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Review Article

Electrostimulation of the posterior tibial nerve in individuals with overactive bladder: a literature review

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Abstract. [Purpose] This study aims to gather scientific evidence to identify whether clinical trials on Electrostimulation of the Posterior Tibial Nerve (ESPTN) in individuals with overactive bladder present an adequate methodological standard according to the PEDro (Physiotherapy Evidence Database) criteria. [Methods] Integral literature review, including randomized controlled clinical trials found in PEDro. [Results] We found 16 articles, of which only one did not meet the inclusion criteria. This article has shown that ESPTN is a conservative tool of physiotherapy that is less invasive than other therapies, is well tolerated by patients and has been shown to be effective in the treatment of overactive bladder. However, few standardized clinical studies have been conducted, and only 26.6% of the articles included in this review obtained a score of more than five items on the PEDro scale. [Conclusion] This article has shown that ESPTN is a conservative tool of physiotherapy that is less invasive than other therapies, is well tolerated by patients and has been shown to be effective in the treatment of overactive bladder. Thus, there is a need for more clinical articles that follow the quality criteria for randomized clinical trials, allowing more reliable scientific results.

Key words: Overactive urinary bladder, Tibial nerve, Transcutaneous electrical nerve stimulation

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INTRODUCTION

Overactive urinary bladder corresponds to an involuntary contraction of the detrusor during the bladder filling phase, accompanied by elevated pressure, which may trigger urinary incontinence, urgency, increased voiding frequency and nocturia[1)]. This detrusor hyperactivity is often associated with diseases of the central or peripheral nervous system, such as multiple sclerosis (MS), stroke and Parkinson's disease (PD), among others, as is classified as neurogenic detrusor hyperactivity (NDH)[2)].

Defined by the International Continence Society (ICS) in 2002, overactive bladder is characterized by the association of complex irritative urinary symptoms, urinary urgency usually accompanied by frequency of urination and nocturia, with or without urgent incontinence, in the absence of lower urinary tract infection or other related diseases. The diagnosis is given through evaluation of symptoms, presence of urinary urgency, complaint of sudden urge to urinate and difficulty in retaining urine. With urodynamic investigation, it is possible to observe this syndrome better, as there are involuntary contractions of the detrusor muscle during the bladder filling stage[3)].

Different techniques have been employed in the treatment of urinary dysfunction, including behavioral modifications,

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physiotherapy, medications, neuromodulation, intravesical injections of botulinum toxin and surgery[4]. For Amarenco et al.[5], the electrostimulation of the posterior tibial nerve provided good results for reducing incontinence episodes and improving quality of life in patients with OAB.

Electrical stimulation of the posterior tibial nerve has been shown to be an option in the treatment of symptoms of lower urinary tract dysfunctions. The electrostimulation of the posterior tibial nerve with superficial electrodes (adhesives) through transcutaneous electrical nerve stimulation (TENS) is easy to apply, low cost and has no adverse effects[6]. Although it has been proposed for more than 20 years for the treatment of women with urinary incontinence, the mechanism of electrostimulation of the posterior tibial nerve (ESPTN) is not yet fully understood[7].

It is known that the posterior tibial nerve is a mixed nerve with motor and sensory fibers that emerge from L5–S3, where some fibers of the parasympathetic nervous system (SNP) originate, which are responsible for the innervation of the bladder[5]. The posterior tibial nerve originates in a branch of the sciatic nerve and protrudes in the same sacral medullary region of the sacral center of micturition. It activates inhibitory reflexes by the afferent of the pudendal nerves, through the projection of the spinal cord, in the same place as bladder projections[5]. Thus, it is believed that the inhibition of involuntary contractions of the detrusor muscle occurs by the activation of the sympathetic fibers in the pelvic ganglia[5, 8]. For Monteiro et al.[8], bladder activity could be inhibited by electrostimulation through the somatic depolarization of the sacral and lumbar afferent fibers.

