Efficacy of Parasacral Transcutaneous Electrical Nerve Stimulation in Treatment of Children with Overactive Bladder

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Abstract: Overactive bladder is one of the most common lower urinary tract dysfunction in children. The purpose of this study was to evaluate the efficacy of parasacral transcutaneous electrical nerve stimulation in treatment of children with overactive bladder. Forty children with overactive bladder, aged from 5 to 10 years with mean 7.6±1.63, were assigned randomly into two groups of equal number: study group received 20 minutes parasacral transcutaneous electrical nerve stimulation 3 times weekly for 2 months and control group received placebo parasacral transcutaneous electrical nerve stimulation with no current for the same time and number of sessions as in study group. The parents of the children in both groups were given advices in how to deal with their overactive bladder children. Amplitude per turn in mV of pelvic floor muscles and number of voids daily were assessed pre-treatment and 2 months post-treatment and visual analogue scale for complete improvement in symptoms was assessed only 2 months post-treatment in both groups. Results showed significant improvement in the 3 outcomes in study group (p<0.05) with non significant improvement in control group (p>0.05). It could be concluded that parasacral transcutaneous electrical nerve stimulation is effective non-invasive treatment of children with overactive bladder.

Key words: Parasacral Transcutaneous Electrical Nerve Stimulation - Overactive Bladder - Electromyography

INTRODUCTION

Overactive bladder (OAB), dysfunctional voiding and underactive bladder are lower urinary tract dysfunctions (LUTD) in children [1]. Pediatric LUTD is a disturbance of the emptying or filling phase of the LUT in children without neurological problems. Overactive bladder (OAB) is an alteration of the filling phase of the LUT and presents clinically by urgency. Frequency and both daytime and night-time incontinence are also usually present. In addition to the above uncomfortable symptoms, OAB may be associated with urinary tract infection, constipation, kidney scars and psychological problems [2]. Approximately 20% of 7-year-old children have moderate to severe urinary urgency and up to 20% of 4 to 6-year-old children experience occasional daytime incontinence, with 3% have wetting accidents twice or more weekly [3].

The pathophysiology of OAB is not well understood. Traditionally, OAB thought to be the result of maturation delay [4]. Recently, researchers shown that OAB may an association with sexual dysfunction. Researchers also suggest that OAB may come from the centrally located neurological dysfunction. The normal urination function needs the coordination of the brain, pons, spinal cord, peripheral autonomic sensory and somatic nervous system and the anatomical components of lower urinary tract [5]. Overactive bladder may also have a myogenic origin. The prevailing theory for many years has been that myogenic abnormalities are a primary cause of overactive bladder [6].

The diagnosis of pediatric OAB depends on the results of detailed history taking [7], physical and neurological examination [8], laboratory studies, urinary tract ultrasonography [9, 10], uroflowmetry with electromyography (EMG) [11] and urodynamic studies.
The treatment are composed of therapy for urinary tract infection, relief of constipation, anticholinergics, behavioral therapy, biofeedback therapy, \( \alpha \)-blockers, surgical treatment for anatomical bladder outlet obstruction and Botulinum-A toxin injections for refractory OAB or idiopathic sphincter dyssynergia [8].

Electrical stimulation was introduced as an alternative to treat OAB in children. The transcutaneous electrical nerve stimulation (TENS) unit is a noninvasive means of delivering surface electrical stimulation. TENS considered as one modality of physical therapy that used mainly to relief pain. Several studies have evaluated the use of surface neuromodulation in children with urgency and/or urge incontinence, but these studies have rarely focused on children with OAB. Hoebeke [12] and Bower [13] et al. first described the use of parasacral transcutaneous electrical stimulation (PSTENS) in children with refractory OAB and found good results with daily sessions during a period of 5 to 6 months.

The purpose of this study was to examine the efficacy of parasacral transcutaneous electrical nerve stimulation (PSTENS) in the treatment of children with overactive bladder (OAB).

**MATERIALS AND METHODS**

**Study Design:** This study was a randomized controlled trial, performed over the period from May to September 2011 at the physiotherapy department in New Kasr El-Aini Teaching Hospital, Cairo University, Egypt.

