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Management of refractory overactive bladder in children by transcutaneous posterior tibial nerve stimulation: A controlled study

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Summary

Objective
To assess the objective efficacy of transcutaneous posterior tibial nerve stimulation in children presenting with overactive bladder resistant to well conducted treatment.

Material and method
This was a randomized, double-blind, controlled study on 20 children with OAB. All patients were previously treated with anticholinergic drugs associated with detrusor rehabilitation, diet advice, bladder-voiding hygiene and constipation treatment, with poor clinical results. Patients were randomized into two groups:

-Group A: treatment with PTNS (n = 11).
-Group B: sham treatment (n = 9).

The program lasted 12 consecutive weeks with two 30-minutes sessions a week.

Each patient underwent pre-stimulation urodynamic testing to validate bladder overactivity followed by a post-stimulation testing. Pre- and post-stimulation urodynamic parameters were compared in order to objectively evaluate the treatment's efficacy.

The patients noted their incontinence episodes for 7 consecutive days in a diary before the beginning of the program, in the middle and at the end of it: this led to computing an incontinence score (score ranged from 0 to 13, from good to poor). The difference between the pre-stimulation and post-stimulation score enabled to express clinical results in terms of poor (less than a 3-point decrease), medium (a 3 to 5-point decrease), good (6 to 8-point decrease), very good (final score ranged between 0 and 3). Children were questioned regarding their impression of being stimulated or not.

Results
In Group A, there were five very good clinical results (45%), one medium (10%) and five poor results (45%). In group B, nine very good results (66%) and three poor results (33%) were noted. Regarding urodynamic testing, volume voided during urgency (184 mL to 265 mL), maximal cystomanometry volume (215 mL to 274 mL) and volume at the onset of the first overactive detrusor contraction (ODC) (48 mL to 174 mL) were significantly increased in Group A ($p = 0.002$, $p = 0.024$ and $p = 0.001$) and maximal bladder pressure during ODC had decreased (61 to 46) ($p = 0.042$).

85% children in group A thought they were being stimulated vs. 70% in group B.

Conclusion
Even though we noticed urodynamics improvements in group A, which objectively supports the efficacy of TCTPNS, clinical results remained the same between the two groups. In spite of the small size of our sample, this underlines the placebo effect of any type management in this pediatric population. Studying precisely the maximal useful voltage and duration of stimulation should then be relevant in order to yield maximal benefits from this easy-to-use procedure.

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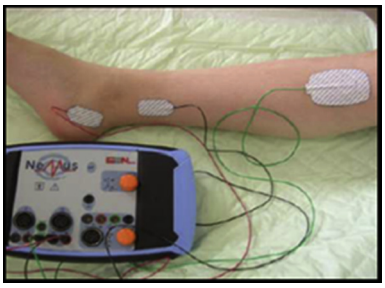

		Volume voided during urgency (mL)	Maximum pressure during overactive detrusor contraction	Volume at the first overactive detrusor contraction (mL)
Group A: Treated with PTNS	Initial mean	184	61	48
	Final mean	265	46	174
Group B: Placebo	Initial mean	184	56	61
	Final mean	181	67	80

Introduction

Overactive bladder (OAB) leads to functional disorders, urinary urgency, incontinence, pollakiuria and/or nocturia, all having an impact on the quality of life. In children, OAB is defined, according to the International Children's Continence Society (ICCS) [1], as involuntary detrusor contractions (spontaneous or provoked) observed during urodynamic testing when the bladder is filling up. Guidelines from the ICCS [2,3] recommend initially treating OAB with bladder rehabilitation and anticholinergic therapy.

Sacral anterior root stimulation (Brindley stimulator) has been validated in subjects with neurogenic and non-neurogenic bladder dysfunctions (even if its underlying mechanisms of action are still being debated) [4—8]. In children with idiopathic detrusor overactivity (IDOA), some studies on percutaneous and transcutaneous sacral anterior root stimulation or suprapubic bladder stimulation reported the same encouraging results validated in adults.

Posterior tibial nerve stimulation (PTNS) is *a priori* based on the same principle as sacral anterior root stimulation. It consists of stimulating the sensory afferent fibers of the posterior tibial nerve, located in the same area as the sacral anterior roots [9—11].

In adults, several publications on PTNS have underlined the efficacy of this technique on clinical, urodynamic, and quality of life criteria [9—20]. Furthermore, authors have reported that transcutaneous (with adhesive electrodes) PTNS (TCPTNS) yielded results similar to those obtained with percutaneous PTNS [7,9,21].

TCPTNS has several advantages in pediatric use: it is simple, non-invasive (even when compared to the percutaneous method), painless, and without any reported adverse events or drug interactions. The few reported side effects were skin reactions under the adhesive electrodes [22]. Contraindications to PTNS are rare (e.g., pacemaker), especially in children.

The stimulation is easy to use at home, and some portable devices are available upon medical prescription. But the management of such disorders in children may be quite complex due to psychological aspects or the environment.

This study focused on evaluating the objective efficacy of TCPTNS for the improvement of overactive bladder symptoms and their negative clinical, social and psychological consequences in children resistant to anticholinergic treatments.

Material and methods

This was a double-blind, randomized, controlled study on a sample of children presenting with OAB resistant to anticholinergic treatments.

These children were divided into two randomized groups: group A, TCPTNS; and group B, placebo (i.e., the same protocol without electrostimulation).

Inclusion criteria were:

- children over the age of 6 with primary or secondary non-neurogenic OAB validated clinically and by urodynamic tests according to the criteria defined by the ICCS,
- absence of anatomical abnormality in the lower urinary tract,
- partial response or non-response to anticholinergics after a well-conducted treatment of at least 6 consecutive months,
- contraindication to anticholinergics,
- anticholinergics were to be stopped during the entire duration of the study.

Exclusion criteria were:

- contraindications to treatment (history of cancer or radiotherapy, arrhythmia, pacemaker);
- presence of local lesions on both ankles,
- metal implants in the stimulated area,
- peripheral neuropathy,
- interruption of the protocol for more than two consecutive sessions led to data exclusion.

Two evaluation criteria were determined.

- The first was the urinary score calculated from a pre-established bladder diary over 7 consecutive days. This diary recorded the frequency of micturition episodes, urgency, daytime urinary continence as well as the presence of nocturia or enuresis (Appendix 1). We then established a score ranging from 0 to 13, from the best situation "0" to the worst one "13" (Appendix 2).

This score was calculated at the beginning, in the middle and at the end of the study. The results were then analyzed