



Original Article

The Effect of Biofeedback versus Functional Electrical Stimulation in the Treatment of Stress Urinary Incontinence

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ABSTRACT

Background: Urinary Stress Incontinence (SUI) is the most common type of urinary incontinence among the young and middle-aged women, which occurs due to weak pelvic floor muscles and urethral sphincter in addition to many other factors. The objective of the research was to assess the effect of biofeedback versus functional electrical stimulation in the treatment of SUI.

Methods: In this study, 30 married women affected by SUI were selected randomly. The participants were divided into two equal groups and treated during 15 weeks with 1 session per week. The changes in SUI severity and their satisfaction were assessed by ICIQ-SF Questionnaire, and the rate of urine leakage was measured by applying Pad Test. Data were recorded and analyzed using SPSS Version 19 software. Specifically, Paired t-test, Independent t-test, and Mann-Whitney test were utilized.

Results: The results revealed that the mean quantity of urinary leakage, maximal PFM force, and ICIQ Score did not have significant differences in both groups ($P > 0.05$). However, there was a significant difference between biofeedback and FES group post-treatment regarding the quantity of urinary leakage ($P < 0.05$). Patients in the biofeedback group expressed more satisfaction and improvement than those in the FES group.

Conclusion: Both treatment methods were effective in the treatment of SUI. However, biofeedback proved to be superior in reducing the quantity of urinary leakage. Further, because of a higher degree of patients' subjective satisfaction and improvement with biofeedback, this method of treatment is recommended.

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Introduction

The most common urinary incontinence among women is stress urinary incontinence. There are many etiologies related to stress urinary incontinence. Among them, weak pelvic floor muscles and urethral sphincter insufficiency are considered to be the major factors. Urinary incontinence refers to an inability to prevent urine leakage during heavy activities such as exercise,

sneezing, and even coughing. Urinary incontinence may have major effects on a woman's quality of life and their health, and could result in mental-social disorders such as depression, lack of self-confidence, limitation in daily life activities, and feeling of worthlessness. [1-4]. Around 10 to 30% of women aged between 15 and 46 as well as 50% of people living in nursing homes in central regions are affected by urinary incontinence [5]. Although most aged women (more than 65 years) complain about urinary incontinence, the issue is more problematic in younger women [6]. The major methods for urinary incontinence treatment are surgical and conservative treatments along with some changes in

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lifestyle. Since there is a 10 to 40% potential risk of recurrence of SUI after surgical interventions, and due to the high costs of surgery and its possible side effects, conservative treatments are more common. Among these conservative methods for handling SUI, for many years exercise-based treatments on pelvic floor muscles (PFM), presented by Kegel in 1948, has been considered as one of the effective methods for preventing and improving SUI [7]. The main aim of the conservative treatments is strengthening the weak pelvic floor muscles to maintain urethral closure pressure, which has been recommended as the first-line treatment. Overall, we can point to non-surgical treatments of SUI as drug-based interventions and rehabilitation interventions such as Kegel exercise, biofeedback, functional electrical stimulation (FES), and bladder training. Clinical biofeedback as a treatment could help patients learn to increase or decrease the muscle contractions voluntarily and control the urine. Researchers note that biofeedback provides the opportunity for patients to maintain the proper electrophysical responses of pelvic floor muscles in accordance with audiovisual signals [8-13]. FES induces the pelvic floor innervation and contracts paralyzed muscles for creating functional movements [14]. There have been many studies for comparing the effectiveness of various rehabilitation methods and conservative treatment methods on pelvic floor muscles strengthening and improving SUI. Due to availability, low cost, lack of side effects, and clinical preferences, we selected biofeedback and FES as two effective methods for improving SUI. Additionally, the small number of studies in this area guided us to assess the effect of biofeedback versus FES in the treatment of SUI.

