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

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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.

Key Words: urinary bladder; urinary incontinence, stress; pelvic floor; magnetic field therapy; risk

Abbreviations and Acronyms

ICI = International Consultation on Incontinence

ICIQ-LUTSqol = ICI Questionnaire-Lower Urinary Tract Symptoms Quality of Life

ICIQ-UI SF = ICI Questionnaire for Urinary Incontinence-Short Form

PFM = pelvic floor muscle

PFMT = PFM training

PGI-I = Patient Global Impression of Improvement

PMS = pulsed magnetic stimulation

SUI = stress urinary incontinence

STRESS urinary incontinence is a common and distressing condition.[1,2] The 5th ICI advocated PFMT with success rates of 15% to 56% as the gold standard nonsurgical treatment.[3,4] However, there is no standardized PFMT regimen[5] and the success of PFMT is often limited by poor compliance.[6,7] Other nonsurgical options (eg biofeedback, vaginal cones and electrical stimulation) are limited by low success rates of 9% to 63%,

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side effects and embarrassment from probe insertion into the vagina.[8–10]

In contrast, the gold standard surgical intervention (midurethral slings) has had a superior success rate of 56% to 98% at 1 year.[11–13] However, Blaivas recently reviewed more than 1,000 published studies and reported serious complications, defined as 5.6% of cases that required further surgery, 15.3% that were refractory to treatment and 8% with surgical failure 5 years postoperatively.[14] In a health care database survey in the United States in 155,458 women who underwent SUI surgery, the 9-year cumulative incidence of repeat surgery was 14.5%.[15] Furthermore, approximately 75,000 federal lawsuits against transvaginal mesh manufacturers in the United States have been reported due to "false and misleading information" about product effectiveness and safety.[16]

In an epidemiology study in 3,934 females with SUI Coyne et al reported comorbidities such as hypertension in 34.3% of participants and diabetes in 9.3%, which may increase the risk of surgery.[17] Cross-sectional surveys of patient treatment-seeking behavior indicated that most patients preferred nonsurgical options.[18,19]

PMS has been used as a nonsurgical option for SUI since 1998 due to its established safety, automatic contractions, no discomfort from probe insertion and ease of administration since it is machine operated.[20] An embedded magnetic coil generates pulsed electromagnetic fields that are able to penetrate deep into the PFMs, leading to pelvic floor nerve stimulation and contraction. The proposed mechanism is to increase PFM strength and endurance through repetitive contractions, similar to PFMT. EAU (European Association of Urology) and the 5th ICI emphasized that current evidence is insufficient to guide any recommendation on PMS use for urinary incontinence and well powered, randomized, controlled trials are needed to study the effects of PMS in different diagnostic groups.[3,21]

Our group previously reported a systematic review of existing evidence focusing on the efficacy of PMS for urinary incontinence.[20] Most published studies had key limitations, including small sample size, no sham arm, nonstandardized outcome measures, poor reporting based on the CONSORT (Consolidated Standards of Reporting Trials) statement and short followup.[20,22] We designed a multicenter, randomized, double-blind, sham controlled trial to address the limitations noted.[3,23]

MATERIALS AND METHODS

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, a ICIQ-UI SF score of 6 points or greater and the ability to perform the 1-hour pad test.[23] Subjects were excluded from analysis if they had 1) other subtypes of urinary incontinence, 2) severe cardiac arrhythmia, 3) a cardiac pacemaker, 4) a neurological condition (eg stroke, epilepsy, Parkinson's disease or multiple sclerosis), 4) pelvic irradiation, 6) previous surgery for SUI, 7) previous treatment with PMS, 8) medication that can affect continence mechanisms, 9) prolapse stage III or IV, 10) severe urethral sphincter weakness/defect or urethral/vesical fistula, 11) post-void residual volume greater than 200 ml or 12) pregnancy.

Intervention and Randomization
A total of 120 subjects were recruited and assigned 1:1 to either active or sham PMS using computer generated, permuted block randomization (fig. 1). The device utilized [F1] was the QRS®-1010 PelviCenter, which uses a PMS repetition cycle of 50 Hz in an 8 seconds on-4 seconds off pulsing manner. To ensure similar experiences, the same PMS device was used for the sham arm but with the magnetic coil tilted 22 degrees down. This sham method provided an 8-week total energy output of only 136 kJ, far less than a single 20-minute active mode run, which provided 408 kJ.

