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Original Research Article

URODYNAMIC EFFECT OF PERCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION FOR URINARY INCONTINENCE IN PARAPARETIC PATIENTS

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ABSTRACT

Background: Urinary incontinence is one of the most inconvenient problems in patients with spinal cord injury. This study was done to evaluate the effectiveness of Percutaneous Posterior Tibial Nerve Stimulation (PPTNS) in treatment of urinary incontinence in patients with dorsal level (T7-T12) Paraparesis.

Materials and Methods: This study was a randomized controlled study included 30 traumatic paraparetic patients of both sexes. They were randomly divided into two equal groups: Group I (GI) was a control group treated by physical therapy program for bladder training and placebo PPTNS. Group II (GII) was an experimental group treated by the same physical therapy program in addition to real PPTNS. All patients received the treatment program for 40 minutes, three days/week day after day for 12 weeks. All patients were assessed before initiating conservative treatment and after the end of treatment program by: Electromyographic measurement for detrusor and pelvic floor muscles' activity, urine testing by cystometry and bladder residual volume measurement.

Results: There was a statistically significant improvement in GII than GI, regarding all variables (P <0.001).

Conclusion: PPTNS is an effective method in treating urinary incontinence in paraparetic patients and considered as a treatment modality filling the gap between conservative and surgical therapies in patients with certain types of urinary incontinence.

KEY WORDS: Percutaneous Posterior Tibial Nerve Stimulation, Cystometry, Electromyography, Urinary Incontinence, Paraparesis.

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INTRODUCTION

Spinal cord injury (SCI) is a destructive neurological insult that produces different degrees of sensorimotor losses and sphincteric disturbances which may become permanent and irreversible in some cases [1]. Forty to eighty new cases per million populations a year; was the global incidence estimated by the World Health Organization for SCI in 2013 [2]. Although causes of SCI vary considerably on the basis of the prevailing circumstances in the country in which they occur; up to 90% of SCIs have been traumatic in origin [3].

Dysfunctional voiding patterns soon arise after

SCI. Micturition is significantly impaired after SCI and results, at first, in detrusor underactivity or areflexia which later turned to neurogenic detrusor overactivity, depending on the level of the lesion [4]. Urinary incontinence and urodynamic abnormalities not only cause social Embarrassment, but could lead to vesicoureteric reflux, upper tract dilatation, recurrent urinary tract infection and hydronephrosis. This leads to a long-term damage to the urinary tract, with eventual renal failure [5]. Incontinence could be classified into different subtypes as: stress incontinence, mixed urinary incontinence, overflow incontinence, and transient incontinence [6]. More than 40% of people with overactive bladder have incontinence and most people with the condition have problems for years [7].

The pelvic floor consists of the bony pelvis, endopelvic fascia and muscles. The passive support from the bony pelvis and endopelvic fascia along with the dynamic backboard function served by pelvic floor muscles; maintain the pelvic organs in their abdominopelvic positions. From a urodynamic perspective; during bladder storage, the pelvic floor muscles facilitate urethral closure while indirectly provide support for the lower urinary tract and adjacent organs [8]. During certain situations as coughing, sneezing or physical activity, the pelvic floor muscles enhance the urethral closure via a rapid contraction; despite that, the primary responsible for urethral closure during bladder filling and storage is the rhabdosphincter muscle [9].

Individual with SCI and associated bladder problems will need a urinary catheter to manage their bladder problems [10]. Complications of using indwelling catheters for a long period of time may include urinary tract infections, sepsis, dyssynergia, kidney or bladder stones and bladder cancer [11]. Fortunately, incidence of urinary tract infections and skin irritation or infection could decreases with using different therapeutic modalities for treating urinary incontinence. From not so long, intermittent PPTNS was introduced as a treatment modality to fill the gap between conservative and surgical therapies in patients with certain types of lower urinary tract dysfunction [12].

In October 2010; the National Institute for Health and Clinical Excellence in the United Kingdom issued a guidance stating “PTNS for overactive bladder demonstrates effectiveness without major safety concerns” [13]. Percutaneous posterior tibial nerve stimulation have been declared by The United States Food and Drug Administration as a treatment for overactive bladder and the associated symptoms of urinary frequency, urgency, and urge incontinence [14].

