



EFFICACY OF EXTRACORPOREAL ELECTROMAGNETIC STIMULATION FOR THE TREATMENT OF URINARY INCONTINENCE AND THE PREDICTIVE FACTORS FOR SATISFACTION

EKSTRAKORPOREAL ELEKTROMANYETİK STİMÜLASYONUN ÜRİNER İNKONTİNANS TEDAVİSİNDE ETKİNLİĞİ VE BAŞARIYI ETKİLEYEN FAKTÖRLERİN ANALİZİ

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ABSTRACT

Objective: Extracorporeal electromagnetic stimulation (ExMS) has been used widely to treat Urinary Incontinence (UI). We aim to analyze the subjective and objective outcomes of ExMS treatment and evaluate factors that could predict satisfaction.

Material and Method: Patients who underwent ExMS treatment for UI were evaluated. ExMS was performed twice weekly with 20-minute sessions for six-eight weeks. Subjective satisfaction and objective improvement were evaluated before and three months after treatment with a bladder diary, pad test, and pelvic floor muscle strength assessment. King's Health Questionnaire was used to evaluate quality of life.

Result: Eighty-one patients were included. The mean age was 50.4±9.7 (30-76). Forty four (54.3%) patients suffered from mixed UI, and 19 (23.5%) and 18 (22.2%) suffered from stress UI and urge UI, respectively. Six patients were cured, 64 (79.1%) were better than before, and the rest noticed no change. After treatment, there were significant improvements in bladder diary, pelvic floor muscle strength, pad test, and King's Health Questionnaire. There was a significant correlation between the type of UI and satisfaction after treatment; women suffering from stress UI were less satisfied when compared to urge or mixed UI. No correlations were found between treatment satisfaction and age, pretreatment pelvic floor muscle strength, 1-hour pad test,

ÖZET

Amaç: Elektromanyetik dalgalarla tedavi (ExMS) üriner inkontinansın tedavisinde sıklıkla kullanılmaktadır. Bu çalışmada, Üriner inkontinansın (İÜ) şikayetleri olan hastalarda EXMS tedavisinin etkinliğinin değerlendirilmesi ve tedavi memnuniyetini etkileyen faktörlerin analiz edilmesi amaçlanmıştır.

Gereç ve Yöntem: Üriner inkontinans nedeniyle ExMS tedavisi uygulanan hastalar retrospektif olarak değerlendirilmiştir. ExMS, manyetik stimülasyon sandalyesi kullanılarak, haftada üç seans ve her seans 20 dakika olmak üzere altı-sekiz hafta boyunca uygulanmıştır. Subjektif memnuniyet, tedavi öncesi ve sonrasında ürojinekolojik semptomlar, bir saatlik ped testi, dört günlük üriner günlük, pelvik taban kas gücü ve King Sağlık Anketi değerlendirilmiştir.

Bulgular: Seksen bir hasta çalışmaya dahil edilmiştir. Ortalama yaş 50,4±9,7'dir (30-76). Kırkdört (%54,3) hasta mikst İÜ, 19 hasta (%23,5) stres İÜ ve 18 hasta (%22,2) acil İÜ tanısı almıştır. ExMS tedavisinden memnuniyet değerlendirildiğinde, altı hasta tamamen iyileştiklerini, 64 hasta (%79,1) daha iyi olduklarını, geri kalan hastalar değişiklik olmadığını belirtmiştir. Tedavi sonrası üriner günlük, pelvik taban kas gücü, bir saatlik ped testi ve King Sağlık Anketi sonuçlarında anlamlı düzelmeye görülmüştür. Üriner inkontinans tipi ile memnuniyet arasında anlamlı ilişki bulunmuştur. Stres İÜ şikayeti olan kadınlarda memnuniyet urge veya mikst

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or mean number of leakage and urgency episodes. No complications developed.

Conclusion: ExMS is an effective treatment for UI with almost 80% subjective satisfaction. Quality of life, pad test, bladder diary, and pelvic floor muscle strength were improved significantly. The UI type (urge or mixed UI) was a significant predictive factor for treatment satisfaction.

Keywords: Electromagnetic stimulation, mixed urinary incontinence, overactive bladder syndrome, quality of life, stress urinary incontinence, urinary incontinence

Üİ olanlara göre daha düşük bulunmuştur. Bunun dışında yaş, ped testi, pelvik taban kas gücü ve ortalama kaçak ve aciliyet sayısı ile memnuniyet arasında anlamlı ilişki bulunamamıştır. Tedavi esnasında veya sonrasında herhangi bir komplikasyon gelişmemiştir.

