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Functional magnetic stimulation: A new method for the treatment of girls with primary nocturnal enuresis?

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Abstract *Objective:* The aim of our ongoing study was to evaluate the potential clinical and urodynamic effects of functional magnetic stimulation (FMS) compared to a placebo in the treatment of girls with primary nocturnal enuresis (PNE).
Patients and methods: Twenty girls with PNE (mean age 10.8 years, range 6—14 years) were included in the study and randomly divided into two groups, the active FMS group (10 girls) and the placebo group (10 girls). All girls were asked to wear Pulsegen stimulators day and night for 2 months. FMS was applied continuously at 18.5 Hz. Clinical parameters were documented and urodynamic evaluation was performed before and after FMS. Data were analyzed using non-parametric statistics.
Results: The number of weekly PNE episodes decreased significantly after FMS compared to the placebo ($P = 0.007$). In the active group the number of PNE episodes fell from 3.1 to 1.3 per week ($P = 0.028$). Three girls from the active group were completely dry and four were significantly improved. In the FMS group a significant ($P = 0.022$) increase in bladder volume at the strong desire to void was observed. Also, an increase in bladder volume at the first desire to void was observed, although this was not statistically significant ($P = 0.059$).
Conclusion: According to the preliminary results of our study, FMS represents a promising new method for the treatment of girls with PNE.

Introduction

Primary nocturnal enuresis (PNE) is considered to be a benign, but very common and unpleasant, disorder in healthy children. It is defined as

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monosymptomatic bedwetting in children of at least 5 years of age who have never been dry at night for an uninterrupted period of at least 6 months [1]. A great variety of treatments have been used over the years for bedwetting children, e.g. behavioral therapy (motivation therapy, bladder training, alarm systems) [2,3], pharmacotherapy (desmopressin, imipramine, anticholinergics) [4—6] and anal maximal electric stimulation [7]. None of these treatments has proved to be completely successful, probably because nocturnal enuresis is accepted to be a multifactorial condition, although the exact pathophysiology has yet to be defined [8]. Among possible pathogenic factors in PNE, detrusor instability and a reduction in functional bladder capacity have been suggested by some authors, particularly in those patients with refractory symptoms and treatment failure [9—11].

In recent years functional magnetic stimulation (FMS) has been proposed as an alternative to electrical stimulation for the conservative treatment of bladder overactivity [12,13]. At present, treatment results are available only in women. There are no data available on the potential efficacy of this method for the treatment of PNE in girls. The aim of our pilot study was to establish whether FMS is also effective in the treatment of girls with PNE.

Patients and methods

Twenty girls with documented PNE, diagnosed in our Pediatric Nephrology Unit, were included in this randomized, placebo-controlled and double-blind pilot study. To ensure that the girls had monosymptomatic PNE a detailed voiding history was obtained for each case, with even minor signs of voiding dysfunction being sought [2]. Definitions and recommendations, presented at the first International Children's Continence Society meeting, were used [1]. The study was approved by the local ethics committee and written informed consent was obtained from each parent. At least 3 months prior to entry into the study all the girls had unsuccessfully undergone at least one mode of treatment. Physical examination, urinalysis, and pre- and post-voiding ultrasound of the urinary tract were normal. In all girls pre-treatment urodynamic studies were performed in the presence of their parents, according to the methods described elsewhere [14].

Active or placebo Pulsegen devices (Fig. 1), identical in appearance and labeled with serial numbers, were randomly assigned to the girls as they entered the study. The girls were instructed to wear the devices continuously for 2 months, in specially designed underpants, and to keep a detailed written voiding diary, including voiding times, evidence of each dry night, possible treatment side effects and the time when the device was worn.

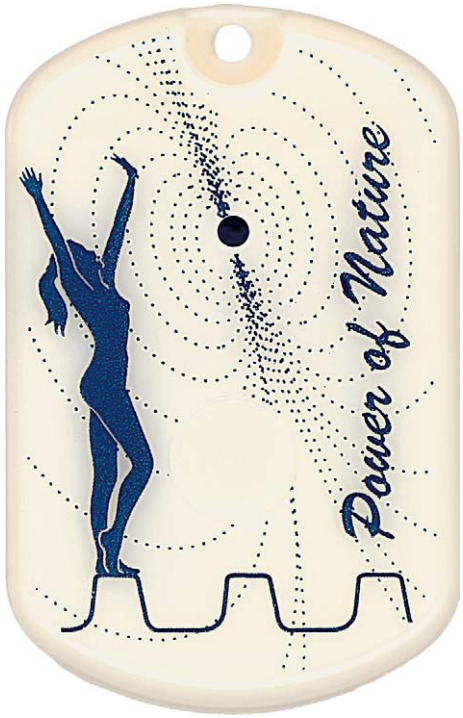

Figure 1 The Pulsegen device.

The active device generates a pulsating electromagnetic field of low frequencies. It is in a plastic case and designed for home use (dimensions: 45 mm long, 30 mm wide and 10 mm thick; weight without battery, 9.5 g). The Pulsegen stimulator is powered by a 3 V battery, allowing 8 weeks of continuous FMS (pulse frequency of 18.5 Hz, intensity of $B = 10\ \mu T$ at a distance of 7.5 cm from the case). The device is turned on by pressing a small switch located on its front, with a green light blinking on the front while the device is active.

Shortly after 2 months of continuous treatment, urodynamic studies were repeated and the clinical effect of treatment assessed by the girls and their parents. The girls were considered to have a significant response to the treatment when there was a 50% or greater decrease in the number of wet nights. After termination of treatment all the girls were asked to continue the detailed voiding diary. The study results were analyzed by the statistician, the only person aware of the list of active