

# Percutaneous Posterior Tibial Nerve Electrical Stimulation Versus Sham for Detrusor Overactivity in Children

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## ABSTRACT

*The purpose of this study was to evaluate the effectiveness of percutaneous posterior tibial nerve electrical stimulation versus sham for detrusor overactivity in children. Forty patients with overactive bladder (urge incontinence) participated in this study. Their age ranged from 6 to 15 years. Patients were randomly divided into two groups of equal number; Group (A): received posterior tibial nerve electrical stimulation of faradic type, biphasic continuous rectangular, with frequency of 20 Hz, with maximum tolerable intensity. The duration of each session 15 minutes, three days weekly, for 12 weeks. Group (B): received sham posterior tibial nerve electrical stimulation for 15 min, three days weekly, for 12 weeks also. First desire to void which reveals bladder sensation, bladder stability (number of uninhibited detrusor contractility), bladder compliance were the variables measured before the treatment and after 12 weeks of treatment. Results of this study revealed a highly significant differences between both groups, regarding first desire to void, bladder stability, bladder compliance (P values < 0.05). On conclusion, the percutaneous posterior tibial nerve electrical stimulation is effective compared to sham for detrusor overactivity in children.*

**Key words:** Posterior Tibial Nerve, Electrical Stimulation, Sham Electrical Stimulation Incontinence, Overactive bladder, Urgency, Detrusor Instability, Urodynamic Parameters.

## INTRODUCTION

**D**etrusor overactivity (DO) is the most common voiding dysfunction in children. Detrusor overactivity is also known as Overactive bladder (OAB), urge syndrome, hyperactive bladder syndrome, persistent infantile bladder, detrusor hyperreflexia, detrusor instability and detrusor hypertonia. Its onset can be slow and insidious with a gradual increase in the strength of the urge to void that can occur during a long period. It can also be quite sudden with

dramatic episodes of incontinence in children who were normally dry in a brief period<sup>7,22</sup>.

The negative impact of DO on quality of life is significant, and its adverse effects on patients should not be underestimated. The literature supports the fact that in many patients, DO results in impaired mobility, social isolation, impaired work-related productivity, depression, disturbed sleep, and impaired domestic and sexual function<sup>8,26</sup>. The impact of enuresis in children can be quite profound. It can affect life socially, emotionally and behaviorally, and it will also impact the everyday life of the Family<sup>1</sup>.

Overactive bladder (OAB) is a urological condition that is frequently observed in children and requires treatment. In the pediatric literature, OAB is often referred to as urge syndrome and is best characterized by frequent episodes of an urgent need to void, countered by contraction of the pelvic floor muscles and holding maneuvers such as squatting and the vincent curtsy sign<sup>4</sup>.

The cardinal symptom of OAB is urgency, which is defined as a sudden compelling desire to void that is often difficult to defer. Urgency must be differentiated from the urge to void, which is a normal sensation experienced by all individuals and may be intense when urine is held for a prolonged period<sup>21</sup>.

The definition of urinary frequency in a child is not well established. However, many believe that a child who has a normal fluid intake and who voids more than 7 times per day has urinary frequency. The International Continence Society (ICS) defines nocturia as the need to wake at night 1 or more times to void<sup>12</sup>.

Treatment of OAB is aimed at reducing the debilitating symptoms in order to improve the overall the quality of life in affected patients<sup>23</sup>. Anticholinergic agents that target the muscarinic receptors in the bladder (antimuscarinic agents) are the medical treatment of choice because they reduce the

contractility of the detrusor muscle. However, the use of antimuscarinic drugs is limited by certain adverse effects, particularly dry mouth and constipation<sup>3,5</sup>. Behavioral therapy focusing on dietary and lifestyle modification, voiding regimens, and pelvic floor muscle exercises is also helpful in the management of OAB and may be used by itself or in conjunction with antimuscarinic therapy<sup>28</sup>.