Sonuç: ExMS, Üİ şikayeti olan kadınlarda etkin bir tedavidir. Subjektif tatmin oranları %80'e varmaktadır. Objektif olarak ped testi, pelvik taban kas gücü, üriner günlük ve hayat kalitesinde anlamlı düzelmeye neden olmaktadır. Üriner inkontinans tipi (urge veya mikst Üİ) tedavi memnuniyeti etkileyen bir faktördür.

Anahtar Kelimeler: Elektromanyetik stimülasyon, üriner inkontinans, mikst üriner inkontinans, stres üriner inkontinans, aşırı aktif mesane, hayat kalitesi

INTRODUCTION

Urinary incontinence (UI), the involuntary leakage of urine, is a frequent problem among women with an adverse effect on quality of life (1). The first-line treatment for UI is conservative, with several treatment options, such as behavioral modification and pharmacotherapy with anticholinergic medications (2). In addition, physical therapies, including vaginal cones, biofeedback, electrical stimulation or peripheral or sacral neuromodulation methods, and extracorporeal magnetic stimulation (ExMS) may be used for the treatment of UI (2).

ExMS is commonly used in the world and our country. ExMS achieves nerve stimulation and neuromodulation by generating an electrical activity that penetrates tissues without alteration and induces controlled depolarization of the nerves. Therefore, a greater effect can be achieved on deeper neural tissue with minimal discomfort at the application point (3). ExMS treatment stimulates the pelvis's central and peripheral nerve pathways and induces pelvic floor muscle contraction (4, 5). The main advantages of ExMS include its non-invasive and relatively painless nature, the lack of internal electrodes, and the ability to be fully clothed during treatment.

In this study, we aimed to analyze the subjective satisfaction and objective results of ExMS in the treatment of UI. The primary outcome was subjective improvement in UI and satisfaction. Secondary outcomes were objective improvement rates in bladder diary, pad test, quality of life, pelvic floor muscle strength, and defining factors that could affect the outcome of ExMS treatment.

MATERIAL and METHODS

One hundred twenty-five patients suffering from UI and treated with ExMS were included. The inclusion criteria for ExMS treatment were a history of UI of at least six months, written informed consent for the treatment and the presence of detailed history and urogynecology evaluation.

Exclusion criteria for ExMS treatment were the presence of a cardiac pacemaker or other implantable devices, pregnancy, and active urinary tract infection. Exclusion criteria for the study needed to include data during pre-treatment evaluation and follow-up. Ethical approval was obtained from İstanbul Faculty of Medicine, Clinical Research Ethics Committee (Date: 02.04.2021, No: 08). All patients signed the informed consent form.

Before treatment, all patients were evaluated, including medical history, dipstick urine test, and urine culture, stress test, pelvic organ prolapse evaluation using POP-Q system, Q-tip test, pelvic floor muscle strength using digital palpation and perineometer, four-day bladder diary, one-hour pad test, and urodynamics. Urodynamics, including cystometry and uroflowmetry, were performed using the MMS UD 2000 Urodynamics System (MMS UD-2000, Medical Measurement System, Enschede, The Netherlands). All women completed the Turkish-validated version of King's Health Questionnaire for the quality of life assessment (6).

ExMS was performed in hospital settings using a MAGTHER E-6000 magnetic stimulation chair for pelvic rehabilitation. All patients were treated every three days for six-eight weeks. The duration of each session was 20 minutes, made up of two episodes of 10 minutes with a resting interval of 10 minutes. As suggested in previous studies, 50 Hz frequency was used for patients suffering from stress UI, and 10 Hz frequency was used for patients suffering from urge UI (7). Patients with mixed UI were treated for 10 minutes with 50 Hz and 10 minutes with 10 Hz.

Two months after completing the treatment program, medical history, pelvic floor muscle strength, pad test, four-day bladder diary, and King's Health Questionnaire were performed. The patients either received biofeedback or were educated regarding pelvic floor muscle exercises depending on their muscle strength after the treatment.

The primary outcome was subjective improvement in UI: women who suggested that they were either completely dry or that their UI was improved. Subjective evaluation by the patients was reported as 'cure,' 'better than before,' 'no change at all,' and 'worse than before.'

