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The comparison of EMG-biofeedback and extracorporeal magnetic innervation treatments in women with urinary incontinence

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Summary

Purpose: This study aimed to compare the effectiveness of EMG-biofeedback (EMG-BF), extracorporeal magnetic innervation (ExMI), and pelvic floor muscle training (PFMT) treatments on women with stress urinary incontinence (SUI). *Materials and Methods:* The study included 67 women with SUI. Pelvic floor muscles (PFMs) were evaluated with electromyography and the quality of life (QoL) with Incontinence Quality of Life (I-QoL) questionnaire; afterwards, the subjects were divided into three groups; EMG-BF group (n=23), ExMI group (n=20), and PFMT group (n=24). EMG-BF group and ExMI group were given training in urogynecological physiotherapy clinic. PFMT group were given eight-week home exercises. Each group was assessed before training and after eight weeks. *Results:* All three groups showed a significant improvement in EMG activity values and average QoL scores. The greatest improvement was observed in the EMG-BF training group for QoL scores. *Conclusions:* This study demonstrated that all of the three methods performed with the purpose of increasing PFM strength were effective. The increase in PFM strength reduces incontinence associated symptoms and thus improves QoL.

Key words: EMG-biofeedback; Extracorporeal magnetic innervation; Pelvic floor muscle training; Urinary incontinence.

Introduction

The International Continence Society (ICS) defines urinary incontinence as an involuntary leakage of urine [1]. It has a high prevalence among women of all age groups, and prevalence increases with aging [2]. One in three women experience urinary incontinence, which significantly affects quality of life (QoL) [3]. Stress urinary incontinence (SUI) is caused by pelvic floor muscle (PFM) weakness; risk factors include pregnancy, age, childbirth, body mass index (BMI) and hormonal status. The condition is associated with negative psychological effects including avoidance of sexual activity, social isolation, and decreased physical activity [4]. The ICS recommends conservative treatments the first line of treatment for incontinence. This mainly involves correction and increase of PFM activities, which has no serious adverse effects and results in improvement or cure in two-thirds of patients [2, 5]. The method of strengthening PFMs proposed by Kegel made non-surgical treatment popular for SUI and led to the development of many other therapeutic techniques [6, 7]. One of these techniques is electromyographic-biofeedback (EMG-BF) training and can be used to learn the method of contracting PFMs, or to increase the performance of training. It enables more selective control of pelvic floor musculature, which results in decrease of micturition, defecation or sexual symptoms [8]. The other is extracorporeal magnetic innervation therapy (ExMI) which is a newer technique based on principles of natural physics. According to Faraday's law of magnetic induction, a current flows in a conducting medium to respond to a changing magnetic field. The ExMI technique employs this rule to induce a controlled depolarization of adjacent nerves and resulting muscle contraction. Previous studies reported 50% improvement in 69% of patients, with 44% dry in two weeks, and objective improvement in 58% of patients. Magnetic stimulation has been applied for non-invasive stimulation of the central and peripheral nervous system. An electrical field is induced by a varying magnetic field in a specified loop in the vicinity. Primary autonomic and somatic innervation in the lower urinary tract, which includes pelvic floor, bladder, vaginal wall, rectum, and urethra, is the root area of sacral nerves S2-S4. Stimulation of these roots is an effective method of regulating pelvic floor and then to control pelvic organs [7, 9].

In the literature, it is seen that pelvic floor muscle training (PFMT), ExMI, and EMG-BF training are all individually effective in the treatment of urinary incontinence [8, 10-13]. However, no previous study has evaluated the best and most effective of these three treatment methods. This study compared three conservative therapy strategies for PFMT: ExMI, EMG-BF, and home exercises.

