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Effect of extracorporeal magnetic energy stimulation on bothersome lower urinary tract symptoms and quality of life in female patients with stress urinary incontinence and overactive bladder

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Abstract

Aims: The aim of this study was to investigate the efficacy of extracorporeal magnetic stimulation (EMS) for the treatment of bothersome and severe symptoms of stress urinary incontinence (SUI) and overactive bladder syndrome (OAB) in female patients.

Material and Methods: A retrospective review was conducted on patients with SUI and OAB who were referred to EMS therapy. Successful treatment for the bothersome symptoms of OAB and SUI was defined as score ≤1 for questions 2 and 3 on the Urodynamic Distress Inventory-6. The objective cure of SUI and OAB was defined as no urinary leakage during the cough stress test and any urgency, urge incontinence and voiding frequency of less than eight times per 24 h based on the 3-day bladder diary, after the 9 weeks of treatment, respectively.

Results: Ninety-three patients with SUI or OAB underwent a 9-week course of EMS at 20 min twice weekly. Seventy-two (77%) patients completed EMS treatment. Geographical factor and poor economic status were two main factors for dropout. A total of 94.1% (32 of 34) and 86.8% (33 of 38) of subjects had successful treatment for the bothersome symptoms of OAB and SUI, respectively. In contrast, the cure rate for OAB and SUI was only 61.7% and 42.1%, respectively. There was also a significant improvement in both Urogenital Distress Inventory Short Form (bothersome on lower urinary tract symptoms) and the Incontinence Impact Questionnaire Short Form (quality of life) total score in both groups after EMS.

Conclusions: EMS is a safe and effective alternative method for treating SUI and OAB. Further studies are needed to evaluate the long-term efficacy.

Key words: extracorporeal magnetic stimulation, Incontinence Impact Questionnaire Short Form, overactive bladder, stress urinary incontinence, Urodynamic Distress Inventory-6.

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Introduction

Urinary incontinence (UI) is a condition which can affect many areas of a woman's life.[1–3] The most common form of UI is stress urinary incontinence (SUI) and urgency urinary incontinence (UUI).[4] There is a wide spectrum of treatment options, including conservative and surgical modalities, available for patients with symptomatic SUI. Strong opinions exist as to the 'best' therapy for this condition. The initial management of SUI often involves a variety of non-invasive interventions, including behavioral modification, pelvic floor muscle training (PFMT) with or without biofeedback, and other accessory aids. This is because of the inherent risks in surgical interventions, the cost of hospitalization and the loss of productivity during the convalescent period.[5,6] The perfect therapy for SUI has not yet been identified.

Overactive bladder syndrome (OAB), defined as urgency, with or without UUI, usually with frequency and nocturia, is a common condition affecting quality of life.[4,7] A number of treatments for OAB exist, including lifestyle modifications, behavioral therapy, PFMT, pelvic floor electrical stimulation (PFE), bladder training and drug therapy. However, obtaining effective treatment for an individual patient is difficult.[8,9]

Extracorporeal magnetic stimulation (EMS) is a non-invasive means of stimulating the pelvic floor muscles by inducing an electric current through a magnetic field. EMS is believed to have the same underlying effect as functional electrical stimulation. It generates an electrical field resulting in nerve stimulation, and probable neuromodulation.[10] EMS injects no direct current into the tissues, unlike electrical stimulation. Therefore, activation on skin sensory receptors and C fibers that may cause discomfort or pain to the patient does not occur.[11] However, Ismail *et al*. (2009) reported 52.1% of their patients experienced side-effects in the study of EMS on SUI women. These side-effects included pain in the lower limbs, abdomen and back, cystitis, bowel symptoms and tingling sensation.[12] The obvious clinical effect of EMS is change of the activity in pelvic floor muscle groups. EMS might also change the pattern and rate of firing of the motor nerve fibers, which are responsible for the resting tone of the pelvic floor and sphincter muscles.[13]

This new technology has been applied to pelvic floor therapy and treatment of SUI in clinical practice.[10,11,14–16] There are some data showing that EMS of the sacral nerve roots may suppress detrusor overactivity and have a beneficial effect on women with SUI and OAB.[17–20] Yet, the evaluations are mainly on the improvement of lower urinary tract symptoms but not on the improvement of subjective bothersome symptoms and quality of life. Thus, the aim of our study was to investigate the improvement of subjective bothersome symptoms, quality of life, efficacy, safety and compliance following EMS therapy.