Although there have been a number of recent clinical studies showing the positive effect of PPTNS on urinary incontinence [15,16,17]; such treatment modality hasn’t been widely used for paraparetic patients in clinical setting yet. The purpose of this study was to evaluate the effect of percutaneous posterior tibial nerve stimulation in improving urinary incontinence in paraparetic patients with SCI at dorsal level (T7-T12).

MATERIALS AND METHODS

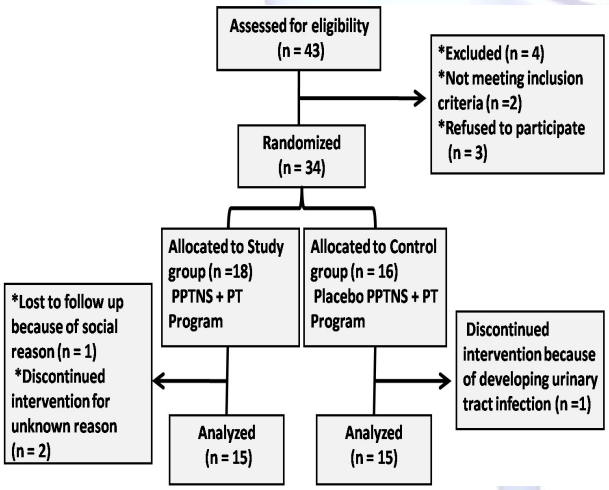
Subjects: Thirty Paraparetic patients of both sexes were selected for this study from the outpatient department, Urology, Neurology and Neurological Rehabilitation, Armed Force hospital, Najran, Saudi Arabia. Patients’ age ranged from 25- 40 years, with a mean value of 35.2(±1.1) years, their weight ranged from 60 to 88kgs. with a mean value of 75.4 (±1.4) kgs and their height ranged from 154-181cm, with a mean value of 163.8(±7.4) cm. Patients were randomly and equally divided into two groups, **Group (I)** as a control group consists of 15 patients of both sexes, was treated by physical therapy program for bladder training (strengthening exercises for abdominal and pelvic floor muscles, tapping, percussion, pressure and scratching and brief icing on lower abdomen) and placebo PPTNS. **Group (II)**, the experimental group was treated by the same physical therapy program in addition to real PPTNS. All subjects received the treatment program for 40 minutes, three days per week day after day, for 12 weeks. Primary outcome measures include investigations such as electromyography for detrusor and pelvic floor muscles, urine testing by cystometry and bladder residual volume measurement. Assessment for all patients was done before initiating conservative treatment and after the end of treatment program.

Inclusion criteria: All patients were medically

stable by measuring vital signs which include (blood pressure, temperature, pulse rate and respiratory rate). All patients were conscious, co-operative, medically, neurologically and psychologically stable and had no disability secondary to orthopedic problems or surgery. All patients had no impairment of general or special Senses.

Exclusion criteria: It includes patients with detrusor sphincter dyssynergia, sacral peripheral nerve lesions, urinary tract infection, serious secondary disease, marked prostatic enlargement, bladder stones, pregnancy, diabetes mellitus and severe cardiopulmonary disease. Patients with a history of previous continence surgery, current bladder malignancy, high-grade dysplasia, or carcinoma and severe degree of disabilities were excluded from the study. Participants' flow chart throughout the study is demonstrated in figure (1).

Study design: This study was a randomized controlled study. After selection of the patients an informed consent was taken from all patients that participated in the study and they were informed about the aims, benefits and procedure of the study. This study was approved by the ethical committee of Faculty of medicine, Najran University, Saudi Arabia.



EVALUATION PROCEDURES

Electromyography (EMG) Unit: The Neuropack SI MEC-9400K EMG apparatus; is composed of: data processing computer unit, disposable surface EMG electrodes, four channel EMG/EP system, disposable and radiolucent electrodes.

Electrodes: The electrodes were self adhesive with active surface area of 1cm² diameter that consist of plastic foam material with a silver plate disc on one side and silver plate snap in the center of the other side. The electrodes were connected to EMG apparatus channels.