The treatment regimen involved 2 sessions per week for 2 months (16 sessions for 20 minutes each), administered by one of the trained nurses not involved in subject assessment. Since to our knowledge the optimum frequency and treatment duration is not established, the treatment schedule (frequency, intensity and duration) and the sham method were chosen based on previous studies and manufacturer recommendations.[20]

After 2 months, subjects who were nonresponders or not satisfied could opt for 16 additional active PMS sessions (open label phase). Subjects were divided into 1 of the 4 arms, including code 0—sham plus no additional PMS, code 1—sham plus additional PMS, code 2—active plus no additional PMS and code 3—active plus additional PMS. Followups were performed at months 5, 8 and 14.

Study Measures
Baseline assessments included demographic data, medical history, examination for prolapse, urinalysis, urine pregnancy test, ultrasound and uroflowmetry with post-void residual volume.

The primary response criterion was a 5-point reduction in the ICIQ-UI SF score (range 0 to 21).[24] The secondary outcome measures included 1) objective cure (leakage less than 1 gm on the 1-hour pad test, 2) subjective cure (a "never" response to question 3 of ICIQ-UI SF, "How often do you leak urine?"); 3) incontinence episode frequency; 4) 1-hour pad test; 5) PFM function; 6) incontinence severity improvement in ICIQ-UI SF category;
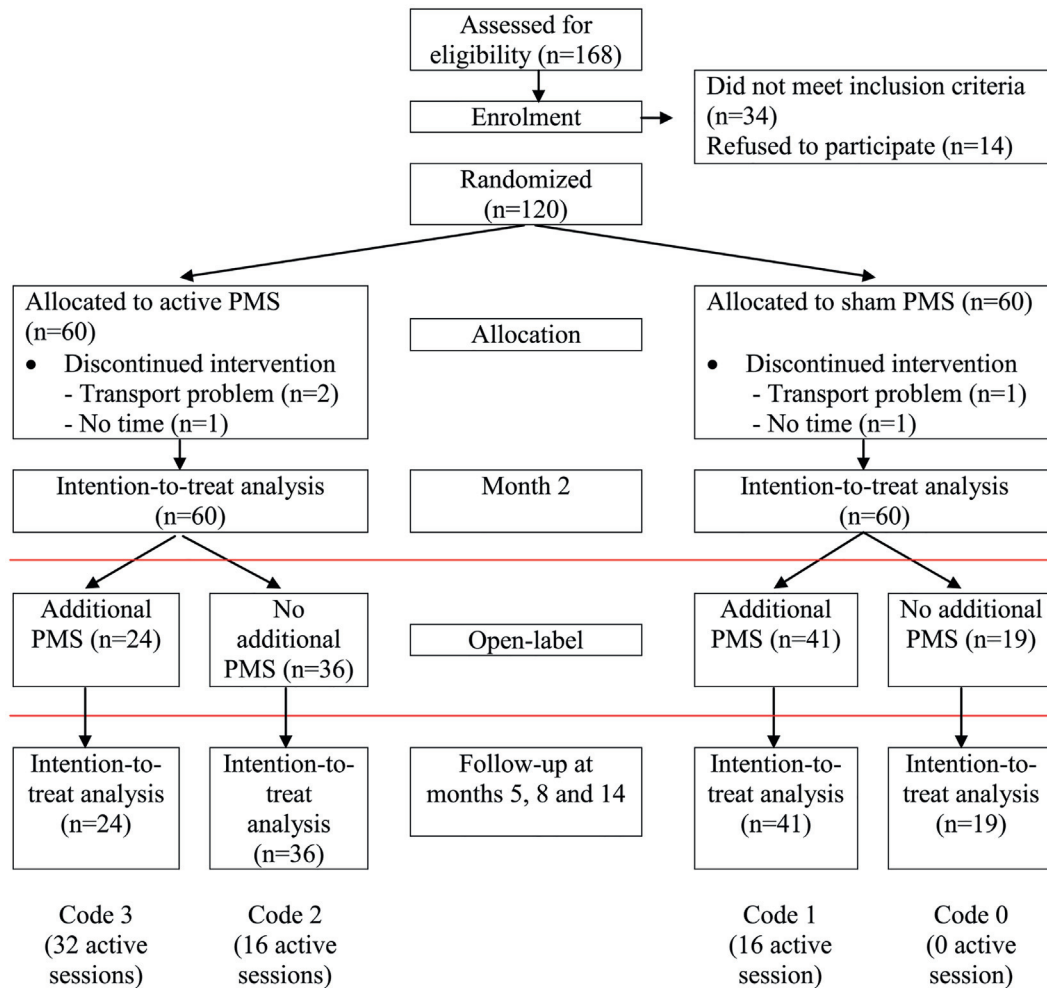
Figure 1. For phase 1, 60 subjects were randomized to active PMS and 60 were randomized to sham PMS for 2 months. For phase 2 after 2 months subjects could opt for 16 additional active PMS sessions (open label phase). For phase 3 subjects returned for followup at months 5, 8 and 14.