Methods

A retrospective review was conducted on patients with SUI and OAB who were referred to the physiotherapy treatment center for EMS therapy at the Chang Gung Memorial Hospital, Linko, Taiwan, between August 2007 and October 2009. Inclusion criteria for SUI were patients with demonstrable urinary leakage during the cough stress test or stress urethral pressure profile and those suffering from bothersome urine leakage symptoms before starting treatment. The inclusion criteria for OAB were patients who had urinary urgency, voiding frequency of at least ten voids per day in the bladder diary and suffering from bothersome urgency symptoms with the duration of 1 month or longer. Exclusion criteria were patients with symptomatic pelvic organ prolapse with prolapse > stage I by Pelvic Organ Prolapse Quantification, pelvic surgery within 6 months, cardiac pacemakers, neurological diseases, pregnancy, atrophic vaginitis, active vaginal lesions or infections, genitourinary tumors, urinary tract infections and history of pelvic irradiation. Patients with concurrent medical treatment, PFMT and PFE for OAB and SUI detected during the study period also were excluded. Ethics approval was obtained through the Institutional Review Board of Chang Gung.

The medical history, urogynecological examination, urinalysis, 3-day bladder diary, 1-h pad test, cough stress test and urodynamic study before treatment of the study patients were reviewed. Urogenital Distress Inventory Short Form (UDI-6) and Incontinence Impact Questionnaire Short Form (IIQ-7) were used as the subjective evaluation of the degree of bother of symptoms and quality of life.[21–24] In this center, a validated Chinese version of UDI-6 and IIQ-7[25] were used at baseline and after the 9 weeks of treatment.

For treatment, the patients were seated, fully clothed, on the electromagnetic chair (BioCon-2000, Mcube Technology). The method of treatment and the position of patients were similar as reported by Galloway *et al*.[10] EMS technology works by applying rapid pulsed magnetic field on the target tissue; the flux induces small

eddy currents to flow into the tissues. These currents will induce depolarization of nerve axons. If it is a terminal motor nerve axon, the propagating impulse will travel to the motor end-plates and cause the obligatory release of acetylcholine. There will be depolarization of the corresponding muscle fibers and contraction of those fibers.[11] Repeated activation of the terminal motor nerve fibers and the motor end-plates will tend to build muscle strength and endurance. EMS was administered for 20 min per session, twice a week for a total of 9 weeks. Previous studies showed that a stimulation frequency of 10 Hz was most effective for inducing bladder inhibition, and 50 Hz was most effective for urethral closure.[26] In this study, we used the pulsed field, which emitted intermittent high-frequency stimulation (50 Hz) for 20 min with a stimulating phase of 3 s followed by a resting phase of 6 s and intermittent low-frequency stimulation (10 Hz) for 3 s followed by a resting phase of 6 s in the SUI group and OAB group, respectively.

The definition of success in treating the bothersome symptoms of OAB (bothersome cure) was the UDI-6 question 2 assessment index score of 1 or less, that is, subjects were delighted, happy or mostly satisfied with improvement on core symptoms of OAB (urgency) at the end of the treatment period. Similarly, definition for success in treating the bothersome symptoms of SUI (bothersome cure) was the UDI-6 question 3 assessment index score of 1 or less, that is, subjects were delighted, happy or mostly satisfied with improvement on urine leakage related to physical activity, coughing or sneezing at the end of the treatment period. On the other hand, the objective cure (symptom cure) from SUI and OAB was defined as no urinary leakage during the cough stress test, and no urgency, urge incontinence, and voiding frequency less than eight times per 24 h based on the 3-day bladder diary after the 9 weeks of treatment, respectively.

A post-hoc sample size calculation of 35 subjects was needed to detect a difference in failure rate of 25%, with a confidence level of 95% and statistical power of 80%.[19] The baseline characteristics between the EMS group and the group of those who discontinued EMS were compared. Normality of quantitative data was confirmed before using the Student's *t*-test. The Wilcoxon signed rank test was used to analyze the change of urinary symptoms and QoL from baseline to 9 weeks after the treatment by EMS. Pearson's correlation was used to perform the correlation analysis. A P-value < 0.05 was used to define statistical significance.

