Efficacy of transcutaneous electrical nerve stimulation versus biofeedback training on bladder and erectile dysfunction in patients with spinal cord injury

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Background
Spinal cord injury is associated with urinary and erectile dysfunction.
Objective
This study compared the efficacy of transcutaneous electrical nerve stimulation (TENS) with pelvic floor biofeedback (PFBFB) training in the treatment of bladder and erectile dysfunction for male patients with traumatic partial spinal cord injury.
Methods
The study included 30 male patients with bladder and erectile dysfunction (precipitancy overactive bladder) after traumatic partial spinal cord injury above the level of T12 within 6–18 months after injury. Patients were randomly divided into two equal groups: the study group was subjected to TENS and pelvic floor exercises and the control group was subjected to PFBFB training in addition the exercises. Patients were assessed before and after treatment by means of cystometric measurements, electromyography activity of pelvic-floor muscles, and International Index of Erectile Function (IIEF-5) Questionnaire.
Results
Before treatment, there was no significant difference in cystometric measurements, pelvic-floor muscle strength, and IIEF-5 score. In the TENS group, the treatment produced significant improvement in bladder volume at first desire to void ($P = 0.001$), maximum bladder capacity ($P = 0.001$) and maximum flow rate ($P = 0.001$), detrusor pressure at maximum flow ($P = 0.002$), strength of pelvic floor muscles ($P = 0.001$), and IIEF-5 score ($P = 0.001$). PFBFB training resulted in significant improvement only in the maximum flow rate ($P = 0.042$).
Conclusion
TENS of pelvic floor muscles is a promising, safe, effective, and inexpensive physical therapy technique to improve urinary and erectile dysfunction in patients with partial suprasacral spinal cord injuries.

Keywords:
erectile dysfunction, pelvic floor biofeedback, spinal cord injury, transcutaneous electrical nerve stimulation, urinary dysfunction

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Introduction

Spinal cord injury (SCI) is not a notifiable disease and therefore figures for the annual incidence are inaccurate and may vary on the basis of the source. On the basis of quality country-level studies of SCI, the WHO had estimated a global incidence for SCI from 40 to 80 new cases per million populations per year [1]. Up to 90% of SCIs have been traumatic in origin. In general, road traffic accidents account for the largest number, followed by falls, sports injuries, and violence, although causes vary considerably on the basis of the prevailing circumstances in the country in which they occur [2]. In Egypt, 12 000 deaths have been reported yearly due to road traffic crashes, in addition to many thousands of nonfatal injuries, some of them with long-term disability [3].

After SCI, dysfunctional voiding patterns soon emerge. It significantly impairs micturition and results, initially, in areflexia or detrusor underactivity and, later, in neurogenic detrusor overactivity, based on the level of the lesion [4]. Quite apart from socially incapacitating incontinence, the resulting urodynamic abnormalities can lead to recurrent urinary tract infection, vesicoureteric reflux, upper tract dilatation, and hydronephrosis. This results in long-term damage to the urinary tract, with eventual renal failure. Constant urological vigilance is therefore an essential part of management [5].

SCI results in sexual impairment. Its effect depends on the level and severity of injury. It causes erectile dysfunction, impaired ejaculation, and changes in genital orgasmic perception [6]. During the immediate postinjury period, patients lose reflexive sexual responses. Thereafter, they regain reflexive arousal with genital stimulation [7]. However, these responses are limited to the duration of stimulation and do not achieve a fully satisfactory response [8]. Erectile dysfunction in men with SCI can be treated pharmacologically with phosphodiesterase-5 inhibitors [9,10]. Poor responders may respond better to direct injection of vasodilatory medications into the corpus cavernosum. In addition, vacuum erection devices or implanted penile prostheses may be an option [11].

The purpose of this study was to compare the efficacy of transcutaneous electrical nerve stimulation (TENS) and biofeedback training in the treatment of bladder and erectile dysfunction for male patients with traumatic partial SCI.