Methods

The type of this study was a clinical trial with an IRCT code of 43362. Thirty married female patients with SUI who met the inclusion criteria were selected randomly and visited by a urologist. The inclusion criteria were defined as the ability to adequately retain the vaginal probe and to cooperate with the study protocol, and the ability to understand randomization and finally to give informed consent. Exclusion criteria included pelvic organ prolapse of grade II or greater, detrusor instability, extra urethral incontinence, inability to perform a voluntary pelvic floor contraction, pregnancy, breastfeeding, pelvic malignancy, cardiac pacemaker, diagnosed neurological conditions, diabetes, and evidence of vaginal or urinary tract infection verified by a urologist.

After history taking, physical examination, urinalysis, and urodynamic study, the patients were referred to Physical Medicine and Rehabilitation Department of the Kashani Hospital of Isfahan Medical University. They were divided randomly and evenly into two groups (Biofeedback group and FES group) (n=15). The mean age of participants in the biofeedback group was 41.2 ± 2.5 and 39.6 ± 3.6 for participants in FES group. Note that none of them had undergone a rehabilitation

program for their SUI. Two patients in the biofeedback group and one patient in the FES group had a previous history of anti-incontinence surgery. Additionally, the mean number of successful pregnancies and delivery was 2.1 ± 0.5 for participants in the biofeedback group and 2.6 ± 0.6 for those in the FES group. For the subjective evaluation of treatment changes in terms of incontinence severity, the amount of urinary leakage and discomfort, ICIQ-SF questionnaire was used. The ICIQ-SF questionnaire includes 6 questions; at the end of the 5th question, the ICIQ Score can be determined. Answers to the questions were given a score from 0 to 10. The last question was related to the patient's improvement. The reliability and validity of the Persian version of ICIQ-SF had also been already verified [15]. Objective changes in incontinence were also evaluated using pelvic floor muscle (PFM) force through the biofeedback training and using pad tested for quantity of urinary leakage. In the biofeedback group, the patients received special training from a physiatrist and were told to pay attention to the monitor while they are performing the exercise. The FES group received periodic electrical stimulation [16] at 50 Hz frequency and 300 μ s pulse width. Both groups were asked to do the same Kegel exercises at home every day and received treatment for 15 min per session, 1 session per week for a total period of 15 weeks [17]. Note that both the examiner and subjects were not blind to the study and none of the subjects were excluded from the study. Data were recorded and analyzed using SPSS Version 19 software. Since the normal distribution of data was tested using Kolmogorov-Smirnov test, Paired t-test and Independent t-test were used for the quantity of urinary leakage, Maximal PFM force, and ICIQ-SF Score. Mann-Whitney test was employed for investigating the magnitude of patients' subjective satisfaction and improvement.

Results

The within-group comparison after treatment showed that the maximal PFM force in the biofeedback group and FES group increased significantly ($P < 0.05$), while the changes in the severity of SUI and quantity of urinary leakage decreased ($P < 0.05$).

On the other hand, the mean quantity of urinary leakage, maximal PFM force, and ICIQ Score did not have significant differences in both groups ($P > 0.05$) (Table 1). However, there was a significant difference between biofeedback and FES group post-treatment regarding the quantity of urinary leakage ($P < 0.05$).

Mann-Whitney test showed the extent of patients' subjective satisfaction and improvement (0-25%, 25-50%, 50-75%, and 75-100%) in both groups (Table 2).

Patients in the biofeedback group expressed more satisfaction and improvement (as a subjective evaluation) than those in the FES group (80% of patients in the biofeedback group improved up to 50%, compared to 46.7% in the FES group) (Figure 1).