Percutaneous tibial nerve stimulation (PTNS), also referred to as posterior tibial nerve stimulation, is the least invasive forms of neuromodulation used to treat OAB and the associated symptoms of urinary urgency, urinary frequency and urge incontinence.

Percutaneous tibial nerve stimulation is tolerated by children but has been poorly studied<sup>16,29</sup>.

Percutaneous tibial nerve stimulation (PTNS) offers a nondestructive alternative for patients with urge incontinence caused by over active bladder that is refractory to conservative treatment modalities. detrusor overactivity inhibition is achieved by acute electrical stimulation of afferent somatic sacral nerve fibers by PTNS, the rationale of treatment is based on the existence of spinal inhibitory systems that are capable of interrupting detrusor contraction<sup>11</sup>.

Due to feasibility problems with placebo studies the majority of the studies were noncontrolled, some of them clinical trials on acute urodynamic changes during electrical stimulation or experimental research in animals. Overall only a few randomized trials were found. The aim of the study is to compare the efficacy of percutaneous posterior tibial nerve electrical stimulation versus sham for detrusor overactivity in children.

## PATIENTS AND METHODS

### Subjects

This study was carried out on 40 patients (22 boys and 18 girls) with overactive bladder (urge incontinence). They were recruited from the department of urodynamics of the "The National Institute of Urology and Nephrology". All patients undergone a physical examination and a complete history had be taken, including previous urological symptoms as frequency, urgency, nocturnal, or

incontinence. Neurological evaluation in all patients was performed with special attention to perineal sensation, anal sphincter tone, and the anal and bulbocavernosus reflexes, which are important for assessing sacral cord function.

Detailed analysis of the present overactive bladder symptoms had been carried. Medical history including drugs in actual use especially diuretics, and anti-diabetic drugs had been considered. Urologic examination had been carried by the staff of urology department of the National Institute of Urology and Nephrology. Laboratory investigations, mainly fasting and postprandial blood glucose, complete urine analysis had been carried out. Urodynamic studies had been carried by the staff of urodynamic unit, to confirm the diagnosis of overactive bladder and urgency. Detrusor overactivity was defined as an involuntary detrusor contraction of more than 15 cm. water during the filling phase.

Spinal magnetic resonance imaging was done when plain x-ray showed a neurological or spinal abnormality. Children with neurological abnormalities or spina bifida were excluded from study. No patient had constipation or encopresis. Surgery had been done for vesicoureteral reflux in 1 child 3 years before study entry. Voiding cystourethrography before study entry revealed mild vesicoureteral reflux in 3 cases. Patients with anatomical abnormalities of the urethra, such as posterior urethral valves or ring stricture of the bulbar urethra, were also excluded from study.

The criteria for entry into the treatment were; the patient's age ranged from 6 to 15 years. Elapsed time since the beginning of the disease was less than 2 year. The patients were randomly divided into two groups of equal number; Group (A): received posterior tibial nerve electrical stimulation of faradic type, biphasic continuous rectangular, with frequency of 20 Hz, with maximum tolerable intensity. The duration of each session 15 minutes, three days weekly, for 12 weeks. Group (B): received sham posterior tibial nerve electrical stimulation for 15 min, three days weekly, for 12 weeks also.

### **Ethical consideration**

The experimental protocol was explained in details for each patient before the initial assessment and signed informed consent was obtained from each participant before enrollment in the study (from their families). The trial protocol was approved by the meeting of the department of surgery, faculty of physical therapy, Cairo university. There was no harm inflicted on the patients. On the contrary, all had benefited from the final results of the study.

### **Measurements**

DANTIC UD5000/500 urodynamic investigation system used to perform the urodynamic investigations, as voiding cystometry. It is comprised of a trolley-mounted unit with integral printer and monitor, a mobile patient unit with built in H<sub>2</sub>O and CO<sub>2</sub> pumps, a stand-mounted uroflow transducer and a stand-mounted puller mechanism. Measurement had been done by the staff of the urodynamic unit. All patients had been subjected to multichannel cystometry before starting the study and after 12 weeks. The urodynamic studies are valid and reliable. The variables measured were first desire to void which reveals bladder sensation, bladder stability (number of uninhibited detrusor contractility), bladder compliance.