According to Amarenco et al.[5], neuromodulation occurs through a convergence of signals, where a long medullary reflex occurs along with the reorganization of the nerve synapses, which are activated by a reflex pathway of the inhibitory sympathetic neurons (by the activation of the hypogastric nerve) and by the inhibition of the excitatory parasympathetic neurons (by the pelvic nerve).

Clinical studies should have a high degree of methodological quality. To evaluate the quality of such studies, criteria are needed to classify the study design and statistical analyses. The PEDro scale provides these criteria. The Physiotherapy Evidence Database (PEDro)[9] scale is composed of the following criteria: 1) specification of inclusion criteria (item not scored); 2) random allocation; 3) secrecy in the allocation; 4) similarity of the groups in the initial or basal phase; 5) masking of participants; 6) masking of the therapist; 7) masking of the evaluator; 8) measurement of at least one primary outcome in 85% of participants allocated; 9) analysis of intention to treat; 10) comparing groups of at least one primary endpoint and 11) reporting variability measures and estimating the parameters of at least one primary variable[9, 10]. Clinical studies are classified based on the details they mention. If a clinical study does not refer specifically to a particular criterion, it will be scored as nonexistent[9, 10].

The available studies on electrostimulation of the posterior tibial nerve present differences in terms of stimulation intensity, treatment strategy and positioning of the electrodes. Most studies were uncontrolled and therefore did not evaluate the placebo effect. Thus, the objective of the present study was to use the PEDro scale to gather scientific evidence to identify whether published articles on ESPTN in individuals with overactive bladder syndrome (OBS) present an adequate methodological standard.

METHODS

The present study is an integrative review of literature that analyzed the methodological quality of the studies on the effects of transcutaneous electrostimulation of the posterior tibial nerve on urinary incontinence. In general, the review of literature study is exempt from ethics approval as the study authors will be collecting and synthesizing data from previous clinical trials in which informed consent has already been obtained by the trial investigators. The literature search was performed by one reviewer in January 2018. The research was performed using PEDro (https://www.pedro.org.au/). The following descriptors were used: overactive bladder and tibial nerve.

Inclusion criteria

The study included randomized clinical trials and quasi-experimental studies related to superficial ESPTN and other treatments, such as pharmacological therapies, Pelvic Floor Muscle Training (PFMT) or no other treatment. This study included articles with varying patient characteristics (multiple sclerosis, Parkinson's disease, and women with OAB), men, women and different statistical analyses. Only studies published as complete texts were included. Papers published in all languages and with full texts available were included.

Exclusion criteria

Literature review studies or guidelines were excluded.

RESULTS

Sixteen clinical articles were found, with one being excluded because it was a literature review. Thus, we included 15 randomized clinical trials.

The included articles presented different scores on the PEDro scale (Table 1). The treatments described by the studies included training of the pelvic floor muscles, pharmacological treatment and electrostimulation of the posterior tibial nerve.