Evaluation procedures: Patient's preparation before attaching EMG electrodes over the skin for each patient was performed by shaving the hair at the picking areas and cleaning it by alcohol to remove the dead layers of the skin in site of EMG electrodes (detrusor and pelvic floor muscles). For pelvic floor muscles EMG technique, the surface patch electrodes are attached adjacent to the mucocutaneous line of anus bilaterally. The electrode wires need to be positioned away from the urine stream [18]. For the detrusor EMG recording, electrodes are placed in an array in front of the pubic bone on the lower abdomen. The common electrode can be placed on the thigh or trochanter [19].

Electrodiagnostic Test: Technical steps of EMG application includes; electrode placement, skin temperature correction, determination of nerve stimulation intensity and analysis of the evoked neuro-electrical response. The registry system stores all electrophysiological data including raw wave forms and limited demographic information (age, height, weight and gender).

Urodynamic Measurements (Incontinence testing):

Cystometry Measurement: It was performed with the patient in the Supine position using the (MMS Solar Digital Urodynamic Device, Dover, N.H.). Intravesical and abdominal pressures were measured with double lumen 8F air-charged catheters with a rectal balloon (T-1D00C Company, Wilmington, Del). The detrusor pressure was calculated as the difference between the intravesical and abdominal pressure.Cystometry was performed with normal saline solution at room temperature with filling rate 50 mL/min. Volume at the first involuntary detrusor contraction and volume at maximum cystometric capacity (MCC) were noted. Second cystometry was performed immediately after PTNS at 50mL/min filling rate. A comparison was performed between volume at the first involuntary detrusor contraction and at MCC for standard cystometry and for Cystometry during PTNS. Maximum cystometric capacity was defined previously for the patient with urge urinary

incontinence [12].

Routine cystometry at 50 ml/minute was done to select the patients with involuntary detrusor contractions appearing before 400 ml. maximum filling volume. The test was considered positive if volume at the first involuntary detrusor contraction and/or at maximum cystometric capacity increased 100 ml. or 50% during stimulation in comparison with standard volumes.

Post-void residual volume: This test measures the amount of urine left after the patient empty his/her bladder. This measurement was also performed before and after the completion of therapeutic intervention course.

Treatment Procedures:

Percutaneous Posterior Tibial Nerve Stimulation: This form of electrical stimulation inhibits bladder activity by depolarization of somatic afferent fibers and lumbar sacral fibers, resulting in motor and sensory responses to stimulation of posterior tibial nerve area. The technique consists of stimulating the nerve by surface electrode placed 4-5 cm cephalic to the medial malleolus. Once the current is applied, the flexion of the big toe or the movement of the other toes confirms the correct positioning of the electrodes. The electric current is a continuous, square wave form with duration of 200µs and a frequency of 20 Hz for 30 minutes. The current intensity is determined by the highest level tolerated by the patient. The stimulation sessions last for 30 minutes and are performed day after day in a week for 12 weeks.

Pelvic Floor Exercises: Consists of repetitive voluntary contractions of the pelvic floor muscles that increase muscle strength and hence urinary continence by stimulating the activity of the urethral sphincter. The exercises are effective for urge incontinence because they reinforce the reflex contraction of the pelvic floor, causing inhibition of detrusor overactivity. Pelvic floor exercises (Kegel exercises) can be done anytime as follow: a) Pretend you are trying to stop the flow of urine. b) Hold the squeeze for 10 seconds, c) then rest for 10 seconds. Do it three or four sets daily.

Timed voiding and bladder training: First, the patient has to complete a chart of the times that he/she urinate and the times of leak. Patients can also "retrain" their bladder, gradually increasing the time between bathroom visits. Kegel exercises are also helpful. It aims to increase the storage capacity of the bladder.

Voiding Exercises: It was encouraged in one of several ways, such as: Anal or Rectal Stretch for relaxing the urinary sphincter is usually used along with an abdominal corset.

Crede method: involves manually pressing down on the bladder. Area over the bladder is tapped with the fingertips or the side of the hand, lightly and repeatedly, to stimulate detrusor muscle contractions and voiding.

Valsalva method: involves increasing pressure inside the abdomen by bearing down as if you were going to have a bowel movement. Voiding Diary of patients was performed as a self-monitoring data for at least 24 hours (can be made up to 3 days), recording the following information: time, volume and frequency of urination, incontinence episodes, frequency of use of absorbent (day, time and night), Water intake and intestinal habits.

