

# Applicability of Parasacral Transcutaneous Electrical Nerve Stimulation in the Treatment of Overactive Bladder

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## ABSTRACT

Overactive bladder is defined as a syndrome whose main symptom is urinary urgency in the absence of infectious factors. It is also characterized by the presence or absence of incontinence, which may or may not be accompanied by pollakiuria and nocturia. The present study aimed to evaluate the effect of Parasacral transcutaneous electrical nerve stimulation in the treatment of overactive bladder of non-neurological origin. This is a bibliographic review through research in databases such as Pubmed, Lilacs and Virtual Health Library with the descriptors: parasacral electrical stimulation, transcutaneous neuromodulation, bladder hyperactivity, urinary urgency and Overactive Urinary Bladder, in Portuguese and English. Sixteen articles were found, involving studies that addressed parasacral transcutaneous electrical nerve stimulation in the treatment of idiopathic overactive bladder. From this review, it became possible to conclude that although previous studies clarified that parasacral transcutaneous electrical nerve stimulation is effective, in some way, for the improvement of clinical symptoms of idiopathic overactive bladder, it was not possible to standardize the best protocols, to parameters such as frequency, pulse width and current intensity, as well as the number of sessions, treatment time and frequency. However, there was a prevalence of studies using protocols with low frequency and high pulse width. Possibly, the number of weekly sessions is not a predictor of improvement.

**Keywords:** Overactive Bladder; Urinary Urgency; Parasacral Transcutaneous Electrical Nerve Stimulation

## Introduction

Overactive bladder is a pathology of the lower urinary tract that negatively affects the quality of life of its sufferers. The main symptom for its definition is urinary urgency, in the absence of infections or other pathologies, which can be defined as a sudden irresistible desire to urinate. It is also characterized by the presence or absence of incontinence, usually accompanied by urinary frequency and nocturia [1]. The use of physiotherapy for the treatment of urinary urgency in overactive bladder has been growing more and more because it is a low cost treatment, with minimal adverse reactions, non-invasive, and can be used associated or not with drugs and surgeries [2]. In the literature, there are several studies demonstrating the effectiveness

of parasacral transcutaneous electrical nerve stimulation in the treatment of overactive bladder, but there is a lot of diversity regarding the form of application, regarding the number of sessions necessary for the treatment, the number of weekly sessions, the time of application of electrostimulation, as well as the pulse width applied in therapy. Currently, the great difficulty of commuting in large cities and, mainly, the cost of this commuting for the most needy populations, hinders treatments in which the patient has to attend the health service several times in the same week. In addition, patients from smaller urban centers end up unable to receive this type of treatment. Therefore, the number of weekly sessions can reduce the patient's adherence to treatment or even make it impossible [3]. Hence the importance of

comparing the results of the protocols used in different research centers, making it possible for professionals in the field to adapt them to the daily reality of their patients. Due to the lack of standardization in the literature on treatment protocols, a bibliographical study is necessary, presenting the different theoretical currents already developed on the proposed theme, contributing significantly to the area of Physical Therapy in Women's Health.

## Methods

This work was developed from the perspective of a qualitative bibliographic study, presenting the different theoretical currents already developed by researchers related to the proposed theme. According to Gil (2006)<sup>4</sup>, qualitative research considers the interpretation of phenomena and the attribution of meanings, not requiring the use of statistical methods and techniques, and bibliographical research uses previously published material, consisting basically of books, journal articles and, currently, of information made available on the internet. To carry out this literature review, a survey of bibliographic references was carried out, through a search in databases, such as Pubmed, Lilacs and Virtual Health Library, with the following descriptors: parasacral electrical stimulation, transcutaneous neuromodulation, bladder hyperactivity, urinary urgency and Overactive Urinary Bladder, in Portuguese and English, searching for clinical studies carried out in human beings. In addition, we followed the citations of the primary references, looking for relevant articles that the

database was unable to locate.