Table 1. Articles included in the integrative review and its characteristics

Title	Authors	PEDro scale score (/10)	Sample	Type of intervention	Frequency	Conclusion
Randomized trial of percutaneous tibial nerve stimulation versus sham efficacy in the treatment of overactive bladder syndrome[11]	Peters KM, Carrico DJ, Perez-Marrero RA, Khan AU, Wooldridge LS, Davis GL, MacDiarmid SA	8/10	220 adults with overactive bladder (OAB) symptoms	Percutaneous tibial nerve stimulation or sham therapy	12 weeks of treatment	This pivotal multicenter, double-blind, randomized, sham controlled trial provides evidence that percutaneous tibial nerve stimulation is safe and effective in treating OAB symptoms. The compelling efficacy of percutaneous tibial nerve stimulation demonstrated in this trial is consistent with other published reports and supports the use of peripheral neuromodulation therapy for OAB.
Neuromodulation for overactive bladder with transcutaneous electrical nerve stimulation in adults −a randomized clinical study[12]	Surbala L, Khuman PR, Mital V, Devanshi B	7/10	44 adult participants with OAB	Neuromodulation with TENS at sacral foramina (SF), the posterior tibial nerve (PTN) and the combination of SF + PTN	4 weeks	The study concluded that TENS is safe and acceptable with potential clinical effects in reducing symptoms of OAB in adult participants.
Transcutaneous tibial nerve stimulation in the treatment of lower urinary tract symptoms and its impact on health-related quality of life in patients with Parkinson disease[13]	Perissinotto MC, d'Ancona CAL, Lucio A, Campos RM, Abreu A	6/10	Thirteen patients with a diagnosis of PD and bothersome LUTS	Transcutaneous tibial nerve stimulation (TTNS) and sham TTNS	5 weeks	These findings suggest that TTNS is effective in the treatment of LUTS in patients with PD, reducing urgency and nocturia episodes and improving urodynamic parameters and symptom scores measured by the OAB-V8 and health-related quality-of-life scores measured by the ICIQ-SF.
Percutaneous tibial nerve stimulation versus tolterodine for overactive bladder in women: a randomised controlled trial[14]	Preyer O, Umek W, Laml T, Bjelic-Radisic V, Gabriel B, Mittlboeck M, Hanzal E	6/10	36 patients with symptoms of OAB	Percutaneous tibial nerve stimulation (PTNS) versus tolterodine	3 months	PTNS and tolterodine were both effective in reducing incontinence episodes and improving QoL in patients with OAB but not micturition frequencies. PTNS had fewer side effects.
Percutaneous tibial nerve stimulation versus electrical stimulation with pelvic floor muscle training for overactive bladder syndrome in women: results of a randomized controlled study[15]	Scaldazza CV, Morosetti C, Giampieretti R, Lorenzetti R, Baroni M	5/10	60 women with OAB	PTNS versus electrical stimulation with pelvic floor muscle training (ES + PFMT)	6 weeks	This study demonstrates the effectiveness of PTNS and ES with PFMT in women with OAB, but greater improvements were found with PTNS.
Pelvic floor muscle training with and without electrical stimulation in the treatment of lower urinary tract symptoms in women with multiple sclerosis[16]	Lucio A, d'Ancona CAL, Perissinotto MC, McLean L, Damasceno BP, de Moraes Lopes MHB	5/10	Thirty women with multiple sclerosis (MS)	PFMT, intravaginal neuromuscular electrical stimulation (NMES) and TTNS	12 weeks	Results suggest that PFMT alone or in combination with intravaginal NMES or TTNS is effective in the treatment of LUTS in patients with MS. The combination of PFMT and NMES offers some advantage in the reduction of PFM tone and symptoms of OAB.

