STUDY REPORT presented at AUA (American Urology Association) San Diego May 2016
Study 6 month follow-up report QRS-PelviCenter

Title: Initial, mid-term and durable response of pulsed magnetic stimulation for female stress urinary incontinence

Introduction and Objective

Despite significant differences in success rates between surgical and non-surgical treatments for female stress urinary incontinence (SUI), a few cross-sectional surveys reported that most patients still prefer the latter. Our preliminary results showed that active pulsed magnetic stimulation (PMS) was 3.5 times more likely to improve SUI symptoms compared with sham. We report the mid-term and durable response of this promising yet under-studied non-surgical option.

Methods

120 SUI subjects were randomized 1:1 to active or sham PMS for 8 weeks (16 sessions). The primary response criterion was a 5-point reduction in the International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form (ICIQ-UI SF) score. Key secondary response criteria were objective and subjective cure, supplemented by other secondary criteria. After 8 weeks, subjects who were non-responders or not satisfied with treatment outcome were given extra eight weeks of active PMS (open-label). The mid-term and durable responses were evaluated at 6-months post-treatment.

Results

At week 8, 45 of 60 subjects (75%) in the active and 13 of 60 subjects (21.7%) in the sham arms were treatment responders. 36 (60%) subjects from the initial active and 19 (31.7%) subjects from the initial sham arms opted for no additional treatment. 65 subjects entered the open-label phase; 24 (40.0%) from active and 41 (68.3%) from sham arms. At 6-months post-treatment, 32 active sessions resulted in the highest percentage of treatment responders (n=19/24, 79.2%) (Table 1). 22 of 36 subjects (61.1%) in the active and 5 of 19 subjects (26.3%) in the sham arms continued to respond without additional treatment (durable response) (p=0.031). Regardless of

initial randomization, subjects who received 16 active sessions had comparable efficacy (61.1% versus 75.6%, p=0.131). Key secondary criteria showed higher cure rates in 16 versus 32 sessions. Due to the open-label, cross-over nature, the 32 sessions arm (11.67 ± 6.79) had higher severity (measured by ICIQ-UI SF score) than the 16 sessions arm; ('initial active + no extra': 8.78 ± 2.73, 'initial sham + extra active': 9.61 ± 3.98).

Conclusions

Subjects treated with active PMS were significantly more likely to have initial, mid-term and durable responses than those treated with sham PMS.