## Result

Clinical studies carried out on human beings published in English and Portuguese were considered eligible. The criteria for selecting articles were those that treated idiopathic overactive bladder and its symptoms using transcutaneous parasacral electrical stimulation with analysis of clinical improvement. Studies in which overactive bladder was or was not diagnosed by urodynamic study, or by another form of evaluation, such as specific questionnaires for this purpose, were considered. Studies whose treatment was not transcutaneous (percutaneous electrical stimulation, tibial nerve stimulation, anal stimulation, vaginal/penile stimulation or implanted devices), which did not describe the parameters of frequency and/or pulse width, articles that did not were available in full and that referred to treatments for overactive bladder of neurological origin or on fecal incontinence. After the search, the duplicated results were removed and the analysis of the sample began, firstly, by the abstracts and later by the article in its entirety, in order to confirm the inclusion or exclusion of the article. Initially, a total of 244 articles were identified. After applying the exclusion criteria, 235 articles were removed and, following the citations of the primary references, seven studies were included for analysis. The results obtained, with the characterization of the studies and their interventions, are available in (Tables 1 & 2).

**Table 1:** Comparison between study designs.

Study	Study Design	Age (media)	Sample	Evaluated Instruments	Results Found
(Bower, et al. [14])	Superficial neuromodulation - randomization into three groups regarding electrode placement: Sacral, Suprapubic and Sham	79 women (48 with detrusor instability and 31 with sensory urgency)	56.5 years (56.4 in the detrusor instability and 56.3 in the sensory urgency group)	Urodynamic study	There was no significant difference between groups  Transcutaneous electrical stimulation, in the Sham group, did not change outcome measures before and after treatment.  In the neuromodulation performed on the suprapubic and sacral skin, there was a reduction in the maximum pressure of the detrusor and an increase in the first micturition desire. There was no change in the maximum cystometric capacity.
(Namima, et al. [15])	Evaluation before and after therapy	16 patients (9 men and 7 women)	49.2 years (8 to 78 years old)	Urodynamic study	Increased bladder storage function.
(Bower et, al. [16])	Assessment before and after therapy - Sacral Transcutaneous Neuromodulation	20 children	7.5 ± 2.3 years	Visual analogue scale and voiding diary	73.3% of the children became dry, the average urgency score improved and there was a significant increase in the average volume of urine.
(Hoebeke, et al. [17])	Evaluation of the clinical effects of transcutaneous sacral neuromodulation	41 children	10.2 years (girls) 10.7 years (boys)	voiding diary	After 1 month - increased bladder capacity, decreased urgency, decreased incontinence and/or better sensitivity.  After 6 months of therapy - significant increase in bladder capacity, decrease in urination frequency and decrease in incontinence

(Yokozuka, et al. [18])	Assessment before and after therapy – therapeutic electrical stimulation of the sacral surface.	18 patients (7 men and 11 women)	46.5 years (9 to 86 years)	Voiding diary and Urodynamic study.	Incontinence frequency / day decreased; Maximum bladder capacity increased; Uninhibited contraction decreased
(Barroso, et al. [19])	Series of children with lower urinary tract dysfunction, urgency was treated by electrical stimulation and voiding dysfunction by biofeedback;	36 children	7 years (3 to 14 years)	Voiding diary, uroflowmetry with electromyography and ultrasound	Of the 19 children, 12 showed a complete clinical improvement, six with a significant improvement and a slight improvement
(Malm-Buatsi, et al. [13])	Evaluation of the use of transcutaneous stimulation in children with overactive bladder refractory to behavioral and anticholinergic therapy.	18 children	9.4 ± 3.1 years (5 to 14 years)	Voiding diary and uroflowmetry	Of the 15 patients with incontinence, 2 became dry, 9 improved significantly, and 4 showed no improvement. Of 12 children with increased urinary frequency, 8 showed significant subjective improvement. Two patients with no improvement in incontinence showed improvement in low back pain and bladder spasm symptoms. One patient who initially had both urinary frequency and pelvic pain showed significant improvement in both. Of the 7 patients with nocturnal enuresis, 1 became dry at night and 6 showed no improvement.
(Hagstroem, et al. [20])	They studied the effect of transcutaneous electrical nerve stimulation (TENS), comparing two groups: TENS and Sham	27 children	8.7 ± 2.0 years – active TENS 8.5 ± 1.2 years – Sham TENS	Voiding diary, Visual analogue scale and Urodynamic study	The active TENS group had a significant drop in incontinence scores, wet days per week, number of daily urinary incontinence episodes, and improved urge response (VAS). None of these parameters changed significantly in the Sham group. Bladder reservoir function did not change in either group.
(Lordelo, et al. [12])	Long-term evaluation of transcutaneous parasacral electrical stimulation (TCPSE) – more than 6 months.	49 children	10.2 years (5 to 17 years)	Urgency, daytime incontinence and urinary tract infection	Initial success was demonstrated in 79% of patients for urgency, 76% for incontinence, and 77% for all symptoms. Continued success was seen in 84% of patients for urge, 74% for daytime incontinence, and 78% for all symptoms. Recurrence of symptoms after a complete response was seen in 10% of cases. Two of the 33 patients (6%) with a urinary tract infection before the procedure still had an infection after treatment.
(Lordelo, et al. [21])	Randomized trial to evaluate the effectiveness of transcutaneous parasacral electrical nerve stimulation (PTENS) test group (active treatment) or sham group (superficial scapular electrical stimulation)	37 children	7.6 years (4 to 12 years)	Self-reported cure, or significant improvement; visual analogue scale; percentage improvement; modified Toronto score; voiding diary.	In the active treatment group, 61.9% of the parents reported cure, in the sham group, no parent reported cure (p<0.001). Regarding the visual analogue scale, 10 was indicated by 13 parents in the test group, while 1 parent in the simulated group indicated a score of 9 (p=0.002). Additionally, 100% improvement was reported by 12 parents in the test group and no parents in the sham group. The Toronto score significantly improved in the test group (p<0.001) and sham group (p=0.008). However, the score was reduced more significantly in the test group compared to the sham group (p=0.011). In the test group, mean and maximum volumes showed a statistically significant increase and the number of urinations decreased daily.