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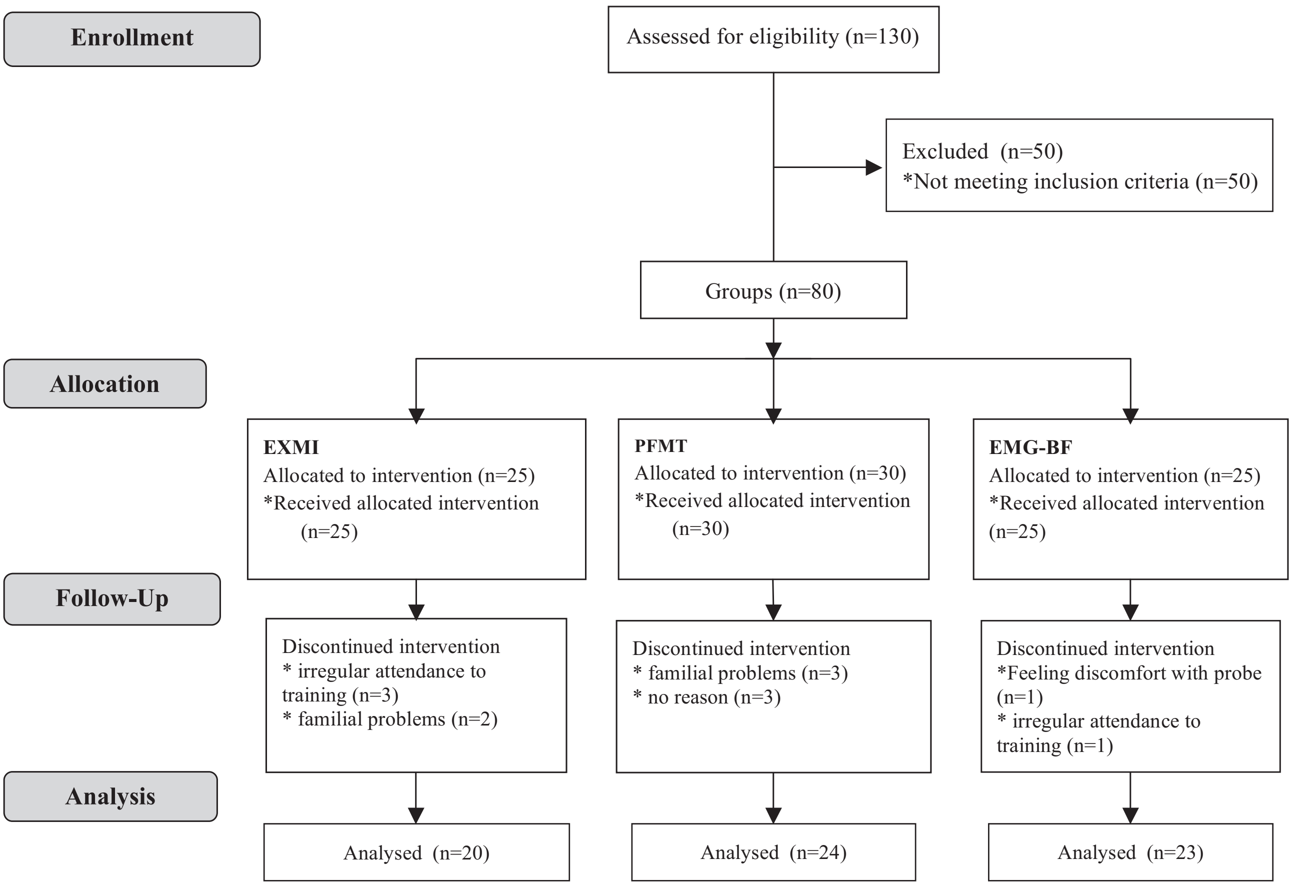

Figure 1. — CONSORT 2010 Flow Diagram.