Secondary outcomes included improved quality of life, pad test, four-day bladder diary, pelvic floor muscle strength, and defining predictive factors that could affect satisfaction after ExMS treatment.

Statistical analysis

Statistical analysis was performed with the computer program IBM Statistical Package for the Social Sciences (SPSS) version 20.0 (IBM SPSS Corp., Armonk, NY, USA). Descriptive tests were used to describe patients' characteristics. Data were expressed as mean ± standard deviation. Because the Kolmogorov-Smirnov test indicated that data distribution deviated significantly from normality, the Wilcoxon signed-rank test was used for pre-treatment and post-treatment comparison. Spearman's correlation test was used to determine any association between type of UI, age, 1-hour pad test, pelvic floor muscle strength, bladder diary, and satisfaction. A p-value <0.05 was considered statistically significant.

RESULTS

One hundred twenty-five women received ExMS for treatment of UI. Forty-four women were excluded because of missing data during follow-up regarding either measurement of pelvic muscle strength, bladder diary, or 1-hour pad test. Total number of women included was 81.

The demographic variables of the patients are summarized in Table 1. The mean age of the patients was 50.4±9.7 (30-76). Forty-six patients were in the postmenopausal period. The mean body mass index was 29.9±5.4 kg/m². Mean number of deliveries was 2.3±1.4 (0-5); six

patients were nulliparous, 64 patients delivered vaginally, three patients had a history of vacuum extraction, and eight patients had a history of cesarean section. Six patients had diabetes, five patients had depression, and two patients suffered from disc hernia. Two patients had undergone an anti-incontinence surgery before. Four patients had a history of total abdominal hysterectomy, and three patients underwent vaginal hysterectomy. Forty-four patients suffered from mixed UI (54.3%), and 19 patients (23.5%) and 18 patients (22.2%) suffered from stress UI and urge UI, respectively. Sixteen patients suffered from coital incontinence. Fifty-six (69.1%) patients were using pads for UI every day.

All patients completed the treatment program, and no adverse events developed during treatment. Self-reported satisfaction related to ExMS treatment was as follows: Six patients suggested that they were cured, 64 patients (79.1%) suggested that they were better than before, and 11 patients (13.6%) noticed no change.

Four-day bladder diary results before and after treatment are summarized in Table 2. The mean number of voiding and urgency episodes before treatment was 8.6±3.5 and 2.2±3.8, respectively. The mean number of leakage episodes was 2.2±3.7 before treatment. Mean number of nocturia was 0.9±0.9. There was significant improvement after treatment in all these parameters. The mean number of voiding episodes was 6.4±1.7, the mean number of urgency episodes was 0.83±1.6, the mean number of leakage episodes was 0.6±1.4, and the mean number of nocturia was 0.5±0.8 after treatment.

There were significant changes in pelvic floor muscle strength and 1-hour pad test results after treatment (Table 2). The mean pelvic floor muscle strength was 18.7±9.5 cmH₂O and 23.7±11.9 cmH₂O before and after treatment. The mean pad tests were 26.8±43.4 gr and 1.2±2.5 gr before and after treatment. The distribution of the pad weight results of the women are summarized in Table 3. Forty patients (49.4%) had a negative pad test before treatment, whereas 70 patients (86.4%) had a negative pad test after treatment. Twelve patients (14.8%) had a pad test above 50 gr before treatment, but none had a pad test above 45 gr after treatment; four patients (4.9%) had a pad test between 10 gr and 45 gr.

There were significant changes in all domains and total scores of the King's Health Questionnaire except for personal relationships and symptom severity domains when the pre-treatment and posttreatment results were compared. The pretreatment and posttreatment total scores of the King's Health Questionnaire were 422.4±205.5 and 297.9±212.5, respectively. The results are summarized in Table 4.