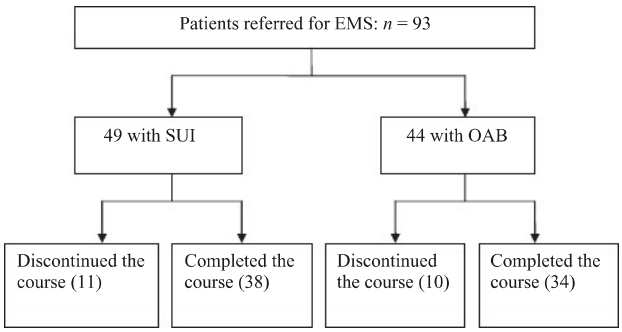

Figure 1 Patient disposition. EMS, extracorporeal magnetic stimulation; SUI, stress urinary incontinence; OAB, overactive bladder.

Results

A total of 93 patients with SUI or OAB meeting the inclusion criteria were enrolled. The flow chart and follow-up are shown in Figure 1. The reasons for dropout from EMS treatment were analyzed among the 21 patients. There was a geographical factor (the transportation problem and limitation of access) in 13 patients and poor economic status in eight patients.

The urodynamics revealed 49 cases of urodynamic stress incontinence; none had leak point pressure less than 60mmH2O in the SUI group of 49 patients, 37 had bladder oversensitivity, and seven had detrusor overactivity in the group of 44 OAB patients.

There were no differences in the baseline characteristics in the group of patients who completed the full course of EMS and the group of patients who discontinued EMS (Table 1).

All of the patients in the OAB group presented with frequency, urgency and a significant degree of bother of urgency symptoms before treatment (Fig. 2). The overall cure rate of OAB symptoms (considered as no complaint of any symptoms in each patient) was 61.7% (21/34). The cure rate on OAB symptoms under intention-to-treat analysis was 47.7% (21/44). The comparisons of bothersome lower urinary tract symptoms and QoL in OAB before and after the EMS are shown in Table 2.

In the SUI group, the objective cure rate as evidenced by negative cough test was seen in 42.1% of the subjects after 18 sessions of treatment (Fig. 3). The cure rate on clinical outcome on SUI under intention-to-treat analysis was 32.7% (16/49). Table 3 shows the comparison of SUI lower urinary tract bothersome symptoms and QoL from UDI-6 and IIQ-7, before and after the EMS.

Table 1 Characteristics of the study population (completed EMS and EMS discontinuation)

Characteristics	Completed EMS ($n = 72$)	EMS discontinuation ($n = 21$)	*P*-value
Mean age in years	53.0 ± 11.0 (50.5–55.6)	56.3 ± 14.1 (50.3–62.3)	0.23*
Mean BMI	29.2 ± 4.3 (28.2–30.2)	28.9 ± 5.1 (26.7–31.1)	0.77*
Parity			0.28**
0–2	18 (25%)	5 (24%)	
3–5	50 (69%)	13 (72%)	
≥6	4 (6%)	3 (14%)	
Menopause	36 (50%)	11 (52%)	0.96**
POP-Q stage			0.88**
Stage 0	24 (33%)	8 (36%)	
Stage I	48 (67%)	13 (64%)	

*Calculated with Student's *t*-test. **Calculated with Fisher's exact test. Data listed as either mean ± standard deviation with 95% confidence interval in parentheses or median with a range in parentheses. BMI, body mass index; POP-Q, Pelvic Organ Prolapse Quantification.

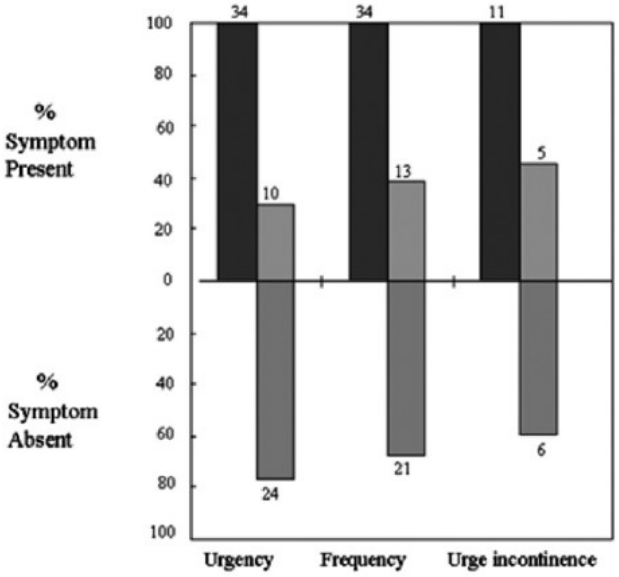

Figure 2 Overactive bladder syndrome (OAB) symptoms (assessed by bladder diary) changes after treatment. ■, baseline; ■, after extracorporeal magnetic stimulation (EMS).