**Subjects:** Forty children aged 5-10 years (26 girls and 14 boys) referred to the physical therapy department from pediatric urologist with clinical diagnosis of OAB, were participated in this study. Children were selected for the study randomly assigned to two groups of equal number, study and control groups. They met the following inclusive criteria, which are 5 years or older and clinically diagnosed as OAB which was defined as the presence of characteristic symptoms of urgency, with or without daytime incontinence, accompanied by holding maneuvers to postpone voiding. Exclusion criteria consisted of LUT symptoms secondary to anatomical anomaly such as posterior urethral valves, ureterocele or ectopic ureter; neurogenic bladder; history of PSTENS in their past treatment and inability to comply with treatment requirements.

**Outcome Measures:** Outcomes measures were performed before and after 2 months treatment intervention. Baseline demographic variables include name, age and gender carried out. We use 3 criteria to evaluate the outcome in intent to treat analysis. First, measurement of myogenic activity (EMG activities) of the pelvic floor musculature (PFM), using Toennies NeuroScreen Plus system EMG biofeedback unit (Amplitude per turn A/T in mV of the pelvic floor). The surface electrodes were placed around the anal sphincter one on each side when child positioned in a comfortable crock-lying position and the ground electrode was placed in any distal part to the active electrodes as to the thigh. Children were instructed to contract repeatedly the PFM for 10 sec. and relax for 10 sec. with an empty bladder for 10 times without increasing abdominal pressure to inhibit the overactive detrusor contraction. When EMG showed detrusor-sphincter dyssynergia, children were also told to relax the anal sphincter during measurement [14]. Second, Visual Analogue Scale (VAS) from 0 to 10 was used by parents, in which 0 means no improvement and 10 means complete resolution of symptoms. VAS was assessed only 2 months post-treatment [15]. Third, the number of voids daily (NV) before and after treatment were evaluated in a voiding diary [16].

**Treatment Intervention**

**In Study Group (Group 1):** Twenty OAB children were subjected to be treated by TENS application, children were comfortably positioned in prone position, 2 superficial 3.5 cm electrodes were placed on each side of S3 and S2 [17]. Electrical energy produced by a generator (ACUTENS- HS- 922, GÉZANNE®). The procedure consisted of 24 sessions of TENS for 20 minutes each for 2 months, 3 times weekly. Frequency used was 10 Hz with a generated pulse of 700 \( \mu \)s [15]. Current intensity was increased to maximum level tolerated by the child.

**The Control Group (Group 2):** Twenty OAB children were subjected to be treated by TENS application with no current output to the children, as a placebo treatment, children were comfortably positioned in prone position, 2 superficial 3.5 cm electrodes were placed on each side of S3 and S2. The type generator, time of sessions and number of session were as in the study group.

The parents of all children in both groups of this study were given the following advices in how to deal with your OAB child: 1) voiding before sleeping, 2)
increasing volume of liquid ingested daily, 3) eating foods rich in fiber, 4) refraining from postponement of voiding when experiencing symptoms of urgency, 5) girls were asked to prioritize voiding comfort by postponement, 6) options of toilet seat adapters and foot supports to adjust for height issues, 7) at the moment of urination the child should slightly flex the spine and relax the abdominal musculature, 8) the stomach “should be sleeping” at the time of urination and 9) no medication was given to patients before or during treatment program.

All parents signed an agreement to participate in the study. Parents were told that one group of patients would receive inactive treatment.

Data Analysis: All statistics were calculated by using the statistical package of social sciences (SPSS) version 16. Descriptive statistics (mean and standard deviation) were computed for all data. Paired t-test was applied within the group for A/T in mV of the PFM and NV daily. Unpaired t-test was applied for age, A/T in mV of the PFM and NV daily and Mann-Whitney U-test was applied to compare measureable parameters for VAS for complete resolution of the symptoms between groups.

RESULTS

The mean age was 7.6±1.69 years of the study group and was 7.5±1.61 years of the control. There were no significant differences in age between the study and control group as P-value was 0.92 (P> 0.05).

