Intravaginal Functional Electrical Stimulation in the Treatment of Overactive Bladder: Results of 3 Years Follow-up

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Abstract

Objective: *To evaluate the long term results of intravaginal functional electrical stimulation therapy in women with over-active bladder.*
Study Design: *Functional electrical stimulation was applied in 65 cases with over active bladder and 52 of them completed 3 years follow-up period. The cases were evaluated by urinary diary and multi-channel urodynamics. Urinary symptoms and quality of life scores were recorded before and after the treatment.*
Results: *The quality of life scores before and after functional electrical stimulation (1 week, 1 year and 3 years) were 13.1 ± 7.45, 3.21 ± 4.71, 2.52 ± 2.93, 3.26 ± 4.28, respectively (P< 0.05). The urinary symptoms (urgency, urge incontinence, frequency) were also significantly improved after functional electrical stimulation.*
Conclusion: *Functional electrical stimulation is a simple, non-invasive, cheap and effective therapeutic option for detrusor over activity. The quality of life scores of our cases were improved significantly even 3 years after the therapy.*
Keywords: *Over-active bladder, FES, QOL score*

Introduction

At 2002, the International Continence Society redefined overactive bladder (OAB) as a syndrome of urgency with or without urge incontinence, usually associated with increased frequency of micturition and nocturia. The major objective findings of OAB are the diminished compliance and detrusor contraction during filling or storage phase of cystometry but the urodynamic findings are not exist in all cases. So the diagnosis of OAB is based on history, QOL scores and exclusion of the urological, gynecological and other irritative factors for the bladder and the urethra. The frequency of OAB in women with urinary incontinence is reported to be 9-55%, whereas it increases in pediatric and geriatric populations[1,2,3].

The electrical stimulation was first used in the treatment of urinary incontinence in human beings in 1963 by Caldwell[4]. FES became more feasible in the treatment of urinary incontinence after the design of vaginal electrodes for chronic use[5,6]. It has been suggested as a first-line therapy since it is easily applicable, repeatable, cheap, and free from side effects and as effective as the alternative methods[7-18]. Employing low frequency (5-21 Hz) electric current through vaginal route is now generally accepted by many researchers due to its ease of use[5-22]. Although, 43-95% success rates have been reported in the management of OAB by using low frequency (10-20 Hz) electrical stimulation[6-22], the rate of urodynamically stable bladder was 45-50%[10-14]. The long-term success rate of FES has been reported to be lower[19].

The aim of this study was to determine the immediate and long-term results of vaginal FES therapy in women with OAB.

Materials and methods

This is a prospective cohort study which was performed in the urogynecology clinic of Süleymaniye Maternity and Women's Disease Research and Teaching Hospital between April 1998 and June 2006. In this time period, 67 cases with OAB were enrolled to the study. The diagnosis OAB was established from comprehensive urogynecologic history, neurologic and gynecologic examinations, 24 hours voiding diary, urine culture, complete urine analysis, fasting blood glucose, multichannel urodynamic testing (UD, 2000 Medical Measurement System 6000-Holland). Cysto-urethroscopy was performed in cases with low bladder (less than 300 ml) capacity or painful urination. The cases with any etiologic factor for OAB and/or other types of incontinence were not included in the study. The study was approved by the local ethical committee and informed consent was obtained from all of the cases.

Cysto-urethroscopy was performed in 11 cases and two of them (one case with urethral polip and one case with bladder diverticula) were excluded from the study. FES was performed totally in 65 cases with OAB who did not accepted medical or behavioral treatment for OAB or who could not continue antimuscarinic therapy because of its side effects. The cases whose were operated for urinary incontinence, urological or gynecological diseases excluded from the study. Fifty-two cases completed 3 years follow-up period after FES. One case had died because of myocardial infarction, 3 cases were operated for gynecological or urological diseases (1 total abdominal hysterectomy for intractable uterine bleeding, 1 total abdominal hysterectomy and bilateral salpingoooferectomy for an adnexal mass, 1 operation for urinary calculus). Nine cases were lost at follow up period and totally 13 cases could not complete the 3 years follow-up.

All patients underwent twice weekly FES sessions of 15 minutes each during the 6 weeks treatment period in the outpatient clinic. Biphasic current with a frequency of 12.5 Hz (current between 0-100 mA) was applied by a two-channeled stimulator with vaginal probe (Liberty, Ultra Pelvic Floor Exerciser, USA). The duty cycle was scheduled to be 5 seconds (5 sec. work - 5 sec. rest), and the current was increased gradually (5 mA) to reach the maximum tolerable level where the patient began to experience muscular contractions or discomfort. The level reached in the last session, was attempted to be exceeded in the next one. FES was not performed during menstrual period.