Patients and methods

This study included 30 male patients suffering from bladder and erectile dysfunction (precipitancy overactive bladder) after traumatic partial SCI above the level of T12 within 6–18 months after injury. Patients were recruited from the Neurology Outpatient Clinic of Kasr El-Aini Teaching Hospital, and Faculty of Physical Therapy, Cairo University. Patients were randomly divided into two equal groups: the TENS (study) group was subjected to pelvic floor exercises and TENS and the pelvic floor biofeedback (PFBFB) (control) group was subjected to PFBFB training in addition to the exercises. The study was approved by the Ethical Committees of the two institutions. All participants provided informed consent before participation in the study.

Clinical evaluations, including neurological, musculoskeletal, and genitourinary assessments, were performed to all patients. Patients between 20 and 35 years of age with precipitancy overactive bladder and erectile dysfunction due to partial spinal cord lesion were included in the study. Diagnosis was confirmed by means of clinical and radiological assessments by urologist and neurologist. All patients were medically fit to participate in the study. Patients with SCI below T12, with a history of bladder and erectile dysfunction before the SCI, those with severe psychological disorder, pre-existing lung diseases, cardiac diseases, major neurological, or musculoskeletal or metabolic disorders were excluded from the study.

Assessment procedure

All patients were subjected to the following procedures before starting the study and after completing the 6-week treatment regimen:

(1) Cystometry.
(2) Pelvic-floor muscle activity measurement.
(3) International Index of Erectile Function (IIEF-5) Questionnaire.

Cystometry was assessed with a DANTIC UD 5000/5500 Urodynamic Investigation System (Megamed, Germany). All patients were subjected to multichannel cystometry before starting the study and at the end of 6-week treatment [12]. The following parameters were measured: volume at first desire to void, maximum cystometric capacity, maximum flow rate (Q_{max}), and detrusor pressure at Q_{max}.

Electromyography activity (EMG) of pelvic-floor muscles was measured using Toennies Neuro Screen Plus System EMG biofeedback device [13]. Two parameters were assessed: amplitude per time (A/T) and upper centile amplitude.

Erectile dysfunction is a self-reported condition. It was assessed with the IIEF-5 score, which is the sum of the ordinal responses to the five items; thus, the score can range from five to 25. Erectile dysfunction severity was classified into the following five categories based on IIEF-5 scores: severe (5–7), moderate (8–11), mild to moderate (12–16), mild (17–21), and no erectile dysfunction (22–25) [14].

Therapeutic intervention

Treatment regimen was carried out on 12 sessions, twice weekly for 6 weeks. The study group was managed with TENS using the Sonopuls-992 (Enraf-Nonius, Dimeq Bu, the Netherlands). It was used to exercise the pelvic floor muscles to inhibit involuntary detrusor muscle contractions. Electrical stimulation was delivered through two surface electrodes placed on the skin above the S3. The control group was managed with PFBFB using the Electromyography Biofeedback Device (Toennies Neuro Screen Plus System EMG biofeedback device).

Treatment procedures

(1) Pelvic floor exercises: all patients (n = 30) were taught how to tighten and lift the pelvic floor muscles, as if they were interrupting the flow of urine midstream. Initial contractions were performed for 5–10 s with 10–20 s rest, with 12–20 repetitions. Endurance exercise focused on maintaining muscle contraction at 65–75%

of maximum strength and holding for 20–30 s with 8–10 repetitions. Speed was achieved with sets of quick repetitive contractions in a 10 s span with a 20 s rest. Purposeful control involved gradual recruitment to maximal contraction with a 5 s hold and a slow release with a rest period of 15–30 s [15]. The patients were asked to perform 30 contractions in the morning, afternoon, and evening at home.

(2) TENS session: this technique was carried out with an empty bladder, with two surface electrodes placed directly over the skin of S3. Stimulator was adjusted to a frequency of 50 Hz, duration of 30 min, 250 μs pulse width, and biphasic continuous rectangular waveform.