A significant correlation was found between the type of UI and satisfaction related to ExMS treatment (r=0.16,

Table 1: Demographic variables of the women included in the study

	n=81
Age	50.4±9.7 (30-76)
Menopause n (%)	46 (56.7%)
Body mass index (kg/m ²)	29.9±5.4
Number of deliveries	2.3±1.4 (0-5)
Anti-incontinence surgery n (%)	2 (2.4%)
Type of UI	
Stress UI n (%)	19 (23.5%)
Urge UI n (%)	18 (22.2%)
Mixed UI n (%)	44 (54.3%)

UI: Urinary incontinence

Table 2: The 4-day bladder diary, pelvic floor muscle strength measured by a perineometer, and 1-hour pad test results before and after treatment

	Pretreatment	Posttreatment	P value
The mean number of voiding episodes	8.6±3.5 (5-25)	6.4±1.7 (5-15)	0.001
The mean number of urgency episodes	2.2±3.8 (0-13)	0.83±1.6 (0-8)	0.001
The mean number of leakages	2.2±3.7 (0-20)	0.6±1.4 (0-10)	0.001
The mean number of nocturia	0.9±0.9 (0-9)	0.5±0.8 (0-5)	0.001
Pelvic floor muscle strength measured by perineometer (cmH ₂ O)	18.7±9.5 (1-45)	23.7±11.9 (1-54)	0.01
1-hour pad test (gr)	26.8±43.4 (0-200)	1.2±2.5 (0-45)	0.001

Wilcoxon signed rank test was used

Table 3: Distribution of the 1-hour pad test results of the women before and after treatment

	Pretreatment n (%)	Posttreatment n (%)
<2 gr	40 (49.4%)	70 (86.4%)
2≤10 gr	15 (18.5%)	7 (8.6%)
10≤ 50 gr	14 (17.3%)	4 (4.9%)
≥50 gr	12 (14.8%)	0

Table 4: Results of the King's Health Questionnaire before and after treatment

	Pretreatment	Posttreatment	P value
General health perceptions	48.8±20.3	40.9±19.7	0.04
Incontinence impact	68.5±35.6	46.9±40.7	0.03
Role limitations	53.2±34.9	40.1±35.5	0.03
Physical limitations	54.6±36.7	37.9±37.1	0.04
Social limitations	40.4±32.7	23.2±28.5	0.003
Personal relationships	19.4±26.0	11.4±23.2	0.25
Emotions	49.1±31.9	30.8±32.2	0.003
Sleep/energy	36.1±28.0	24.9±26.1	0.03
Symptom severity	50.2±23.2	38.9±32.9	0.10
Total score	422.4±205.5	297.9±212.5	0.003

Wilcoxon signed rank test was used

p=0.037). Women suffering from stress UI had a lower rate of satisfaction (47.3%±36.0%) when compared to women suffering from urge UI (59.9%±28.4%) or mixed

UI (62.0%±29.5%). No significant correlations were observed between age (r=0.13, p=0.08), pretreatment pelvic floor muscle strength (r=0.04, p=0.609), 1-hour pad test (r=0.01, p=0.99), and a mean number of pretreatment leakage (r=-0.064, p= 0.398) or urgency episodes (r=0.01, p=0.86).

No pain or adverse effects developed during ExMS. No complications were observed during the treatment or posttreatment periods.

DISCUSSION

ExMS is a recent technique used for the treatment of UI. ExMS uses Faraday's law of magnetic induction; membrane depolarization of adjacent nerves occurs, leading to subsequent muscle contraction (8). The targets of ExMS treatment are sacral S2-S4 nerve roots, which are the primary autonomic and somatic innervation of the urethra and bladder. ExMS stimulates pelvic floor muscles, urethral sphincter, and pudendal nerve afferents, which results in detrusor inhibition (3).

As the study's primary outcome, we have shown that ExMS led to greater than 60% improvement in women suffering from UI with no pain or adverse effects during or after treatment. In our study, there were significant changes in pad test, bladder diary, pelvic floor muscle strength, and quality of life in patients suffering from stress, urge, and mixed UI. The decreases in the mean leakage, urgency, and voiding episodes show that ExMS effectively treats urge UI.

Success rates regarding ExMS treatment vary between studies. In a prospective multicenter study, Galloway et al., reported cure and improvement rates of 34% and 66%, respectively, in 83 patients with stress UI (9). In this study, 50 women had longer than three months of follow-up. In addition, they showed a reduction in pad usage and pad weight. Detrusor instability was found in five women before treatment and was present in a single patient during follow-up. Yamanishi et al., reported that 86% of patients with stress UI and 75% of patients with

