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Comparison of the Effects of Extracorporeal Magnetic Innervation on Stress Incontinence and Stroke Related Urinary Incontinence

Ekstrakorporeal Manyetik İnnervasyonun Stres İnkontinans ve İnme ile İlişkili Üriner İnkontinans Üzerindeki Etkilerinin Karşılaştırılması

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ABSTRACT Objective: The aim of this study was to compare the effects of extracorporeal magnetic innervation (EXMI) treatment on stress incontinence (SI) and post-stroke urinary incontinence (PSUI). **Material and Methods:** A retrospective examination was made of the records of 19 female patients with SI and 10 female patients with PSUI who received EXMI treatment for a period of 1 year (January 2018-January 2019). EXMI treatment was applied to each patient for 12 sessions (twice a week, 6 weeks). Patients were assessed with a visual analog scale (VAS) for general incontinence severity, a 10-point analog scale for urinary symptoms (nocturia, dysuria, incontinence with coughing, sneezing, laughing and walking), the Urogenital Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7) to assess quality of life of the patients before and after treatment. **Results:** Baseline VAS, UDI-6, IIQ-7 and urinary symptom severity scores (nocturia, dysuria, incontinence with coughing, sneezing, laughing and walking) were not significantly different between the groups ($p>0.05$). In the pre and post-treatment comparisons within both groups, there were observed to be significant decreases in the VAS, UDI-6, IIQ-7, incontinence with coughing, sneezing, laughing and walking scores ($p<0.05$), and no significant changes in nocturia and dysuria symptoms. The comparison between groups revealed a significant difference in the changes in VAS, IIQ-7 and UDI-6 in the SI group compared to the PSUI group ($p=0.021$, $p=0.008$, $p=0.003$, $p=0.008$, respectively). **Conclusion:** EXMI is an effective treatment method in PSUI treatment, although the effect is not as great as on SI. To the best of our knowledge, this is the first study to have examined the effects of EXMI treatment on PSUI. The study results show that EXMI is a effective treatment method in PSUI treatment, although not to the same extent as in SI treatment.

Keywords: Extracorporeal magnetic innervation therapy; stroke; stress incontinance

ÖZET Amaç: Bu çalışmanın amacı, ekstrakorporeal manyetik innervasyon [extracorporeal magnetic innervation (EXMI)] tedavisinin stres inkontinans ve inme sonrası üriner inkontinans üzerindeki etkilerini karşılaştırmaktır. **Gereç ve Yöntemler:** Bir yıl süreyle (Ocak 2018-Ocak 2019) EXMI tedavisi alan 19 stres inkontinans ve 10 inme sonrası inkontinansı olan kadın hastanın, kayıtları geriye dönük olarak incelendi. EXMI tedavisi her hastaya 12 seans (haftada 2 kez, 6 hafta) olarak uygulandı. Hastalar tedaviden önce ve sonra genel inkontinans şiddeti için vizüel analog skala (VAS), idrar semptomları için 10 puanlık bir analog skala (noktüri, dizüri, öksürük, hapşırma, gülme ve yürüme ile inkontinans) ve hastaların yaşam kalitesini değerlendirmek için Ürogenital Distres Envanteri [Urogenital Distress Inventory (UDI-6)] ve İnkontinans Etki Anketi [Incontinence Impact Questionnaire (IIQ-7)] uygulandı. **Bulgular:** Başlangıç VAS, UDI-6, IIQ-7 ve idrar semptom şiddeti skorları (noktüri, dizüri, öksürme ile inkontinans, hapşırma, gülme ve yürüme) gruplar arasında anlamlı farklılık göstermedi ($p>0,05$). Her iki grupta tedavi öncesi ve sonrası karşılaştırmalarda; VAS, UDI-6, IIQ-7, öksürme, hapşırma, gülme ve yürüme ile inkontinans skorlarında anlamlı düşüşler görüldü ($p<0,05$) ancak noktüri ve dizüri semptomlarındaki değişiklikler anlamlı değildi. Gruplar arası karşılaştırmada stres inkontinans grubundaki VAS, IIQ-7 ve UDI-6 değişikliklerinde PSUI grubuna göre anlamlı bir fark olduğunu ortaya koydu (sırasıyla $p=0,021$, $p=0,008$, $p=0,003$, $p=0,008$). **Sonuç:** EXMI, stres inkontinas üzerindeki etkisi kadar büyük olmasa da inme sonrası üriner inkontinansta tedavisinde etkili bir yöntemdir. Bildiğimiz kadarıyla bu EXMI işleminin, inme sonrası üriner inkontinans üzerindeki etkilerini inceleyen ilk çalışmadır. Çalışma sonuçları, SI tedavisindeki kadar olmasa da, EXMI'nin PSUI tedavisinde etkili bir tedavi yöntemi olduğunu göstermektedir.