7) PGI-I and 8) ICIQ-LUTSqol (range 19 to 76). PFM function was measured using a Peritron™ perineometer. Subjects were asked to perform maximal pelvic floor contraction. The peak, average and duration of contraction for 3 consecutive contractions were recorded.

Statistical Analysis
To set the 2-sided significance level at 0.05 with 80% power, 120 subjects were required, assuming a 60% response in the active arm and a 30% response in the sham arm with 25% attrition.[23] Data were analyzed according to the intent to treat principle.

For univariate analysis, the chi-square test was used for responder analysis at individual time points. For multivariate analysis, data were analyzed by a longitudinal method using a linear mixed model for continuous variables and a generalized linear mixed model for dichotomous variables. For responder analysis at the 2-month and 1-year followups, subjects who withdrew/dropped out after randomization were considered treatment failures and included in the denominator. Statistical

analyses were performed by an independent statistician blinded to patient assessments.

RESULTS

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 [T1] changes in the mean ± SE ICIQ-UI SF total score between the active and sham arms ($M_{diff} = -5.72 \pm 0.67$ vs -2.69 ± 0.67, p = 0.002, fig. 2). Responder [F2] rates of all secondary criteria significantly differed

Table 1. *Responder analysis of binary outcome measures at months 1 and 2 in 60 subjects with active and 60 with sham PMS*

Outcome Measures	No. PMS (%) Active	No. PMS (%) Sham	RR (95% CI)		p Value (chi-square test)
Mo 1					
ICIQ-UI SF	21 (35.0)	6 (10.0)	3.50	(1.52—8.06)	0.001
Cure:					
Objective	21 (35.0)	5 (8.3)	4.20	(1.70—10.41)	<0.001
Subjective	14 (23.3)	1 (1.7)	14.00	(1.90—103.13)	<0.001
Incontinence episode frequency	38 (63.3)	10 (16.7)	3.80	(2.09—6.91)	<0.001
1-Hr pad test	36 (60.0)	17 (28.3)	2.12	(1.35—3.33)	<0.001
Incontinence severity	34 (56.7)	21 (35.0)	1.62	(1.08—2.44)	0.017
PGI-I	19 (31.7)	4 (6.7)	4.75	(1.72—13.14)	0.001
Mo 2					
ICIQ-UI SF	45 (75.0)	13 (21.7)	3.46	(2.09—5.72)	<0.001
Cure:					
Objective	25 (41.7)	4 (6.7)	6.25	(2.32—16.87)	<0.001
Subjective	19 (31.7)	3 (5)	6.33	(1.98—20.28)	<0.001
Incontinence episode frequency	46 (76.7)	12 (20.0)	3.83	(2.27—6.48)	<0.001
1-Hr pad test	49 (81.6)	16 (26.7)	3.06	(1.98—4.74)	<0.001
Incontinence severity	49 (81.7)	22 (36.7)	2.23	(1.56—3.17)	<0.001
PGI-I	39 (65.0)	11 (18.3)	3.55	(2.01—6.24)	<0.001

between the active and sham arms after 1 and 2 months of treatment (p <0.05, table 1).

In the assessment of blinding, 26 subjects (46%) in the active arm and 38 (66%) in the sham arm thought that they received active PMS, while 28 (49%) and 16 (28%), respectively, indicated "don't know" (chi-square test p = 0.06). Of all evaluable subjects 3 of 57 (5.3%) in the active arm and 5 of 58 (8.6%) in the sham arm experienced adverse events
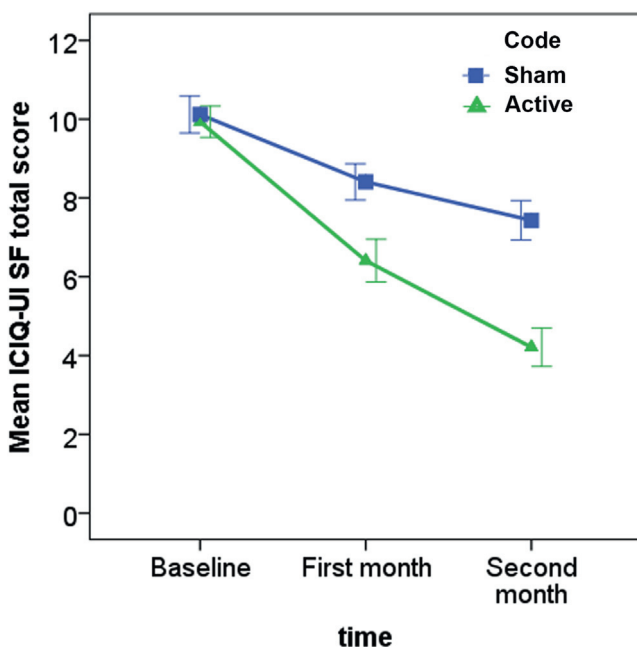

Figure 2. Mean ICIQ-UI SF total scores from baseline to month 2.