Discussion

The aim of this study was to investigate the improvement of subjective bothersome symptoms, quality of life, efficacy, safety and compliance following EMS therapy for OAB and SUI.

There were high positive responses (88.2–94.1%) in the degree of bother of symptoms of OAB as evaluated by the UDI-6 questionnaire in this study. In contrast, the objective assessment on clinical symptom cure outcomes revealed much poorer results (54.5–70.6%). Despite a discrepancy in the magnitude of the observation between the two assessments methods, the positive feedback on the reduction of degree of bother of symptoms was consistent, with an encouraging relief of symptoms of OAB. Based on these findings and evidenced by improvement of UDI-6 and IIQ-7 assessment index, patients with OAB benefited from EMS treatment. In addition, the study provided the evidence on the impact of the patient's psychosocial health from symptoms of frequency, urgency and urine leakage, which improved significantly after EMS treatment.

A similar trend with a lower objective than subjective cure rate was observed by Chandi *et al.*[16] They assessed the efficacy of EMS and reported that there was an objective improvement of 58% and subjective improvement of 71%. A previous prospective study on EMS by Choe *et al.*[20] reported that cure rates at 2 weeks after treatment were 68.8%, 56.3%, and 50% for urgency, frequency and urgency incontinence, respectively. Evidences from the published reports on cure rates after EMS for OAB are consistent with our result on the short-term effectiveness in this study. These results of EMS are compatible with the treatment results of PFMT (38.2%) and PFE (51.4%).[9] Yet, to date, no study has confirmed the efficacy of the reduction of the degree of bother of symptoms of OAB related to EMS treatment. We did not evaluate the sustainability effect of EMS in urinary incontinence in the long term but previous studies reported that beneficial effects of EMS deteriorated over time.[10,11,15]

In the SUI group, after completing 18 sessions of treatment, the symptom cure rate of SUI was 42.1%. Ünsal *et al.*[14] prospectively studied 35 patients with SUI

Table 2 Urinary symptoms and quality of life scores at baseline and after extracorporeal magnetic stimulation in overactive bladder syndrome group ($n = 34$)

Item	Mean score ± SD (95%CI)			Score ≤1 or ≤7 *n* (%)		
	Baseline	9 Weeks	*P**	Baseline	9 Weeks	*P***
Q1	2.8 ± 1.3 (2.4–3.0)	0.7 ± 0.9 (0.4–1.0)	<0.01	16 (47.1%)	30 (88.2%)	<0.01
Q2	2.5 ± 1.6 (1.9–3.0)	0.4 ± 0.8 (0.1–0.6)	<0.01	0 (0%)	32 (94.1%)	<0.01
Q3	1.5 ± 1.5 (1.0–2.0)	0.9 ± 0.9 (0.6–1.2)	0.29	29 (85.3%)	32 (94.1%)	0.21
Q4	1.4 ± 1.5 (0.9–1.9)	0.5 ± 0.8 (0.2–0.7)	<0.01	24 (70.6%)	32 (94.1%)	0.04
Q5	1.6 ± 1.5 (1.1–2.1)	1.0 ± 0.6 (0.8–1.2)	0.18	28 (82.4%)	30 (88.2%)	0.73
Q6	0.9 ± 1.2 (0.5–1.3)	0.6 ± 0.8 (0.4–0.9)	0.65	31 (91.2%)	32 (94.1%)	1.00
UDI-6	9.7 ± 4.2 (8.3–11.2)	4.0 ± 1.7 (3.4–4.5)	<0.01	18 (52.9%)	31 (91.2%)	<0.01
IIQ-7	10.8 ± 8.1 (8.1–13.5)	3.5 ± 4.4 (2.0–5.0)	<0.01	16 (47.1%)	29 (95.3%)	0.01

*Calculated with Student's *t*-test. **Calculated with χ^2-test. CI, confidence interval; IIQ-7, Incontinence Impact Questionnaire Short Form; Q1, question 1 on UDI-6; Q2, question 2 on UDI-6; Q3, question 3 on UDI-6; Q4, question 4 on UDI-6; Q5, question 5 on UDI-6; Q6, question 6 on UDI-6; SD, standard deviation; UDI-6, Urogenital Distress Inventory Short Form.