Post-treatment evaluations were done by using urinary diary, monitoring urogynecologic symptoms and Stress, Emptying, Anatomy, Protection, Inhibition (SEAPI) Quality-of-life scores proposed by Raz and Ericson[9]. The lower SEAPI scores corrolate with improvement. The first follow-up visit was performed within first week after the final session was over. The long-term effects were evaluated at the first year and 3 years after the completion of the therapy.

During the assessment of the data obtained from the study, NCSS 2007 & PASS 2008 Statistical Software program was used for statistical analysis. Repeated measures test was used for the comparison of descriptive statistical methods (Mean, Standard deviation, frequency) in addition to comparison of pre-treatment and post-treatment (immediately after FES, 1 year and 3 years after FES) qualitative data distributed normally and the *paired samples t-test* adjusted with the *Bonferroni correction* for post hoc assessment. Friedman Repeated Measures Anova test was used for the comparison of pre-treatment and post-treatment parameters (immediately after FES, 1 year and 3 years after FES) which were not distributed normally and Wilcoxon Signed rank test adjusted with the *Bonferroni correction* for post hoc assessment. Cochran's Q test and Mc Nemar test were used for assessment of urge incontinence, urgency and pad user coded as categorically. Results were given in 95 % confidence interval and significance was accepted at p<0, 05 level.

Results

Fifty-two cases completed 3 years follow-up period without any complication. Mean age, gravidity and parity were 42.51 ± 9.24, 4.28 ± 2.43, and 3.01± 1.65, respectively. The average current used at the first application was 48.7 + 8.98 mA and maximum current applied throughout the FES therapy was 85.5 +12.61 mA. The average current was 67.1 + 9.48 mA, and in 19 cases (36.5%) it reached 100 mA.

The mean SEAPI score decreased significantly immediately after FES therapy (p<0.001) and the mean SEAPI scores at follow-up visits were found to be statistically similar (p >0.05), which indicates the continuation of the satisfaction during 3 years after the FES therapy. The mean volume of daily fluid intake and total voided urine volume was similar before and after FES (p<0.05). While the mean urine volume per urination was increased significantly after the FES therapy (p<0.05), it was similar at follow-up visits (p>0.05) (Table 1).

Table 1

Clinical symptoms and findings before and after the FES therapy

Symptoms	Pre-treatment	Post-treatment 1 week	Post-treatment 1 year	Post-treatment 3 years	P
SEAPI	13.1 + 7.45	3.21 + 4.71†	2.52 + 2.93†‡	3.26 + 4.28†	<0.001
No of diurnal urinations	9.38 + 2.61	5.42 + 2.07†	5.50 + 1.92†	5.90 + 2.91†	<0.05
No of nocturnal urinations	1.67 + 1.06	0.60 + 0.93†	0.54 + 0.61†	1.27 + 1.34#	<0.001
No of pads/day	1.96 + 1.27	0.58 + 0.78†	0.38 + 0.56†	0.67 + 0.79†	<0.05
Total liquid intake/day (ml)	1459 + 238	1430 + 196	1467 + 188	1479 + 183	>0.05
Urine volume/day (ml)	1281 + 217	1262 + 175	1256 + 161	1253 + 137	>0.05
Urine volume/urination (ml)	144 + 40	251 + 65*	247 + 66†	244 + 89†	<0.05
No of cases with urge inc.	43 (83%)	22 (42%)*	17 (33%)†	24 (46%)†	<0.05
No of cases with urgency	52 (100%)	33 (60%)*	18 (35%)†	26 (50%)†	<0.05
No of pad user cases	42 (80%)	16 (31%)*	14 (27%)†#	21 (40%)†	<0.05

Mean +SD; n (%)

*† p<0.001 compared with pretreatment; * p<0.05 compared with pretreatment; ‡ p<0.05 compared with posttreatment; # p<0.001 compared with posttreatment*

The rates of urgency and urge incontinence episodes, mean number of diurnal voids, mean number of pads used per day and the number of cases using pad in the post-treatment period were statistically lower than the corresponding pre-treatment values (p<0.05), but the differences between the values observed at follow-up visits were not statistically significant (p>0.05) (Table 1).

The differences between the mean number of nocturnal voids before treatment and the values at immediately after and one year after the therapy were statistically significant (p<0.001). The mean number of nocturnal voids was increased three years after therapy and the increase was statistically significant compared with the values obtained immediately after and one year after the therapy (p <0.05), it was similar with the pre-treatment value (p >0.05) (Table 1).