Materials and Methods

Patients were diagnosed by a gynecologist by means of patient history, clinical, and physical examinations. Among 130 patients referred as having SUI, those with prosthesis, other implanted metallic devices, cardiac pacemaker, arrhythmia, pelvic malignancies, under radiotherapy, pelvic floor defect, previous surgery for urinary incontinence, and neurological diseases were excluded and the study that began with 80 patients. Thirteen of these left the study due to reasons such as familial problems, irregular attendance to training, feeling discomfort with probe, and for no reason. A total of 67 patients completed the study. Flow diagram is shown Figure 1. The patients were informed about the treatment. The study was approved by the Ethics Committee of Abant Izzet Baysal University.

The following patient information was recorded: height, weight, BMI, occupational status, education level, medical and obstetrical history (number of gravidity, parity, abortus, dilatation and curettage, type of delivery, and the status of having episiotomy and/or perineal tears), used medications, urinary symptoms such as urgency, incontinence conditions (coughing, laughing, sneezing, lifting heavy items, jumping, walking), and duration of incontinence problem.

The Turkish version of the Incontinence Quality of Life (I-QoL) instrument was used to evaluate the effect of SUI on QoL. The patients were asked to score the degree of bother via a four-point rating scale: 0 = not at all, 1 = slightly, 2 = moderately, and 3 = greatly. The survey comprises 28 questions and overall scores range from 0–84. Total scores were recorded for the analysis [14, 15].

A Myomed 932 biofeedback and EMG unit recorded vaginal squeeze in microvolts (μV) to measure PFM EMG activity during three maximal voluntary contraction (MVC) attempts. The patients were asked to lie in a supine position and bend their knees with their legs slightly apart. A physiotherapist used a vaginal probe to measure PFM EMG activity at rest and during MVC. The mean value of three attempts was recorded [16].

All evaluations were made at baseline and at the end of the procedure. Following the first assessment, patients were informed about each of the three treatment methods (ExMI, EMG-BF, and PFMT as home program) and asked to choose one for their treatment. The treatment method was determined by considering the desires of patients.

For the ExMI procedure, patients were requested to sit fully clothed on a special chair and to remove all metallic objects they were wearing (jewelry, watch etc.). The chair contains a magnetic field generator (therapy head) that is controlled by an external power unit. The power output can be adjusted by the physiotherapist. The size and strength of the magnetic field is determined by adjusting the amplitude of the device. The pulse has a steep leading edge that creates a step gradient magnetic field directed vertically through the seat of the chair. The perineum is located in the middle of the seat when the patient is seated. In this position, the PFM and sphincters are located directly on the primary axis of the pulsing magnetic field. Magnetic field flux can directly penetrate

Table 1. — *Demographic characteristics of patients.*

	ExMI (n=20)	PFMT (n=24)	EMG-BF (n=23)	c^2	*p*
Age (years)	53.55±8.62	51.54±7.13	50.86±7.35	1.03	0.59
Body weight (kg)	72.46±15.68	71.96±11.33	79.04±14.41	2.57	0.27
Height (m)	1.57±.04	1.57±0.06	1.57±.04	0.17	0.91
BMI (kg/m²)	29.14±6.33	29.25±4.90	31.72±5.39	2.53	0.28

Table 2. — *Pre- and post-EMG activity values of groups.*

	EMG Activity Value (μV) Pre	EMG Activity Value (μV) Post	Z	*p*
ExMI (n=20)	14.55±8.91	20.60±8.54	-3.86	0.00*
PFMT (n=24)	13.87±7.33	20.12±7.83	-4.11	0.00*
EMG-BF (n=23)	11.78±6.78	19.17±7.51	-4.20	0.00*

*$p < 0.05$.

Table 3. — *Comparison of EMG activity values between groups.*

EMG Activity Value (μV)	X±SD	Rank mean	c^2	SD	p
ExMI (n=20)	6.05±4.69	32.18			
PFMT (n=24)	6.25±5.53	31.77	1.426	2	.49
EMG-BF (n=23)	7.39±4.68	37.91			

Table 4. — *Pre- and post-I-QoL instrument values of groups.*

	I-QoL instrument-pre	I-QoL instrument-post	Z	*p*
ExMI (n=20)	38.15±27.36	22.65±25.22	-3.74	0.00*
PFMT (n=24)	24.00±21.26	15.70±19.63	-3.36	0.00*
EMG-BF (n=23)	29.82±25.91	8.08±13.30	-4.10	0.00*

*$p < 0.05$.

