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New device and new concept for treating nocturnal enuresis: Preliminary results of a phase one study

Ubirajara Barroso Jr [a,*], Patrícia Lordêlo [b], Alcina Teles [b], Daniel Moreira Silveira [b], Catherine Renson [c], Piet Hoebeke [c]

[a] *Division of Urology, Section of Pediatric Urology, Federal University of Bahia, Salvador, Bahia, Brazil*
[b] *Bahiana School of Medicine, Salvador, Bahia, Brazil*
[c] *Department of Urology, Section of Pediatric Urology, Ghent University, Ghent, Belgium*

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Abstract *Objective:* This new device for nocturnal enuresis (NE) consists of a humidity sensor, which beyond activating the sound also triggers an electrical stimulus, contracts the pelvic floor muscles and closes the urethra, thereby interrupting the void. The aim of this study is to test if the theoretical principle described above is true and if the device used is safe. As a secondary endpoint, we studied the efficacy of this device in a small number of patients with NE.
Material and methods: The age of the patients ranged from 7 to 20 years old, with an average of 11 years. Two surface electrodes are placed at 3 and 9 o'clock on the perineum area. When the humidity sensor is activated it triggers an electrical circuit with a current frequency of 50 Hz. After 20 s of perineal contraction, if the patient does not turn down the device, a buzz sounds and the parents or the child will wake up. In this way, the child is taught to go to the toilet and void. All patients who used the device were also treated with behavior modifications. The definition of resolution of NE was 1 month of dry consecutive nights.
Results: All patients had daily or almost daily NE (two failed with DDAVP and alarm treatment). Four patients had monosymptomatic NE and two had the non-monosymptomatic form. In five patients the device worked as expected and one patient continued wetting the bed and dropped out of the treatment. The five patients who kept using the device had the symptoms resolved completely. There were no recognizable side effects associated with this treatment.
Conclusion: The presented device works as a conventional enuresis alarm with the addition of a pelvic floor contraction. This has the advantage of the children not wetting the bed during treatment. This principle was proved by this study and the device demonstrated itself to be safe.

* Corresponding author. Av. Alphaville, Cond. esidencial Itapuã, Rua Pajuçara, 335, Alphaville 1, CEP 41701015, Salvador, Bahia, Brazil.
E-mail address: ubarroso@uol.com.br (U.Barroso).

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Introduction

Nocturnal enuresis (NE) occurs in about 15% of 5-year-old children, 5% of those who are 10 years old and 1% of young adults [1]. NE is associated with low self-esteem, social isolation and may affect the child-parent relationship [2,3]. Therefore, NE must be managed at the appropriate age. The two first-line types of treatment are desmopressin and the alarm [4]. Desmopressin is the most utilized medication; however, the rate of complete resolution of the symptom ranges around 35% [5,6].

The concept of a bed-wetting alarm system was first described in detail in 1938 [7]. It is the most effective treatment for NE in the long term, with a rate of success close to 50% [6—9]. The enuresis alarm is a device that consists of a humidity sensor that activates a sound circuit when dampened. However, during the treatment it is common that the child keeps wetting the bed, because the alarm sound is usually ineffective in waking him/her up. When the parents wake up, the child has already voided. This may cause a lack of motivation and the dropout rate for the treatment of NE with an alarm is high [6—9]. In a study, the most common reason given for noncompliance with medical and/or alarm therapy was ineffective control of urinary incontinence [5].

A device was created that tries to overcome these enuresis alarm disadvantages. It consists of a humidity sensor, which beyond activating the sound also triggers an electrical circuit that, without pain, contracts the pelvic floor muscles and closes the urethra, thereby interrupting the void. The transducers are used on the surface of the perineum and the frequency of the current used is 50 Hz. The aim of this treatment is to activate the external urethral sphincter, which leads to an interruption of the micturition and probably relaxes the bladder by reflex. With this action the child may be able to wake up and void in the toilet with a full bladder.

