

Clinical efficacy study of pelvic floor electrical stimulation for idiopathic detrusor overactivity and urodynamic stress incontinence[☆]

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Abstract

Objective. To investigate the efficacy of pelvic floor electrical stimulation (PFES) using surface electrode combined with pelvic floor training (PFT) under intensive supervision for female with idiopathic detrusor overactivity (IDO) and urodynamic stress incontinence (USI). **Methods.** PFES using surface electrode and PFT under intensive supervision were performed on 70 women (age ranged from 31 to 64 years, average age 40 ± 7 years old) with IDO and USI for twelve weeks. Urinary diary, International Continence Inquiring Committee's Questionnaire (ICI-Q-SF) scores were recorded and urodynamic study was performed before and after the treatment. **Results.** In total, fifty women (71%) finally completed treatment for twelve weeks, and urinary incontinence disappeared in 8 (16%), detrusor overactivity disappeared in 10 (20%), and leakage was no found in 6 (12%) in leakage point pressure measurement. Moreover, the total time of voiding (72 h), total time of leakage (72 h), total scores of ICI-Q-SF, max detrusor uninhibited contraction pressure and detrusor uninhibited contraction duration were significantly lower than those before treatment; max voided volume, normal desired cystometric capacity, maximum cystometric capacity, Valsalva leak point pressure and max urethral closure pressure were significantly higher than those before treatment ($P < 0.05$). The effective rate following up three months was 60%, not significantly lower than that after treatment ($P > 0.05$). **Conclusions.** PFES using surface electrode combined with PFT under intensive supervision is a useful therapy to treat women with IDO and USI. [Life Science Journal. 2009; 6(2): 55 – 61] (ISSN: 1097 – 8135).

Keywords: urodynamic stress incontinence; idiopathic detrusor overactivity; pelvic floor electrical stimulation; pelvic floor training

1 Introduction

It is well known that urodynamic stress incontinence (USI) is a common and heterogeneous disorder^[1]. The overall prevalence of USI among Chinese women is as high as 18% to 55%, moreover, the trend is increasing year by year, seriously affecting their quality of life. The best choice for first-line treatment is mostly behavior therapy mainly including pelvic floor training (PFT) and

pelvic floor electrical stimulation (PFES), with advantages of being simple, noninvasive and economic, and only for serious patients surgical treatment can be carried out^[2].

However, there are many problems for good outcome of the women with USI in traditional behavior therapy^[3]. For one thing, it is important and not easily assured that the validity and duration of the PFT. For another thing, the vaginal electrode used in the PFES could bring remarkably discomfort^[4]. Moreover, no matter what kind of treatment is used, after urodynamic checkup up to 50% of patients are found to be complicated by detrusor overactivity, which is the main reason for no

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improvement in the quality of lives of the patients after the treatment, but also significantly increases the severity of urinary incontinence^[5]. Furthermore, the causes for the women with USI and detrusor overactivity are still not clear, and the clinical treatments and its efficacy are also of much controversy. Therefore, it is imperative to investigate the outcome on the women with USI and detrusor overactivity treated by improved behavior therapy.

The purposes of this study were to prospectively evaluate the efficacy of PFES using surface electrode combined PFT under intensive supervision for female with idiopathic detrusor overactivity (IDO) and USI. We hoped it would provide valuable insights into the pathogenesis and helpful in improving the outcome of them.

2 Materials and Methods

2.1 Patients

In this study, seventy women (mean age 40 ± 7 year, range 31 to 64 year, all had childbearing history by vaginal delivery with an average of 1.2 parities) with USI and IDO were confirmed by urodynamic study, consecutively collected in the Urology and Urodynamic Center of the First Affiliated Hospital of Zhengzhou University from December 2006 to June 2008. The definition of USI and IDO was in according with that of International Continence Society (ICS)^[6], which the former is noted during filling cystometry and is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction, the latter is a urodynamic observation characterised by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked when there is no defined cause. The criteria of patients for inclusion are that the patients have not any treatment since the onset of urinary incontinence, and genital prolapsed within the vaginal orifice when the body examination was carried out. What's more, the exclusive standard was for the patients who were diagnosed to have urinary tract infection, diabetes, bladder vaginal fistula, bladder cancer and trauma, as well as neurogenic bladder dysfunction through the urinoscopy, urography and imaging examination of nervous system. According to the sub-standard of severity of USI^[7], this study included 35 mild cases, 23 moderate cases, and 12 cases of severe, and the course of disease was from 6 months to 29 years.