Table 1. Continued

Title	Authors	PEDro scale score (/10)	Sample	Type of intervention	Frequency	Conclusion
Kinesitherapie et symptomes du bas appareil urinaire chez des patients atteints de la sclerose en plaques: etude controlee randomisee (Physiotherapy and neurogenic lower urinary tract dysfunction in multiple sclerosis patients: a randomized controlled trial)[17]	Gaspard L, Tombal B, Opsomer RJ, Castille Y, Pesch V, Detrembleur C	5/10	Women with MS	Pelvic floor muscle training vs. transcutaneous posterior tibial nerve stimulation	9 sessions	Pelvic floor muscle training and transcutaneous posterior tibial nerve stimulation improved symptoms related to urgency in the same way in MS patients with mild disability.
Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial[18]	Peters KM, MacDiarmid SA, Wooldridge LS, Leong FC, Shobeiri SA, Rovner ES, Siegel SW, Tate SB, Jarnagin BK, Rosenblatt PL, Feagins BA	5/10	100 adults with urinary frequency	Percutaneous tibial nerve stimulation to extended-release tolterodine	12 weeks	This multicenter, randomized trial demonstrates that percutaneous tibial nerve stimulation is safe with statistically significant improvements in patient assessment of OAB symptoms, and with objective effectiveness comparable to that of pharmacotherapy. Percutaneous tibial nerve stimulation may be considered a clinically significant alternative therapy for OAB.
Posterior tibial nerve stimulation for treating neurologic bladder in women: a randomized clinical trial[19]	Eftekhar T, Teimoory N, Miri E, Nikfallah A, Naeimi M, Ghajarzadeh M	4/10	Fifty women with OAB	Posterior tibial nerve stimulation) plus tolterodine or tolterodine alone treatment	12 weeks	Posterior tibial nerve stimulation could help urinary problems in women with a neurologic bladder.
Solifenacin succinate versus percutaneous tibial nerve stimulation in women with overactive bladder syndrome: results of a randomized controlled crossover study[20]	Vecchioli-Scaldazza C, Morosetti C, Berouz A, Giannubilo W, Ferrara V	4/10	40 women with OAB	Solifenacin succinate (SS) versus PTNS		This study demonstrates the effectiveness of SS and PTNS in women with OAB symptoms. However, greater improvements were found with PTNS.
Electroestimulacion del nervio tibial posterior para el tratamiento de la vejiga hiperactiva. Estudio prospectivo y controlado (Posterior tibial nerve stimulation in the management of overactive bladder: a prospective and controlled study)[21]	Bellette PO, Rodrigues-Palma PC, Hermann V, Riccetto C, Bigozzi M, Olivares JM	4/10	37 women with overactivity bladder symptoms	Posterior Tibial Nerve Stimulation and Sham Group	8 sessions	The posterior tibial nerve electrical stimulation is an effective treatment in OAB.
Posterior tibial nerve stimulation: is the once-a-week protocol the best option?[22]	Finazzi Agro E, Campagna A, Sciobica F, Petta F, Germani S, Zuccala A, Miano R	4/10	35 patients (28 females, 7 males) with OAB syndrome	Posterior tibial nerve stimulation	weekly stimulation sessions and 3 times per week	Our findings seem to show that the periodicity of stimulation does not effect the results of posterior tibial nerve stimulation treatment. The advantage of more frequent stimulation sessions is to achieve earlier to clinical improvement.

Table 1. Continued

Title	Authors	PEDro scale score (/10)	Sample	Type of intervention	Frequency	Conclusion
Prospective and randomized comparison of electrical stimulation of the posterior tibial nerve versus oxybutynin versus their combination for treatment of women with overactive bladder syndrome[23]	Souto SC, Reis LO, Palma T, Palma P, Denardi F	3/10	75 women with OAB	Combination of TENS with oxybutynin	12 weeks	The multimodal treatment was more effective and TENS alone or in association presented longer lasting results for clinical symptoms of OAB and QoL.
Effect of 12-weeks posterior tibial nerve stimulation in treatment of overactive bladder[24]	Ebid AA	3/10	60 women with OAB	Posterior tibial nerve stimulation and exercises	12 weeks	PTNS is effective to suppress detrusor overactivity
Neuromodulative treatment of overactive bladder–noninvasive tibial nerve stimulation[25]	Svihra J, Kurca E, Luptak J, Kliment J	2/10	28 women with OAB	Non-invasive stimulation of the tibial nerve	11weeks	Noninvasive stimulation had improved symptoms related to OAB, had no adverse events and was well tolerated.

The important variables found in the studies included the presence of symptoms of urinary frequency, urinary urgency, nocturia and/or urinary incontinence associated with bladder hyperactivity and the improvement of these symptoms after treatment. These variables guided the evaluation and direction of treatment for these patients. The evaluation methods found in the studies were varied. Regarding the quality of life, all of the studies used the same form of evaluation; however, there was a difference in the questionnaires used.

For the analysis of the methodological quality of the selected studies, the Portuguese version of the PEDro scale was used. The results are described in Table 2.

The main finding was the low and/or medium methodological quality of the studies, which may interfere with their reliability and application in clinical practice, although most of the studies presented a considerable number of samples. Thus, there is a need for more well-designed clinical trials on this participant.