The mean changes in A/T in mV of the PFM and NV daily for the study and control group pre and post-treatment in both groups are summarized in Table 1. Comparison revealed that there were no significant differences in mean changes for all measurements between the two groups pre-treatment (P> 0.05). Results of A/T in mV of the PFM and NV daily showed that there was a significant difference pre and post-treatment in study group (P<0.05) while there was no significant difference in control group (P> 0.05). Fig. 1 demonstrates the mean values difference of A/T in mV of the PFM pre and post-treatment in both groups and Fig. 2 demonstrates the mean values difference of NV daily pre and post treatment in both groups.

The results of the VAS of complete resolution of the symptoms for the study and control group post-treatment in both groups are summarized in Table 2. Results revealed statistically significant difference between both groups post-treatment (P<0.05) in favor of the study

Table 1: Amplitude per turn (A/T) in mV of the PFM and NV daily for the study and control group

<table>
<thead>
<tr>
<th></th>
<th>Study group</th>
<th>Control group</th>
<th>P-value</th>
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<tbody>
<tr>
<td>A/T in mV</td>
<td></td>
<td></td>
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<tr>
<td>Pre-treatment</td>
<td>0.22±0.16</td>
<td>0.21±0.01</td>
<td>0.935</td>
</tr>
<tr>
<td>Post- treatment</td>
<td>0.07±0.07</td>
<td>0.21±0.01</td>
<td>0.001</td>
</tr>
<tr>
<td>NV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-treatment</td>
<td>8.05±0.83</td>
<td>7.85±0.81</td>
<td>0.772</td>
</tr>
<tr>
<td>Post- treatment</td>
<td>4.60±0.99</td>
<td>7.65±0.59</td>
<td>0.003</td>
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</tbody>
</table>

Table 2: Visual Analogue Scale (VAS) of complete resolution of the symptoms for the study and control group post-treatment

<table>
<thead>
<tr>
<th></th>
<th>Study group</th>
<th>Control group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groups</td>
<td>Post-treatment</td>
<td></td>
<td></td>
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<tr>
<td>Study group</td>
<td>5.00±4.60</td>
<td></td>
<td>0.002</td>
</tr>
<tr>
<td>Control group</td>
<td>0.50±0.51</td>
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Fig. 1: Amplitude per turn (A/T) in mV of the PFM pre and post-treatment in both groups

Fig. 2: Number of voids daily pre and post-treatment in both groups

Fig. 3: Visual Analogue Scale (VAS) of complete resolution of the symptoms post-treatment in both groups
group. Fig. 3 illustrates the mean values difference of VAS of complete resolution of the symptoms post-treatment in both groups.

**DISCUSSION**

This study was carried out to examine the efficacy of PSTENS in the treatment of children with OAB. Children with OAB experience not only urinary urgency and/or incontinence, but also might be predisposed to urinary tract infections and, in rare instances, renal injury [12, 18]. Treatment of OAB in pediatric patients typically begins with conservative measures such as timed voiding and treatment of constipation [19]. For children whose symptoms persist, the addition of pharmacologic therapy typically involves anticholinergic medications, such as oxybutynin, which antagonize the muscarinic receptors in the detrusor muscle of the bladder, thereby increasing the bladder capacity and micturition threshold pressure [20]. The use of anticholinergics has disadvantages, such as low compliance, prolonged use and side effects [21].

Clinically a noted effect of PSTENS is improved rectal sensation and evacuation. This is understandable as the sacral nerves supply parasympathetic input to activate the descending colon, sigmoid and rectum and inhibit the internal anal sphincter. Neuromodulation of the bowel is possible and given the influence of the bowel on bladder function [1].

Results of this study demonstrated significant improvements in all the 3 outcomes criteria [there was a viable reduction in myogenic activity (Δ/T in mV) of PFM, there was a reduction in NV daily and there was a complete improvement in symptoms (VAS)] in the study group which treated with active PSTENS plus advices to the parents of the children in how to deal with their OAB children and no significant improvement in control group which treated with inactive PSTENS as a placebo treatment. It is the first time to use EMG only without uroflowmetry to measure the myogenic activity of pelvic floor musculature in children with OAB.