### **Measurement technique by Cystometry**

Patients had been instructed to empty the bladder as completely as possible through enema the night before the test. Patients assumed on the examination couch the crock lying position. Catheterization with a single lumen catheter had been applied using a sterile technique and the Y-piece mounted on the catheter. One prong was connected with the manometer connecting tube and the other had been applied via a damping tube to the infusion pump. Rectal balloon catheter inserted to record intra-abdominal pressure and the system had been emptied from air. Infusion of 37 °C warm, sterile normal saline (at a medium rate of 50 ml/min) filling of the bladder and recording had been started. The patient instructed to tell when bladder filling is felt. This event had been marked on the curve of voiding cystometry (first desire to void)<sup>2</sup>.

The patient had been asked to cough as a provocative test for detrusor instability and he was instructed to void. From the cystometrogram the following measurements had been recorded:

Storage phase : is the passive or filling phase of cystometry during which the bladder had been filled at a filling rate of about 50 ml/min. and it explains the relationships between levels of infused volumes, detrusor pressures, and the bladder compliance. Voiding phase: is the active phase during which the patient had been instructed to void and it detects the following; the voiding time, the flow time, the maximum flow rate, and the detrusor pressure at maximum flow rate & detrusor contractility<sup>18</sup>.

### **Treatment Procedures**

For group (A): posterior tibial nerve electrical stimulation of faradic type, biphasic continuous rectangular, with frequency of 20 Hz, with maximum tolerable intensity was done. Electrical stimulation had been delivered to the posterior tibial nerve via a combination of electrode and generator components, including a small 34-gauge needle electrode, surface electrode, lead wires and hand held electrical generator. The low-voltage stimulator (9 volts) with a fixed pulse width of 200 microseconds. The device produces an adjustable electrical impulse that travels to the sacral nerve plexus via the tibial nerve. The duration of each session 15 minutes, three days weekly, for 12 weeks<sup>18</sup>.

All subjects were asked to evacuate their bladder before starting the treatment sessions to ensure that they be relaxed and comfortable during the session. Patient sit in a frog position with the soles of the feet touching each other and the knee flexed. The medial aspect of the lower extremity was palpated and sensitive pressure point was identified approximately three-finger breadth cephalad from the medial malleolus. This point was about one fingerbreadth posterior from the edge of the tibia<sup>15</sup>.

A 34 gauge, solid stainless steel needle was advanced through the skin with the aid of an overlying plastic cylinder that was 3 mm, shorter than the needle. Once the skin was pierced the cylinder was removed, and the

needle was advanced approximately 3 to 4 cm posteriors to the tibia. A reference electrode was placed over the medial aspect of the calcaneus. A stimulator was then connected to the needle and the ipsilateral reference electrode. and the stimulation is increased as tolerated<sup>30</sup>.

As the goal is to send stimulation through the tibial nerve, it is important to have the needle electrode near (but not on) the tibial nerve. With correct placement of the needle electrode and level of electrical impulse, there is often an involuntary toe flex or fan, or an extension of the entire foot. However, for some patients, the correct placement and stimulation may only result in a mild sensation in the ankle area or across the sole of the foot<sup>9</sup>. For group (B): received sham posterior tibial nerve electrical stimulation for 15 min, three days weekly, for 12 weeks. Since subjects with the PTNS felt foot stimulation, the sham was devised to mimic this feeling without the tibial nerve being stimulated. A needle is used at the tibial nerve insertion site to simulate needle placement without puncturing the skin. The needle be taped in place as in the PTNS procedure. A reference electrode was placed over the medial aspect of the calcaneus. A stimulator was then connected to the needle and the ipsilateral reference electrode but without turn on the stimulator<sup>25</sup>.

