Predictors of outcome in children and adolescents with overactive bladder treated with parasacral transcutaneous electrical nerve stimulation

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Summary

Background
Parasacral transcutaneous electrical nerve stimulation (TENS) has emerged as an effective treatment for overactive bladder (OAB) in view of its high success rates in improving lower urinary tract symptoms and constipation, with no direct side effects. However, the clinical characteristics associated with the outcomes remain to be established.

Objective
The aim of this study was to evaluate potential predictors of outcome in children with OAB treated using parasacral TENS.

Study design
This was a prospective study of children with symptoms of isolated OAB, enrolled consecutively to the study and treated with parasacral TENS (figure). Isolated OAB was defined as the presence of urinary urgency with no signs of dysfunctional voiding. The symptoms were considered completely resolved when a patient’s parents/guardians or the patients themselves reported a 100% improvement. Parasacral TENS was performed twice weekly for a total of 20 sessions of 20 min each at 10 Hz. The potential predictive factors evaluated were: sex, age, daytime incontinence, nocturia, a prior history of urinary tract infection, the presence of nocturnal enuresis, constipation and holding maneuvers.

Results
Eighty-three patients with a mean age of 7.8 ± 2.8 years were included in the study. Complete resolution of symptoms was achieved in 47 (56.6%). Following parasacral TENS treatment, a significant response was reported in 96.4% of cases. Of the 55 patients with nocturnal enuresis, partial resolution was achieved in 30 cases (54.5%), with a statistically significant association between nocturnal enuresis and the patient’s response to treatment (p < 0.004; OR = 4.4, 95% CI 1.5 – 12.5). No other factor was associated with response to treatment.

Discussion
To the best of our knowledge, this association between nocturnal enuresis and failure to respond to parasacral TENS treatment for lower urinary tract dysfunction has not previously been reported. The identification of factors capable of predicting therapeutic failure may allow professionals to select those specific patients who would benefit from a multimodal approach in the treatment of this pathology, which has such a significant impact on the quality of life of affected patients.

Conclusions
Nocturnal enuresis was the only symptom associated with a poor outcome following parasacral TENS treatment in children with OAB.

Figure
Child during a session of parasacral TENS.
Introduction

Overactive bladder (OAB) is a clinical condition characterized by the presence of "urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection (UTI) or other obvious pathology" [1]. OAB is present in around 5–12% of children between 5 and 10 years of age [2]. In its isolated form in which the emptying phase of the lower urinary tract (LUT) is normal, a bell or tower-shaped curve is seen at uroflowmetry and there is no post-void residual urine. In addition, electromyography will reveal no perineal activity [1].

OAB is associated with vesicoureteral reflux, urinary tract infection, psychological problems, and constipation [3]. When not properly treated, OAB increases the likelihood of developing LUT symptoms (LUTS) in adulthood [4].

The usual initial treatment of OAB is standard urotherapy (behavioral therapy). However, the success rate with this treatment is not high, particularly in more symptomatic patients [5]. The most common pharmacological management for OAB is the use of oxybutynin. However, although most patients show some improvement with this drug, the rate of complete resolution of LUTS is low and well-known side effects affect around half of all patients [6].

Neuromodulation has emerged as an effective treatment for OAB in view of its high success rates in improving LUTS and constipation with no direct side effects [7,8]. In 2006, this same group of investigators described the short-term treatment results obtained with transcutaneous parasacral electrical nerve stimulation (parasacral TENS) in outpatient children. Symptoms improved significantly in 94% of cases [9]. In 2009, a long-term follow-up study showed complete resolution of urinary symptoms in 73% of cases [10]. Two randomized clinical trials confirmed the effectiveness of parasacral TENS for the treatment of OAB in children [11,12]. Although high improvement rates have been documented, no studies have evaluated factors associated with the response to parasacral TENS in patients with OAB. The objective of the present study was to identify which factors are predictive of a patient’s response to parasacral TENS.

Materials and methods

The institute’s internal review board approved this study protocol, and all participants or their legal guardians signed an informed consent form. Eighty-three patients aged 4–16 years diagnosed with OAB were studied prospectively. In all cases, initial evaluation included collecting patients’ clinical data and investigating past urinary infections, diseases affecting the genital and urinary tracts, and alterations to bowel habits. The children were then submitted to a general physical examination, urological examination, and a directed neurological examination. The Dysfunctional Voiding Scoring System (DVSS), validated for use in Brazilian Portuguese [13], was used to evaluate symptoms, while constipation was evaluated using the Rome III criteria.

Next, patients or their parents/guardians were asked to fill out a 3-day bladder diary and the following tests were requested: urinalysis, urine culture with antimicrobial susceptibility testing, ultrasonography with measurement of post-void residual urine volume, and uroflowmetry.

All patients undergoing parasacral TENS were screened consecutively for inclusion in the study. The inclusion criteria consisted of individuals aged 4–16 years with a complaint of urinary urgency, a bell-shaped curve at uroflowmetry [1], and post-void residual volume <10% of the expected bladder capacity for age or <20 mL at ultrasonography [1]. The exclusion criteria were the presence of neurogenic bladder, anatomical abnormalities of the genital and urinary tracts, current urinary infection, and present or past use of any medication for the treatment of urinary dysfunction (such as anticholinergics). The potential predictive factors evaluated were age, sex, daytime incontinence, urinary frequency, nocturia, history of UTI, nocturnal enuresis, holding maneuvers, and constipation.

The presence of nocturnal enuresis was established from the answer to a yes/no question. Those who responded positively were then asked about the frequency, with possible answers being five to seven times a week, two to four times a week, once a week, or occasionally. For the purpose of analysis, children’s age was dichotomized as ≤9 years or ≥10 years of age. This cut-off point was chosen with the objective of creating two evenly sized groups. For some of the variables evaluated, the number of individuals is less than the total number of participants in the study because some data from patient follow-up were not collected, particularly data on constipation.

Parasacral TENS consisted of the application of electric currents through surface electrodes on the parasacral region. Electrical stimulation was produced using a Dualpex Uro 961 electrical stimulus generator (Quark, Piracicaba, SP, Brazil). To generate stimuli, 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. The 20-min sessions were administered three times a week for a total of 20 sessions, always by the same physiotherapist.

The patients did not receive any treatment for OAB prior to neuromodulation. All the patients received standard urotherapy consisting of a booklet containing illustrations aimed at providing the patient with information on (1) voiding before sleeping, (2) increasing fluid intake, (3) eating foods rich in fiber, and (4) avoiding postponing voiding when experiencing urgency. No medication with any effect on the bladder was used prior to or during treatment.

The patients were re-evaluated soon after the end of treatment using a questionnaire to collect data on urinary and bowel symptoms. In addition, the DVSS and the Rome III criteria were applied. To evaluate the effectiveness of the method, a visual analog scale (VAS) was used to record the improvement reported by the parents/guardians or by the patients themselves at the end of parasacral TENS treatment. The criteria defined by the International Children’s Continence Society [1] were applied: no response, 0–49%; partial response, 50–89%; response, 90–99%; and complete response, 100% improvement.

Data analysis was performed using the SPSS statistical software program, version 21 (IBM, Armonk, NY, USA). The chi-square test was used to evaluate the cause and effect
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