Extracorporeal Electromagnetic Stimulation for Overactive Bladder Patients with Urinary Incontinence: A Single Institute Experience

Yu-Hua Lin¹, Hsu-Che Huang¹, Bing-Juin Chiang¹,
Min-Hui Wang²,*, Chun-Hou Liao¹,3,*

ABSTRACT

Background and purpose: Overactive bladder (OAB) is a syndrome characterized by urgency and frequency, with or without urge incontinence. Extracorporeal electromagnetic stimulation (EMS) has been successfully applied for the treatment of stress and urinary urge incontinence. We report our experience of using extracorporeal electromagnetic stimulation for patients with OAB and urinary incontinence, and investigate predictors for successful treatment.

Methods: Between 2009 and 2016, 162 patients (88 women and 74 men), who presented with OAB symptoms and urinary incontinence treated with EMS treatment, were enrolled in this study. Treatment results were assessed by global response assessment. The overactive bladder symptom score (OAB-SS) questionnaire was recorded before and after treatment. Logistic regression analysis was used to identify predictors for an improved outcome.

Results: All patients tolerated the treatment without any adverse event and mean age was 66.9 ± 13.8 years. In total, 103 patients (63.6%) reported improved outcomes (GRA ≥ 1). The mean total OABSS score decreased significantly after treatment (10.4 ± 3.1 versus 6.1 ± 3.5, p < 0.01). Pure stress urinary incontinence patients showed less improvement when compared to patients with mixed urinary incontinence or pure urgency urinary incontinence. Male patients without a previous history of transurethral resection of prostate history (odds ratio = 3.17, p=0.03) could serve as predictors of a satisfactory outcome.

Conclusions: Treatment course involving EMS of the pelvic floor can improve the symptoms of most OAB patients with synchronous incontinence symptoms. EMS could therefore be considered as an alternative treatment for patients with OAB.

Keywords: Extracorporeal electromagnetic stimulation, overactive bladder, urinary incontinence
Key Messages: EMS of the pelvic floor can improve the symptoms of most OAB patients with synchronous incontinence symptoms. Pure stress urinary incontinence patients showed less improvement when compared to patients with mixed urinary incontinence or pure urgency urinary incontinence.

INTRODUCTION

The International Continence Society defines urinary incontinence as an involuntary loss of urine that is objectively demonstrable and a social or hygiene problem (1). Treatment alternatives for incontinence range from physical therapies and medicine to surgery, although patients are reluctant to undergo surgical treatment until the symptoms of incontinence become severe. Extracorporeal electromagnetic stimulation of the pelvic floor (EMS), as an alternative to conventional electrical stimulation, is a non-invasive neuromodulation utilizing magnetic flux. The pelvic muscles were stimulated by utilizing the magnetic flux, which is associated with a similar physiological mode of action of electrical stimulation. However, less invasive and painless during treatment are the most attractive benefits. EMS has many other potential advantages over conventional electrical stimulation, including the lack of internal electrodes and the option for patients to remain fully clothed during treatment. EMS has been successfully applied for the treatment of stress and urinary urge incontinence, however, there were scarce studies about overactive bladder (OAB) patients and those presented with urinary incontinence.

In this study, we aimed to investigate the treatment effects of EMS for patients with an overactive bladder and synchronous urinary incontinence who failed to respond to first-line oral medication for at least 6 weeks.

MATERIALS AND METHODS

Participants

This study was approved by the Institutional Review Board and Ethics Committee of Cardinal Tien Hospital (IRB number: CTH-106-3-5-020). Between 2008 and 2016, 162 patients (88 women and 74 men) who had been diagnosed with overactive bladder and synchronous urinary incontinence and who were receiving EMS, were enrolled in this study. Three-day frequency-volume charts were applied to confirm the diagnosis of overactive bladder in these patients. Urgency incontinence was defined as the observation of involuntary leakage from the urethra synchronous with the sensation of a sudden, compelling desire to void (1). Stress urinary incontinence was defined as the involuntary loss of urine on effort or physical exertion including sporting activities (1). The NeoControl chair (NeoTonus, Marietta, GA, USA) was used, and the treatment course consisted of 2 sessions per week for 9 weeks. During each session of treatment, patients were requested to remain seated on the chair for 25 to 30 minutes. Treatment results were assessed by global response assessment (GRA) after the treatment course had been completed. Patients with a GRA ≥ 1 were able to receive another course of treatment. The overactive bladder symptom score (OAB-SS) questionnaire was completed before and after treatment in some of the enrolled patients (due to some of the medical records lack of OAB-SS questionnaire after the treatment for comparison). Logistic regression analysis was used to identify predictors for improved outcome (GRA ≥ 1).
Statistical analysis