(Fisher exact test p = 0.72). These events included pain at the gluteal muscles and the hip bone, yellow vaginal discharge, constipation, diarrhea, mouth ulcer, delayed menstruation, burning sensation or difficulty in passing urine. All uroflowmetry parameters did not significantly differ between the treatment arms (p >0.05).

Long-Term Response Rates at 14 Months
Of the 120 subjects who enrolled 24 (40%) in the active arm and 41 (68%) in the sham arm elected additional active PMS sessions (p = 0.002, fig. 1). A total of 106 subjects completed followup at 14 months, including 23 in the active plus additional PMS arm, 31 in the active plus no additional PMS arm, 40 in the sham plus additional PMS arm and 12 in the sham plus no additional PMS arm. Of the 120 subjects some did not return for followups due to a transport problem in 6, no time in 5 and inability to be contacted in 3.

Primary Outcome
Responder Analysis. Using the primary criterion for response, subjects who received 32 sessions of active PMS (code 3) had the highest percentage of treatment responders (18 of 24 or 75.0%) (table 2). Regardless of the number of PMS sessions (16 or 32), subjects who received active PMS were more likely to be treatment responders than subjects who did not receive any active PMS (0 active sessions) (p <0.001).

Continuous Outcome Data Analysis. Subjects who received active PMS had a statistically significantly higher reduction in the ICIQ-UI SF total score (code 1 mean $M_{diff} = -5.63 \pm 0.73$, code 2 $M_{diff} = -7.13 \pm 0.80$ and code 3 $M_{diff} = -6.80 \pm 0.95$) compared with subjects who received only sham PMS (mean $M_{diff} = -3.46 \pm 1.21$, supplementary table 2 and supplementary fig. 1, http://jurology.com/).

Secondary Outcomes
Responder Analysis. Responder rates of all secondary outcomes were statistically significantly different for subjects who received active PMS (codes 1, 2 and 3) vs subjects who received only sham PMS (code 0) (p <0.05, table 2). Subjects who received 32 sessions of active PMS (code 3) had lower objective and subjective cure rates but similar PGI-I improvement (subjects felt "much better" or "very much better") compared with subjects who received only 16 sessions of active PMS (codes 1 and 2).

Continuous Outcome Data Analysis. There were significant differences in most secondary outcome measures between subjects in the treatment arms who received active PMS (16 or 32 sessions) compared with subjects who received only sham

Table 2. *Responder analysis of binary outcome measures at month 14*

	No. Code (%)*				Code p Value†			
	0	1	2	3	1 vs 0	2 vs 0	3 vs 0	3 vs 2
PMS sessions	0	16	16	32	—	—	—	—
Subjects	19	41	36	24	—	—	—	—
ICIQ-UI SF	4 (21.1)	28 (68.3)	26 (72.2)	18 (75.0)	<0.001	<0.001	0.001	0.812
Cure:								
Objective	2 (10.5)	25 (61.0)	24 (66.7)	11 (45.8)	<0.001	<0.001	0.007	0.109
Subjective	0	12 (29.3)	20 (55.6)	6 (25.0)	<0.001	<0.001	<0.001	0.019
Incontinence episode frequency	3 (15.8)	24 (58.5)	27 (75.0)	17 (70.8)	0.005	<0.001	0.004	0.721
1-Hr pad test	3 (15.8)	34 (82.9)	27 (75.0)	20 (83.3)	<0.001	<0.001	<0.001	0.443
Incontinence severity	6 (31.6)	31 (75.6)	29 (80.6)	20 (83.3)	<0.001	<0.001	0.001	0.785
PGI-I	2 (10.5)	25 (61.0)	29 (80.6)	19 (79.2)	<0.001	<0.001	<0.001	0.895

* Code 0—sham plus no additional PMS, 1—sham plus additional PMS, 2—active plus no additional PMS and 3—active plus additional PMS.
† Generalized linear mixed model (binary logistic regression) and for each overall binary outcome measure p <0.001.

PMS (supplementary table 2 and supplementary fig. 2, http://jurology.com/).