(Barroso, et al. [22])	Comparison between the results of parasacral transcutaneous electrical nerve stimulation and posterior tibial nerve stimulation (PTNS).	59 children	Parasacral TENS - 7.5 years $\pm$ 2.8 years PTNS - 8.4 years $\pm$ 3.8 years	Visual analogue scale and dysfunctional voiding symptom score and by the level of improvement of each specific symptom	Parasacral TENS is most effective in resolving symptoms of overactive bladder, which matches the perception of parents. However, there were no statistically significant differences in the dysfunctional inactivity symptom score assessment, or in complete resolution of urge or daytime incontinence.
(Lima, et al. [23])	Randomization into two groups: group A (Transcutaneous Parasacral Electrotherapy, (PTENS) with placebo oxybutynin) and group B (oxybutynin with scapular electrotherapy).	28 children	6.4 years $\pm$ 2.18 years	Rate of complete resolution of symptoms; Visual Analog Scale (VAS); DVSS; Voiding diary; ROME III; and side effects	PTENS was as effective as oxybutynin in treating overactive bladder in children, but more effective in constipation and was not associated with detectable side effects. Oxybutynin, on the other hand, was more effective in reducing urinary frequency.
(Sillén, et al. [24])	Randomization between standard treatment of urotherapy alone or with a combination of urotherapy and TENS	62 children	8 years (5.3 to 11.5 years)	Voiding diary	There was no difference between groups
(Alcântara, et al. [25])	Assessment before and after therapy - Transcutaneous parasacral electrical nerve stimulation	25 children	7.80 $\pm$ 2.22 years	Voiding diary, ultrasound and questionnaire.	Regression of urinary incontinence; Reduction in the percentage of children with detrusor contractions (not significant)
(Barroso, et al. [26])	Assess urodynamic changes immediately after the first session (acute effect) and after the last parasacral TENS session	18 children	8.7 years	Urodynamic study	There was no change in urodynamic parameters immediately after the first stimulation session. After the last session, the only urodynamic finding that showed improvement was bladder capacity.
(De Paula, et al. [3])	Randomization into two groups: GE (PTENS + urotherapy) and GC (placebo electrical stimulation + urotherapy)	16 children	GE: 6.5 years (6 to 7.7 years) GC: 8.5 years (5.5 to 10 years)	Voiding diary, Visual Analog Scale (VAS), Rome III and Bristol Scale	PTENS performed in single weekly sessions is effective in treating the bladder for symptoms of urinary urgency, enuresis and in the perception of those responsible for the children.