Anahtar Kelimeler: Ekstrakorporeal manyetik inervasyon tedavisi; inme; stres inkontinans

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Urinary incontinence, which can present with various disorders, is a health problem with negative effects on quality of life. According to the Standardization Steering Committee, there are three main urinary incontinence types: Urge incontinence, stress incontinence (SI), and mixed incontinence.[1] The most common form is SI. Pelvic floor muscle weakness, older age, and comorbid disorders such as diabetes mellitus are among the causes of SI. Pelvic floor muscle training, medical management, biofeedback, electrical stimulation and extracorporeal magnetic innervation (EXMI) are used in the treatment of urinary incontinence.[2]

Urinary incontinence is a common problem especially for stroke patients in the acute stage. Although the urinary incontinence rate decreases with the positive effect of neuroplasticity in the early period, chronicity occurs in approximately 13% of cases.[3] Stroke severity and older age are associated with the incidence of urinary incontinence in patients with stroke. The most common urodynamic findings are decreased bladder volume and detrusor hyperreflexia, which cause urgency, frequency and urge incontinence.[4] Bladder training, pelvic floor muscle training, fluid management, medications such as antimuscarinic therapy, and intravesical botulinum toxin injection are used in the treatment of urinary incontinence in patients with stroke.[5,6]

EXMI is a non-invasive method, which was developed as an alternative to electrical stimulation. It generates a pulsed magnetic field that penetrates the pelvis and induces electrical depolarization of the motor fibers of visceral and pudendal nerves that cause contraction in the pelvic floor muscles.[7] EXMI is more preferable to electrical stimulation because it is non-invasive, can be applied while wearing clothing and does not require any probe (anal, vaginal) placement. Although there are studies in the literature that EXMI is used in the treatment of stress urinary incontinence, there has been no study examining the effect of EXMI in patients with stroke.[8-11]

Urodynamic studies performed with EXMI have shown that it increases functional bladder volume and decreases detrusor hyperactivity.[12] Therefore, the hypothesis of this study was that EXMI therapy may be beneficial in post-stroke urinary incontinence (PSUI), the main problem of which is detrusor hyperactivity. There are studies in the literature showing the positive effects of electrical stimulation in PSUI treatment for the same purpose.[13,14] As in many EXMI studies, it is difficult to form a control group because of the contraction sensation in the pelvic floor muscles and gluteal muscles of the patients during the treatment. Therefore, the study was designed to compare the effects of EXMI on PSUI and on SI, which has been studied many times before.

MATERIAL AND METHODS

STUDY DESIGN AND PARTICIPANTS

A retrospective review was made of the medical records of 10 female patients with PSUI and 19 female patients with SI, who were treated with EXMI between January 2018 and January 2019. All patients who received EXMI were referred from the inpatient clinic of the department of physical medicine and rehabilitation. SI patients were selected from patients hospitalized for orthopedic reasons (osteoarthritis etc.). The patients included in the study were those aged 18-65 years, with a confirmed diagnosis of SI and PSUI according to the diagnosis criteria of the American Stroke Association and the International Continence Society. Patients who had previously undergone incontinence surgery, had a history of pelvic trauma, pelvic malignancy, intrauterine device, cardiac pacemaker, epilepsy or arrhythmia were excluded from the study. In addition, patients with any neurological disease in the SI group and patients with urinary incontinence prior to stroke or additional neurological disease other than stroke (Parkinson, dementia etc.) in the PSUI group were not included in the study. Patients with chronic ischemic stroke were included in the study to exclude improvement of urinary incontinence due to neuroplasticity, especially in the acute and subacute periods. The Karabük University Non-entrepreneurial Clinical Researches Ethics Committee and Kastamonu Rehabilitation Centre approved the study protocol (E-77192459-050.99-8297, 25.9.2020). This study was conducted in accordance with the principles of the Declaration of Helsinki.