### Statistical Analysis

Data were expressed as mean  $\pm$  standard deviation (SD). Student t test was used to

assess the difference between the studied parameters (Age, duration of disease, first desire to void) between both groups while paired t test was used to analyze these parameters within the group. Stability and compliance between the two groups were compared using the Mann-Whitney U test, and compared in time within each of the two groups using the Wilcoxon test. Analysis was performed using SPSS/PC software (SPSS Inc., Chicago, IL, USA). All p values less than 0.05 were considered to be statistically significant.

## RESULTS

Data concerning the patients' demographic data (age, sex, duration of disease) as well as clinical characteristics (first desire of void, stability and compliance) had been collected at the beginning of the study. Follow up evaluation of first desire of void, stability and compliance had been performed after 12 weeks of treatment.

Demographic and clinical characteristics of the patients:

As shown in table (1), there were no statistical significant differences ( $P > 0.05$ ) observed between both groups concerning general characteristics (age, sex, duration of disease) as well as clinical characteristics (first desire to void, stability, compliance) at the beginning of the study.

**Table (1): Statistical analysis of the demographic and clinical characteristics of patients between both groups at the beginning of the study.**

	Group (A) (n=20)	Group (B) (n=20)	P-value
Age (years)	10.65 $\pm$ 3.03	11.95 $\pm$ 3.10	0.188*
Sex( boy/girl)	7/13	11/9	0.209*
Duration of disease (months)	15.8 $\pm$ 4.89	14.6 $\pm$ 5.39	0.466*
First desire to void(cm <sup>3</sup> )	97.8 $\pm$ 13.15	92.75 $\pm$ 26.73	0.453*
Stability (stable/un stable)	6/16	8/12	0.513*
Compliance(compliance/un compliance)	9/11	6/14	0.333*

X = mean, SD = Standard Deviation, P-value=Probability level, \* Non-Significant ( $P > 0.05$ ).

### Results of group (A):

As shown in table (2) the mean value, standard deviation and p value of first desire to void pre and post treatment for group A as well as frequency, P value of stability and

compliance pre and post treatment for group A. The results showed a highly significant differences pre and post treatment for group1 as P value  $< 0.05$ .

**Table (2): Results of First desire to void, Stability and Compliance pre and post treatment of group A.**

	Pre	Post	P value
	X±SD	X±SD	
First desire to void	97.8±13.15	132.7±19.04	0.000*
	(n=20)	(n=20)	
Stability (stable/un stable)	6/16	17/3	0.001*
Compliance(compliance/un compliance)	9/11	16/4	0.035**

X=mean, SD=Standard Deviation, P-value=Probability level, \* highly significant, \*\* significant (P<0.05).

**Results of group (B):**

As shown in table (3) the mean value, standard deviation and p value of first desire to void pre and post treatment for group B as well as frequency, p value of stability and

compliance pre and post treatment for group B. The results showed no significant differences pre and post treatment for group B as P value >0.05.

**Table (3): Results of First desire to void, Stability and Compliance pre and post treatment of group B.**

	Pre	Post	P value
	X±SD	X±SD	
First desire to void	92.5±26.75	99.5±20.61	0.081*
	(n=20)	(n=20)	
Stability (stable/un stable)	8/12	9/11	0.730*
Compliance(compliance/un compliance)	6/14	7/13	0.739*

X = mean, SD = Standard Deviation, P-value = Probability level, \* non significant (P>0.05).

Comparative analysis of First desire to void, Stability and Compliance between both groups post treatment.

