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A Randomized Prospective Study Comparing New Vaginal Cone and FES-Biofeedback

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Several different methods of enhancing pelvic floor functions have been developed and modified. The aim of this study was to compare the efficacy of a new vaginal cone with conventional FES-Biofeedback therapy for female urinary incontinence, with respect to pelvic floor rehabilitation. One hundred and twenty patients, who required a non-surgical treatment for urinary incontinence, were divided randomly into two groups; (1) the Functional Electrical Stimulation (FES)- Biofeedback group (or BFB group) and (2) the new vaginal cone group (or cone group). For a period of six weeks, two training sessions each week were carried out on the BFB group. The new 150-gram dumbbell-shaped vaginal cone, made of fine ceramic material, was developed domestically. A therapist instructed patients in the cone group upon its use for pelvic floor exercise, and directed the exercise to be repeated at home daily; these patients had follow-up visits every week. Objective improvements were obvious in both groups. 88.3% and 91.6% of the cone and BFB groups showed an improvement after treatment, respectively. There was no significant difference in the improvement or dissatisfaction scores of the two groups. In conclusion, no significant differences in the therapeutic effects were observed between the FES- Biofeedback and the new vaginal cone groups. Considering improvements in the quality of life and objective symptoms, the therapeutic effects of the two techniques showed no significant differences. The new vaginal cone is relatively easy to use at home and aids in pelvic floor muscle exercises. Consequently, the new vaginal cone could be used as an alternative non-surgical treatment modality in female stress urinary incontinence.

Key Words: Female stress urinary incontinence, vaginal cone, FES-Biofeedback

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INTRODUCTION

In terms of non-surgical treatment for stress urinary incontinence, various treatment methods have been developed and applied since Kegel[1,2] first designed a pelvic floor muscle (PFM) exercise. The ultimate goal of all non-surgical treatments is to enhance pelvic floor muscular power, which supports the bladder neck and urethra, resulting in sufficient muscular contraction to prevent urine leakage.

PFM exercise using a combination of FES (functional electrical stimulation)-Biofeedback and a vaginal cone is one of the most popular methods of enhancing the effect of PFM exercise. These methods give positive feedback which help patients to become aware of PFM, and to perform the PFM exercise in the correct manner, thus, enhancing the muscular power of the PFM.

With correct cone positioning and PFM contraction, PFM exercises using a vaginal cone are considered easy to perform at home. In addition, patients are able to learn how to contract the PFM through repeated exercise.

Recently, a new type of vaginal cone has been developed to meet these aims. This study was undertaken to investigate the treatment effect of the new vaginal cone, and to compare its treatment efficacy with that of FES-Biofeedback.

MATERIAS AND METHODS

The present study was a multi-center, randomized prospective study. 120 female stress uri-

nary incontinence patients, who required non-surgical treatment were divided into two groups; FES-Biofeedback (BFB) and vaginal cone (cone) groups.

The FES-Biofeedback treatment consisted of two 20-minute sessions per week, for 6 weeks and was programmed to perform FES and biofeedback alternately; FES applies simultaneous electrical stimulation of 35 Hz and 50 Hz for 24 seconds, with this cycle repeated for 20 minutes. The new vaginal cone was domestically developed, has a dumbbell shape, a weight of 150 gm and was made of a fine ceramic material (Fig. 1A). This cone has two different cone head sizes, so a patient has a choice according to her vaginal width and PFM strength. It was designed such that its concave middle portion can be easily positioned to the pelvic floor muscle when the proximal end of the cone is properly inserted into the patient's vagina (Fig. 1B). This helps the patient to become aware of her PFM and also helps PFM exercise to be performed more easily. The weight bearing effect of the cone depends on the patient's position. In a supine position, the weight effect is approximately 0%, in the oblique leaning position 50% and in the upright sitting position 100% of the cone weight. Therefore, the patients were educated to start their PFM exercise in a position whereby the cone does not expulse when the PFM is contracted, and to change position gradually to an upright sitting position when they had developed enough contractile power to prevent cone expulsion. The PFM exercise with the cone consisted of 5 seconds of PFM contraction and 10 seconds of relaxation, with this cycle rapidly repeating this cycle 3-5 times for at least 5 minutes daily for 6 weeks.

