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FES-Biofeedback versus Intensive Pelvic Floor Muscle Exercise for the Prevention and Treatment of Genuine Stress Incontinence

We undertook this work to compare the treatment efficacies and the changes of quality of life after pelvic floor muscle (PFM) exercise and the functional electrical stimulation (FES)-biofeedback treatment, both of which are being widely used as conservative treatment methods for female urinary incontinence. We randomly selected 60 female incontinence patients who visited our department and divided them evenly into two groups. They were treated for a period of 6 weeks. The subjective changes in the severity of incontinence and discomfort in daily and social life were measured using a translated version of the questionnaire by Jackson. Objective changes of pelvic muscle contraction force were measured using a perineometer. Pre- and post-treatment maximal pelvic floor muscle contractile (PMC) pressure and changes in the severity of urinary incontinence and discomfort of the two groups showed statistically significant differences ($p<0.001$). In particular the FES-biofeedback group showed significantly increased maximal PMC pressure and a decreased severity of urinary incontinence and discomfort compared to the intensive PFM exercise group ($p<0.001$). In conclusion, FES-biofeedback proved more effective than simple PFM exercise.

Key Words: *Urinary Incontinence, Stress; Pelvic Floor; Exercise Therapy; Electrical Stimulation Therapy; Biofeedback (Psychology)*

Myoung Sook Sung, Jae Yup Hong*, Young Hee Choi†, Sung Hee Baik†, Hana Yoon*

Department of Nursing, College of Medicine, Hallym University, Seoul, Korea
Department of Urology*, College of Medicine and College of Nursing Science†, Ewha Womans University, Seoul, Korea

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Address for correspondence
Hana Yoon, M.D.
Department of Urology, College of Medicine, Ewha Womans University, 911-1 Mok-dong, Yangchon-gu, Seoul 158-710, Korea
Tel: +82.2-650-5157, Fax: +82.2-654-3682
E-mail: wowhana@yahoo.co.kr

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INTRODUCTION

Nowadays, profound changes in socioeconomic structure have caused women to participate more actively in the economy and society. As a result, women's well-being and health has taken on greater importance. In particular female urinary incontinence is now recognized as a health problem that has to be properly addressed (1).

In Korea, public awareness of urinary incontinence has also changed. It is no longer viewed as something that inevitably comes with childbirth and aging, but as a disease that can be and should be treated.

Among the various treatment methods for female urinary incontinence, pelvic floor muscle (PFM) exercise, which was initially developed by Kegel (2) to strengthen the pelvic floor muscle and has been proven an effective physiotherapy, has been recommended as a first-line treatment. The most important element in PFM exercise is accurate and continuous exercise. Therefore, many physicians have proposed various methods for effectively exercising. Clinically, biofeedback therapy, which allows patients to see their PFM contractility and accuracy of muscle contraction by watching monitors while they are performing PFM exercises, is the most widely used these days, and many authors have reported variable research results (3-8). We wished to compare the efficacy of these two major physiotherapies, and the level of inconvenience patients felt after treatment. In an effort to determine which of the two methods is the most effective in terms of efficacy and patient convenience.

MATERIALS AND METHODS

Subjects

We randomly selected 60 married female patients who visited our Department from September 1997 to September 1998, due to female urinary incontinence and obtained their informed consent to participate in this study. After history taking, voiding diary, physical examination, urinalysis, urodynamic study and measurement

of residual urine, we evenly divided them into two groups of 30 patients on the basis of treatment methods, i.e. an intensive PFM exercise treatment group and a FES-biofeedback treatment group.

Methods

The intensive PFM exercise group was trained to perform the programmed PFM exercise, according to the method by Bø (9). Patients received special training from a physiotherapist and were told to follow the directions on the exercise videotape. They were asked to do the same exercises at home everyday and to visit the incontinence clinic once a week for 6 weeks, to check the accuracy and intensity of their PFM contractions. The FES-biofeedback therapy group received FES-biofeedback treatment for 20 min per session, 2 sessions a week for a total period of 6 weeks. They were also asked to visit the incontinence clinic to check the accuracy of their PFM contractions periodically. FES-biofeedback consisted of electrical stimulation and biofeedback alternatively for 20 min. Periodic electrical stimulation was given for 24 seconds at 35 and 50 Hz simultaneously. This was followed by biofeedback which was composed of 3 phases of contraction and lasted for a total of 32 seconds (Elite compact® model, ECL electromedical, Ligon, France).