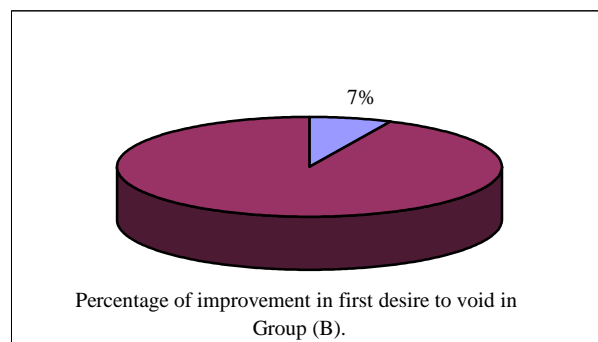
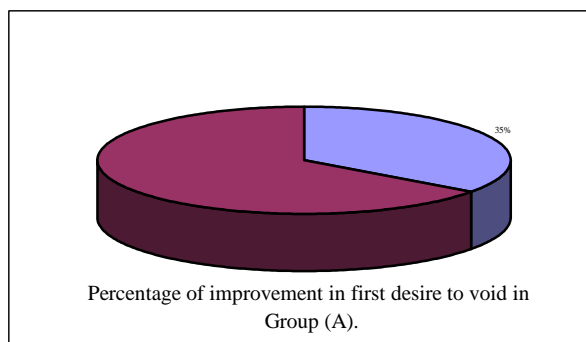
As shown in table (4) the mean value, standard deviation and p value of first desire to

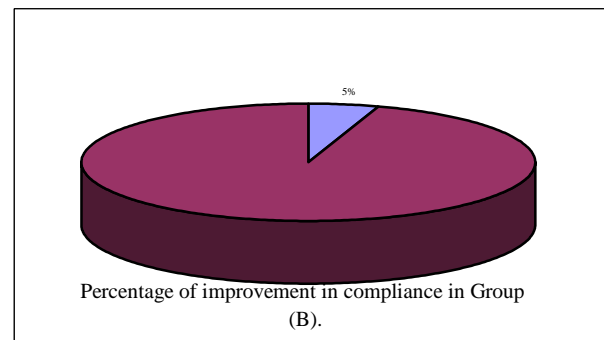
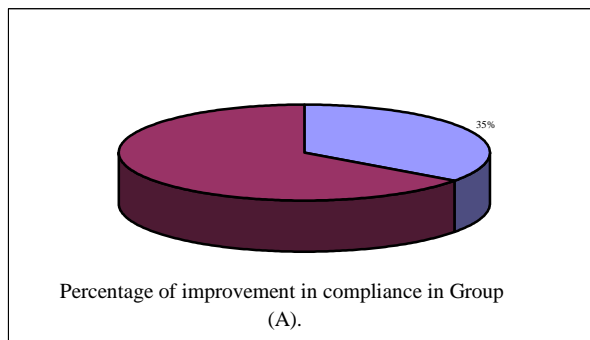
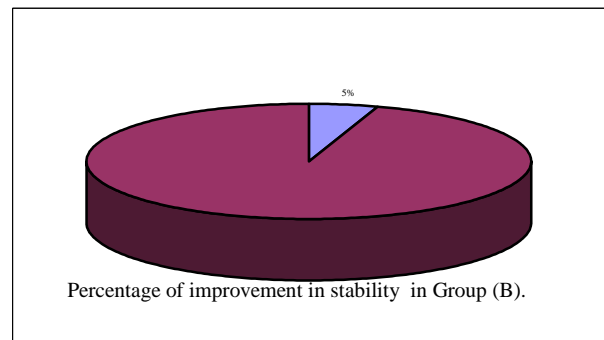
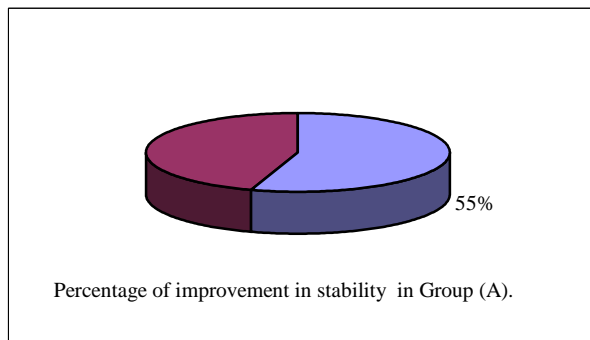
void as well as frequency, P value of stability and compliance between both groups post treatment. The results showed highly significant differences as P value ≤ 0.05.