(3) PFBFB training session: this exercise was performed with an empty bladder, and contraction of the pelvic floor muscles was performed in the fowler lying position. With the EMG Biofeedback Device, the site of positive electrode (red) was marked with a marker at the base of the penis 1 cm lateral to the median line of the perineum on the right side, and the site of negative electrode (black) was marked at the bulk of pelvic-floor muscles, especially ischiocavernosus and bulbospongiosus muscles, about 3 cm from the positive electrode site and one centimeter lateral to the median line of the perineum, which is also on the right side. The positive and negative electrodes were filled with gel and were connected to the marked site, and was fixed with an adhesive plaster. The patients were asked to perform short (a second) and long (6–10 s) contractions of target muscles. They were asked to look at the screen of the computer to watch the EMG biofeedback activities during muscle contraction, and also the patient was asked to listen to the sound caused by contraction of the pelvic floor muscles. The same procedure was conducted on the left side of the perineal muscles.

Statistical analysis

Data were analyzed using IBM SPSS Advanced Statistics version 22.0 (SPSS Inc., Chicago, Illinois, USA). All assessment variables were tested for normality of distribution (Shapiro–Wilk test); all variables were found to be non-normally distributed. Thus, two-way analysis was not performed. Comparison between two groups was made using the Mann–Whitney test. The Wilcoxon Signed-Rank test was used to compare pretest and post-test measurements in each group separately. A *P*-value less than 0.05 was considered significant.

Results

The two groups were comparable as regards age, height, weight, and BMI as shown in Table 1, and Table 2 shows cystometric measurements in the two studied groups before and after treatment. Before treatment, there was no significant difference in bladder volume at first desire to void ($P = 0.744$), maximum bladder capacity ($P = 0.148$), and maximum flow rate ($P = 0.285$), but the detrusor pressure at maximum flow rate was significantly higher in the TENS group ($P = 0.008$). After treatment, there was no significant difference between the two groups except for detrusor pressure at maximum flow ($P = 0.001$).

Table 3 shows EMG measurements of the pelvic floor muscles in the two studied groups before and after treatment. Before treatment, there was no significant difference in the strength of the muscles between the two groups. After treatment, the strength of the muscles on both sides was significantly higher in the TENS group. Similarly, IIEF-5 score was comparable before treatment ($P = 0.624$) and was significantly higher after treatment in the TENS group ($P = 0.013$) (Table 3).

Table 1 Demographic and clinical characteristics of the studied groups

Parameters	Group TENS (*n* = 15)	Group PFBFB (*n* = 15)	*P*-value
Age (years)	28.1 ± 5.4	28.3 ± 5.1	0.918
Height (cm)	166.6 ± 8.2	167.3 ± 7.4	0.799
Weight (kg)	69.5 ± 10.6	72.2 ± 8.1	0.434
BMI (kg/m^2)	25.0 ± 3.3	25.9 ± 3.2	0.467

Data expressed as mean ± SD; PFBFB, pelvic floor biofeedback; TENS, transcutaneous electrical nerve stimulation.

Table 2 Cystometric measurements in the studied groups before and after treatment

Variables	Group TENS (*n* = 15)	Group PFBFB (*n* = 15)	*P*-value
Volume at first desire to void (ml)			
Before treatment	264.1 ± 89.8	264.6 ± 102.5	0.744
After treatment	299.7 ± 93.5	268.9 ± 106.8	0.595
Maximum cystometric capacity (ml)			
Before Treatment	235.1 ± 54.5	267.1 ± 92.8	0.148
After Treatment	261.9 ± 56.8	267.7 ± 92.2	0.595
Detrusor pressure at Q_{max} (cmH_2O)			
Before treatment	79.8 ± 24.8	55.0 ± 28.9	0.008*
After treatment	90.3 ± 28.1	56.4 ± 28.5	0.001*
Maximum flow rate (ml/s)			
Before treatment	5.8 ± 2.2	6.6 ± 1.9	0.285
After treatment	7.9 ± 2.1	6.8 ± 1.9	0.161

Data expressed as mean ± SD; PFBFB, pelvic floor biofeedback; Q_{max}, maximum flow rate; TENS, transcutaneous electrical nerve stimulation; *Significant at $P < 0.01$.