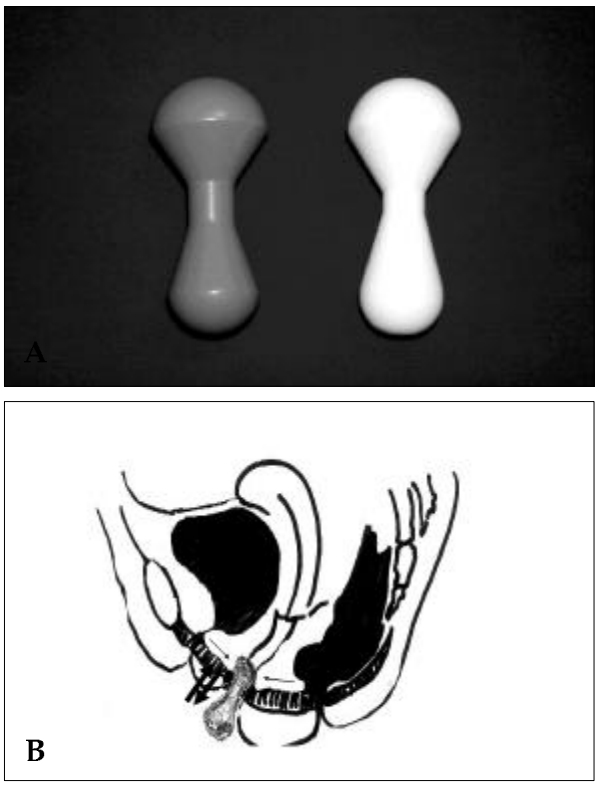

Fig. 1. (A) The new vaginal cone is dumbbell shaped and allows PFM exercise to be easily performed. (B) PFM movement (narrow arrows) and movement of new vaginal cone (thick arrows) upon PFM contraction.

Patients in the cone group were instructed by a specially trained nurse, and encouraged to perform the PFM exercise with the cone once daily. PFM awareness and compliance were assessed at the hospital once a week.

History taking, U/A, pre- and post- treatment voiding diaries, PFM check, perineometer and questionnaire testing were performed for all patients. To compare discomfort with regard to their urinary symptoms, answers to questions were scored according to the degree of discomfort (not at all, 0; very uncomfortable, 5).

For the statistical analysis, with the paired t-test, $p<0.05$ was taken as indicating a statistical significance.

RESULTS

The mean patient ages were 42.7 ± 11.3 and 44.5 ± 12.1 years in the BFB and cone groups, respectively. There were no significant differences between the two groups in terms of age, weight or parity (Table 1) ($p>0.05$).

Overall, 91.6 (55/60) and 88.3% (53/60) of the BFB and cone groups, respectively showed an improvement in the degree of incontinence. There were significant improvement in pad test results, maximal PFM contractile power (maximal vaginal pressure) and duration, the symptoms related to incontinence and the degree of discomfort in both groups (Table 2 and 3). The objective parameters used to detect changes in incontinence were; the

Table 1. Characteristics of the Study Groups

	FES & Biofeedback	New cone	*p*-value*
No.	60	60	
mean age (years old)	42.7 ± 11.3	44.5 ± 12.1	0.63
body weight (kg)	56.8 ± 8.7	59.7 ± 7.4	0.12
parity (number of times)	2.3 ± 2.0	2.7 ± 2.1	0.54

*$p>0.05$.

Table 2. Changes in Objective Parameters in the Two Groups

	FES & Biofeedback	New cone	Intergroup difference *p*-value†
Pad test			
Baseline	5.56 ± 6.05	6.51 ± 2.55	0.210
Post Tx.	3.38 ± 5.37	3.72 ± 6.73	0.843
p value*	0.049*	0.028*	
Maximal urethral closing pressure (mmH_2O)			
Baseline	63.51 ± 27.69	62.36 ± 25.98	0.114
PostTx.	77.93 ± 30.96	78.38 ± 18.30	0.344
p value*	0.001*	0.003*	
Maximal vaginal pressure (mmHg)			
Baseline	17.78 ± 10.96	23.01 ± 11.70	0.231
PostTx.	33.64 ± 16.72	27.20 ± 13.21	0.294
p value*	0.001*	0.007*	
Duration of PFM contraction (sec)			
Baseline	4.86 ± 2.31	5.47 ± 3.48	0.581
PostTx.	10.17 ± 5.74	9.25 ± 5.44	0.511
p value*	0.001*	0.021*	

*p: comparing values between pre and post treatment, $p<0.05$.
†p: comparing values between the FES-Biofeedback and new cone groups.

pad test, maximal PFM contractile power and duration, and the maximal urethral closure pressure (MUCP). Post treatment changes in these parameters were not significantly different between the two groups (Table 2).

The changes in the discomfort pre- and post-treatment were compared using a voiding symptom questionnaire. In the BFB group, the frequency, stress incontinence, frequency of incontinence episodes, bothersome score of incontinence symptoms in daily life, tendency to avoid particular places due to voiding symptoms and effect of voiding symptoms on physical activities, such as exercise and quality of life showed that significant improvements resulted from treatment (Table 3). However, sexual life and interpersonal relationships did not improve significantly. However, in the new cone group, significant improvements were observed with respect to the frequency, frequency of incontinence episodes, amount of urine leakage and limitation of physical activities, but not in sexual life, daily life limitations, interpersonal relationships and the avoidance of particular places (Table 3).

