Journal of Pediatric Urology (2016) 12, 293.e1–293.e5

Parasacral transcutaneous electrical stimulation for overactive bladder in children: An assessment per session

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Keywords
Urinary bladder; Overactive; Transcutaneous electrical nerve stimulation; Incontinence; Children

Received 25 November 2015
Accepted 20 March 2016
Available online 16 April 2016

Summary

Objective
Neuromodulation has emerged as an effective therapeutic option for treatment of OAB in children. However, to our knowledge, no study has yet evaluated the results of neuromodulation on a session-by-session basis. The aim of this study was to evaluate the rate of complete response of overactive bladder (OAB) symptoms for each session of transcutaneous electrical stimulation (TENS), in a protocol of 20 sessions of therapy.

Method
This is a prospective study of the improvement of LUTS in children with isolated OAB. Included in this study were children over the age of 4 years who complained of urinary urgency, had bell—or tower-shaped uroflowmetry patterns, and post-void residual <10% of expected capacity for their age and/or less than 20 mL. No patient was treated with an anticholinergic. Children were excluded with lower urinary tract symptoms (LUTS) secondary to urinary tract abnormalities. All patients underwent parasacral transcutaneous neurostimulation (TENS). The development of symptoms was observed right before each session using a visual analog scale (VAS) in which 0 means the absence of improvement and 10 represents maximum improvement of symptoms.

Results
We noted a complete resolution of symptoms (urgency, urge incontinence, frequency, and holding maneuvers) in some patients starting after the third session. In the 10th and 20th (last) sessions, 12 (17.4%) and 38 (55.1%) patients reported a complete resolution of symptoms. After complete resolution, 12 (17.4%) patients reported that their symptoms worsened to a minimum level of 40% improvement, but this was temporary and all returned to 100% improvement. Children who showed an improvement level greater than 50% in the fifth treatment session were 4.18 ($p = 0.007$) times more likely to have success in the last treatment session.

Conclusion
We found that a patient can experience complete symptom resolution as quickly as following the third session of TENS. The complete response rate progressively increases with the number of sessions, slowly until the 12th session and more rapidly after that. When symptom improvement of at least 50% is reported in the fifth session, there is a higher chance that the patient will have full resolution of symptoms at the end of treatment.

Table Demonstration of demographic and clinical data ($n = 69$ children).

Girls (%)	42 (60.9%)
Age, years (average ± SD)	8.44 (±3.05)
Urgency (69)	69 (100%)
Urge incontinence (69)	54 (78%)
Frequency (69)	45 (65%)
Enuresis (63)	42 (66.7%)
Holding maneuvers (69)	46 (66%)
Urinary tract infection (69)	38 (55%)
Constipation (36)	18 (50%)

http://dx.doi.org/10.1016/j.jpurol.2016.03.011

Introduction

Overactive bladder (OAB) is characterized by the presence of urgency, with or without urge incontinence, generally with frequency and nocturia, in the absence of any neurological or anatomical disease [1]. OAB is associated with lower urinary tract infections, constipation, urinary incontinence, and vesicoureteral reflux, and has psychological repercussions in children [2—4].

Electrical stimulation has emerged as an effective therapeutic option in such cases. In 2001, Hoebeke et al. and Bower et al. first described the results of the use of transcutaneous electrical nerve stimulation (TENS) in treatment of lower urinary tract symptoms (LUTS) [5,6]. Although they reported success with this technique, the treatment consisted of daily sessions over the course of months.

In a study conducted in 2006, this research group showed that electrical nerve stimulation treatment conducted on an outpatient basis three times a week for a total of 20 sessions successfully resolved symptoms of OAB in 62% of patients [7]. In another long-term study with the same methodology, this same group showed that patients with urinary urgency or incontinence prior to treatment (84% and 74%, respectively) remained asymptomatic for at least 2 years following parasacral TENS treatment [8].

Two randomized studies have shown parasacral TENS to be more effective than placebo treatment [9,10]. However, there is still no real standardization of the parameters used in electrical stimulation. The frequency, pulse width, application time, and number of sessions used differ from study to study [11,12].

