-SMS intervention. We administered the U-UDI (primary outcome measure) and the OAB-q at 3-week intervals during the follow-up period until 18 weeks after the final intervention.

Results: The experimental group exhibited significant improvements in both U-UDI and OAB-q scores postintervention ($P=.011-.014$) and at follow-up visits ($P<.001-.007$) compared with the sham group. In addition, significant increases in bladder capacity, urethral functional length, and the pressure transmission ratio ($P=.009-.033$) were noted postintervention. Multivariate regression analysis revealed that patients with more severe symptoms benefited more from SMS. A poorer baseline U-UDI score and a shorter urethral functional length were associated with a greater response to SMS.

Conclusions: Our observations of a greater response to SMS in patients with more severe SUI than in those with mild symptoms, as well as the long-term benefits of the treatment, confirm the efficacy of SMS in treating SUI.

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Neuromodulation with electrical or magnetic stimulation is an effective second-line treatment for refractory urinary incontinence. Insufficient response and lack of long-term adherence are typically the major obstacles to first-line management of urinary incontinence through pharmacotherapy or pelvic floor muscle training.^{1,2} Magnetic neuromodulation is a noninvasive technique

associated with minimal adverse effects as compared with implanted electrical stimulation.^{3,4} Both magnetic stimulation and surface electrical stimulation were effective in treating symptoms associated with detrusor overactivity^{5,6}; however, magnetic stimulation exhibited greater efficacy in detrusor suppression and bladder capacity augmentation than did electric stimulation.⁷ Numerous studies have investigated the efficacy of pelvic floor magnetic stimulation. Few studies have evaluated the effects of sacral magnetic stimulation (SMS) administered using a coil-type stimulator on urinary incontinence.

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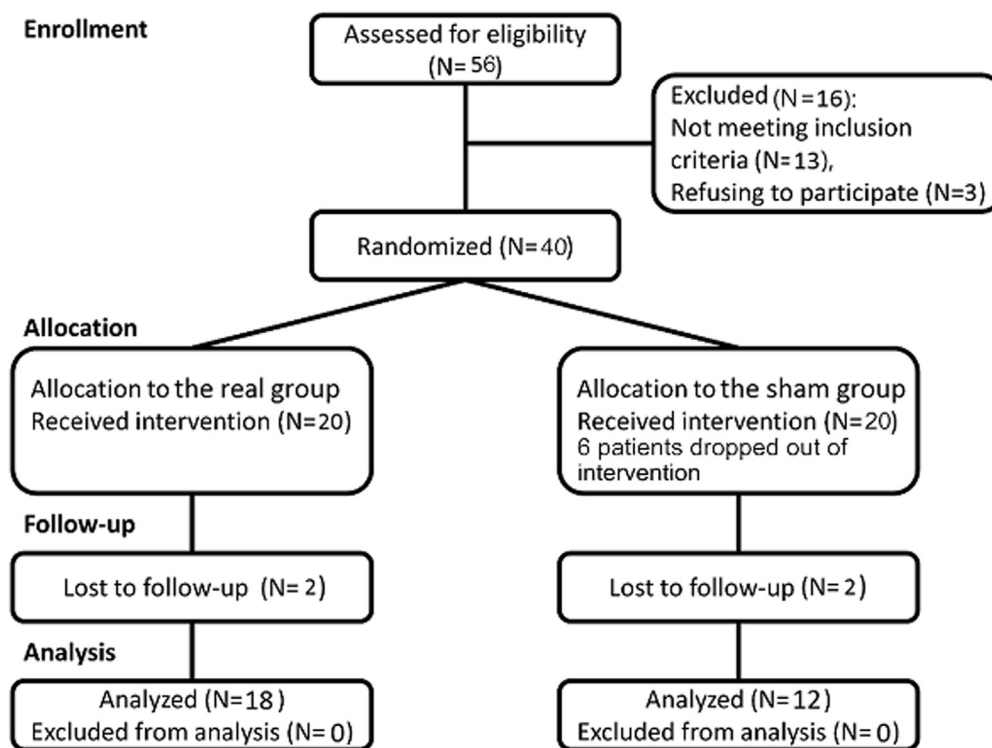


Fig 1 Flowchart for recruitment, group allocation, treatment, follow-up, and analysis.

Most previous studies on SMS have investigated the acute effects of SMS on neurogenic bladder or nonneurogenic detrusor overactivity.⁸⁻¹¹ Clinical outcome measures such as the number of leak episodes and quality-of-life (QOL) scores indicated significant improvement 1 week after treatment.^{10,11} Although studies have demonstrated the short-term effects of SMS on urinary incontinence, the long-term effects of multiple sessions of SMS are yet to be evaluated.

The exact mechanisms through which SMS mitigates incontinence remain unclear. SMS induces an electrical current in the autonomic and somatic nervous systems, innervating the lower urinary tract in a manner similar to that of electrical stimulation.¹²⁻¹⁴ Animal experiments have indicated that SMS ameliorates bladder hyperreflexia by desensitizing C-afferent fibers and reducing *c-fos* gene expression.^{15,16} Considering the proposed mechanisms and urodynamic results of previous studies on SMS, we hypothesized that multiple sessions of SMS can produce sustained effects on stress urinary incontinence (SUI). In this randomized sham-controlled study, we assessed the short-term and ongoing efficacy of an SMS protocol in improving the symptoms of patients with refractory SUI over an 18-week follow-up period and evaluated the urodynamic changes engendered by the protocol.

List of Abbreviations:

MUCP	maximum urethral closure pressure
OAB-q	Overactive Bladder Questionnaire
QOL	quality of life
SMS	sacral magnetic stimulation
SUI	stress urinary incontinence
UPP	urethral pressure profile
U-UDI	Urge-Urinary Distress Inventory

Methods

Patients

Fifty-six patients who visited our outpatient clinic were evaluated consecutively for eligibility to participate in this study from January 2010 to December 2012. Forty patients fulfilled the inclusion criteria (fig 1), namely, (1) a diagnosis of SUI, with or without detrusor overactivity, confirmed by urodynamic results; (2) an SUI history of at least 6 months, which remained refractory after at least 1 month of first-line management; (3) no history of surgery or hormone replacement therapy for SUI; (4) an absence of severe pelvic prolapse (>grade 3 prolapse or $Q_{\max} < 15\text{mL/s}$); and (5) no contraindication for SMS, such as a pacemaker or metallic device. No patients received anticholinergic medication in the 2 weeks before participation or during the follow-up period. All the patients provided written informed consent before participation, and this study was conducted in accordance with the 2008 Declaration of Helsinki and with the approval of the local institutional review board.

Experimental design

We conducted a sham-controlled, double-blinded, parallel design study. A total of 40 women (age, 45–75y) were randomly assigned to either an experimental group or a sham group. However, 6 patients in the sham group withdrew from the sham treatment sessions. Table 1 lists the average group values of the biographic data and baseline scores of all patients. The patients in the experimental group (n=20) underwent 20 minutes of SMS treatment over the third sacral roots on a daily basis for 12 consecutive weekdays. Each side of the S3 root was conditioned for 10 minutes consecutively in 1 session, with the patient in a prone position. The patients in the sham group (n=14) and the

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