**Table (4): Comparative analysis of First desire to void, Stability and Compliance between both groups post treatment.**

	Group ( A)	Group (B)	P value
	X±SD	X±SD	
First desire to void	132.7±19.04	99.5±20.61	0.000*
	(n=20)	(n=20)	
Stability (stable/un stable)	17/3	9/11	0.000*
Compliance(compliance/un compliance)	16/5	7/13	0.004*

X = mean, SD = Standard Deviation, P-value = Probability level, \* highly significant





## DISCUSSION

Patients with DO suffer from sleep disturbance, psychological distress from embarrassment due to incontinence and disruption to social and work life. Quality of life scores (QOL) are consistently reduced in this group of patients<sup>17</sup>.

Posterior tibial nerve electrical stimulation (PTNS) was chosen as the physiotherapeutic method because it is an interesting alternative for the treatment of OAB, which is effective and without side effects, despite the fact that pharmacological treatment is currently the first option for the treatment of patient with clinical symptoms of overactive bladder, adherence to treatment is low, especially due to side effects which lead to discontinuation in 60% of cases. Posterior tibial nerve electrical stimulation is considered to be a simpler, less invasive and easy to apply form of peripheral sacral stimulation that is well tolerated by patients and more affordable<sup>24</sup>.

This study was conducted to compare the effectiveness of PTNS versus sham in the treatment of detrusor instability in children. Patients were divided into two groups of equal number, Group (A): received PTNS of faradic type, biphasic continuous rectangular, with

frequency of 20 Hz, with maximum tolerable intensity. The duration of each session 15 minutes, three days weekly, for 12 weeks. Group (B): received sham posterior tibial nerve electrical stimulation for 15 min, three days weekly, for 12 weeks also.

Results of study showed that there were highly significant differences between both groups post treatment as regard to first desire to void, stability and compliance. The percentage of improvement in group A as regard to first desire to void, stability and compliance were 35%, 55%, 35% respectively, while in group B The percentage of improvement as regard to first desire to void, stability and compliance were 7%, 5%, 5% respectively. This confirm the effectiveness of PTNS for the treatment of detrusor instability. The effectiveness of PTNS may attributed to facilitation of the retrograde electrical stimulation to the sacral nerve plexus through percutaneous electrical stimulation of the posterior tibial nerve. The posterior tibial nerve contains mixed sensory motor nerve fibers that originate from L4 through S3, which modulate the innervation to the bladder, urinary sphincter, and pelvic floor. This may improve blood flow and change in neurochemical balance along the neurons. This neuromodulative technique may have a direct

effect on the detrusor or a central effect on the micturition centers of the brain while in group B (sham PTNS), no stimulation occur to sacral roots which modulate bladder.

These results were in agreement with Dmochowski and Gomelsky<sup>12</sup> who stated that percutaneous tibial nerve stimulation continues to display superiority to sham treatment and benefits similar to antimuscarinic therapy may be observed. This therapy is well tolerated and durable outcomes have been seen at 12 months of follow-up.

Peters et al.,<sup>25</sup> reported that voiding diary parameters after 12 weeks of PTN therapy showed percutaneous tibial nerve stimulation subjects had statistically significant improvements in frequency, nighttime voids, voids with moderate to severe urgency and urinary urge incontinence episodes compared to sham. No serious device related adverse events or malfunctions were reported.

Wooldridge<sup>31</sup> reported that a course of 12 PTNS sessions was prescribed and administered in the context of an independent community-based, nurse practitioner-led continence practice. The results of this analysis indicated that patients treated with PTNS therapy experienced statistically significant decreases in both day and night voids, and in episodes of urge incontinence. This study confirmed the results of previous studies indicating that PTNS therapy is a safe and effective treatment that can be successfully incorporated in a community-based setting.

Coyne, et al.,<sup>6</sup> concluded that posterior tibial nerve electrical stimulation was an effective, safe and noninvasive treatment that significantly improved the OAB symptoms and quality of life of the patients.