On comparing the treatment efficacy between the two groups, no significant differences were found with respect to discomfort, other that more discomfort due to urine leakage in the cone group

Table 3. Subjective Symptom Score Changes in the Questionnaire

Symptoms	FES & Biofeedback		New cone	
	Score changes*	p	Score changes*	p-value
Daytime frequency	-0.59 ± 0.18	0.039†	-0.47 ± 0.16	0.008†
Episode of urine leakage	-1.05 ± 0.17	0.001†	-0.63 ± 0.19	0.004†
Amount of urine leakage	-0.63 ± 0.20	0.005†	-0.63 ± 0.23	0.014†
Difficulty in exercises due to incontinence	-0.59 ± 0.18	0.004†	-0.36 ± 0.17	0.049†
Sexual life	-0.19 ± 0.12	0.157	-0.11 ± 0.13	0.326
Daily life	-0.27 ± 0.11	0.031†	-0.12 ± 0.15	0.480
Avoiding places	-0.29 ± 0.14	0.012†	-0.13 ± 0.15	0.429
Difficulty in personal relationships	-0.29 ± 0.14	0.055	-0.06 ± 0.09	0.578
Quality of life	-0.27 ± 0.13	0.048†	-0.42 ± 0.12	0.002†

*score change, score of pre-treatment - score of post-treatment.
†$p<0.05$.

(cone 2.63, BFB 0.00, $p<0.05$).

In general, symptomatic improvements in the degree of incontinence were significant in both groups, but no significant difference was observed in terms of degree of improvement between the two groups ($p>0.05$).

DISCUSSION

The treatment requirements for female urinary incontinence depend on changes in the quality of life. Therefore, the non-surgical treatment goal of urinary incontinence is not only the prevention of urine leakage, but also the improvement of the patient's quality of life.

The basic principle of the non-surgical treatment of incontinence is to enhance the strength of the weakened PFM. For this purpose, the simplest, most cost-effective way is to perform PFM exercises, which are more than 90% effective when applied to properly selected patients with mild symptoms.[3] However, the treatment efficacy is highly dependent on a patient's motivation, awareness, proper education and induction and therefore, varies between authors.[4-8]

In 1985, Plevnik[9] proposed the use of PFM exercises by retaining a cone in the vagina. This cone helps patients learn the location of the PFM to be contracted via a biofeedback mechanism. The feeling of losing the cone from the vagina initiates a powerful sensory biofeedback response, causing the PFM to contract around the cone for its retention. Typical sets of vaginal cones consist of cones of equal volume, but increasing weights. Thus, patients learn to perform the PFM exercise and gradually increase the cone weight.[10,11] However, it is possible to perform the exercise incorrectly when the cone is transversely-positioned to prevent its loss from the vagina. Therefore, to avoid this situation, and for the PFM exercise to be performed correctly, a 150 gm ceramic dumbbell-shaped cone, with asymmetrically sized heads on either end, has been developed. This new type of ceramic cone was designed to center naturally into the correct position and would be expelled when the patient performs the PFM exercise incorrectly. Patients can modify their exercise position according to their PFM awareness and contractility, by gradually changing their exercise position from supine to erect. This dumbbell-shaped cone is positioned between the pelvic floor muscle groups, not on the proximal part of the pelvic floor muscle groups, which reduces the risk of incorrect positioning, which allows the patient to easily control the PFM exercise. When a patient repeatedly contracts her PFM against gravity, the muscle strength is enhanced, as in essence, the exercise is a form of weight training.

The PFM exercise with the cone helps with its accurate monitoring and is easily performed daily

in the privacy of the patient's home unlike perinometer, biofeedback and functional electrical stimulation (FES).[12,13] Several studies have reported that vaginal cone exercises are an effective method of enhancing the PFM exercise effect, particularly with respect to cost-effectiveness, the degree of difficulty in terms of learning the exercise and of recognizing the PFM.[14-17] The PFM exercise with the new cone is easy to learn and comfortably performed at home.

The PFM exercise stimulates the slow-twitch fibers (type I) with relaxation, and the fast-twitch fibers (type II) with reflexive and passive muscle contraction.[14] Another merit of this method is that a patient learns how to contract her PFM with repeated cone exercises. However, Pieber et al.[18] failed to see any significant difference in the effectiveness of the PFM exercise performed with the cone or by the simple PFM exercise in mild to moderate stress urinary incontinence. Kondo et al.[19] also reported a low success rate with cones; only seven out of fifty women were cured or improved. However, in their study, they did not follow up or modulate the extent of the PFM exercise accuracy and awareness, which resulted in a low success rate.

In this study, the treatment effects of the newly developed cone were compared with those of FES-Biofeedback. When objective parameters were used to compare changes in the PFM contractility the FES-Biofeedback group showed better results; however, patients' subjective parameters, such as the degree of dissatisfaction and quality of life, on significant differences were shown between the two groups. It is our belief that this indirectly proves the effectiveness of new cone as a non-surgical treatment of incontinence. Patients were randomly selected and the treatments applied, regardless of the symptom severity. Therefore, in properly selected patients with a mild degree of incontinence, this cone is expected will give satisfactory results.

In conclusion, both treatment methods, the new vaginal cone and FES-Biofeedback improved various symptoms associated with stress urinary incontinence. In addition, these two treatments showed no differences in terms of the improvements in the subjective degree of discomfort, with the new vaginal cone offering an effective non-surgical treatment method in properly selected patients.

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