Table 4 shows the mean and 95% confidence interval (CI) of the difference between pretreatment and post-treatment measurements of cystometric parameters, EMG values, and IIEF-5 score in the two groups. All of the measurements increased significantly after treatment in the TENS group. In contrast, only maximum flow rate (P = 0.042) increased significantly after treatment in the PFBEB group. The changes in all cystometric and EMG measurements and IIE-5 scores were significantly higher in the TENS group (P < 0.001, for all).

Table 3 Electromyography measurements of the pelvic floor muscles in the two studied groups before and after treatment

Variables	Group TENS (n = 15)	Group PFBFB (n = 15)	P value
Amplitude per time, RT (mV)			
Before treatment	0.22 ± 0.06	0.19 ± 0.05	0.098
After treatment	0.26 ± 0.04	0.19 ± 0.05	0.001**
Amplitude per time, LT (mV)			
Before treatment	0.21 ± 0.06	0.19 ± 0.05	0.050
After treatment	0.25 ± 0.05	0.19 ± 0.04	0.001**
Upper centile amplitude, RT (mV)			
Before treatment	0.31 ± 0.10	0.28 ± 0.06	0.595
After treatment	0.34 ± 0.10	0.28 ± 0.06	0.029*
Upper centile amplitude, LT (mV)			
Before treatment	0.31 ± 0.11	0.28 ± 0.06	0.539
After treatment	0.35 ± 0.10	0.28 ± 0.06	0.041*
International index of erectile function			
Before treatment	14.1 ± 4.1	13.4 ± 4.2	0.624
After treatment	18.9 ± 5.1	14.1 ± 4.7	0.013*

Data expressed as mean ± SD; LT, left side; PFBFB, pelvic floor biofeedback; RT, right side; TENS, transcutaneous electrical nerve stimulation; *Significant at $P < 0.05$; **Significant at $P < 0.01$.

Discussion

The results of this study demonstrated superiority of transcutaneous electric stimulation of pelvic floor muscles compared with biofeedback training in improving urinary and erectile dysfunction in patients with partial suprasacral spinal cord injuries. TENS resulted in significant increase in bladder volume at first desire to void (P = 0.001), maximum bladder capacity (P = 0.001) and maximum flow rate (P = 0.001), and detrusor pressure at maximum flow (P = 0.002). It also significantly increased amplitude per time and upper centile amplitudes of the pelvic floor muscles in addition to significant improvement in the IIEF score (P = 0.001). PFBFB training resulted in significant improvement only of the maximum flow rate (P = 0.042).

In the current study, all patients suffered from suprasacral traumatic injuries to the spinal cord. Such lesions lead to interruption of the spinobulbospinal reflex, the end result of which is detrusor hyperreflexia and detrusor-sphincter dyssynergia [16]. In this study, we compared two modalities of nonpharmacologic treatment of such bladder dysfunctions: TENS and biofeedback training of the pelvic floor muscles for the purpose of neuromodulation [17]. This process of neuromodulation involves the use of external electrodes to stimulate reflex inhibition of pelvic efferent nerves or activation of hypogastric efferents, which causes downregulation of detrusor activity [18]. All patients in this study were prescribed pelvic floor exercises as a basic treatment. The two techniques stimulate pelvic floor muscles either actively (BFBT) or passively (TENS). Thus far, neuromodulation has not been considered a first-line therapy due to insufficient physiological and evidence-based studies. The current study can be considered a preliminary trial testing these two techniques. It demonstrated a significant