For the subjective evaluation of treatment changes in terms of incontinence severity, quantity of urinary leakage and discomfort caused by urinary incontinence, we used Jackson's Bristol Female Urinary Symptoms Questionnaire (10) after translating it into Korean. To compare pre- and post-treatment efficacy, answers to the questions were given scores from one to five (1: not a problem, 2; a bit of a problem, 3; quite a problem, 4; serious problem, 5; very serious problem). The mean score of each question was compared for the two groups. Objective changes in incontinence were also evaluated using a vaginal perineometer, maximal pelvic floor muscle contractile (PMC) pressure and the duration of pelvic floor muscle contraction.

Statistical analysis

Data was analysed using a SAS PC program. Severity of incontinence, mean vaginal contractile pressure and maximal vaginal contractile pressure of the two groups were compared using Schaffe's multiple comparative method and ANOVA.

RESULTS

Pelvic floor muscle contraction

Maximal PMC pressure in the FES-biofeedback group and intensive PFM exercise group were increased significantly by treatment ($p<0.001$ in FES-biofeedback group; $p<0.05$ in intensive PFM exercise group). The degree of PMC pressure change was significantly higher in the FES-biofeedback group than in the intensive PFM exercise group. The changes of PMC duration were also significant for both groups, which showed increased PMC duration after treatment. However, there were no significant differences between the two groups (Table 1).

Inconvenience due to urinary incontinence

The FES-biofeedback group showed a statistically significant decrease in the quantity and frequency of urine leakage after treatment compared with the intensive PFM exercise group ($p<0.001$). The FES-biofeedback group also showed a significant decrease in the severity of the incontinence compared with the intensive PFM exercise group ($p<0.001$) (Table 2).

Discomfort due to incontinence reduced significantly in the FES-biofeedback group, but not in the intensive PFM exercise group ($p<0.001$).

The changing frequency of pads and inconvenience due

Table 1. Effect of PFM exercise of the two groups upon maximal pelvic muscle contractile pressure, and duration of pelvic muscle contraction

		Group	
		FES-biofeedback	Intensive PFM exercise
		Mean±SD	Mean±SD
PMC pressure (mmHg)	Pre treatment	35.4±8.5	37.7±7.2
	Post treatment	41.5±9.8§	38.7±7.8†,*
PMC duration (sec)	Pre treatment	1.6±1.1	1.5±0.5
	Post treatment	2.3±1.2†	2.2±0.5§

PMC: pelvic floor muscle contraction

*: Significant difference between FES-biofeedback and intensive PFM exercise ($p<0.001$)

†,†,§: Significant difference between pre and post treatment ($^{\dagger}p<0.05$, $^{\dagger}p<0.01$, $^{\S}p<0.001$)

Table 2. Effect of PFM exercise on the severity and quantity of incontinence between two groups

Symptoms		Group	
		FES-biofeedback Mean±SD	Intensive PFM exercise Mean±SD
Frequency of incontinence	Pre treatment	2.7±1.3	2.2±0.4
	Post treatment	1.7±1.0§	2.0±0.5†,*
Quantity of urine leakage	Pre treatment	2.5±1.1	2.3±0.4
	Post treatment	1.8±0.9§	2.1±0.5†,*
Severity of incontinence	Pre treatment	3.0±1.0	2.4±0.7
	Post treatment	1.8±0.8§	2.1±0.7†,*
Discomfort due to incontinence	Pre treatment	2.7±0.8	2.1±0.7
	Post treatment	1.8±0.8§	2.0±0.7*
Wearing of protection	Pre treatment	2.1±.1	1.3±0.6
	Post treatment	1.6±1.1	1.4±0.6*
Discomfort due to wearing of protection	Pre treatment	1.9±0.9	1.1±0.3
	Post treatment	1.3±0.6†	1.2±0.4*

*: Significant difference between FES-biofeedback and intensive PFM exercise ($p<0.001$)
†,†,§: Significant difference between pre and post treatment ($^{\dagger}p<0.05$, $^{\dagger}p<0.01$, $^{\S}p<0.001$)