Table 5. — *Comparison of I-QoL instrument values between groups.*

I-QoL instrument Value (μV)	X±SD	Rank mean	c^2	SD	*p*
ExMI (n=20)	15.50±17.23	33.98			
PFMT (n=24)	8.29±9.96	26.56	7.17	2	0.02*
EMG-BF(n=23)	21.73±20.17	41.78			

*$p < 0.05$.

Table 6. — *Indication of difference of I-QoL instrument values between groups.*

I-QoL instrument	Rank mean	Sum of ranks	U	*p*
ExMI (n=20)	24.95	499.00	191.00	0.24
PFMT (n=24)	20.46	491.00		
ExMI (n=20)	19.52	390.50	180.50	0.22
EMG-BF (n=23)	24.15	555.50		
PFMT (n=24)	18.60	446.50	146.50	0.00*
EMG-BF (n=23)	29.63	681.50		

*$p < 0.05$.

all perineal tissues. The procedure only generates a magnetic flux but delivers no electrical charge to the patient's body. The frequency of the pulsed magnetic field was adjusted to five Hz for ten minutes intermittently. Following a five-minute resting period, the second treatment period was applied intermittently at 50 Hz for 10 minutes [17]. Patients were offered treatment sessions of 20 minutes three times a week for a period of eight weeks.

For EMG-BF training, patients received PFMT from a physiotherapist three times during eight weeks using a device with an intravaginal probe. Patients were asked to contract PFMs during visual and audial EMG signals. Individualized training programs were prepared and all patients were instructed to perform PFM contractions in an isolated way. Each program was prepared according to repetition number, the patient's muscle strength, endurance, and tolerance. Before starting the training, each patient's maximum PFM contraction period was recorded and was increased as the maximal contraction period increased. There were ten-second resting breaks between contraction periods. One session lasted for approximately 20 minutes [18].

As home program, patients were asked to perform exercises as contracting and relaxing for fast-twitch muscles and contracting slowly for slow-twitch muscles (by counting to ten; holding contract by counting to ten; relaxing slowly by counting to ten). Patients initially performed five sets of ten repetitions. They added five more sets each week until reaching 30 sets per day, and then continued with this number. An eight-week PFM exercise tracking chart was given to patients to help them remember the exercises and to perform the exercises in a more disciplined way [16].

Data were analyzed using SPSS (version 16.0, demo. Quantitative and qualitative data are presented in the form of mean, standard deviation and percentage, and frequency (%), respectively. Wilcoxon matched-pairs test, Kruskal Wallis test, and Mann-Whitney test were used for statistical analysis. A p value ≤ 0.05 was considered as statistically significant.

Results

Table 1 shows patients' demographic characteristics. There was no difference in demographic characteristics between groups. Patients' EMG activity values revealed a significant improvement after treatment procedures in all groups according to Wilcoxon matched-pairs analysis ($p \leq 0.00$, Table 2). There was no difference in EMG activity values between groups by Kruskal Wallis analysis (Table 3). All three groups showed a significant improvement in average QoL scores based on Wilcoxon matched-pairs test (Table 4). The greatest improvement was observed in the EMG-BF training group according to Mann-Whitney test (Tables 5 and 6).

Discussion

This study revealed that EXMI, EMG-BF, and a home program of PFM exercises improved QoL and increased PFM strength in patients with SUI. There was no difference between the three methods with regards to improving

PFM strength; however, the EMG-BF method provided superior improvements to QoL.