Gennaro et al.,<sup>14</sup> reported in their study that include 23 children suffered from un responsive lower urinary tract symptoms that PTNS produce improvement of over activity symptoms and normalized the bladder cytometric capacity, detrusor pressure at maximum flow rate and maximum flow rate.

Hoebcke, et al.,<sup>16</sup> reported that Percutaneous tibial nerve stimulation is reliable and effective for nonneurogenic, refractory lower urinary tract dysfunction in

children. Efficacy seems better in dysfunctional voiding than in overactive bladder cases. There is evidence that percutaneous tibial nerve stimulation should be part of the pediatric urology when treating Functional incontinence.

MacDiarmid, et al.,<sup>19</sup> stated that Statistically significant overactive bladder symptom improvement achieved with 12 weekly percutaneous tibial nerve stimulation treatments demonstrates excellent durability through 12 months. The durability of response demonstrates the effectiveness of percutaneous tibial nerve stimulation as a viable, long-term therapy for overactive bladder.

Matzel et al.,<sup>20</sup> found that the improvement rate in stress incontinent patients was 66%, while it was 72% in patients with detrusor instability after applying electrical stimulation, and detrusor instability became stable in 89% of men with detrusor instability while De Gennaro, et al.,<sup>10</sup> concluded that percutaneous tibial nerve stimulation is safe, minimally painful and feasible in children.

In the disagreement with the results of the present study Zhao and Nordling<sup>32</sup> demonstrated that PTNS in patients with interstitial cystitis had no significant clinical effect and it may give some response but less than through sacral root itself.

Fjorback et al.,<sup>13</sup> reported that PTNS had no effect or failed to suppress detrusor contraction on neurological detrusal over activity patients but the bladder volume during the first contraction and cytometric bladder capacity was increase.

On conclusion, posterior tibial nerve is considered an effective method compared to sham in the treatment of detrusor overactivity.

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### الملخص العربي

#### التنبيه الكهربائي لعصب القصب الخلفي عبر الجلد مقارنة بالإيحاءى لفرط نشاط العضلة النافضة للمثانة في الأطفال

يهدف هذا البحث إلى دراسة تأثير التنبيه الكهربائي لعصب القصب الخلفي عبر الجلد مقارنة بالإيحاءى لفرط نشاط العضلة النافضة للمثانة في الأطفال . وقد أجريت هذه الدراسة على أربعين مريضاً تتراوح أعمارهم بين 6 إلى 15 سنة ممن يعانون من فرط نشاط العضلة النافضة للمثانة . وقد تم تقسيمهم عشوائياً إلى مجموعتين متساويتين في العدد. المجموعة الأولى (أ): تلقت التنبيه الكهربائي لعصب القصب الخلفي عبر الجلد بتردد 20 هيرتز ، 30 دقيقة في الجلسة بواقع 3 جلسات أسبوعياً وذلك لمدة 12 أسبوعاً بينما المجموعة الثانية (ب): تلقت التنبيه الكهربائي الإيحاءى لعصب القصب الخلفي ، 30 دقيقة في الجلسة بواقع 3 جلسات أسبوعياً وذلك لمدة 12 أسبوعاً أيضاً. وقد تم قياس عامل الإحساس بالحاجة إلى التبول واستقرار وامتثال المثانة قبل وبعد 12 أسبوعاً للمجموعتين باستخدام جهاز ديناميكية البول وقد أظهرت النتائج فروق ذات دلالة إحصائية بين المجموعتين بعد العلاج بالنسبة لعامل الإحساس بالحاجة إلى التبول واستقرار وامتثال المثانة. ويمكن أن نستخلص أن التنبيه الكهربائي لعصب القصب الخلفي عبر الجلد له تأثير واضح مقارنة بالإيحاءى لفرط نشاط العضلة النافضة للمثانة في الأطفال .

**الكلمات الدالة :** عصب القصب الخلفي ، التنبيه الكهربائي ، التنبيه الكهربائي الإيحاءى ، سلس البول ، فرط نشاط العضلة النافضة للمثانة والإلحاح ، ديناميكية البول .