Demographic and clinical data including age, weight, body mass index, incontinence duration,

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post-stroke duration, number of gravida-parity, previous treatments, comorbidities and urinary symptoms (nocturia, dysuria, incontinence with coughing, sneezing, laughing and walking) were recorded.

TREATMENT PROTOCOL

For each treatment session, the patients were seated on a chair, fully clothed, and the magnetic field generator (EMD, E-6000 Magther, Turkey), which is powered and controlled by an external power unit, was positioned below the chair seat. When the patient was seated, the perineum was centered in the middle of the seat, which places the muscles of the pelvic floor and the sphincters directly on the primary axis of the pulsing magnetic field. Thus, the therapeutic magnetic field penetrates the pelvis minor organs and motor fibers of visceral and pudendal nerves. During the treatment the patients can feel the perineum muscles contraction.

All patients were administered a 12-session EXMI treatment program of 20 min, 2 days a week for a total of 6 weeks. The frequency of the pulsed magnetic field was intermittently 5 Hz for 10 min, followed by a rest period of 5 min and a second treatment at intermittent 50 Hz for 10 min. To avoid muscle fatigue, treatment intervals were designed as intermittent.

OUTCOME MEASURES

Subjects were evaluated at baseline before treatment and at the end of the treatment with a 10-point visual analog scale (VAS), where 0=continent and 10=complete incontinence in respect of general incontinence severity and urinary symptoms (nocturia, dysuria, incontinence with coughing, sneezing, laughing and walking).[15] The impact of urinary incontinence on quality of life was assessed with 2 questionnaires; the Urogenital Distress Inventory-Short Form six-item questionnaire (UDI-6) and the seven-item Incontinence Impact Questionnaire-Short Form (IIQ-7). In both questionnaires, patients rated the degree of disturbance using a 4-point rating scale (0=Not at all, 1=Slightly, 2=Moderately and 3=Greatly). The validity and reliability of these questionnaires for Turkish patients was performed by Cam et al.[16] All assessments were administered at baseline and at the end of the treatment program.

STATISTICAL ANALYSIS

In our study, all patients who received EXMI treatment between January 2018 and January 2019 were included, and when the alpha error rate was taken as 0.05, the power of the study was 0.662. Statistical data analyses were performed using SPSS for Windows vn. 20.0 software (SPSS Inc, USA). Descriptive statistics were expressed as mean±standard deviation values for continuous variables and as number and percentage for discrete variables. Normal distribution of the data was assessed with the Shapiro-Wilk test. The intra-group variations in the continuous variables from pre-treatment to post-treatment were analyzed with the related samples Wilcoxon signed rank test. Inter-group comparisons were performed with the independent samples Mann-Whitney U test. The level of statistical significance was set at $p<0.05$.

RESULTS

The baseline demographic data of the patients are given in Table 1. No significant difference was found between the groups in terms of any demographic variable ($p>0.05$). Baseline VAS, UDI-6, IIQ-7 and urinary symptom severity scores (nocturia, dysuria, incontinence with coughing, sneezing, laughing and walking) were not significantly different between the groups ($p>0.05$)

The intra-group comparisons of baseline VAS, UDI-6, IIQ-7 and urinary symptom scores (nocturia, dysuria, incontinence with coughing, sneezing, laughing and walking) are presented in Table 2. Statistically significant decreases were determined in the VAS, UDI-6, and IIQ-7, incontinence with coughing, sneezing, laughing and walking scores in the within group comparisons in both groups after the treatment compared to baseline ($p<0.05$). There were no significant changes in nocturia and dysuria symptoms.

The comparisons between the groups revealed statistically significant differences in changes in VAS, IIQ-7 and UDI-6 in the SI group compared to the PSUI group ($p=0.021$, $p=0.008$, $p=0.003$, respectively). There was no statistically significant difference between the groups in terms of changes in

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TABLE 1: Demographics of the groups.