Table 1: Comparing pre- and post-treatment variables in biofeedback and FES group

Variable	Group		P value
	Biofeedback Mean±SD	FES Mean±SD	
Quantity of urinary leakage			
Pre treatment	14.6±7.1	17.1±7.1	0.34
Post treatment	3.5±2.1	8.3±6.0	0.04*
Difference	-11.1±5.0	-8.8±1.1	0.49
Maximal PFM force			
Pre treatment	16.7±7.8	12.8±3.4	0.09
Post treatment	45.5±18.2	40.1±13.7	0.36
Difference	28.8±10.4	27.3±10.3	0.74
ICIQ-SF Score			
Pre treatment	9.4±3.8	10.8±3.4	0.32
Post treatment	2.8±1.1	3.7±1.1	0.26
Difference	-6.6±2.7	-7.1±2.3	0.97

*P<0.05; PFM: Pelvic Floor Muscle; ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form

Table 2: Degree of patients' subjective satisfaction and improvement in biofeedback and FES groups

Degree of patients' subjective Satisfaction and Improvement after treatment	Groups			
	Biofeedback		FES	
	n	%	n	%
0-25%	1	6.7	3	20
25-50%	2	13.3	5	33.3
50-75%	3	20	1	6.7
75-100%	9	60	6	40

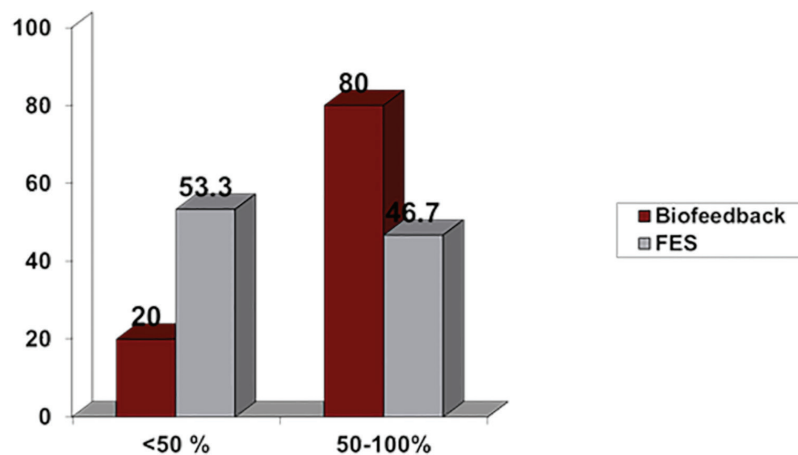


Figure 1: Frequency of patients' satisfaction and improvement in biofeedback and FES groups

Discussion

All these cause many women with SUI to seek effective treatments with no side effects and hospitalization for their problem so that they could recover faster as they demand to live their busy and active lives. This in turn has encouraged clinical physicians to find effective treatment methods for this condition which compromises the quality of life of these women. Accordingly, this study aimed to assess the effect of biofeedback versus functional electrical stimulation in the treatment of SUI.

PFM exercise is a non-invasive, safe technique, with relatively fewer side effects. It is recommended as the first-line of therapy in the management of SUI [18]. PFM exercise strengthens the Levatorani muscle and the external urethral sphincter muscle, which is associated with this form of continence [8-11]. The biofeedback method, which has gained popularity among clinical physicians recently, includes PFM exercises and simultaneously allows

patients to learn how to contract pelvic floor muscle. As a result, it treats incontinence more effectively than the PFM exercise does alone [12, 13, 19].

There are many individual studies on PFM exercise, biofeedback, and FES as a treatment method of SUI, but there are is enough research to compare these methods. Many researchers have reported a success rate of 16% to 17% using PFM exercise and have acknowledged its effectiveness [8-11]. Bump et al. [20] found that 25% of the women practiced the Kegel technique in a way that it aggravated the incontinence, and only 49% exercised it properly. It is very important to mention that various factors affect the effectiveness of the PFM exercise including the severity of incontinence, quality of communication with patients, awareness of PFM, and continuing the exercise [10]. Therefore, it is essential to fully educate patients and encourage their interest in the treatment as we did in this study.

In 2000, Sung et al. [21] compared FES-biofeedback

versus intensive pelvic floor muscle exercise for treatment of SUI. The FES-biofeedback group indicated a greater increase in PFM contractility than the PFM exercise-alone group. This result is in agreement with many reports claiming that the cure/improvement rate of PFM exercise is 20% to 52%, while biofeedback gives a corresponding result of 54% to 87% [8-13, 22-27].