Statistical analysis: The results of the two groups were statistically analyzed by using paired t-test to compare the differences within each group and unpaired t-test to compare between the two groups. The arithmetic mean average describing the central tendency of observation was the standard deviation (SD) that used to describe the results around means. The statistical package of Social science (SPSS version 18) was used for data processing. The P-value 0.05 level considered as significant.

RESULTS

Thirty males and females subjects participated in the study, their ages ranged between (25-40) years with mean age (35.2±0.1) years, their weights ranged between (60-88) kg with mean value (75±1.4) kg, and their height ranged from 154-181cm, with a mean value of 163.8(±7.4) cm. There was no significant difference between mean values of ages, weights or heights in both groups as shown in table (1).

Table (2) shows the results of within and between groups' comparisons. There were non-significant differences between the two groups in the base line measurements of the

Table 1: Characteristics of subjects in both groups.

***SD: standard deviation, P: probability, NS: non-significant.**

	Group (I)		Group (II)		T	P	Sig
	Mean	S.D	Mean	S.D			
Age (yrs)	35.2	±6.3	35.2	±6.3	0.45	0.81	NS
Weight (Kg)	75.3	±6.8	74.8	±8.7	0.67	0.87	NS
Height (cm)	165.6	± 8.74	162.07	± 5.47	-1.33	0.195	NS

Table 2: Within and between groups' comparison of patients' EMG amplitudes, cystometry tests and residual urine volume before and after interventions. Data is presented as mean ± SD.

Variables	Within group						Between groups			
	Group I (n=15)			Group II (n=15)			Pre-treatment		Post-treatment	
	Pre	Post	P	Pre	Post	P	t	P	t	P
EMG of detrusor muscle	0.6± 0.1	0.9± 0.1	0.1	0.6± 0.1	1.5± 0.1	0.001	-0.374	0.711	-15.19	0.002
EMG of pelvic floor muscles	0.6 ± 0.1	0.9 ± 0.1	0.1	0.6 ± 0.1	1.1 ± 0.1	0.001	-0.132	0.896	-2.93	0.007
Cystometry test	117.3 ± 0.3	160.8 ± 0.4	0.1	118.3 ± 0.3	196.8 ± 0.3	0.001	-0.542	0.592	-15.94	0.001
Residual urine volume	108.64 ± 0.3	82.4 ± 0.4	0.1	108.04 ± 0.3	60.7 ± 0.3	0.001	0.6	0.97	-6.38	0.001

***P: probability.**

EMG amplitudes of detrusor & pelvic floor muscles, cystometric tests and the residual urine volumes (P > 0.05). After interventions, significant differences have been observed in both groups with more improvements in study group (II) than control group (I). In group (II), there were significant differences (within group comparison) between baseline and post-treatment measurements of all measured variables (p= 0.001). Within group comparison in the control group (I) revealed non-significant differences between pre & post treatment measurements for all measures (p= 0.1). Between groups comparison after treatment revealed significant improvement in the EMG amplitudes of detrusor & pelvic floor muscles, cystometric tests and the residual urine volumes (p= 0.002), (p= 0.007) and (p= 0.001) respectively.

DISCUSSION

The purpose of this study was to determine the efficacy of PPTNS in promoting urinary continence in paraparetic patients with (T7-T12) SCI. The results showed that, there was a statistically significant improvement in the study than the control group regarding all measured variables (P <0.001).

Posterior tibial nerve electrical stimulation is considered as a form of peripheral sacral stimulation characterized by a simpler application, less invasive, well tolerated by patients and less expensive [20]. It has been proven to be an interesting alternative and effective treatment for patients with over active bladder and without any side effects [21].

Results of this study comes in agreement with Dmochowski and Gomelsky [22], who stated that PPTNS not only could provide benefits similar to antimuscarinic therapy, but also continues to demonstrate dominance to sham treatment. Peters et al. [23] compared applying PTNS to tolterodine 4 mg extended release in a randomized controlled study. It was found, that the reductions in urinary frequency, incontinence episodes, urge severity, night-time voids and improvement in voided volume; was similar in both groups. The Authors concluded that PTNS offers improvements in overactive bladder symptoms that were comparable to pharmacotherapy. Wooldridge [24] also reported that patients treated with PTNS therapy experienced statistically significant reduction in episodes of urge incontinence and in both day and night number of voids.