**Table 2:** Parameters used in electrostimulation.

Study	Positioning of the Electrodes	Intensity (mA)	Pulse Width ( $\mu$ s)	Frequency (Hz)	Time (min.)	Frequency of Treatment	Number of Sessions
(Bower, et al. [14])	Sacral suprapubic Sham	Max. tolerable feeling	200 200 -	10 150 -	-	Study of the acute effect of treatment	
(Namima, et al. [15])	Sacral	Submax. tolerated	0.3 ms	20 10'' on / 5'' off	15	Study of the acute effect of treatment	
(Bower, et al. [16])	Sacral	Highest tolerated setting no discomfort	-	10	60	twice/day	Minimum 1 month

(Hoebeke, et al. [17])	Sacral	Maximum tolerable intensity	150	2	120	once/day	Minimum 1 month
(Yokozuka, et al. [18])	Sacral	Contraction of the anal sphincter	0.3 ms	20 10'' on / 5'' off	15	twice/day	Minimum 1 month
(Barroso, et al. [19])	Sacral	Tolerated sensory threshold	-	10	20	three times/week	Media of 13.1 (4 to 20 sessions)
(Malm-Buatsi, et al. [13])	Sacral	Tolerated sensory threshold	100	-	20	twice/day	Media of 8 months
(Hagstroem, et al. [20])	Parasacral (S2-S3)	Max. tolerated up to 40mA	200	10	120	once/day	Minimum 4 weeks
(Lordêlo, et al. [12])	Parasacral (S2-S3)	Tolerated sensory threshold	700	10	20	Three times / week	20
(Lordêlo, et al. [21])	Parasacral Scapular	Maximum tolerated level	700	10	20	Three times / week	20
(Barroso, et al. [22])	PTNS TENS parasacral	Patient sensitivity and tolerance level	400	20	30	once / week	12
			700	10	20	Three times / week	20
(Lima, et al. [23])	Parasacral	Level just below motor threshold	700	10	20	Three times / week	20
(Sillén, et al. [24])	Parasacral TENS Urotherapy	Maximum tolerated level – up to 40 mA	-	10	20	twice / day	12 weeks
(Alcântara, et al. [25])	Parasacral	-	700	10	20	Twice / week	20
(Barroso, et al. [26])	Parasacral TENS	Sensitivity limit	700	10	20	Three times / week	20
(De Paula, et al. [3])	Parasacral Scapular	Child tolerance threshold	700	10	20	Once / week	20

## Discussion

### Physiological Effects of Electrostimulation in the Treatment of Idiopathic Overactive Bladder

Electrostimulation consists of the use of electrical currents for the treatment of patients with different indications. The use of electrical stimulation as a treatment began in Egypt, with a species of electric eel found in the Nile River. It is known that this treatment is capable of activating peripheral, sensitive and autonomic nervous system nerve fibers [5]. Electrostimulation for the treatment of overactive bladder has been described as being used intravesically, anally, genitally, by sacral implants, transcutaneously or percutaneously (Barroso, et al. [6]). demonstrated in a meta-analysis that, while for the other methods there are only case series, the transcutaneous technique is effective at level 1 of scientific evidence. The mechanism of action of electrostimulation in the treatment of overactive bladder is

still not entirely clear. It was believed that there is an improvement in the function of the bladder wall, by promoting a partial activation of denervated muscle fibers; and that transcutaneous electrical stimulation acts by modulating the micturition reflex at different points in the central nervous system. However, it was assumed that the stimulation of sacral roots is only effective when performed chronically and continuously [7]. (Lindstrom, et al. [8]) and Fall and Lindstrom [9] demonstrated through experimental studies in cats, that electrical stimulation causes activation, via reflex, of inhibitory sympathetic neurons and inhibition of excitatory parasympathetic neurons, inhibiting involuntary detrusor contractions and providing the reorganization of the central nervous system [5].

(Lisieux, et al. [10]) indicated that neuromodulation produces a physiological reconditioning effect, promoting synapse remodeling through neuroplasticity, possibly generating definitive neural

reconditioning. (Dasgupta, et al. [11]) through the study of neuro-imaging, verified how neuromodulation acts on the brain centers involved in bladder control. They demonstrated that its therapeutic effect is achieved due to the recovery of brain activity associated with self-regulation and attenuation of cingulate gyrus activity, reinnervating partially denervated muscle fibers. In 2009, (Lordelo, et al. [12]). described parasacral transcutaneous electrical stimulation as a continuous electrical current passing through two electrodes placed in the child's sacral region. They reported that its mechanism of action was due to the fact that the inhibitory reflex was stimulated by low-frequency electrical impulses, causing inhibition of the detrusor muscle. Thus, (Malm-Buatsi, et al. [13]). considered transcutaneous parasacral electrical stimulation to be safe and well tolerated. Being described as a non-drug therapy, effective, non-invasive, easy to apply and low cost for public agencies [3].