2.2 Method

All the patients were treated by PFES using surface

electrode through neuromuscular electrical stimulation instrument (NeuroTrac™ ETS, produced by VML Denmark's company). The patients were asked to lie down, then the skin surface electrode was selected and placed in the perineal area that was besides the line of the vagina and anus. The sequential stimulation programmes were the same as those in previous research^[8]. The stimulating cycle was 4S stimulation and 4S rest afterwards. The current strength of stimulus increased by 1% to 5% each time from 0 mA, until the patients had the feelings, while on computer screen electromyogram of perineum and muscle of perineum and anus contraction was observed, but without any significant discomfort. The treatment course was 3 times a week, each time 60 minutes, for 12 weeks.

At the same time, all the patients were given PFT under intensive supervision. First of all, doctors should supervise the patients to identify the correct pelvic floor muscles needing to be trained, by the method that the patients putting the index finger and middle finger in the vagina, they felt pressure around the fingers when anus contracted. In addition, when this method was applied, the contraction from other muscles such as the thighs, back and abdominal muscles should be avoided as far as possible at the same time. PFT program was that after emptying their bladder, the patients were asked to made a quick, maximum and sustained pelvic floor muscles contraction for three times, and then relax the pelvic floor muscles, further a slow, maximum and sustained pelvic floor muscles contraction for three times, and relax the pelvic floor muscles, repeat the above process. The patients should take a rest for 5 to 10 seconds after every contraction. PFT lasted for 30 minutes every time, 2 times per day, for 12 weeks. The patients were required to go to the hospital and carried out pelvic floor muscle training in dorsal position at least 4 times a week, and PFES treatment could process at the same time. And the rest of PFT were allowed to carry out at home in dorsal, standing or sitting position.

Urinary diary and International Continence Inquiring Committee's Questionnaire (ICI-Q-SF) scores were recorded and urodynamic study was performed before and after the treatment. The urodynamic study included free uroflowmetry, cystometry, pressure-flow electromyography (EMG), valsalva leak point pressure (P_{VLP}) and static urethral pressure measurement in all patients, using the Duet Logic urodynamic unit (Medtronic Corporation, Denmark) according to the recommendations of ICS^[9]. The observation variables of efficiency included the maximum voiding volume (MVV), the total voiding (TOV), the total times of leakage (LT), ICI-Q-SF (total

scores were 21), maximum flow rate (MFR), maximum detrusor uninhibited contraction pressure (MDUCP), detrusor uninhibited contraction duration (DUCD), bladder compliance (BC), normal desired cystometric capacity (NDCC), maximum cystometric capacity (MCC), P_{VLP} , maximum urethral closure pressure (MCP) and the functional urethral length (SFL).

The total efficiency were also followed up immediately and three months after the treatment in out-patient or on the phone. According to the standard^[10], the cured were those whose conscious incontinence symptoms disappeared completely; the effective were those whose conscious incontinence symptoms improved significantly, and the leakage times reduced by more than 50%; the ineffective were those whose conscious incontinence symptoms didn't improve obviously, the times of leakage reduced by less than 50%. The effective rate was calculated based on the above cure and effective groups, with the formula (number of cured cases and effective cases)/total number of cases.

2.3 Statistical analysis

Statistical analyses were carried out by using the Statistical Package for Social Sciences, version 10.0 for windows. The paired samples *t* test and Chi-square test were used. *P*-values of < 0.05 were considered to be statistically significant.