Statistically significant improvements in the number of voids, voided volume, incontinence episodes and Incontinence quality of life score in patient group treated with PTNS, not in a placebo control group; were showed in a prospective double blind, placebo controlled study designed to explore the possible placebo effects of PTNS on detrusor overactivity incontinence. The authors demonstrated that the relevance of a placebo effect was trivial in this patients' population [25].

Vandoninck et al. [26] evaluated 90 patients with

overactive bladder and found that PTNS increases the patients' bladder cystometric capacity, delayed the onset of detrusor instability and increases the threshold of appearance of involuntary detrusor contractions. Matzel et al. [27] found that stress incontinent patients had an improvement rate about 66%, while it was 72% in patients with detrusor instability after applying electrical stimulation. Moreover, PTNS had great results with a significant improvement in maximum cystometric capacity [21]; and considerable decline in leakage episodes, frequency and nocturia [28,29].

The rational of using PPTNS is based on the presence of spinal inhibitory systems that are capable of interrupting detrusor contraction [24]. A section from the spinal roots L4–S3 gives rise to the posterior tibial nerve; also the autonomic and somatic nervous supplies to the pelvic floor arises from the same spinal nerve roots. It is believed that through this crossover; the modulation of innervations to the bladder, urinary sphincter and pelvic floor could take place through stimulation of the tibial nerve. This neuromodulation may have a direct effect on the detrusor muscle or it could be a central effect on the micturition centers of the brain [30].

The pontine micturition center (PMC), is the neural center that contains the neural switching circuit for controlling bladder capacity. Tai et al. [31] derived that the increase in bladder capacity is likely results from either suppression of afferent input to the PMC gating circuit or by direct modulation of that circuit. Choudhary and colleagues [32], recently conducted a study on rats with overactive detrusors stimulated by acetic acid; and found that PTNS increases bladder compliance and, consequently, elevate pressures at which the voiding reflex is initiated. The increased bladder storage capacity was accomplished via inhibition of afferent signaling by applying the PTNS.

Number of studies suggested the existence of both sensory and motor neuro-modulatory effects of PTNS confirmed by the changes in the brain cortex during PTNS were similar to those reported by sacral nerve stimulation [33,34]. Other studies have also suggested a role of certain neurotransmitter receptors in the mechanism of action for PTNS. Matsua and colleagues [35] performed a study on cat's bladder and found that intravenous inhibition of the metabotropic glutamate receptors and opioid receptors reduced PTNS efficacy in bladder overactivity.

The posterior tibial nerve stimulation effect on supraspinal centers has been verified in humans in a study published by Finazzi Agro and colleagues [36] in which they found a significant increase in amplitude of long latency somatosensory evoked potentials recorded 24 hours after termination of a 12 sessions PTNS. This finding could imply a probable reorganization of cortical excitability after application of PTNS.

In the disagreement with the results of the present study, Zhao and Nordling [37] demonstrated that applying PTNS in patients with interstitial cystitis had no significant clinical effect otherwise the noticeable response could appear through stimulation of sacral root itself. Fjorback et al. [38] also reported that PTNS showed no effect or failed to suppress detrusor contraction in patients with neurological detrusal overactivity, but there was an increase in the cyctometric bladder capacity and bladder volume during the first contraction after PTNS application.

CONCLUSION

Results of this study proposed an objective and promising effects of PPTNS on urodynamic parameters in patients with paraparesis. Improved bladder incontinence is an encouraging argument to recommend posterior tibial nerve stimulation as a non-invasive treatment modality in clinical practice. In consideration of these supportive results and as suggested by some authors; PPTNS is a safe modality, with no major complications reported in literature that could be offered early in the course of urinary incontinence treatment.

ABBREVIATIONS

EMG - Electromyography.
MCC - Maximum cystometric capacity.
PMC - Pontine micturition center.
PPTNS - Percutaneous Posterior Tibial Nerve Stimulation.
PTNS - Posterior Tibial Nerve Stimulation.

SCI - Spinal Cord Injury.
SD - Standard deviation.
SPSS - Statistical package of Social science

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Conflicts of interest: None

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