### **Protocols and Results in the Application of Parasacral Transcutaneous Electrical Nerve Stimulation in the Treatment of Idiopathic Overactive Bladder**

It can be seen that there is a wide variety of electrostimulation techniques in the literature for the treatment of overactive bladder. In the research carried out, the authors who described studies using transcutaneous parasacral electrical stimulation were: (Bower, et al. [12-26]) Of the 16 studies included, only three were composed of adults, probably because the positioning of electrodes for the treatment of urinary pathologies usually uses intracavitary spaces, through stimulation of the pudendal nerve. Although, some authors have demonstrated in their studies the undesirable effects found in intravaginal electrostimulation: vaginal irritation, infections and pain [27]. In addition, intracavitary electrodes are for individual use, which increases the cost of treatment, making it less accessible in public services or for the low-income population [5]. The duration of treatment and the number of sessions per week varied between studies. Two studies evaluated, through urodynamic studies in adults, the acute effects of the treatment, that is, the one reached immediately after the electrostimulation session. They found different results, most likely due to the difference in electrostimulation parameters (Bower, et al. [14]) used a pulse width of 200  $\mu$ s and a frequency of 10 Hz, found a reduction in the maximum pressure of the detrusor, increase in the first micturition desire and, there was no alteration in the maximum cystometric capacity. While (Namima, et al. [15]), used 300  $\mu$ s of pulse width and 20 Hz (10" on / 5"off), not finding an increase in the bladder storage function). Six studies applied daily sessions of electrostimulation [13, 16-18, 20,24], but they differed regarding the time and parameters of electrostimulation (Table 2), which hinders the real comparison between their results. Even so, all these studies reached satisfactory results in important aspects presented in the overactive bladder (Table 1). Six studies applied electrical stimulation three times a week [12,19,21-23,26], with the same protocol of treatment (intensity at the tolerated sensory threshold, 700  $\mu$ s, 10

Hz, 20 minutes of application) (Table 2). Similar results can be observed in these studies (Table 1), with emphasis on two studies in which a comparison was made between transcutaneous parasacral electrical stimulation and stimulation of the posterior tibial nerve, and with oxybutynin [22-23], showing no difference between the mentioned treatments. Two surveys repeated the same survey protocol described above, only modifying the number of weekly sessions. (Alcântara, et al. [25]) studied electrostimulation performed with two weekly sessions, while (De Paula, et al. [3]) applied electrostimulation in single weekly sessions. Both also found satisfactory results regarding the improvement of the studied symptoms. Thus, (De Paula, et al. [3]) suggested that parasacral transcutaneous electrical stimulation, associated with urotherapy, is effective in the treatment of children and that the number of weekly sessions does not suggest better use; however, he stressed that new studies with larger populations are needed to ensure these results. In view of what is presented in this review, we consider that all studies carried out indicate that parasacral transcutaneous electrical nerve stimulation is somehow effective for idiopathic overactive bladder. From the analysis of treatment parameters, it was not possible to standardize treatment protocols, since, as previously reported, some improvement was found in all studies. Thus, we suggest randomized clinical trials that compare the various electrostimulation techniques currently employed. One of the important limitations found in this research refers to the use of different nomenclatures in the studies, which, because there is no standardization of the terms, are sometimes confused with each other, making it difficult to search for studies that used the studied technique. Another limitation refers to the fact that some studies did not make the technique or parameters used clear. Even so, we consider that the findings of this study brought a great theoretical and practical contribution to the applicability of parasacral transcutaneous electrical nerve stimulation in the treatment of overactive bladder of non-neurological origin.

### **Conclusion**

Based on this review, it was possible to conclude that although previous studies clarified that parasacral transcutaneous electrical stimulation is effective to improve the clinical symptoms of idiopathic overactive bladder, it was not possible to a standardization of the best protocols, for parameters such as frequency, pulse width and current intensity, as well as for the number of sessions, time and frequency of treatment. However, there was a prevalence of studies using protocols with low frequency and high pulse width. Possibly the number of weekly sessions is not a predictor of improvement. Thus, that conducting randomized clinical trials that compare the various electrostimulation techniques and protocols currently employed are the way to find out which methods of applying parasacral transcutaneous electrical stimulation are the most indicated therapy for the treatment of overactive bladder of origin not neurological.

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