In 9 (%20.9) cases, urge incontinence continued, nevertheless, out of them in 8 cases the number of pads used daily and in 5 cases the number of diurnal and nocturnal urinations decreased significantly. SEAPI scores did not change in six cases (11.5 %) before and after treatment. It was interesting to observe that some of our patients were dissatisfied with the results immediately after the FES therapy, they were satisfied at the first year follow-up.

Discussions

We evaluated the effectiveness of intravaginal FES therapy by using SEAPI scores, proposed by Raz and Erickson[9]. Brubaker and colleagues[10] studied the subjective and objective effectiveness of the intravaginal electrical stimulation therapy by using urinary diary (diurnal and nocturnal voiding frequency, number of incontinent episodes, number of pads used) and SEAPI scores that included physical, emotional, functional, social and physician relationship as the outcome parameters. Raz[9] and Brubaker[10] had used the results of urodynamic investigations as objective criteria. We did not use urodynamic investigation after FES therapy because of its low predictive rates and presence of a significant correlation between subjective and objective parameters[9-11,18]. The urinary incontinence is known to have a social aspect, meaning that we do not treat the urodynamic and cysto-urethroscopic findings. This is the reason why the quality-of-life assessment should be done to evaluate the result of the treatment. In our study, urodynamic investigations were not used after the treatment since our patients found it very disturbing and too expensive. A decrease in the number of micturition during a 24-hour period was accepted as an indirect indicator of an increase in the volume of the bladder, in addition to the settlement in urgency and episodes of incontinence which showed a decrease in detrussor over activity. We used 24-hour urinary diary for assessment of the objective improvement. While the mean volume of the daily fluid intake and voided urine were similar before and after FES, the mean volume for the urine per urination increased significantly.

In our study, continence maintaining rates were 58%, 67% and 54% immediately after, one year after and three years after FES therapy, respectively. The rates of pad users were 81%, 31%, 27% and 40% before, immediately after, one year after and three years after the FES therapy, respectively. If the number of cases who did not use pad is accepted as an indicator of clinical satisfaction, the FES therapy can be considered as a satisfactory method in the treatment of OAB. The FES therapy significantly improved both the quality of life scores and the symptoms of frequency, urgency, urge incontinence and nocturia in cases with OAB. We found a correlation between the subjective and objective improvement rates. In our study, we observed that maximum subjective and objective improvement was achieved after the 1 year of FES therapy. Currently there is no neurophysiologic explanation for this carryover effect which it may be due to the increased awareness of patients about their bladder functions and control of them. Because any kind

of stimulation (physical, social, psychological) can effect the bladder function as a behavioral treatment modality. As a result, we believe that the long-term effectiveness of FES is satisfactory in terms of subjective and objective improvements as in some other studies[18-22] with a follow-up period as long as 5 years[21].

We have found that the only symptom worsened after the FES therapy was the number of voids at night, at the third year. This may be due to more liquid consumption in the evening as a consequence of cases, feeling themselves well in respect of bladder functions.

In the literature, there are also some studies with unexpected results. In a study of Kulseng-Hanssen et al[23] they applied FES to 18 patients with detrusor over activity. They found significant subjective improvement after FES however none of the objective measures were significantly improved. The authors stated that they were disappointed by the results and have stopped using the method[23]. This study has the disadvantage of small sample size and without enough power to deny the effectiveness of FES.

Several studies reported a 13-23% urge incontinence recurrence rate[7-21]. We have found the recurrence rate to be 16% at third year and it was similar the results in the literature. It is expected that the recurrence rate depends on the duration of the follow-up and it could be greater in the longer duration[10-21].

Despite the resolution in some symptoms of OAB, SEAPI scores did not changed in six cases (11.5 %) so they accepted as refractory to FES. A substantial minority of patients whose are refractory to these interventions may be improved by the other treatment methods, such as magnetic stimulation or sacral nueromodulation. Although sacral neuromodulation is not a complication free, cheap and non-invasive technique, it can be used in refractory or recurrent cases as a minimally invasive and reversible treatment prior to consideration of more invasive and irreversible treatment modalities such as augmentation cystoplasty[24,25]. Nowadays, use of FES may decrease and replace with more comfortable and simplified methods which have similar mechanism of action such as "magnetic chair". Magnetic chair has the advantage of applicability in an outpatient clinic without undressing. In our opinion, therapeutic value of electrical stimulation will not change soon because of its applicability at home by patient's own self. The patients may prefer one of these two methods depending on their special circumstances.

Consequently, FES therapy is effective and relatively cheap, easy to use, and free from side effects as compared to the alternative treatment options. All of the cases completed FES therapy with no serious side effect so we consider it as a convenient and tolerable method. The therapeutic effect of FES therapy was still satisfactory even 3 years after completion of the therapy. So, we still use intravaginal FES therapy in cases with OAB, as an outpatient treatment. ■

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