The aim of this study is to test if the theoretical principle described above is true and if the device used is safe. As a secondary endpoint we studied the efficacy of this device in a small number of patients with NE.

Material and methods

This is a trial involving two institutions where the device was tested in six patients (five boys and one girl). It was approved by the Institutional Review Board and all have signed an informed consent. The age of the patients ranged from 7 to 20 years old, with an average of 11 years. As inclusion criteria the patients should be at least 7 years old and have primary NE with at least two episodes of bedwetting per week. Patients with psychiatric conditions, anatomical or neurogenic abnormalities of the lower urinary tract were excluded from the study.

All patients were evaluated by voiding diary and presented normal voided volume and number of micturition. Patients with non-monosymptomatic NE had no post-void residual urine detected by ultrasound and uroflowmetry showed normal urinary stream. Patients with monosymptomatic enuresis did not perform any exam for the lower urinary tract evaluation. No patient had constipation or a history of UTI.

Description of the device

The device (patent UB) consists of a box that is connected to two electrode pads and to a humidity sensor (Fig. 1). Two surface electrodes are placed at 3 and 9 o'clock on the perineum area. When the humidity sensor is activated it triggers an electrical circuit with a current frequency of 50 Hz. It shares the same principle of any TENS used by physiotherapists for muscle recuperation. The intensity of the current is set for each patient individually in a way that we are able to reach perineal contraction without causing pain. After 20 s of perineal contraction, if the patient does not turn down the device, a buzz sounds and the parents or the child will wake up. In this way, the child is taught to go to the toilet and void. The patient/parent was taught to use the device by a urotherapist.

All patients who used the device were also treated with behavior modifications such as positive reinforcement after dry nights, good fluid intake during the day and avoidance during the night, and voidance before going to the bed. The last meal should be low in caffeine and sodium. Patients with non-monosymptomatic NE were taught not to postpone micturition and to time voiding.

The patients were seen by the urotherapist every 15 days. They recorded the presence or not of bedwetting every night. The definition of resolution of NE was 1 month of dry consecutive nights. All patients were instructed to

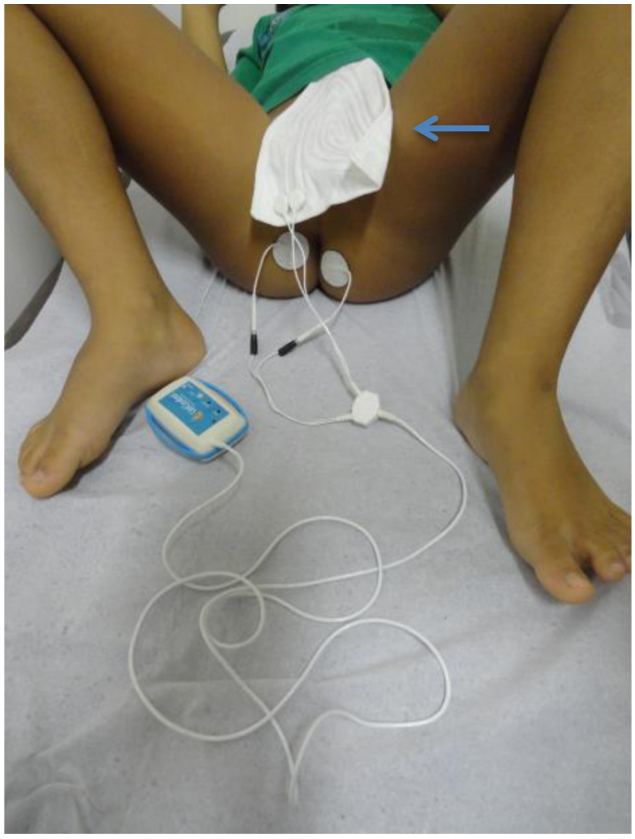

Figure 1 Patient using the device during the test phase. Two surface electrodes are placed on the perineum. The arrow shows the humidity sensor.