Table 4 The differences between pretest and post-test measurements of cystometric parameters, electromyography values, and International Index of Erectile Function score in the two groups

Variables	Group TENS (n = 15)				Group PFBFB (n = 15)			
	Paired differences			P value	Paired differences			P value
	Mean	95% CI			Mean	95% CI		
		Lower	Upper			Lower	Upper	
First desire to void	35.6	24.8	46.4	0.001	4.3	−0.9	9.6	0.080
Maximum cystometric capacity	26.9	20.0	33.7	0.001	0.6	−1.4	2.6	0.498
Detrusor pressure at Q_{max}	10.5	6.3	14.6	0.002	1.4	−0.9	3.7	0.141
Max flow rate	2.1	1.7	2.6	0.001	0.2	0.0	0.4	0.042*
RT A/T	0.03	0.02	0.04	0.001	0.00	−0.01	0.00	0.276
LT A/T	0.03	0.02	0.03	0.001	0.00	0.00	0.00	1.000
RT UCA	0.04	0.03	0.05	0.001	0.00	−0.01	0.00	0.334
LT UCA	0.04	0.03	0.05	0.001	0.00	−0.01	0.00	0.216
IIEF-5	4.8	3.0	6.6	0.001	0.7	0.0	1.3	0.063

A/T, amplitude per time; CI, confidence interval; IIEF-5, International Index of Erectile Function; LT, left side; PFBFB, pelvic floor biofeedback; Q_{max}, maximum flow rate; RT, right side; TENS, transcutaneous electrical nerve stimulation; UCA, upper centile amplitude; *Significant at $P < 0.05$.

effect of TENS in improving both urinary and erectile dysfunction.

Overactive bladder is a sequel of partial SCI – as in the current study. In these cases, pelvic floor muscle exercises are anticipated to play a role in inhibiting involuntary detrusor contractions. The idea arose from the observation that electric stimulation of the pelvic floor caused partial or complete inhibition of detrusor contractions. Godec *et al.* [19] performed 3-min electric stimulation of pelvic floor muscles. Cystometric testing found that involuntary detrusor activity was reduced or completely stopped during electric stimulation and for 1 min after stimulation had ceased.

The notion behind biofeedback is to improve muscle awareness and control, which may subsequently improve pelvic floor dysfunction to enhance inhibition of detrusor activity. The exact therapeutic mechanism for biofeedback in bladder overactivity is indefinable. Potential mechanisms are neural sensitization and relaxing the stimulating input from overactive levator muscles [20].

Burgio *et al.* [21] found that 8 weeks of biofeedback-augmented pelvic floor muscle training resulted in greater improvement in women with urge incontinence compared with anticholinergic drugs. Combined treatment of biofeedback and drug therapy increased improvement [22]. A large multicenter trial [23] reported 70% or greater reduction in frequency of urge incontinence episodes after 8 months of BFB training. Other studies reported similar findings [24,25]. A systematic review confirmed superiority of pelvic floor muscle training in the treatment of stress urinary incontinence [26]. A Cochrane review on biofeedback for various types of urinary incontinence concluded that this treatment is beneficial in women with incontinence [27].

However, most of the studies reported results of BFB in women with overactive bladder not due to SCI. The majority of studies conducted in men included those who had undergone prostatectomy for prostatic cancer. The main objective of BFB training was improvement in urinary incontinence rather than bladder overactivity [28].

An important limitation of biofeedback training and pelvic floor muscle training in general is the difficulty in identifying the specific muscles to be trained. Some patients are capable of identifying these muscles and develop their own behavioral modification to manage the muscles in the clinic or even at home. In contrast, some require more formal program with intensive instructions to help them control their muscles. Sometimes, the pelvic floor muscles are very weak to involve in active contraction by the patient. Combination with electrical stimulation can improve the efficacy of pelvic floor muscle training by helping patients to better identify and consequently strengthen their muscles for better treatment outcome.