The Chi-square test was used to compare categorical data, including gender, history of cerebrovascular accident (CVA), diabetes mellitus (DM) history, hypertension (HTN), and coronary artery disease (CAD) history. Due to the relatively small number of patients with medical records including OAB-SS, voided volume, Q_max, post-void residual urine amount, and bladder capacity, we used the Wilcoxon signed rank test for comparative analysis for these factors. The two-sided t-test was applied for all other numerical data, including GRA and age. A p value < 0.05 was considered to be statistically significant. All data were analyzed with commercial statistical software (SPSS version 22.0 for windows, SPSS Inc.).

RESULTS

A total of 162 patients were included in this study. All patients tolerated the treatment without any adverse event. Mean patient age was 66.9 ± 13.8 years and 103 patients (63.6%) reported improved outcomes (GRA≥1). There was no significant difference in terms of gender, age, cerebrovascular accident (CVA) history, diabetes mellitus (DM), hypertension (HTN), coronary artery disease (CAD) history, and different urinary incontinence types (Table 1). In terms of our analysis of urinary incontinence type, an increased rate of improvement was observed for patients presenting with urgency urinary incontinence. Pure stress urinary incontinence (SUI) patients showed less improvement compared to mixed urinary incontinence (MUI) or pure urgency urinary incontinence (UUI) patients (successful rate: 53.6% versus 57.4% versus 69.8%, p=0.155) (Figure 1).

A proportion of our patients (67 patients, 41.3%) had medical records showing the OAB-SS questionnaire, voiding diary, uroflowmetry, and post-void residual urine amount (Table 2). Mean total OAB-SS decreased significantly following treatment (10.5 ± 3.0 versus 6.5 ± 3.2, p < 0.001).

Figure 1. Comparison of EMS effects in different types of urinary incontinence (SUI: stress urinary incontinence; MUI: mixed urinary incontinence; UUI: urgency urinary incontinence)
There were significantly decreasing value of all questions (Q1, Q2, Q3, and Q4) in comparison of pretreatment and after the treatment status. Voided urine volume, peak flow rate, post-void residual urine amount, and bladder capacity all showed no significant difference when compared before and after EMS treatment. There was none of found prognostic factors in female broup (not shown in table). Logistic regression analysis for the subgroup of male patients indicated that men without a history of previous transurethral resection of prostate (TURP) history (odds ratio (OR) = 3.17, p=0.03) could serve as predictors for satisfactory outcome (Table 1).

**DISCUSSION**

The etiology of OAB remains unclear and it is commonly believed that there may be multiple causes for this condition. OAB is often associated with over-activity of the detrusor urinae muscle, a pattern of bladder muscle contraction observed during urodynamics. OAB can be managed with several different methods (2-4), and treatments usually synonymous with treatments for detrusor over-activity. The first aspect of treatment usually involves suggestions for life style modification. Bladder retraining and antimuscarinic drugs usually represent second line therapy if life style changes fail to have an effect. In fact, only 40% of patients show an obvious improvement after first line medical treatment in clinical symptoms. Surgical intervention involves the enlargement of the bladder using bowel tissues, although generally this is used as a last resort (3). This procedure can significantly enlarge urinary volume in the bladder but it is difficult to convince patients to undergo this procedure in the Taiwan culture. Electromagnetic stimulation is another choice for patients who respond poorly to medication.

The treatment of urinary incontinence consists of conservative and operative techniques. Most patients respond poorly to drug therapies and behavioral modification. The treatment of incontinence by electrostimulation can consist of either electrical or magnetic stimulation. Due to the high impedance of tissues and bones, a greater electrical current is required to modulate the nerves when using electrical stimulation and this can lead to an unpleasant sensation (5). The magnetic field used during magnetic stimulation penetrates all tissues; consequently, it is possible to use a lower intensity, thus causing fewer complaints. EMS has been regarded as a minimally invasive therapy for urinary incontinence (5-7). Previous reports have also demonstrated the treatment effect of EMS for patients with chronic pelvic pain syndrome (8).

The mechanism of EMS is considered to be the same as that of electrical stimulation, which involves reflex inhibition of detrusor contraction by the activation of afferent fibers within the pudendal nerves. EMS is also useful for activating deep proximal nerves, which are difficult to activate by electrical stimulation (9).