DISCUSSION

The objective of the study was to evaluate the methodological quality of articles of the randomized clinical trial type on ESPTN in individuals with OBS through the criteria of the PEDro scale. We analyzed 15 articles; none of the articles included scores in all items of the PEDro scale.

Clinical studies are classified by the application of a scale (PEDro scale). The PEDro scale considers two aspects related to the quality of the clinical study: the internal validity and the fact that the clinical study presents enough statistical information that makes it interpretable. The PEDro scale classifies neither the external validity of the clinical trial nor the magnitude of the treatment effect.

To evaluate the internal validity, we verified the unequivocal existence of several criteria, including the randomization of the groups under study, concealment of the distribution by groups, initial comparability of the groups, the fact that patients, therapists and evaluators remained "blinded", analysis by "intention to treat" and suitability of the follow-up period. To evaluate the interpretability, we verified the existence of statistical comparisons between groups, estimates and measures of variability. These criteria form a scale with 10 items[9, 10].

Except for two items in the PEDro scale, the rest are based on the Delphi list, developed by Verhagen et al[26]. The Delphi list consists of a list of clinical study characteristics that are considered indicative of their quality by a group of clinical trial experts[26]. The PEDro scale includes additional items related to suitability of the follow-up period and statistical comparisons between groups. One Delphi list item (relative to eligibility criteria) is related to external validity, which does not reflect the quality dimensions assessed by the PEDro scale. This item is not used to calculate the methodology score that is presented in the search results (which is why 11 items in the scale provide a score of 10). However, this item has been maintained so that all items in the Delphi list are represented in the PEDro scale[9, 10].

It is important to emphasize that there are other guidelines that can be used as methodological guides to evaluate the procedures used in randomized clinical articles. According to Surbala et al.[12], the results of the study show that all neuromodulation methods were significantly effective ($p<0.05$) in reducing the symptoms of OAB. Perissinotto et al.[13] found

Table 2. Methodological evaluation by the PEDro scale of the studies that analyzed the effects of tibial posterior nerve stimulation in individuals with overactive bladder

Título	2	3	4	5	6	7	8	9	10	11	Total
Randomized trial of percutaneous tibial nerve stimulation versus sham efficacy in the treatment of overactive bladder syndrome[11]	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	8/10
Neuromodulation for overactive bladder with transcutaneous electrical nerve stimulation in adults −a randomized clinical study[12]	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	7/10
Transcutaneous tibial nerve stimulation in the treatment of lower urinary tract symptoms and its impact on health-related quality of life in patients with Parkinson disease[13]	Yes	No	Yes	Yes	No	Yes	No	No	Yes	Yes	6/10
Percutaneous tibial nerve stimulation versus tolterodine for overactive bladder in women: a randomised controlled trial[14]	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	6/10
Percutaneous tibial nerve stimulation versus electrical stimulation with pelvic floor muscle training for overactive bladder syndrome in women: results of a randomized controlled study[15]	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	5/10
Pelvic floor muscle training with and without electrical stimulation in the treatment of lower urinary tract symptoms in women with multiple sclerosis[16]	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	5/10
Kinesitherapie et symptomes du bas appareil urinaire chez des patients atteints de la sclerose en plaques: etude controlee randomisee (Physiotherapy and neurogenic lower urinary tract dysfunction in multiple sclerosis patients: a randomized controlled trial)[17]	Yes	No	Yes	No	No	No	No	Yes	Yes	Yes	5/10
Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial[18]	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	5/10
Posterior tibial nerve stimulation for treating neurologic bladder in women: a randomized clinical trial[19]	Yes	No	Yes	No	No	No	No	No	Yes	Yes	4/10
Solifenacin succinate versus percutaneous tibial nerve stimulation in women with overactive bladder syndrome: results of a randomized controlled crossover study[20]	Yes	No	Yes	No	No	No	No	No	Yes	Yes	4/10
Electroestimulacion del nervio tibial posterior para el tratamiento de la vejiga hiperactiva. Estudio prospectivo y controlado (Posterior tibial nerve stimulation in the management of overactive bladder: a prospective and controlled study)[21]	Yes	No	Yes	No	No	No	No	No	Yes	Yes	4/10
Posterior tibial nerve stimulation: is the once-a-week protocol the best option?[22]	Yes	No	No	No	No	No	Yes	No	Yes	Yes	4/10
Prospective and randomized comparison of electrical stimulation of the posterior tibial nerve versus oxybutynin versus their combination for treatment of women with overactive bladder syndrome[23]	Yes	No	No	No	No	No	No	No	Yes	Yes	3/10
Effect of 12-weeks posterior tibial nerve stimulation in treatment of overactive bladder[24]	Yes	No	No	No	No	No	No	No	Yes	Yes	3/10
Neuromodulative treatment of overactive bladder–noninvasive tibial nerve stimulation[25]	Yes	No	No	No	No	No	No	No	Yes	No	2/10