	SI Group (n=19)	PSUI Group (n=10)	p value
Age (years)	65.4±7.4	64.2±4.7	0.642
Weight (kg)	64.4±6.17	64.2±4.34	0.902
BMI	23.8±2.02	23.6±1.34	0.683
Incontinence duration (month)	35.1±14.8	34.8±16.2	0.960
Post-stroke duration (month)	N/A	35.2±17.2	

SI: Stress incontinence; PSUI: Post-stroke urinary incontinence; BMI: Body mass index mean±standard deviation.

TABLE 2: Intra-group comparisons of urinary symptoms, VAS values, UDI-6 and IIQ-7.

	SI Group (n=19)			PSUI Group (n=10)		
	Pre-treatment median (IQR)	Post-treatment median (IQR)	p value	Pre-treatment median (IQR)	Post-treatment median (IQR)	p value
VAS score	7.0 (6.0-8.0)	3.0 (2.0-4.0)	**<0.001**	7.5 (7.0-8.0)	5.0 (4.0-6.0)	**0.006**
IIQ-7	12.0 (9.0-13.0)	4.0 (3.0-6.0)	**<0.001**	12.5 (10.25-12.5)	8.0 (5.75-9.75)	**0.007**
UDI-6	12.0 (11.0-13.0)	5.0 (4.0-6.0)	**<0.001**	12.0 (10.0-12.0)	7.0 (6.0-9.25)	**0.007**
Nocturia	1.0 (0-2.0)	1.0 (0-2.0)	0.157	2.0 (0-3.0)	2.0 (0-3.0)	1.000
Dysuria	1.0 (0-2.0)	1.0 (0-1.0)	0.157	2.0 (0-2.0)	2.0 (0-2.0)	1.000
Coughing	6.0 (5.0-8.0)	2.0 (2.0-4.0)	**<0.001**	8.0 (6.0-8.0)	4.0 (3.0-6.0)	**0.007**
Sneezing	5.0 (4.0-6.0)	2.0 (2.0-4.0)	**<0.001**	6.0 (5.0-8.0)	4.0 (3.0-6.0)	**0.010**
Laughting	5.0 (4.0-6.0)	2.0 (2.0-3.0)	**0.010**	6.0 (5.0-8.0)	4.0 (2.5-6.0)	**0.010**
Walking	2.0 (0-2.0)	0 (0-2.0)	**0.014**	6.0 (5.0-8.0)	2.5 (2.0-4.25)	**0.006**

VAS: Visual analogue score; UDI-6: Urogenital Distress Inventory; IIQ-7: Incontinence Impact Questionnaire; SI: Stress incontinence; PSUI: Post-stroke urinary incontinence; IQR: Interquartile range.

incontinence with coughing, sneezing, laughing and walking values (Table 3).

TABLE 3: Comparison of the changes (from pre-treatment to post-treatment) of the groups in urinary symptoms, VAS values, UDI-6 and IIQ-7.

	Pretreatment-post treatment, median (IQR)		
	SI Group (n=19)	PSUI Group (n=10)	p value
VAS score	-4.0 (-4, -3)	-2.0 (-3, -2)	**0.021**
IIQ7	-7.0 (-9, -5)	-4.0 (-5, -4)	**0.008**
UDI-6	-8.0 (-9, -5)	-4.0 (-5, -3)	**0.003**
Nocturia	0.0	0.0	0.296
Dysuria	0.0	0.0	0.296
Coughing	-3.0 (-5, -2)	-2.0 (-4, -2)	0.339
Sneezing	-2.0 (-3, -1)	-2.0 (-3, -1)	0.538
Laughing	-2.0 (-4, -1)	-2.0 (-4, -1)	0.944
Walking	-2.0 (-2, 0)	-4 (-4, -1)	0.214

VAS: Visual analogue score; UDI-6: Urogenital Distress Inventory; IIQ-7: Incontinence Impact Questionnaire; IQR: Interquartile range; SI: Stress incontinence; PSUI: Post-stroke urinary incontinence.

No side-effects or complications were observed during or after the treatment.

