Transcutaneous Parasacral Electrical Stimulation vs Oxybutynin for the Treatment of Overactive Bladder in Children: A Randomized Clinical Trial

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Purpose: We determined the effectiveness of 2 methods to treat overactive bladder in children using intragroup and intergroup comparisons in a randomized clinical trial.

Materials and Methods: Nine boys and 19 girls with a mean ± SD age of 6.4 ± 2.18 years were randomly divided into group 1—parasacral transcutaneous electrical stimulation with placebo drug and group 2—oxybutynin with sham scapular electrical therapy. Success was assessed by 1) the rate of complete symptom resolution, 2) a visual analog scale of 0 to 10, 3) the dysfunctional voiding score system, 4) voiding diary records, 5) Rome III criteria and 6) side effect frequency in each group.

Results: A total of 13 and 15 patients were randomized to groups 1 and 2, respectively. Symptoms completely resolved in 6 patients in group 1 (46%) and 3 in group 2 (20%) ($p = 0.204$). A statistically significant improvement was found in the 2 groups in the dysfunctional voiding score system and voiding diary records. However, no statistically significant difference was found between the groups in the visual analog scale score, voiding frequency, and maximum and mean voided volume ($p = 0.295$, 0.098, 0.538 and 0.650, respectively). Constipation improved in 100% of group 1 patients but in only 55% in group 2 ($p = 0.031$ vs 0.073). Group 1 showed no side effects while dry mouth, hyperthermia and hyperemia developed in 58%, 25% and 50% of group 2 patients ($p = 0.002$, 0.096 and 0.005, respectively). Treatment was discontinued by 13.3% of patients in group 2.

Conclusions: Parasacral transcutaneous electrical stimulation was as effective as oxybutynin to treat overactive bladder in children. However, transcutaneous parasacral electrical stimulation was more effective against constipation and showed no detectable side effects. Oxybutynin was more effective for decreasing voiding frequency.

Key Words: urinary bladder, overactive; transcutaneous electric nerve stimulation; oxybutynin; constipation; adverse effects

Abbreviations and Acronyms

DVSS = dysfunctional voiding score system

OAB = overactive bladder

PTENS = parasacral transcutaneous electrical stimulation

UTI = urinary tract infection

VAS = visual analog scale

VF = voiding frequency

VUR = vesicoureteral reflux

VV = voided volume

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Study received institutional review board approval.

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Overactive bladder in children is defined as voiding urgency usually associated with daytime urinary incontinence, frequency and constipation, in addition to nocturnal enuresis or nocturia in some cases.[1]

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It is present in approximately 6% of girls and 3.8% of boys at age 7 years.[2] It is also associated with emotional and behavior changes such as low self-esteem, social isolation, shyness, aggression, transgression and attention deficit hyperactivity disorder.[3,4] OAB is a major cause of UTI in children older than 4 years and a risk factor for VUR.[5,6] The risk of renal scarring increases substantially in children with UTIs and VUR.[7] Therefore, OAB must be diagnosed and properly treated.

Behavioral therapy can improve OAB symptoms but frequently other therapy is required. Antimuscarinics, especially oxybutynin, were claimed to improve approximately 60% of cases,[8,9] although the rate of complete resolution of symptoms has been lower than 30%.[10,11] Side effects such as dry mouth, constipation, hyperemia and hyperthermia develop in about 50% of patients and 10% need to interrupt treatment.[12]

Based on previous studies of home electrical stimulation[13] we began performing outpatient treatment with 20 sessions of PTENS at 10 Hz for 20 minutes each 3 times per week. This treatment achieved complete resolution of symptoms or significant improvement in 94% of cases[14] and long-term (at least 2 years) symptom resolution in 73%.[15] In a randomized clinical trial PTENS was more effective than sham treatment.[16]

Although there are studies of oxybutynin and PTENS to treat OAB in children, to our knowledge no group has compared the 2 methods. In a randomized clinical trial we compared the efficacy of oxybutynin and PTENS in children with OAB. Because oxybutynin has been used for decades and it is a well established treatment for OAB in children, we hypothesized that PTENS would not be inferior to this medication.

MATERIAL AND METHODS

The current prospective, randomized, blinded clinical trial was approved by the institutional review board. We selected children for study inclusion at ages between 4 and 17 years who had urgency, a bell-shaped uroflowmetry curve, post-void residual urine volume less than 10% of bladder capacity expected for age or greater than 20 ml, DVSS greater than normal (6 in boys and 9 in girls), voiding urgency at least 3 times per week and no previous treatment. Patients with signs of neurological disease or urinary tract anatomical problems were excluded from study or excluded if diagnosed after allocation. All parents or legal guardians of participants agreed to treatment and provided free, informed consent.

After the sessions patients were instructed to return for medical appointments at the scheduled time, or as soon as UTI symptoms or changes in the urinary pattern were present.

Each child completed a questionnaire on urinary and intestinal history. Constipation was assessed using Rome III criteria, on which at least 2 positive answers of the 6 questions were considered sufficient for diagnosis. A DVSS score questionnaire validated in Portuguese was applied to the child to assess voiding dysfunction.[17] Physical examination consisted of neurological examination to rule out changes related to dermatome innervations from S2 to S4. If any change was detected, the child was referred to a pediatric neurosurgeon.

We instructed patients to complete a voiding diary for 3 consecutive days, mainly to record VF, and mean and maximum VV. Urinalysis, urine culture, urinary tract ultrasound, post-void residual urine volume measurement, uroflowmetry and voiding cystourethrogram were done in patients with a history of febrile UTI in infancy. When VUR was diagnosed, patients underwent renal scintigraphy with dimercaptosuccinic acid to identify possible renal scarring.

All children received voiding and intestinal instructions, representing standard urotherapy. Instructions included scheduled voiding every 3 hours or not allowing 4 hours to pass without voiding, avoiding the ingestion of coffee, tea, soda, chocolate and citrus fruits during treatment, urinating before bedtime, ingesting a greater amount of liquid during the day, not retaining urine when there was urinary urgency, eating high fiber foods, using the toilet seat reducer when necessary and using a footrest when the toilet was high and the feet of the child could not reach the ground.

We selected 28 patients by randomization using a website (http://randomized.com/). Group 1 included 13 patients who underwent PTENS 3 times per week and receive placebo daily. Group 2 included 15 patients treated with oxybutynin daily and with scapular electrical stimulation (sham treatment) 3 times per week. Patients and parents were blinded to treatment type.

The colors and flavors of oxybutynin and placebo were identical. All patients received the same dose of 0.3 mg/kg per day twice daily for the duration of the electrical stimulation sessions.

The electrical stimulation technique consisted of the application of electrical current produced by a Dualpex Uro 961 generator (Quark®) using surface electrodes for a total of 20 sessions of 20 minutes each 3 times per week on alternate days. We used a symmetrical biphasic square current pulse with a frequency of 10 Hz, pulse width 700 milliseconds and intensity increased up to the level of below the motor threshold (fig. 1). Two surface electrodes were placed symmetrically on the parasacral region and 2 were placed symmetrically on 1 scapula. Stimulation was done using the parasacral and scapular electrodes in groups 1 and 2, respectively.

Posttreatment evaluation was performed 3 months after the beginning of treatment using a questionnaire administered by a professional blinded to patient group. We made intragroup and intergroup comparisons using a VAS to evaluate symptoms, the DVSS, comparative evaluation of voiding diaries, Rome III criteria to assess whether constipation improved and the frequency of side effects in the 2 groups.

If necessary, an active search was performed by telephone to discover why patients discontinued treatment and did not return and why those who completed treatment did not return for consultation. Any study