EMS to the pelvis has been developed for managing stress and urinary urge incontinence, although the results of this procedure have varies across different studies. Yamanishi et al. (10) reported that functional continuous magnetic stimulation may safely and significantly increase maximum intraurethral pressure during stimulation, and maximum urethral closure pressure after stimulation. Galloway et al. (7) described the use of EMS for pelvic floor muscle strengthening in
the treatment of stress urinary incontinence; pad use, and pad weight, were significantly reduced, as was the frequency of leakage episodes and detrusor instability. In another study, Yokoyama et al. (6) conducted a randomized comparative study to investigate EMS and functional electrical stimulation upon urinary incontinence following prostatectomy. This study concluded that both methods can offer earlier continence compared to a control group. In contrast, Voorham-van der Zalm et al. (11) carried out a prospective study and found no significant differences in pelvic floor muscle activity, pad-test, quality of life, voiding diary, and urodynamics in patients treated with EMS. These results

Table 1. Demographic data and clinical characteristics of patients receiving extracorporeal electromagnetic stimulation

<table>
<thead>
<tr>
<th>Variables</th>
<th>GRA≤0</th>
<th>GRA≥1</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>59 (36.4)</td>
<td>103 (63.6)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>68.6 ± 12.7</td>
<td>65.9 ± 14.3</td>
<td>0.225</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22 (37.3)</td>
<td>52 (50.5)</td>
<td>0.105</td>
</tr>
<tr>
<td>Female</td>
<td>37 (62.7)</td>
<td>51 (49.5)</td>
<td></td>
</tr>
<tr>
<td>History</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVA history</td>
<td>6 (10.2)</td>
<td>7 (6.8)</td>
<td>0.447</td>
</tr>
<tr>
<td>DM</td>
<td>16 (27.1)</td>
<td>22 (21.4)</td>
<td>0.405</td>
</tr>
<tr>
<td>HTN</td>
<td>30 (50.8)</td>
<td>39 (37.9)</td>
<td>0.108</td>
</tr>
<tr>
<td>CAD history</td>
<td>13 (22.0)</td>
<td>20 (19.4)</td>
<td>0.691</td>
</tr>
<tr>
<td>Urinary incontinence type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pure SUI</td>
<td>13 (22.0)</td>
<td>15 (14.6)</td>
<td>0.226</td>
</tr>
<tr>
<td>Pure UUI</td>
<td>26 (44.1)</td>
<td>60 (58.3)</td>
<td>0.082</td>
</tr>
<tr>
<td>MUI</td>
<td>20 (33.9)</td>
<td>27 (26.2)</td>
<td>0.300</td>
</tr>
<tr>
<td>Subgroup analysis for male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BPH s/p TURP</td>
<td>12 (54.5)</td>
<td>14 (27.0)</td>
<td>0.027</td>
</tr>
</tbody>
</table>


Table 2. Comparison of OAB-SS and uroflowmetry parameters before and after treatment

<table>
<thead>
<tr>
<th>OAB-SS</th>
<th>Pre-Treatment</th>
<th>Post-Treatment</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>1.1 ± 0.6</td>
<td>0.8 ± 0.6</td>
<td>0.002</td>
</tr>
<tr>
<td>Q2</td>
<td>2.3 ± 1.0</td>
<td>1.7 ± 0.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Q3</td>
<td>3.8 ± 1.7</td>
<td>2.3 ± 0.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Q4</td>
<td>3.3 ± 1.6</td>
<td>1.5 ± 1.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total</td>
<td>10.5 ± 3.0</td>
<td>6.5 ± 3.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Voided volume (ml)</td>
<td>133.9 ± 91.6</td>
<td>182.4 ± 97.4</td>
<td>0.059</td>
</tr>
<tr>
<td>Qmax (ml/s)</td>
<td>12.2 ± 7.0</td>
<td>10.4 ± 3.0</td>
<td>0.689</td>
</tr>
<tr>
<td>Post-void residual (ml)</td>
<td>46.5 ± 48.8</td>
<td>37.8 ± 30.0</td>
<td>0.456</td>
</tr>
<tr>
<td>Bladder capacity (ml)</td>
<td>174.3 ± 85.4</td>
<td>220.3 ± 112.3</td>
<td>0.388</td>
</tr>
</tbody>
</table>

OAB-SS: overactive bladder symptom score; Qmax: peak flow rate
suggested that EMS had no beneficial effects except in training awareness of pelvic floor location. In a small randomized sham-controlled trial, Morris et al. (12) reported that active EMS therapy may significantly reduce the number of urge episodes per day, although there was no statistical improvement in quality of life indices or measured 24-hour urinary loss. In a study investigating the long-term efficacy of EMS for the treatment of woman with urinary incontinence, Dofanay et al. (13) reported a significant improvement in quality of life, and a significant reduction in daily pad use and leakage episodes when tested 6 months after 16 sessions of EMS, although the beneficial effects were temporary and there was a high recurrence rate. Lo et al. (14) used a questionnaire survey before and after EMS treatment sessions for patients suffering from overactive bladder and synchronous stress urinary incontinence and showed significant beneficial effects in terms of urgency, frequency, and incontinence. A multicenter, randomized, sham-controlled study conducted by Yamanishi et al. (15) also concluded that EMS was an effective treatment for overactive bladder patients with urge urinary incontinence, and reported reductions in urinary leakage episodes and urgency complaints.