Table 3. Effect of PFM exercise on the lower urinary symptoms of the two groups

Symptoms		Group	
		FES-biofeedback Mean±SD	Intensive PFM exercise Mean±SD
Daily frequency	Pre treatment	1.9±0.6	2.2±0.6
	Post treatment	1.8±0.6†	2.2±0.6*
Nocturia	Pre treatment	2.6±1.1	1.8±0.7
	Post treatment	1.7±0.8†	1.8±0.6*
Urgency	Pre treatment	2.2±1.3	1.2±0.4
	Post treatment	1.2±0.5	1.2±0.4*
Pain	Pre treatment	1.6±0.8	1.2±0.5
	Post treatment	1.2±0.4	1.2±0.5*
Noctural incontinence	Pre treatment	1.3±0.8	1.1±0.3
	Post treatment	0.0±0.2	1.0±0.2
Changing overwear	Pre treatment	2.1±1.1	1.3±0.6
	Post treatment	1.6±1.0†	1.4±0.6†,*
Hesitancy	Pre treatment	1.9±0.9	1.1±0.3
	Post treatment	1.3±0.6	1.2±0.4*
Straining while voiding	Pre treatment	1.6±1.0	1.2±0.4
	Post treatment	1.1±0.6†	1.1±0.4§,*
Intermittent voiding stream	Pre treatment	1.7±1.0	1.2±0.4
	Post treatment	1.3±0.4	1.1±0.5§,*
Weak voiding stream	Pre treatment	1.5±0.8	1.2±0.4
	Post treatment	1.1±0.3	1.2±0.5*
Retention	Pre treatment	1.7±0.9	1.2±0.4
	Post treatment	1.2±0.5	1.2±0.5*
Urethral burning	Pre treatment	1.0±0.0	1.0±0.1
	Post treatment	1.0±0.0	1.0±0.1
Incomplete emptying	Pre treatment	1.3±0.7	1.0±0.2
	Post treatment	1.1±0.4	1.0±0.2*
Inability to stop midstream	Pre treatment	2.4±1.0	1.3±0.5
	Post treatment	1.4±0.5	1.3±0.6*

*: Significant difference between FES-biofeedback and intensive PFM exercise ($p<0.05$)
†,†,§: Significant difference between pre and post treatment ($^{\dagger}p<0.05$, $^{\dagger}p<0.01$, $^{\S}p<0.001$)

Table 4. Effect of PFM exercise on the quality of life of the two groups

Symptoms		Group	
		FES-biofeedback Mean±SD	Intensive PFM exercise Mean±SD
Fluid intake restriction	Pre treatment	2.2±0.9	1.9±0.3
	Post treatment	2.0±0.5†	1.9±0.3*
Discomfort due to fluid intake restriction	Pre treatment	1.8±1.0	1.1±0.3
	Post treatment	1.4±0.7†	1.1±0.3*
Problems on daily tasks	Pre treatment	1.8±1.0	1.1±0.3
	Post treatment	1.4±0.7§	1.1±0.3*
Avoidance of places & situations	Pre treatment	2.0±1.3	1.4±0.8
	Post treatment	1.4±0.9†	1.4±0.7*
Discomfort due to avoidance of places & situations	Pre treatment	1.8±1.1	1.2±0.4
	Post treatment	1.3±0.7†	1.2±0.4*
Interference in physical activity	Pre treatment	2.1±1.1	1.3±0.5
	Post treatment	1.6±0.8§	1.3±0.4*
Interference in relations with other people	Pre treatment	1.7±1.1	1.1±0.3
	Post treatment	1.2±0.7†	1.1±0.3*

*: Significant difference between FES-biofeedback and intensive PFM exercise ($p<0.01$)
†,‡,§: Significant difference between pre and post treatment (†$p<0.05$, ‡$p<0.01$, §$p<0.001$)

to wearing protection such as pads, were significantly decreased after treatment in the FES-biofeedback group only, scores changed from 2.0 to 1.6 points ($p<0.05$).

Discomfort due to lower urinary symptoms, except for noctural incontinence and burning were significantly different for the two groups (Table 3).

Daily frequency, nocturia, urgency, pain, retention, incomplete emptying, inability to stop mid stream ($p<0.001$), hesitancy, weak voiding stream ($p<0.01$) were improved significantly within the FES-biofeedback group after treatment, but not in the intensive PFM exercise group. Scores associated with changing overwear due to incontinence were reduced in the FES-biofeedback group ($p<0.01$), however, they increased in the intensive PFM exercise group, and were significantly different between the two groups ($p<0.01$). Straining while voiding and interruption of the voiding stream were reduced both in the FES-biofeedback and intensive PFM exercise groups. In general, in answers to questions about voiding symptoms, both groups of patients said that they were satisfied with the improvements in their voiding symptoms after treatment. However, these improvements showed statistical significance only in the FES-biofeedback group ($p<0.001$).