DISCUSSION

The aim of this study was to determine the effect of EXMI treatment, which has not been previously reported in the literature, on patients with PSUI through comparisons with the effect on SI patients. As a result of the study, significant improvements were observed in urinary symptoms other than dysuria and nocturia, and quality of life in the PSUI group, while these improvements were statistically more significant in the SI group.

Electrical stimulation has been used in SI treatment with different success rates since the 1960s.[17] Successful results are obtained when the procedure is performed by experienced technicians and patient compliance is good.[18,19] However, this treatment is re-

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fused by many patients due to the placement of vaginal and anal probes, local irritation of the patch, or the need to undress.[11] EXMI creates controlled depolarization of adjacent nerves and subsequent muscular contraction and has therefore been used in recent years as an alternative to electrical stimulation in many neurology fields.[20,21] It is a more comfortable method compared to electrical stimulation because it is safe, non-invasive, used without removing clothes, does not require vaginal/anal probe and does not cause uncomfortable pain or contraction.[22]

Studies in literature investigating the effectiveness of EXMI have mostly been conducted on SI. While many studies have shown that EXMI has significant effects on urodynamic parameters, urinary symptoms and quality of life indexes in patients with SI, there are also a few studies showing that the effects are insufficient.[7-11,23,24] There are also studies comparing the effects of EXMI on urge incontinence and SI. In a study by Yamanishi et al, the success rate was 86% in SI and 75% in urge incontinence after EXMI treatment applied to the pelvic region.[25] These rates were reported as 94% in SI and 85% in urge incontinence in a study by Yokoyama et al.[12]

There is no accepted consensus on the EXMI treatment algorithm in the literature. In some studies, there are different treatment intensities, such as twice a week for 6 weeks, twice a week for 5 weeks or twice a week for 8 weeks.[7,12,25] Efficacy has been shown to improve with the number of sessions and most study protocols advocate 12-16 sessions.[8] Another controversial issue is optimum pulse duration. It has been reported in previous studies that frequencies between 20-50 Hz are effective in the treatment of SI, but frequencies between 5-20 Hz are the best range for inhibition of detrusor contractions.[26,27] In the present study, EXMI was applied as 5 Hz, for 10 min, followed by a rest period of 5 min and a second treatment at intermittent 50 Hz for 10 min, and the results were satisfactory.

One of the most common complications after stroke that negatively affects the quality of life is urinary incontinence. If it is not properly evaluated and managed, it can lead to morbidity and mortality.[28] Detrusor hyperactivity and functionally decreased bladder volume after stimuli that cannot be inhibited by higher neurological centers are the most important urodynamic findings of urinary incontinence.[4] With this feature, it has a different mechanism than SI and thus the treatment is also different (anitcholinergic, botulinum toxin injection etc.). There is currently no study on EXMI treatment in stroke patients. However, urodynamic studies have revealed that detrusor pressure and maximum cystometric capacity increased significantly with EXMI treatment.[12] In a retrospective study by Shen et al., in which the effects of electrical stimulation on PSUI were examined, it was concluded that electrical stimulation therapy applied twice a week for 8 weeks improved urinary symptoms, decreased urine leakage and increased quality of life.[13] Guo et al. then reported significant improvements in PSUI symptoms and quality of life with 10-week electrical stimulation in a randomized sham-controlled study.[14] Studies related to electrical stimulation on stroke with positive results have promised that EXMI treatment with similar mechanisms can also be successful in this patient group. In the present study, significant improvements were found in the urinary symptoms and quality of life of stroke patients after treatment, although not to the same extent as in the SI group.

Although the urine symptom severity and quality of life of SI and PSUI patients were evaluated in present study, the absence of an objective scale evaluating bladder-related data (urodynamic, electromyography etc.) is an important limitation of the study. The retrospective design and lack of long-term follow-up can be considered other limitations. The strongest aspect of the study is that to the best of our knowledge, this is the first study in which EXMI therapy was used in stroke patients.

CONCLUSION

EXMI therapy is a comfortable treatment method for PSUI patients. Although not as effective as in SI patients, significant improvements were found in urinary symptoms and quality of life of PSUI patients. Nevertheless, there is a need for further studies that use objective scales and have longer follow-up periods.

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