Pulsed Magnetic Stimulation for Stress Urinary Incontinence: 1-Year Followup Results

Author links open overlay panelRenly Lim [a d †], Men Long Liong [b], Wing Seng Leong [c], Nurzalina Abdul Karim Khan [a], Kah Hay Yuen [a]

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Purpose

Despite significant differences in success rates between surgical and nonsurgical treatments for female stress urinary incontinence, a few cross-sectional surveys showed that most patients still prefer the latter. We evaluated the efficacy of the under studied nonsurgical treatment using pulsed magnetic stimulation for female stress urinary incontinence.

Materials and Methods

This randomized, double-blind, sham controlled study was performed in 120 female subjects at least 21 years old with stress urinary incontinence. Treatment involved pulsed magnetic stimulation for 2 sessions per week for 2 months (16 sessions). After 2 months, subjects could opt for 16 additional sessions regardless of initial randomization. The primary response criterion was a 5-point reduction in the ICIQ-UI SF (International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form) score. Key secondary response criteria included objective and subjective cure, supplemented by other secondary criteria. Followups were performed at months 1, 2, 5, 8 and 14.

Results

At 2 months 45 of 60 subjects (75%) in the active arm vs 13 of 60 (21.7%) in the sham arm were treatment responders ($p < 0.001$). After 2 months 24 subjects (40%) in the active arm and 41 (68%) in the sham arm elected additional active

pulsed magnetic stimulation. At 14 months, subjects who received 32 sessions of active pulsed magnetic stimulation had the highest percentage of treatment responders (18 of 24 or 75.0%), followed by those who received 16 sessions (26 of 36 or 72.2% and 28 of 41 or 68.3%) and those who did not receive any active pulsed magnetic stimulation (4 of 19 or 21.1%) ($p < 0.001$).

Conclusions

The encouraging long-term response rates show that pulsed magnetic stimulation is an attractive nonsurgical alternative for patients who do not want to undergo surgery.

Section snippets

Study Design

The detailed study design has been published previously.[23] Briefly, this study (ClinicalTrials.gov Identifier: NCT01924728) was done in participating hospitals in Penang, Malaysia. The study was approved by the Joint Ethics Committee of the School of Pharmaceutical Sciences, USM-HLWE on Clinical Studies (USM-HLWE/IEC/2013[0006]). All subjects provided written informed consent.

Patient Population

Eligible subjects were female and 21 years old or older with urine leak upon coughing, an ICIQ-UI SF score of 6 points

Initial Response Rates at 2 Months

From September 2013 to March 2015, 168 subjects were screened to enroll 120 (fig. 1). The active and sham arms did not differ significantly (supplementary table 1, http://jurology.com/).
Using the primary criterion for response, 45 of 60 subjects (75.0%) in the active arm and 13 of 60 (21.7%) in the sham arm were treatment responders (relative risk 3.46, 95% CI 2.09–5.72, $p < 0.001$, table 1). There was a significant difference in changes in the mean ± SE ICIQ-UI SF total score between the active

Discussion

We performed a randomized, double-blind, sham controlled trial which included validated measures with minimal clinically important difference. We report our results according to the CONSORT statement.[22] Additionally, we present our data as both binary outcomes (responder and nonresponder), which can be perceived

intuitively as more relevant information for clinicians and patients to aid in clinical decision making, and as continuous outcomes, which prevents data loss from dichotomization (table

Conclusions

The choice of treatment modalities for SUI should always be based on the risk-to-benefit ratio and patient personal preference rather than cure or improvement rates alone. The encouraging long-term response rates, improved PFM function, high patient acceptance and low dropout rates show that PMS is an attractive and promising nonsurgical alternative for patients who do not want to undergo surgery. Studies are indicated to compare PMS with PFMT in a long-term, randomized, controlled trial.

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