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Transcutaneous posterior tibial nerve stimulation in pediatric overactive bladder: A preliminary report

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Summary

Background

Non-neurogenic overactive bladder (OAB) is a common problem in children that may affect their quality of life. Various methods of neuromodulation have been reported to treat refractory lower urinary tract dysfunction. Since most of these techniques are invasive, they are less applicable in children.

Objective

To evaluate the efficacy of transcutaneous PTNS in treatment of OAB in children, in a randomized clinical setting.

Study design

This study was single-blinded, prospective, sham controlled randomized trial. 40 children with non-neurogenic OAB refractory to behavioural and anticholinergic therapy were randomized either to test group or sham group. Neuromodulation was performed using two self-adhesive electrodes cephalad to medial malleolus. In test group the stimulation was given with voltage pulse intensity of 0 to 10 mA, pulse width of 200 μ s and frequency of 20 Hz. In sham group patch electrodes were applied to simulate the test group but no stimulation was given. In both groups, weekly session of 30 min was given for a period of 12 weeks. The OAB symptoms, severity of incontinence, number of voids daily (NV), average voided volume (AVV) and maximum voided volume (MVV) were evaluated before and after treatment.

Results

On assessment of subjective improvement of OAB symptoms, 66.66% patients reported cure and 23.81% patients reported significant improvement of symptoms in test group whereas in sham group only 6.25% patients reported significant improvement. In test group 71.42% patients reported complete improvement in incontinence whereas in sham group only 12.5% patient reported complete improvement. The AVV, MVV and NV improved significantly in test group ($p < 0.001$) as compared to sham group (Table).

Discussion

The present study is unique as none of the earlier studies in children were sham controlled. It is also first PTNS study in which patch electrodes were used; therefore it is completely noninvasive. This technique provides better patient acceptability and compliance. This study proved that, there is a definite effect of PTNS as compared to placebo because when patients from sham group were treated actively, they responded well. The present study has few limitations as it has relatively short follow-up period of 12 weeks. Relapse of OAB symptoms and maintenance schedule of PTNS need to be assessed further.

Conclusion

Transcutaneous PTNS is superior to placebo in treatment of non-neurogenic overactive bladder in children. In view of its effectiveness and acceptability we believe that transcutaneous PTNS should be part of pediatric urology armamentarium for treatment of OAB.

Table Assessment of parameters between groups before and after neuromodulation.

Group	Intervention	Incontinence				AVV (mL)	MVV (mL)	NV (no.)
		No	Mild	Moderate	Severe			
Test <i>N</i> = 21	Before PTNS	0	7 (33.33%)	8 (38%)	6 (28.5%)	68 (57–103)	116 (90–205)	11 (10–13)
	After PTNS	15 (71.42%)	5 (23.81%)	1 (4.76%)	0	89 (69–140)	190 (120–300)	7 (6–11)
Sham <i>N</i> = 16	Before PTNS	0	5 (31.25%)	7 (43.75%)	4 (25%)	74 (49–98)	110 (88–193)	10 (9–13)
	After PTNS	2 (12.5%)	5 (31.25%)	6 (37.5%)	3 (18.75%)	79.5 (55–100)	145.5 (105–200)	10 (7–12)

Note. PTNS = posterior tibial nerve stimulation; AVV = average voided volume; MVV = maximum voided volume; NV = number of voids.

Introduction

Non-neurogenic overactive bladder (OAB) is a common problem in children that may affect their quality of life. Conventional treatments such as behavioral techniques, bladder training and anticholinergic drugs are effective in most children with lower urinary tract symptoms. In spite of that, at least 20% of children are refractory to these treatments. Although many patients respond to anti-muscarinic agents, adherence to treatment is poor and discontinuation of these drugs is high due to intolerable side effects, high cost, and insufficient symptom improvement [1].

Neuromodulation therapy incorporates electrical stimulation to target specific nerves that control bladder function. The exact mechanism of action is unknown, but it is postulated that neuromodulation may have a direct effect on the bladder or a central effect on the micturition centers of the brain [2,3]. Various methods of neuromodulation have been reported to treat refractory lower urinary tract dysfunction. Since most of these techniques are invasive, they are less applicable in children. Posterior tibial nerve stimulation (PTNS) delivers neuromodulation to the pelvic floor through the sacral nerve plexus via the less invasive route of the posterior tibial nerve. To our knowledge, no published study has compared the effectiveness of PTNS in

a controlled trial. In this study we evaluated the efficacy of transcutaneous PTNS in treatment of OAB in children in a randomized clinical setting.

Material and methods

This study was a single-blinded, prospective, sham controlled randomized trial. Forty children with non-neurogenic OAB refractory to behavioral and anticholinergic therapy were randomized to either the test group (active treatment) or the sham group (Fig. 1). Inclusion criteria were non-neurogenic OAB unresponsive to behavioral therapy and at least 6 months of anticholinergic medication. Exclusion criteria were neurogenic bladder, dysfunctional voiding, defecation disorders, lower urinary tract surgery, urinary tract infection, and lower urinary symptoms secondary to anatomical anomalies such as posterior urethral valves, ureterocele, or ectopic ureter.

With 99% power and a 5% level of significance, a minimum sample size of 10 was required and using a design effect of two, the total sample size was 20 patients in each group (based on the results of previous uncontrolled studies). The study was approved by the institutional ethics committee.

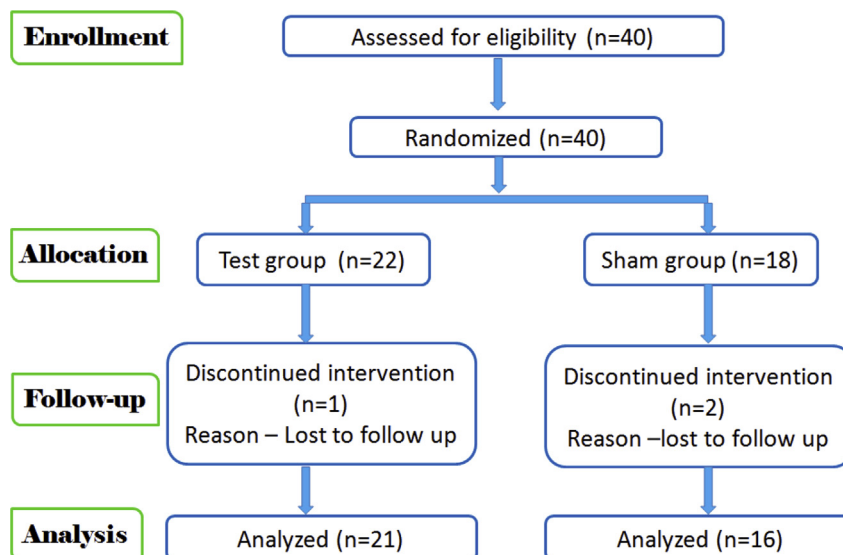


Figure 1 CONSORT diagram.

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