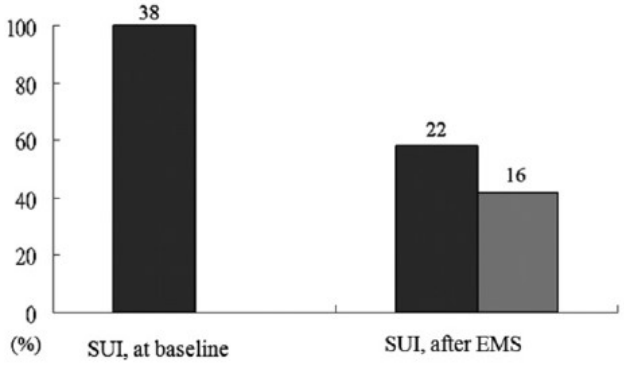

Figure 3 Stress urinary incontinence (SUI) symptoms (assessed by cough stress test) changes after treatment. EMS, extracorporeal magnetic stimulation. ■, symptom present; ■, symptom absent.

and reported 38% and 41% cure and improvement rates of SUI symptoms, respectively. Hoscan *et al*.[19] reported 29.7% cure and 48.1% improvement and a significant improvement in QoL at 3 months after treatment. The present study results are comparable with most of those reported previously.[14,19] One study reported worsening of outcome in 35.5% of women of SUI as measured by pad test; however, this study was underpowered and had a high dropout rate (35.4%).[12]

Nevertheless, the cure and improvement rate after EMS was inferior to the cure rate reported after PFMT, which was 56–60% by patient perception.[6] The possible explanation is that the passive contraction induced with EMS could be less effective than the active voluntary pelvic floor muscle contraction on the muscles' strength training. In addition, a training program of twice a week lasting for 8–10 weeks on EMS is obviously less intensive than a program of PFMT with daily activity for 8 weeks to 6 months. In practice, EMS treatment may be continued for 8 or 10 weeks.[10] Most of the previous studies showed positive responses by using EMS on the pelvic floor with a twice-weekly regime for 8 weeks' duration.[14–16,20] We postulated that a longer period and more EMS treatment sessions for SUI may yield a better result. A 9-week course with 18 sessions was adopted in this study, as we think this provides a reasonable compromise between clinical effectiveness and patients' compliance.

EMS treatment might not be regarded as beneficial to SUI patients as the objective cure rate was just 42.1%. However, when we did an analysis of UDI-6 individual item scores, there were significant improvements in the degree of bothersome symptoms related to urine leakage on physical activity, coughing or sneezing and small amounts of urine leakage after EMS treatment. The successful outcome after EMS treatment of SUI patients who were evaluated with a bothersome symptom assessment was 86.8%. Furthermore, similar results were confirmed on QoL assessment where the UDI-6 total scores and IIQ-7 total assessment indexes were improved. All the results obtained from this study revealed that EMS had excellent responses on the SUI bothersome symptoms reduction. Therefore, EMS may not be a potent treatment of choice for objective symptoms cure of SUI, but it certainly improves the QoL and reduces the degree of bother of SUI-related symptoms effectively.

There are limited data regarding QoL and patient's attitude toward the importance of adhering to the course of treatment. In this study, 72 (77.4%) patients completed the full course of EMS treatment. The barriers to the completion of EMS therapy were the cost of

Table 3 Urinary symptoms and quality of life scores at baseline and after extracorporeal magnetic stimulation in stress urinary incontinence group ($n = 38$)

Item	Mean score ± SD (CI)			Score ≤1 or ≤7 *n* (%)		
	Baseline	9 Weeks	*P**	Baseline	9 Weeks	*P***
Q1	1.7 ± 1.3 (1.3–2.1)	1.0 ± 1.0 (0.7–1.3)	0.12	11 (28.9%)	8 (21.1%)	0.59
Q2	1.1 ± 1.3 (0.8–1.5)	0.8 ± 0.9 (0.5–1.1)	0.38	10 (26.3%)	9 (23.7%)	1.00
Q3	2.5 ± 1.4 (2.1–3.0)	0.9 ± 1.0 (0.6–1.1)	<0.01	0 (0%)	32 (94.1%)	<0.01
Q4	1.6 ± 1.4 (1.2–2.0)	0.8 ± 1.0 (0.4–1.1)	<0.01	10 (26.3%)	32 (94.1%)	0.04
Q5	0.6 ± 1.1 (0.3–1.0)	0.4 ± 0.7 (0.2–0.6)	0.42	5 (13.2%)	3 (7.9%)	0.71
Q6	0.3 ± 0.7 (0.1–0.5)	0.2 ± 0.2 (0.2–0.3)	0.67	2 (5.3%)	2 (5.3%)	1.00
UDI-6	7.7 ± 3.7 (6.6–8.9)	3.9 ± 1.5 (3.4–4.3)	<0.01	14 (36.8%)	34 (89.4%)	<0.01
IIQ-7	8.0 ± 7.1 (5.8–10.3)	3.0 ± 4.1 (1.7–4.3)	<0.01	15(39.5%)	32 (84.2%)	0.01