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 2, supplementary table 2, and supplementary figs. 1 and 2, http://jurology.com/). The 75% response rate at 2 months and the approximately 70% rate at 1-year followup were higher than the expected improvement rate of 60% that was calculated based on previous literature. Differences in treatment protocols (frequency, intensity and duration) and PMS technology (depth and width of contraction) could have contributed to our higher success rates.

The initial results suggested that active PMS improved symptoms significantly compared with sham PMS in female patients with SUI. There were consistently significant improvements in ICIQ-UI SF scores between 1 and 2 months, indicating that 8 weeks of PMS was more effective than 4 weeks. Previous studies using treatments ranging from 2 to 6 weeks may have been inadequate for optimal results. After 2 months, there were significantly more patients in the sham arm who were unsatisfied with treatment outcomes and subsequently chose additional PMS sessions. They could have wanted more treatments in the hope that symptoms would improve. This was unsurprising since 109 subjects (94.8%) said that they would not consider surgical options even if they required further treatment.

During an additional 1 year of followup, the findings suggested that such benefits were sustained over time. Interestingly, subjects who received 32 PMS sessions showed a lower percentage of objective and subjective cure than those treated with 16 sessions. A possible explanation could be that those with 32 sessions had significantly higher baseline ICIQ-UI SF scores (mean 11.67 ± 3.42) compared with patients who had 16 sessions (mean 9.61 ± 3.35 and 8.78 ± 2.23), indicating higher incontinence severity in the former group. The open label, nonrandomized nature of the study after the initial 2-month treatment could have resulted in the heterogeneous baseline scores.

We chose ICIQ-UI SF, a questionnaire highly recommended by the 5th ICI, as our primary outcome measure based on the emerging consensus that patient-reported outcomes are most appropriate when describing treatment success or failure.[25,26] We further defined our primary response criterion as a 5-point decrease based on findings from recent studies that determined the minimal clinically important difference in ICIQ-UI SF.[24,27]

A 2015 Cochrane review assessing the efficacy of midurethral slings at up to 1 year of followup indicated that transobturator slings achieved a mean 85.7% objective and 82.3% subjective cure, while retropubic slings achieved a mean 87.2% objective and 84.4% subjective cure.[12] Comparing the 2 key secondary response criteria, our study showed mean 58% objective and 37% subjective cure rates, which were about half those in the Cochrane review. Lower PMS efficacy should be weighed against no surgical risks, no adverse events, no discomfort, no additional risk of comorbidities and treatments that are easily reproducible.

Several recent Cochrane reviews reported that majority of nonsurgical studies measured outcomes in nonstandardized ways or did not report these treatment outcomes.[8–10] Thus, meaningful comparisons with our study were not possible.

PFMs are a major contributing factor in SUI.[28] Thus, it was logical to assess PFM function changes. At 14 months, subjects who received active PMS sessions showed significantly better PFM function, as measured using a perineometer. Furthermore, we found that 32 PMS sessions resulted in more improvements in maximum and average PFM contractions compared with 16 sessions only. We postulate that treatment efficacy and PFM strength were sustained even 1 year after discontinuing treatment because PMS helped patients regain PFM muscle coordination and awareness. With each 20-minute session comprising 100 contractions, patients would have had 1,600 to 3,200 strong repetitive contractions. Stronger muscles meant that patients were able to actively contract the muscles upon physical exertion.

Our study has a number of strengths. All outcome measures were administered at each followup to ensure consistent monitoring in changes in the response. Furthermore, study investigators remained blinded to treatment allocation until unblinding was done at month 14. We used only validated English, Malay and Chinese questionnaires in our study. We performed blinding assessment and used a valid sham method. The total energy output of 16 sham sessions was 136 kJ (or 8,500 J per session), which was far less than the energy output of a single 20-minute active mode run of 408 kJ at 100% intensity.

Our study has some limitations. While a comparative study between PMS and PFMT could help us better understand the role of PMS in SUI treatment, we chose to perform a sham controlled trial, which is needed first to confirm efficacy.

Moreover, double blinding is not possible when comparing PMS and PFMT, which could lead to significant bias.

Next, the high intensity of the protocol may have limited enrolment. Nevertheless, only 14 eligible subjects (8.3%) refused to participate in our study, which reflects patient acceptability. Our sample size had adequate power for analyses at 2 months. The subsequent open label, nonrandomized study resulted in insufficient statistical power.

Since urodynamic testing was not performed, it is not known whether patients had SUI due to hypermobility and/or intrinsic sphincteric deficiency.

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.

ACKNOWLEDGMENTS

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