urge UI had significant improvements in quality of life, maximum urethral closure pressure, and urgency after treatment (10). Chandi et al. reported objective improvements in 58% of patients treated for urge and mixed UI (11). Significant clinical improvement was seen only in patients with urge UI. They showed no significant change in urodynamic parameters after treatment. Groenendijk et al. evaluated the clinical effects and urodynamic changes in 16 women suffering from stress, urge, and mixed UI treated with ExMS (12). There were no significant differences in bladder diary, pad test, and visual analog scale before and after treatment; however, detrusor overactivity and urethral instability disappeared in 60% and 66% of the patients, respectively, in posttreatment urodynamics. Voorham-van der Zalm et al. evaluated the effect of ExMS on pelvic floor function (8). The authors found no significant difference in the quality of life using KHQ except for role limitations, bladder diary, and pad test. The authors suggested that ExMS may increase awareness of pelvic floor muscles and should be combined with active exercises to strengthen the effect.

On the other hand, Yokoyama et al., reported 53% improvement that lasted until 24 weeks after last treatment in 17 of the 20 patients suffering from urge UI (13). Almedia et al. evaluated the effects of ExMS on 91 women suffering from UI with a follow-up of 1 year (14). Immediately after treatment, quality of life improved by 35%, the number of pads used daily decreased by 40%, and the number of leakage episodes decreased by 54%, with a cure rate of 37%. A 24.3% average increase in leak point pressure and detrusor overactivity disappeared in 77% of the patients. However, at 1-year follow-up, 94% of patients who became dry had a recurrence. Possible reasons for these controversial results among studies are small sample sizes, inclusion of male and female patients, differences in the stimulation protocol, duration of stimulation, and duration of follow-up after treatment.

There are controversial results in studies comparing ExMS with other stimulation methods and sham stimulation. However, But et al. compared the efficacy and safety of ExMS with placebo in the treatment of UI (15). Fifty-five women with UI were randomly assigned to an active treatment group or placebo group. A 56.3% improvement was observed in the active treatment group versus a 26.3% improvement in the placebo group. Compared with placebo, the number of pads used, and pad weight were significantly lower, and the duration and strength of pelvic floor muscle contractions were significantly improved. Bolukbas et al. compared the effectiveness of vaginal electrical stimulation and ExMS in 22 women suffering from UI (16). They found significant improvement in pelvic floor muscle strength and pad test results; however, the improvement in bladder diary was greater in the electrical stimulation group. Fujishiro et al. report-

ed a beneficial effect of ExMS for patients with stress UI over sham stimulation (17). The stimulation group had a 74% improvement, whereas the sham group had a 32% improvement, with improved bladder diary and quality of life results. Gilling et al., in their double-blind, randomized controlled trial, found significant improvements in quality of life and pad test results in the active stimulation group compared to the sham stimulation group; however, these improvements did not reach statistical significance (18).

Lim et al., reported the efficacy of ExMS for treating stress UI with a 1-year follow-up in their multicenter randomized study (19). Seventy five percent of the patients in the active stimulation group responded versus 21.7% in the sham stimulation group. Yamanishi et al. evaluated the effects of ExMS on urodynamic stress UI resistant to pelvic floor muscle training in their randomized sham-controlled study (20). Quality of life scores, severity of UI, and abdominal leak point pressures significantly improved in the active stimulation group. Lim et al., in their systematic review evaluating the efficacy of ExMS for UI, evaluated eight studies, including 494 patients. Two hundred eighty-five underwent active stimulation, whereas 209 received sham treatment (21). The most extended follow-up was six months. The active stimulation group improved incontinence (2.3 times) compared to sham stimulation. The systematic review was weak due to varying inclusion criteria, varying follow-up, and poor reporting. There were controversial results regarding the effects on quality of life.

Main strengths of our study include the adequate sample size and detailed pretreatment and post-treatment evaluation including subjective and objective measures of success. Main limitations of the study are the short follow-up period, lack of sham stimulation as a control group, and lack of correlation with urodynamic findings. In addition, blinding of the patients during treatment assignment was not possible due to the nature of the interventions.

CONCLUSION

In conclusion, ExMS is an effective treatment option for patients suffering from UI, with almost 80% subjective satisfaction and significant improvement in quality of life, pad test, bladder diary, and pelvic floor muscle strength. Further prospective studies are needed for the evaluation of the long-term effects of ExMS and comparison with sham stimulation.

Ethics Committee Approval: The study has ethical approval from the İstanbul Faculty of Medicine, Clinical Research Ethics Committee (Date: 02.04.2021, No: 08).

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