*Calculated with Student's *t*-test. **Calculated with χ^2-test. CI, confidence interval; IIQ-7, Incontinence Impact Questionnaire Short Form; Q1, question 1 on UDI-6; Q2, question 2 on UDI-6; Q3, question 3 on UDI-6; Q4, question 4 on UDI-6; Q5, question 5 on UDI-6; Q6, question 6 on UDI-6; SD, standard deviation; UDI-6, Urogenital Distress Inventory Short Form.

the treatment and distance from home to hospital. The medical expenses for the EMS treatment are not covered by the Taiwanese National Health Insurance and the majority of other commercial insurances. Therefore, it is a substantial burden for patients of poor economic status. In addition, Chang Gung Memorial Hospital, a tertiary referral center, is situated on the outskirts of Taipei city, which poses some inconvenience for medical access. Both the geographical factors and the high cost of the intervention explain the high dropout rate of 22.6%. No adverse event was noted during the EMS stimulation. The present study on safety and acceptability of EMS was supported by previous studies.[14–16] Only one study reported a high rate of adverse effects from EMS therapy.[12] However, those adverse effects were not serious or life-threatening. EMS therapy is convenient to the patient as it can be done without removing or changing clothes. It is also comfortable without the need of an invasive probe or electrode insertion into the vagina or anus. However, a long course of treatment (6–9 weeks) for EMS therapy may appear time-consuming, which is a risk factor for the discontinuation of treatment. As none of the dropouts was related to the EMS therapy itself, it assures the proper acceptability and safety of the treatment.

Optimum pulse duration for EMS therapy has not been determined. It has been reported that frequencies of 20–50 Hz are effective for SUI and significantly increased maximum intraurethral pressure during stimulation,[27] whereas frequencies of 5–20 Hz have been reported to be optimal for the inhibition of detrusor contraction.[28] In order to yield a maximum effect, the upmost threshold was chosen in the present study; that is, 50 Hz for the SUI group and 10 Hz for the OAB group. A stimulating phase of 3 s followed by a resting phase of 6 s was allocated to avoid muscle fatigue. In addition, the treatment sessions, which lasted for 20 min, twice a week for 9 weeks seemed to offer a reasonable compromise between effective treatment services and patient co-operation.

To the best of one's knowledge, this is the first study using the UDI-6 and the IIQ-7 questionnaire to evaluate the degree of bother of urinary symptoms and changes in QoL in patients with SUI and OAB treated with EMS. In the past decade, the reliable and valid outcome measures for the treatment of lower urinary tract dysfunctions have moved from symptom severity assessment to assessment of the degree of bother of the symptoms. As urinary incontinence symptoms rarely threaten life, the degree to which the OAB and SUI symptoms become bothersome or worrying to the patient and disrupt her daily activities usually provides the basis for her decision to seek medical treatment. Therefore, evaluations of the patient's degree of bother due to symptoms rather than symptoms' severity before and after treatment help to establish whether treatment for OAB and SUI is appropriate for her. Prospective assessment adds strength to this study. Furthermore, evaluation of the degree of bother of symptoms is more relevant from the patient's perspective. However, the limitations of this study include the lack of a control group, non-randomization and short-term follow-up. Future research with proper randomization, a control group and longer follow-up is needed to assess the efficacy and durability of EMS treatment.

Conclusion

This study confirmed that EMS therapy is an effective and safe treatment for SUI and OAB in women. The

effectiveness is much clearer and obvious especially in the assessment of the degree of bother of symptoms and quality of life related to SUI and OAB. Besides the geographical factors and high cost of interventions, the patient acceptability on EMS therapy is high. Further randomized controlled study is needed to evaluate the long-term efficacy of this treatment.

Disclosure

None of the authors has relationships with any companies that may have a financial interest in the information contained in the manuscript.

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