The findings of this study are consistent with previously reported results which suggested that treatment of children suffering from OAB with PSTENS. TENS is a very simple method and the recurrence rate is acceptable for PSTENS, ranging from 10% to 25% [3, 12, 15].

Hoebeke [12] and Bower [13] et al. reported the first 2 series of PSTENS over S3 for children with OAB. The treatment was performed at home under parental supervision. Treatment was daily for 1 to 2 hours during a period of 5 to 6 months. Hoebeke et al [12] was performed PSTENS in 15 girls and 26 boys with OAB that was unresponsive to other kinds of treatment. One year after treatment the rate of complete resolution of symptoms was 51.2%. Bower et al. [13] used PSTENS or TENS over the suprapubic area in 15 girls and 2 boys. They used a frequency of 10 Hz, with PSTENS to the lower sacral area. Treatment was twice daily for 1 to 5 months. Each session lasted 1 hour. They reported complete resolution of symptoms in 7 of 15 children with daytime incontinence. In this study, it was a short-term study of PSTENS in children; PSTENS was performed for 20 minutes 3 times weekly for a maximum of 24 sessions in period of 2 months. Frequency used was 10 Hz.

Barroso et al. [22] reported that with a mean number of 13 sessions, 63% patients had resolution of symptoms after treatment. The same group published the longest follow-up for PSTENS in children (mean of 35 months, ranging from 6 to 80 months) [23]. For those with more than 2 years of follow-up (n = 30), 73% had complete improvement of symptoms. Lordelo et al. [15] noted a complete resolution of symptoms in 62% in the test group and in no patient in the sham group (P < 0.001). Partial improvement was reported by 38% and 31% in the test and sham groups, respectively. There was a significant improvement of the average and maximum voided volume in the test compared to the sham group. In the present study we used EMG to examine the efficacy of PSTENS in the myogenic activity of pelvic floor musculature as there was a great reduction in the myogenic activity after treatment children with OAB with PSTENS under the supervision of the physiotherapist in the hospital.

The role of spinal stimulation in children remains to be well defined. It is known that electrical stimulation acts directly not only on the muscle fibers, but also on the reflexes. Activation of the inhibitory sympathetic neurons and inhibition of parasympathetic excitatory neurons that go to the bladder may have a role in the action mechanism of the electrical stimulation. It has been also proposed that the pudendal nerve could be activated. This mechanism consequently would relax the bladder and inhibit detrusor overactivity by external urethral sphincter contraction or by inhibition of interneurons [24]. PSTENS as a neuromodulation is a valuable treatment option for children with OAB. The non-surgical techniques can be applied as an alternative to standard conservative treatment, or may be tried if such a treatment fails.

In the current study we give advices to children’s parents in how to deal with your OAB child in both groups of the study and there was no significant
improvement in treatment with placebo PSTENS in the control group which means that the advices only were not sufficient in complete resolution of the symptoms of OAB in children.

In the present study, more than one method of evaluation was used to confirm findings definite efficacy of PSTENS in the treatment of children with OAB as it is the 1st time to use PSTENS as a short-term study with using EMG to measure the myogenic activity of the PFM. Using placebo PSTENS with the advices to the parents in the control group was non-significant, but use of PSTENS with the advices to the parents gave a significant improvement in study group. The results of this randomized controlled trial contribute to the existing body of knowledge. Evidence has shown that EMG studies A/T in mV of PFM, NV and VAS of complete resolution of the symptoms gave a significant difference in favor of study group. The advices are not sufficient treatment as symptoms were still present after treatment in control group.

CONCLUSION

The finding of this study suggest that using PSTENS in treatment of children with OAB was effective. There was greater improvement in myogenic activity of pelvic floor muscles as it was returned to normality, reduction number of voids daily and complete resolution of the symptoms in children underwent PSTENS in study group compared to the control group.

REFERENCES