2. Random allocation of participants; 3. Hidden allocation of participants; 4. Similarity between groups at baseline; 5. Blinded participants; 6. Blinded therapists; 7. Blinded evaluators; 8. Measurement of 85% of the results; 9. Intention to treat; 10. Comparison between groups; 11. Accuracy and variability.

that after 5 weeks of treatment, the patients allocated to posterior tibial nerve stimulation (PTNS) demonstrated statistically significant reductions in the number of urgency episodes ($p=0.004$) and reductions in nocturia episodes ($p<0.01$).

Preyer et al.[14] reported in their study that micturition frequencies did not decline significantly ($p=0.13$) over time and no significant treatment differences were observed ($p=0.96$). However, another study[15] reported statistically significant reductions in the frequency of daily micturition, episodes of nocturia and urge incontinence in the two groups, but the differences were more substantial in women treated with PTNS; voided volume increased in both groups[15]. In the study by Lúcio et al.[16], all groups showed reductions in pad weight, the frequency of urgency and urge urinary incontinence episodes.

Another study[17] compared the efficacy of pelvic floor muscle training vs. transcutaneous PTNS and found no differences between the groups for quality of life or overactive bladder and frequency of urgency episodes ($p=0.197$, $p=0.532$ and $p=0.788$, respectively). In the study by Peters et al.[18], a 13-week subjective global response assessment for overall bladder

symptoms demonstrated that percutaneous tibial nerve stimulation participants achieved statistically significant improvement in bladder symptoms, with 54.5% of the participants reporting moderately or markedly improved responses from baseline compared to 20.9% of the sham participants ($p<0.001$).

Eftekhar et al.[19] observed that PTNS could alleviate urinary problems in women with a neurologic bladder. According to Vecchioli-Scaldazza et al.[20], PTNS showed greater effectiveness in patient perception of urgency and quality of life. Another study[21] found significant changes in symptoms such as frequency and nocturia ($p=0.003$ and $p=0.001$, respectively). Significant decreases in frequency, urgency, urge incontinence, and pad test results and an increase in fluid intake have also observed with PTNS[24].

All the findings indicate the positive efficacy of posterior tibial nerve stimulation; however, the studies had small sample sizes and included participants with several diseases, and some did not include a control group, complicating comparisons of the treatments and potentially biasing the results.

This article has shown that ESPTN is a conservative tool of physiotherapy that is less invasive than other therapies, is well tolerated by patients and is proving to be effective in the treatment of overactive bladder. However, few standardized clinical studies have been conducted, and only 26.6% of the articles included in this review scored above five items on the PEDro scale. There is a need for more clinical articles that follow the quality criteria for randomized clinical trials, allowing more reliable scientific results. Thus, caution should be exercised in interpreting the results of ESPTN articles. Every effort was made to identify studies in the systematic search of the electronic database. However, unpublished data may be available in dissertations and theses. Such texts were not considered in the selection process, which may be interpreted as a possible limitation of the present review.

Conflict of interest

None.

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