Meanwhile, in this study we compared two groups of biofeedback and FES. The results showed that the maximal PFM force in the biofeedback group and FES group increased while changes in the severity of SUI and quantity of urinary leakage diminished. Note that the mean of maximal PFM force and ICIQ Score did not differ between groups. However, biofeedback showed more effectiveness than FES post-treatment in reducing the quantity of urinary leakage in SUI patients.

Additionally, patients in the biofeedback group expressed more subjective satisfaction and improvement than FES group. This may be dependent on several factors; (a) Unpleasant feeling of electrical stimulation in the pelvic region in FES group, (b) Patients' conception about failure to have personal voluntary control in the course of their treatment in FES group, (c) Better feelings of patients and possibly improvement of their self-stem, and (d) finally constant and correct exercises affecting the buttock and abdominal muscles and better shaping these regions cosmetically.

Although these treatment methods may affect the involuntary urethral muscle contractions, none of the involuntary muscles were assessed in this study. So, further study is required to focus on this issue. Additionally, the research team would like to express their sincere appreciation to the participants of this study who made this work possible. No conflict of interest is also reported.

Conclusion

The results of this study showed that both methods helped patients learn the correct PFM exercise and promote continuous practice, even at home. In other words, both treatment methods were effective in the treatment of SUI. However, biofeedback proved to be superior in reducing the quantity of urinary leakage. The biofeedback method allowed patients to monitor their PFM contractions and to check whether they were contracting the correct muscles. This, in turn, encouraged them to continue their exercise. Finally, because of a greater degree of patients' subjective satisfaction and improvement with biofeedback, this method of treatment is recommended.

Conflict of interest: None declared.