Table 2. The values of urodynamic variables before and after treatment of PFES combined with PFT

	MFR (ml/s)	MDUCP (cmH ₂ O)	DUCD (s)	BC (ml/cmH ₂ O)	NDCC (ml)	MCC (ml)	PVLP (cmH ₂ O)	MCP (cmH ₂ O)	SFL (mm)
Before the treatment	29 ± 7	27 ± 9	13 ± 6	45 ± 13	141 ± 39	178 ± 36	81 ± 15	55 ± 8	27 ± 3
After the treatment	30 ± 6	18 ± 8	8 ± 3	47 ± 15	210 ± 48	247 ± 48	94 ± 11	59 ± 8	28 ± 3
<i>t</i>	1.569	5.003	5.849	1.241	10.412	12.392	5.789	2.776	1.008
<i>P</i>	0.123	0.000	0.000	0.220	0.000	0.000	0.000	0.008	0.318

3.2 The efficiency after treatment and follow-up for three months

The assessment of efficiency in the women with USI and IDO immediately after the treatment and follow-up for 3 months is shown in Table 3. The effective rate was 66% immediately after the treatment, and was 60% when following up for 3 months, which the significant difference was not found between them (*P* > 0.05).

4 Discussion

USI is one of the most common chronic ailments in the women, some of whom is still poor response to treat-

3 Results

3.1 Comparison of the various parameters of women with USI and IDO before and after the treatment

In total, fifty cases (71%) completed 12 weeks of therapy, whose clinical symptoms and urodynamic parameters before and after the treatment were shown in Table 1 and Table 2. Among all the patients, urinary incontinence symptoms completely disappeared in 8 cases (16%), IDO disappeared in 10 cases (20%), no leakage occurrence in 6 cases (12%) during the Valsalva leak point pressure measurement. After treatment, TOV, LT, ICI-Q-SF, MDUCP and DUCD were significantly lower than those before treatment, and MVV, NDCC, MCC, P_{VLP} and MCP were significantly higher than those before treatment (*P* < 0.05).

Table 1. The values of urinary diary and ICI-Q-SF before and after treatment of PFES combined with PFT

	MVV (ml)	TOV(times/72h)	LT (times/72h)	ICI-Q-SF
Before the treatment	159 ± 37	43 ± 8	20 ± 6	17 ± 3
After the treatment	225 ± 48	28 ± 5	10 ± 5	10 ± 3
<i>t</i>	14.671	14.922	10.693	9.076
<i>P</i>	0.000	0.000	0.000	0.000

Table 3. The efficiency of PFES combined with PFT at post-treatment and follow-up for three months

	Total No. (n)	Cured	Effect	Ineff- ective	Effective rate (%)	χ^2	<i>P</i>
After the treatment	50	8 (16)	25 (50)	17 (34)	66	0.386	0.534
Three months after the treatment	50	7 (14)	23 (46)	20 (40)	60		

ment. The dynamic mechanism of USI is that the bladder pressure is higher than urethra pressure during the reserving urine period due to decreased urethra closed capability when a sudden increase of abdominal pressure, and

urethral closure pressure becomes negative. As a result, in order to avoid the urine leakage, the women have to minimize social and sports activities, getting the name “social cancer”. It is usually considered to be related with childbirth, birth trauma, aging and declining estrogen levels and so on. These factors might lead to the bladder neck and urethra support structure damage, which made connective tissue surrounding the urethra relaxing, the activities of the urethra enlarging, pelvic floor muscle reflection delaying, the urethral controlled capability declining. The treatment includes conservative therapy and surgery therapy, whose main purposes are to strengthen the pelvic floor tissues to support the pelvic organs, to restore the urethra and bladder neck to the normal anatomic position, to increase the capacity of urethral continence^[11]. However, when USI is complicated with IDO, even if there is no sudden increase in abdominal pressure or involuntary detrusor contraction, it can also lead to urine leakage through the lower closure capacity urethra, and then frequency and severity of incontinence of the patients increase significantly. Moreover, even if social and sport activities are limited, it can't avoid occurrence of the leakage, making a significant decline in the quality of life^[12]. Furthermore, IDO is also main reason for poor quality of life of USI patients after treatment^[13].