Most studies report the success rate achieved at the end of the final session, with few reporting success rates in patients monitored over longer periods of time [5—9]. The number and the duration of sessions vary in the different studies, ranging from daily sessions to three times a week over periods of 1—6 months [12], showing that the choice of the ideal treatment time is empirical. Parents often ask how long treatment will last and when they can expect to see a partial improvement or complete resolution of symptoms. However, to our knowledge, no study has yet evaluated the result of neuromodulation on a session-by-session basis.

The standard methodology used in this institute for the application of TENS consists of a total of 20 sessions; however, it has yet to be established whether this duration of treatment is ideal. The aim of the present study was to evaluate the rate of complete response to transcutaneous electrical nerve stimulation (TENS) for the treatment of the symptoms of overactive bladder (OAB) at each session in a treatment protocol consisting of 20 sessions.

Materials and methods

This is a prospective study of the improvement in LUTS in children with OAB alone. Children over 4 years of age complaining of urinary urgency, with or without daytime incontinence as perceived by their parents, with bell- or tower-shaped uroflowmetry patterns and post-void residual volume $<$10% of the expected bladder capacity for their age [capacity in mL $=$ (1 $+$ age) $\times$ 30 or $>$20 mL] [1] and/or $<$ 20 mL were included in the study. None of the patients was being treated with anticholinergics. Children with a urinary tract infection were only included in the study if urinary symptoms persisted following treatment of the infection.

The same pediatric urologist evaluated the symptoms in all the children. Children were excluded from the study with LUTS secondary to urinary tract abnormalities such as posterior urethral valve, ureterocele, or ectopic ureter; with neurological disorders; those unable to attend the clinic regularly for treatment; and those whose parents or guardians refused to sign the informed consent form.

The treatment consisted of symmetric application of electric currents through surface electrodes in the parasacral region (between S2 and S4). Electrical stimulation was produced using a Dualpex Uro 961 electrical stimulus generator (Quark, Piracicaba, Brazil). The electrodes used measured 5 $\times$ 5 cm, were coated in rubber, and were self-adhesive. A symmetrical biphasic current with a frequency of 10 Hz and pulse width of 700 μs was applied. The intensity was increased to a level just below the motor threshold, according to the patient's tolerance level. The 20-min sessions were administered three times a week for a total of 20 sessions.

All patients received the following instructions: to go no longer than 3 h without urinating; avoid the intake of coffee, tea, sodas, chocolate, and citrus fruits during treatment; urinate before going to sleep; drink more liquid during the day; and avoid postponing urination when experiencing urgency. If constipated, the children were instructed to eat fiber-rich foods and were referred to a specialist. An illustrated booklet adapted for children and containing the guidelines mentioned above was created. Standard urotherapy was reinforced during each session.

The following criteria were used to evaluate the success of treatment: (1) At the end of each session, the parents/guardians were asked whether they felt that the child was cured, if there had been a slight or major improvement, or whether the clinical condition remained unchanged; (2) The presence of symptoms was evaluated immediately prior to each session using a visual analog scale (VAS) in which 0 reflected the absence of any improvement and 10 represented the greatest improvement possible. The value obtained was multiplied by 10 to transform the variable into a percentage. The symptoms were considered resolved if the parents/guardians reported that the child was asymptomatic and a VAS score of 10 was obtained. The parents/guardians and children were instructed to record a score of 10 if all the daytime symptoms had disappeared. Mean urinary frequency and volume were evaluated using a 3-day bladder diary prior to and following treatment. In addition, urinary symptoms were recorded using the Dysfunctional Voiding Symptom score (DVSS) and constipation was evaluated according to the Rome III criteria for children.

For the descriptive analysis, means and standard deviations were used. Descriptive frequencies, the paired *t* test, and the Wilcoxon test were used to evaluate complete resolution of symptoms according to the number of treatment sessions. The Statistical Package for the Social Sciences (SPSS), version 21.0 for Windows, was used for the