Culligan *et al.* [19] analyzed the effect of ExMI on PFM strength by perineometry in primiparous women. They reported no difference between women who received active or sham ExMI treatment in the early postpartum period. Voorham *et al.* [7] analyzed clinical results of ExMI therapy, concentrating on improvements in pelvic floor musculature, urodynamics, and QoL. They reported no change in PFM function by ExMI. Lee *et al.* [11] reported that PFM exercises combined with extracorporeal biofeedback device were effective in reducing urinary leakage and increasing muscle strength. The literature includes contradictory findings on the effect of ExMI on PFM strength. Some researchers report there is no impact; other reported that there is an increase. In this study, ExMI training increased PFM strength by 38.97%.

PFMT has been evaluated over the years and is recognized as an effective conservative treatment in women with urinary incontinence. A Cochrane review contained 14 randomized controlled trials involving 353 women who received PFMT versus 319 controls, supported PFMT as an effective treatment in reducing the symptoms of stress, urge, and mixed incontinence [20]. Fitz *et al.* [21] reported that PFM strength increased from two to 3.5 on the Oxford scale in a group of 36 women who received PFMT. It is reported in the literature that regular PFMT can improve the function of PFMs [20]. The present study found that regular PFMT over a period of eight weeks increased PFM strength by 44.87%. It is known that increase in PFM strength reduces the symptoms of incontinence [22]. A previous study used pad and leakage tests and reported that increased PFM strength was correlated with decreased leakage [23]. According to statements made by patients, the present authors conclude that incontinence symptoms among patients in the home program group decreased due to the increase in PFM strength.

Morkved *et al.* [24] compared PFMT with and without biofeedback for six months for women with stress incontinence. They assessed PFM strength via vaginal balloon catheter, and reported increased muscle strength in both groups; however, between three and six months, a significant improvement was observed only in the biofeedback group. Yoo *et al.* [25] treated with EMG-BF and electrical stimulation for eight weeks in 86 women with urinary incontinence. Patients were assessed at baseline and at four and eight weeks and three months after treatment. It was found that 57% of patients did not require further treatment. A study of the short- and long-term effects of EMG-BF on PFM strength reported that, after treatment, PFM strength increased and EMG values almost doubled, from 11.3 μV to 21.5 μV [26]. Aukee *et al.* [27] compared PFMT with and without EMG-BF in 30 women with SUI. It was reported that in contrast to the average increase of 10.5 μV in EMG-BF group, the increase in PFMT was 2.3 μV. A similar study was conducted by Jundt *et al.* [8] with EMG-BF assessment with palpation increased from 3 to 4 on the Oxford scale and this effect was maintained. Similarly in the present study, patients in the EMG-BF group showed an increase of 7.57 μV in PFM strength after treatment; although there was no significant difference between groups with regard to the effect on PFM strength, the highest increase was seen in the EMG-BF group. The present authors conclude that EMG-BF training ensured visual, auditory and tactile, stimuli, and that the individual format of the training motivated participants.

In clinical trials of incontinence training, QoL has become an important outcome measure [12]. There is a consensus that UI can have negative physical, social, and sexual impacts on QoL, although it is not considered as a direct risk for affected women [21]. The literature includes many reports that PFMT improves QoL among women with urinary incontinence [12, 17, 21, 28]. In this study, all three of the methods improved the QoL among participants. However, the EMG-BF training had the highest positive effect on QoL. Patients in the EMG-BF group showed the greatest improvement in QoL. Although patients in ExMI group was treated in clinic under observation, those in EMG-BF group tended to improve in every session by means of following visual and audial stimulus via Myomed-932 device. The present authors can attribute this to the fact group members attended urogynecological physiotherapy clinic and were each seen individually by a physiotherapist.

Conclusion

In conclusion, this study demonstrated that all of the three methods performed with the purpose of increasing PFM strength were effective. The increase in PFM strength reduces incontinence associated symptoms and thus improves QoL. The authors believe that after women with incontinence are treated with one of these methods, PFMT should be adopted and performed for the whole lifetime.

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