Inconvenience in daily life, such as fluid intake restriction, difficulties in daily and social life, physical activity and personal relations, and the avoidance of some places and situations due to their voiding symptoms were not changed after intensive PFM exercise. However, the FES-biofeedback group showed a significant decrease in the level of inconvenience during daily life after treatment ($p<0.01$) (Table 4).

DISCUSSION

The increase in living standards has created a group of female urinary incontinent patients who now seek treatment. This in turn has raised the interests of clinical physicians in terms of both effective treatment and the identification of preventive methods, for this condition which is now recognized as a social disease which can seriously affect the quality of life.

PFM exercise is a non-invasive, safe technique, which causes relatively fewer side effects. It is recommended as a first-line therapy in the management of stress urinary incontinence (11). PFM exercise strengthens the levator ani muscle and the external urethral sphincter muscle, which are related to this form of continence, because the contraction of the levator ani and the external urethral sphincter muscles prevents incontinence. Many researchers have reported success rates of 16-17% using PFM exercise and have acknowledged its effectiveness (3-6). In order to successfully treat incontinence by this method, patients have to clearly understand what PFM exercise is, how it works and where the pelvic floor muscle is located. In addition, the patients' trust in the effects of the method is its key to success. Bump et al. (12) found that 25% of the 47 women using the Kegel technique exercised in a way which aggravated the incontinence, and that only 49% exercised properly. Bø et al. (13) also pointed out 70% of patients using the PFM exercise method practiced in the wrong way. Taking this into account, in 1990, Bø (9) developed a physical exercise method, which is easier to follow and makes patients repeat simple postures, as part of an intensive PFM exer-

cise program. The biofeedback method, which gained popularity among clinical physicians recently, includes PFM exercises and simultaneously allows patients to learn how to contract their pelvic floor muscle. As a result, it treats incontinence more effectively than the PFM exercise alone (7, 8, 14).

In this study, we randomly selected one group for the intensive program developed by Bø (9) and another group for the FES-biofeedback treatment. Objective changes in the strength of pelvic floor muscle contraction after the treatments were measured by perineometer, and significant increases in maximal PMC pressure were observed in both groups. Moreover, the duration of muscle contraction also increased in both groups. These findings suggest that repetitive contraction of pelvic muscle in both conscious and unconscious states induces hypertrophy of the pelvic floor muscle and enhances neuromuscular performance, which in return gradually increases the average PMC pressure and duration. Since the patients could see monitors showing whether they contracted the correct muscle, the FES-biofeedback group showed greater increase in PFM contractility than the PFM exercise-alone group. This result is in agreement with many reports, which claim that the cure/improvement rate by PFM exercise is 20-52%, while biofeedback gives corresponding results of 54-87% (7, 8, 15-18). We applied electrical stimulation to the pelvic floor muscle, on a regular basis, in addition to biofeedback treatment.

By subjective evaluation of the treatments using a questionnaire, both the intensive PFM exercise group and the FES-biofeedback group showed meaningful differences in terms of the expression of incontinence symptoms after treatment. However, only the FES-biofeedback group felt that the symptoms were significantly relieved and said they felt more comfortable. The FES-biofeedback treatment proved to be more effective at enhancing the patients' quality of life, which had been adversely affected by incontinence.

PFM exercise produces positive results with few side effects and is easy to practice. However, what determines the success of the treatment is whether patients actively follow the directions given by physicians. In addition, when applying the treatment, the state of the disease has to be taken into account. When selecting a treatment method, doctors should consider the level of discomfort the treatment can cause to the patient as well as its effectiveness in relieving symptoms, because incontinence causes not only displeasure and discomfort but also difficulties in performing daily responsibilities.

Various factors affect the result of the PFM exercise; severity of incontinence, communication with patients, awareness of pelvic floor muscle and continuance of the exercise (5). Therefore, it is essential to fully educate patients and encourage their interest in the treatment. The results of our study show that both Bø's PFM exercise and FES-biofeedback helped patients to learn the right PFM exercise method and promoted continuous practice, even at home. However, when considering both the objective and subjective indicators of each treatment method, the biofeedback method proved to be the more effective, because it allowed patients to monitor their PFM contractions and to check whether they were contracting the correct muscles and this in turn motivated them to continue their exercises.

In conclusion, when considering nonsurgical treatment of genuine stress incontinence, it is essential to select a proper method and to keep encouraging patients to persevere with it to ensure its long term effectiveness.

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