References

- Lemone P, Burke K. Medical-Surgical Nursing, 3rd ed. New Jersey: Pearson Education. 2004;. 733-5.
- Holroyd-Ledue JM, Straus SE. Management of urinary incontinence in women. JAMA. 2004;297:986-95.
- Abreu NS, Baracho ES, Tirado MGA, Dias RC. Quality of life from the prespective of elderly women with urinary incontinence. Rev Bras Fisioter, Sao Carlos. 2007;11:429-39.
- Haylen BT, de Ridder D, Freeman RM, Swift SE et al. An International Urogynecological Association (IUGA)/ International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. IntUrogynecol J Pelvic Floor Dysfunct. 2010; 21:5-26
- Payne CK. Conservative therapy for female urinary incontinence. AUA Update Series. 1996; 15: 34.
- Astro, RA, Ar . Arruda RM, Oliveira E, Zanetti MR, Bortolini MA, Sartori MGF et al. Fisioterapia e incontinencia urinaria de esforco: revisao e analise critica. Femina 2008; 36(12):737-742.
- Bo K, Talseth T, Holme I. Single blind randomised trial of pelvic floor exercises, electrical stimulation, vaginal cones and no treatment in management of genuine stress incontinence women. BMJ. 1999; 318: 487-93.
- Rekers H, Drogendijk AC, Valkenburg H, Rhipagem F. Urinary incontinence in women from 35 to 79 years of age: prevalence and consequences. Eur J Obstet Gynecol Reprod Biol. 1992; 43:229-34.
- Brown JS, Grady D, Ouslander JG, Herzog AR, Varner RE, Posner SF. Prevalence of urinary incontinence and associate risk factors in postmenopausal women. Obstet Gynecol. 1999; 94: 66-70.
- Lachowsky M. Urinary problems around the menopause: emotional and psychological consequences; can we help our patients to cope with them? Maturitas, 2000; 34(Suppl 1): S25-7.
- Hunskar S, Burgio K, Diokno A, Herzog AR, Hjalmas K, Lapitan MC. Epidemiology and natural history of urinary incontinence. Int Urogynecol J. 2000; 11:301-319.
- Oliveira E, Castro RA, Takano CC, et al. Ultrasonographic and Doppler velocimetric evaluation of the levator ani muscle in premenopausal women with and without urinary stress incontinence. Eur J Obstet Gynecol Reprod Biol. 2007; 133(2):213-7.
- Bernstein IT. The pelvic floor muscle: muscle thickness in healthy and urinary incontinent women measured by perineal ultrasonography with reference to the effect of pelvic floor training. Estrogen receptor studies. NeuroUrol Urodyn. 1997; 16:237-75.
- Moreno AL, Benitez CM, Castro RA, Girao MJBC, Baracat EC, de Lima GR. Urodynamic alterations after pelvic floor exercises for treatment of stress urinary incontinence in women. Clin Exp Obstet Gynecol. 2004; 31(3):194-6.
- Hajebrahimi S, Nourizadeh D, Hamedani R, Pezeshki MZ. Validity and reliability of the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form and its correlation with urodynamic findings. Urology journal. 2012 Dec 9;9(4):685-90.
- Schreiner L, Santos TG, Souza AB, Nygaard CC. Electrical stimulation for urinary incontinence in women: a systematic review. International braz j urol. 2013 Aug;39(4):454-64.
- Oliveira M, Ferreira M, Azevedo MJ, Firmino-Machado J, Santos PC. Pelvic floor muscle training protocol for stress urinary incontinence in women: A systematic review. Revista da Associação Médica Brasileira. 2017 Jul;63(7):642-50.
- Santos Patricia Fernandes Diniz, Oliveira Emerson, Zanetti Miriam Raquel Diniz, Arruda Raquel Martins, Sartori Marair Gracio Ferreira, Girao Manoel Joao Batista Castello et al . Eletroestimulacao funcional do assoalho pelvico versus terapia com os cones vaginiais para o tratamento de incontinencia urinaria de esforco. Rev Bras Ginecol Obstet. 2009 Sep; 31(9): 447-452.
- Huebner M, Riegel K, Hinninghofen H, Wallwiener D, Tunn R, Reisenauer C. Pelvic floor muscle training for stress urinary incontinence: A randomized, controlled trial comparing different conservative therapies. Physiotherapy Research International. 2011 Sep;16(3):133-40.
- Bump RC, Hurt WG, Fantl JA, Wyman JF. Assessment of kegel pelvic floor exercise after brief verbal instruction .Am J Obstet Gynecol. 1991;165:322-8.
- Sung M.S, Hong J.Y, Choi Y.H, Baik S.H, Yoon H. FES-Biofeedback versus Intensive Pelvic Floor Muscle Exercise for the Prevention and Treatment of Genuine Stress Incontinence. J Korean Med Sci. 2000;15:303-8.
- Wyman JF, Fantl JA, McClish DK, Harkins SW, Uebersax JS, Ory MG. Quality of life following efficacy of bladder training in older women with urinary incontinence. . Int Urogynecol J. 1997;8:223-9.
- Burns PA, Pranikoff K, Nochajski TH, Hadley EC, Levy KJ, Ory MG. A comparison of effectiveness of biofeedback

- and pelvic muscle exercise treatment of stress incontinence in older community-dwelling women. *J Gerontol.* 1993;48: 167-74
24. Glavind K, Nohr SB, Walter S. Pelvic floor training using biofeedback for muscle awareness in the treatment of stress urinary incontinence: preliminary results. *Int Urogynecol J.* 1992;3:288-91.
25. Burns PA, Pranikoff K, Nochajski TH, Desotelle P, Harwood MK. Treatment of stress incontinence with Pelvic floor exercises and biofeedback. *J Am Geriatr Soc.* 1990;38:341-4.
26. Dehghani M, Shemshaki H, Eshaghi MA, Teimouri M. Diagnostic accuracy of preoperative clinical examination in upper limb injuries. *Journal of Emergencies, Trauma and Shock.* 2011 Oct;4(4):461.
27. Dehghani M, Zarezadeh A, Shemshaki H, Moezi M, Nourbakhsh M. Hour glass constriction in advanced carpal tunnel syndrome. *International journal of preventive medicine.* 2013 Apr;4(4):438.