The current study demonstrated better results for TENS in improving urinary and erectile dysfunction compared with those for BFB training in cases of partial SCI. Electrical stimulation may be provided internally through intravaginal or intra-anal electrodes or transcutaneously (as performed in the current study). The latter is often preferred as a minimally invasive modality due to the poor tolerability of intravaginal and anal plug electrodes resulting from pain or discomfort [29,30]. S2 or S3 dermatome was suggested for TENS in cases of irritative bladder dysfunction. In the current study, we delivered electrical stimulation through two surface electrodes placed directly over the skin of S3 [31].

Many studies reported that electrical stimulation improved symptoms of overactive bladder with variable degrees [32]. Yamanishi *et al.* [33] reported increased satisfaction and bladder capacity after pelvic twice-daily floor electrical stimulation in a group of male and female patients. Brubaker *et al.* [34] reported 50% improvement in overactive bladder symptoms after 8 weeks of twice-daily home pelvic floor electrical stimulation, but no improvement in stress incontinence. A multicenter, prospective, randomized, double-blind trial demonstrated significant improvements in genuine stress incontinence after transvaginal pelvic floor electrical stimulation [35]. In 44 patients with stress incontinence (six men and 38 women), efficacy of electrical stimulation with internal electrodes for 15 min was evaluated in terms of patient satisfaction and urodynamic parameters after 4-week treatment. The treatment results revealed good patient satisfaction in 60% of cases and 45% cure rate [30].

Hoebeke applied neurostimulation using surface electrodes at the level of sacral root S3 in a group of boys and girls with detrusor hyperactivity refractory to anticholinergics. After 6 months of therapy, 76% of patients responded to treatment and 56% were cured after 1 year. They showed significant increase in bladder capacity, decrease in voiding frequency, and decrease in incontinence periods [36]. Another pilot study reported similar positive effects in children [37]. A randomized placebo-controlled trial compared TENS with oxybutynin and with placebo in the management of overactive bladder in 68 patients. ES was superior to oxybutynin in terms of subjective outcome and urodynamic parameters; it resulted in a reduction rate of OAB of 58.4% [38]. In contrast, other studies found no statistical difference between electrical stimulation and drug therapy [39–41].

The second beneficial effect of TENS was improvement in erectile dysfunction. Many previous studies have revealed the effectiveness of physical therapy interventions as safe, inexpensive, and painless noninvasive techniques for improving erectile dysfunction. These studies reported that pelvic floor exercises have a positive effect in these cases [42–45].

The mechanism of improving erection with pelvic floor training may be through decreasing venous outflow due to high pressure at the base of the penis induced by contraction of pelvic-floor muscles [44].

A recent study showed that percutaneous electrostimulation of the perineum produced significant increase in the intracorporeal pressure, with consequent improvement in the strength and duration of erection in cases of neurogenic erectile dysfunction. The authors found that lidocaine block of nerves in the perineum abolished erection induced by electric stimulation [46].

More recently, another study found that 20 sessions of 30-min voluntary contractions of the pelvic floor muscles combined with electrical stimulation resulted in 87% increase in intracavernous pressure and hence improvement in erectile dysfunction [47].

We conclude that transcutaneous electric stimulation of pelvic floor muscles is a promising effective physical therapy technique to improve the quality of life of patients with partial suprasacral spinal cord injuries. It has the advantages of being a safe, inexpensive, easy technique to apply and is readily reversible during application, which can avoid immediate adverse effects. In fact, it did not produce undesirable effects in the current study. Electric stimulation bypasses the possible problem of difficulty in the identification of pelvic floor muscles that need to be strengthened, especially in cases of SCI in which neurologic disturbance can be a real problem. Larger studies may confirm the results of the current study, which is limited by the small sample size.

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Conflicts of interest
There are no conflicts of interest.

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