So far, there is still controversy about the treatment of the women with USI and IDO. It was suggested by some clinicians that simply treat the USI, and some of the women IDO can self-healing, for the continued existence of the IDO can apply for drugs treatment. For example, Duckett JR^[14] reported that the outcome of tension-free vaginal tape (TVT) on 51 women with IDO and USI, and followed up for six months, found that after only 47% of IDO were cured spontaneously, and rest of them who suffered from persistent IDO were given anti-cholinergic drug, but only 22% of the patients released. However, there are also some clinicians holding that IDO should be treated first with oral anticholinergic medication, and then treat USI. Nevertheless, the patients have to endure the pain of urinary incontinence caused by USI during the treatment. Moreover, the side effects of anticholinergic medication is great, IDO is easy to relapse after drug withdrawal^[5].

Animal studies have showed that repeated electrical stimulation, causing the passive contraction of pelvic floor muscles, not only increased the contraction capability of pelvic floor muscles, but also feedback inhibited sympathetic reflex to reduce activity of the bladder^[15]. Moreover, in the previous studies which the author applied PFES using surface electrodes on female stress incontinence and urge incontinence of young people,

the found satisfied effect had been found that symptoms disappeared respectively in 51% and 42% of cases, and it was simple and convenient, non-invasive and clean, and economical^[8,16]. Furthermore, PFT also known as Kegel exercise, is a initiative pelvic floor rehabilitation method, and its treating effect have been proved by a large number of meta-analysis and randomized controlled research, making it the first choice for the women with USI of various types^[17]. The main principle is that the patients repeated the pelvic floor muscles contraction and relaxation under self conscious, it enhance tension of pelvic floor muscles which support the urethra, bladder, uterus and rectum, increase urethral resistance and restore the pelvic floor muscle relaxation to achieve the goal of curing USI. However, simply pelvic floor muscle training can not ensure the correct and effective pelvic floor muscle contraction training, which resulted in its rare application in the clinic.

In present study, the PFES was combined with PFT under intensive supervision, so that pelvic floor muscles got active and passive contraction training, and then treated IDO and USI at the same time. It was found that IDO and USI can be treated simultaneously. Among all the patients, urinary incontinence symptoms completely disappeared in 8 cases (16%), IDO disappeared in 10 cases (20%), 6 patients' (12%) no leakage occurrence in 6 cases (12%) during the Valsalva leak point pressure measurement. Moreover, after treatment, the TOV, LT, ICI-Q-SF, MDUCP and DUCD were significantly decreased, and MVV, NDCC, MCC, PVLV and MCP were also significantly increased.

PFT was satisfied on the condition that PFT was validity and the duration should be at least 8 weeks. In this study, we applied for PFT under intensive supervision. That is, during 12-week course of treatment, patients were required to go the hospital for professional medical advice at least 4 times a week to ensure the validity of PFT during entire course of treatment, to urge and ensure that their PFT at home was carried out, and to enhance the patients' confidence. In view of the above-mentioned requirements, most of the patients in the study came from the vicinity of our city. This study and Konstantinou E^[18] both found that the efficiency of PFT under intensive supervision for female USI was significantly higher than that of simple family PFT reported in the literature^[19]. In addition, in order to improve compliance of the patients, the study carried out PFES using surface electrodes to avoid the side effects of vaginal electrode, such as vaginal infection, bleeding, perineal discomfort and rashes. Moreover, the treatment room was set up and opened all day from Monday to Sunday so that patients

can receive professional medical treatment without a time limit. During the course of treatment, it is important that communication with patients proactively to enhance self-confidence and adjust treatment program timely. In this study, as much as 71% of the patients completed a 12-week treatment and the effective rate after the treatment and following up three months was 66% and 60% respectively.

However, the follow-up time in present study is only three months, the long-term efficacy need further research. Despite these limitations, we believe that our results highlight that PFES using surface electrode and PFT under intensive supervision is a useful therapy to treat women with USI and IDO.

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