In our present study, approximately 63.6% of patients with an overactive bladder with urinary incontinence showed significant improvement. EMS appeared to be more efficient for urge urinary incontinence control and less effective for treating stress urinary incontinence patients, although this was not significantly different when compared to other types of urinary incontinence. This result was similar to previous studies (14,15). For overactive bladder control aspects, our study presented improvement in OAB-SS when compared pre-treatment and post-treatment. Subgroup analysis found that male incontinence patients with a history of transurethral resection of prostate (TURP) were significantly different from those without a history of TURPS and were therefore a predictor for poor response (54.5% versus 27.0%, p value=0.027). In terms of safety considerations for the use of EMS devices in such treatments, we observed no device-related adverse events and no cases of device-related death in the present study.

There are several limitations associated with the present study. For example, the lack of detailed urodynamic evaluations for all patients and objective parameters, such as the number of pads used daily or the 24-hour pad test. Further evaluation using these parameters may help us to measure the severity of incontinence when following up the response to therapeutic measures.

**CONCLUDING MESSAGE**

According to our results, patients with an overactive bladder showed significant improvement following treatment involving extracorporeal electromagnetic stimulation of the pelvic floor. This may be considered as a safe and non-invasive alternative treatment for patients with an overactive bladder. Urge urinary incontinence responded better to EMS treatment while men without a history of transurethral resection of prostate represented a significant predictor of better outcome.

**CONCLUSIONS**

According to our preliminary results, approximately 59% of patients with OAB were significantly improved following EMS treatment.
EMS may therefore be considered as an alternative treatment for patients with OAB, especially for those with poor response to oral medication.

DEVELOPMENT OF INTEREST

This research did not receive any specific grant from any funding agency in the public, commercial, or not-for-profit sector.

REFERENCES


[13]. Doğanay M, Kilic S, Yilmaz N. Long-term effects of extracorporeal magnetic innervations in the treatment of women with urinary incon-


膀胱過動症患者合併尿失禁病人施行體外電磁刺激：
單一機構之研究經驗分享

林佑樺¹, 黃旭澤¹, 姜秉均¹, 王敏慧²*, 劉俊厚¹,³*

中文摘要

研究目的：膀胱過動症為一表現急尿與頻尿之症候群病人且可能合併急迫性尿失禁。體外電磁刺激在過去便已知為應力性尿失禁及急迫性尿失禁之成功治療選擇，但卻不清楚對於膀胱過動症的影響是否也能夠改善，本研究為單一機構在合併性尿失禁的膀胱過動症病患的治療經驗，並且從中尋找可能的治療預測因子。研究方法：自2009至2016年，共162位膀胱過動症合併急迫性尿失禁病患（其中為88位女性及74位男性）接受體外電磁刺激治療，本研究透過個問卷量表評估階段治療後在整體及膀胱過動情況是否有改善。結果：所有病患均沒有副作用且完成階段治療，其中平均年齡為66.9歲，63.6%的病患表達獲得改善的情況，在膀胱過動症合併尿失禁的病人族群中，若其尿失禁類型為單純應力性尿失禁患者相對於急迫性尿失禁與混和性尿失禁患者的改善幅度較小，另外男性病患且之前未曾接受過攝護腺手術者也較有良好的預後（OR:3.17, p=0.03）。結論：體外電磁刺激在同時合併尿失禁的膀胱過動症患者仍為一有效的治療方式，因此更甚至考慮作為膀胱過動症患者的治療選項。

關鍵字：體外電磁刺激；膀胱過動症；尿失禁

1 新北市新店耕莘醫院泌尿外科
2 新北市新店耕莘醫院腎臟內科
3 輔仁大學醫學院
收稿日期：2018年01月05日
接受日期：2018年03月29日
王敏慧及劉俊厚為共同通訊作者身份
通訊作者：王敏慧 電子信箱：paula.minhui@hotmail.com
             劉俊厚 電子信箱：liaoch22@gmail.com