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ORIGINAL ARTICLE

Voiding dysfunction in children. Pelvic-floor exercises or biofeedback therapy: a randomized study

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Abstract Fifty-six patients 5.9–15.2 years old with dysfunctional elimination syndrome (DES) unimproved by previous therapies were randomly distributed into two voiding training programs: group 1 contained 26 patients submitted to 24 training sessions over a 3-month period; group 2 contained 30 patients submitted to 16 sessions over a 2-month period. Both groups adhered to a voiding and drinking schedule, received instruction on adequate toilet posture, were reinforced through the maintenance of voiding diaries, and went through proprioceptive and pelvic floor muscle training (Kegel exercises). Group 2 patients also received biofeedback therapy. Clinical evaluation was carried out before each program's initiation and 1, 6, and 12 months after each program's termination. All patients were submitted to renal ultrasonography and dynamic ultrasonography before and 6 months after each program's conclusion. Millivoltage recordings of pelvic floor muscles were compared before and after training. Urinary continence was improved after completion of either training program. Only those patients who received biofeedback training showed a significant decrease in postvoiding residual (PVR) urine as detected by dynamic ultrasonography. Our results show that either training regime can reduce episodic urinary incontinence and urinary tract infection but that further study is required to identify the optimal training duration.

Keywords Dysfunctional elimination syndrome · Pelvic floor exercises · Biofeedback · Children · Adolescents

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Introduction

Dysfunctional elimination syndrome (DES) denotes an abnormal pattern of elimination for the child's age characterized by urinary and bowel incontinence and withholding [1]. Its etiology is not well defined but includes delayed developmental control, effects of environmental/social factors, urinary tract infection (UTI), and learned behavior [2, 3]. Efforts to maintain urinary continence may lead to urethral and simultaneous anal sphincter contraction, resulting in a high tone of the pelvic floor muscles [4].

Treatment of DES is particularly problematic. The main objective is restoration of a normal micturition pattern, reduction of excess detrusor and pelvic floor activity, and elimination of urinary incontinence, UTI, and constipation. DES management involves a combination of cognitive, behavioral, physical and pharmacological therapies. There are a number of behavioral treatments, which include bladder and pelvic floor muscle training and timed voiding.

Pelvic-floor exercise is a physiotherapeutic, noninvasive treatment that consists of tightening the pelvic muscles and holding the contraction for a few seconds, followed by a rest period. Pelvic floor biofeedback is a technique that uses surface perineal electrodes to monitor external urinary sphincter activity. Biofeedback has been used when more conservative therapy fails [5]. In the treatment of DES, the

goal of pelvic floor therapy with or without biofeedback is to make the children aware of their pelvic floor musculature and to teach them functional ways to use these muscles during voiding. In this study, we evaluated the efficacy of a training program for achieving resolution of urinary incontinence, UTI, and constipation in children and adolescents with DES.

Patients and methods

The dysfunctional voiding outpatient clinic in our institution has actively treated children with urinary incontinence and/or UTI since 1996. Between April 2001 and June 2004, 94 patients with urinary incontinence were recruited to participate in this study, and 35 did not meet the inclusion criteria. Fifty-nine children and adolescents with DES who had not responded to previous treatments were selected for inclusion. Three patients did not complete the protocol, and the reason the parents pointed out was the same: difficulty in attending the sessions twice a week. The study was approved by the local ethics committee, and all parents or guardians gave their written consent prior to their children's participation.

The two voiding training programs consisted of the following: maintenance of a voiding and drinking schedule, training in adequate toilet posture, reinforcement using voiding diaries, and training in the use of proprioceptive and relaxation exercises for the pelvic floor muscles. One program included biofeedback therapy. Screening consisted of recording the patient's history, a clinical examination, and ultrasonography (US) of the urinary tract. Inclusion criteria were age older than 5 years, failure to respond to previous treatment, willingness to undergo the training sessions, and informed consent of parents or guardians.

Prior to their entry into this study, all patients had previously undergone treatment in our outpatient clinic for at least 6 months without any improvement of their urinary incontinence, urgency or urge incontinence, and/or constipation. The outpatient clinic's treatment regime consisted of hydration, training in proper hygiene, timed voiding, constipation treatment (high-fiber diet and/or laxatives), and antibiotic prophylaxis and/or anticholinergic treatment when indicated—a conservative medical therapy. Anticholinergic drugs were discontinued 4 weeks before a patient's inclusion into this study.

Exclusion criteria were occult neurological lesions, complex urinary tract abnormalities [other than vesicoureteral reflux (VUR)], attention deficit hyperactivity disorder, and primary monosymptomatic nocturnal enuresis. Patients were randomly distributed into two groups: group 1, with 26 patients (nine boys, 17 girls; mean age 10.8±1.9 years, age range 7–14.9 years), submitted to 24 sessions of pelvic floor exercises over a 3-month period; group 2, with 30 patients (10 boys, 20 girls; mean age 10.3 ± 2.6 years, age range 5.9–15.2), submitted to 16 sessions of pelvic floor exercises with biofeedback over a 2-month period. Both groups' sessions lasted 60 min. Group 1 patient sessions consisted of a series of seven pelvic floor musculature contraction and relaxation exercises. Group 2 patient treatment included the use of a commercially available biofeedback system that generated electromyography tracing during the contraction and relaxation phases of pelvic floor exercises. To measure electrical activity generated during the pelvic floor muscle exercises, surface electromyography patches were placed on the perineum at 2 o'clock and 10 o'clock. Each child was instructed to perform a series of 5-s contractions, followed by a 10-s rest period. Both groups' participants were also instructed to practice the pelvic floor exercises at home for 20 min three times a week. In the beginning of each session, the examiner discussed any changes from previous visit regarding compliance to home exercises. All patients followed the instructions during the training program.

Each patient provided a detailed voiding history before entering either training program. All patients were clinically evaluated 1 month (M1), 6 months (M6), and 12 months (M12) after the end of the program. Outcome variables included symptom improvement, specifically frequency of diurnal and nocturnal incontinence; UTI during the 12-month period after program completion; and the presence of urge incontinence, constipation, or soiling. UTI was defined as growth of at least 100,000 cfu/ml of a single organism in urine collected during a midstream sample voiding, accompanied by fever (38.0°C or higher) or other overt symptoms of UTI. Constipation was defined as infrequent stool passage (fewer than three times/week) and/or feces that were large and hard or in small pieces, with/without abdominal pain or palpable stool in the abdomen. Children with constipation were placed on high-fiber diets; laxatives were given when diet did not resolve the symptoms.

Renal and bladder US were taken before the training program and 6 months after its end by the same examiner (MTF). Dynamic US of the urinary tract was developed to evaluate bladder wall thickness and estimate postvoiding residual (PVR) urine volume and estimated bladder capacity (BC). This technique also aids in the evaluation of detrusor activity by detecting involuntary and pelvic floor contractions and linking those contractions with urine leakage. Our experience has shown that this technique is a valuable tool for the detection of upper and lower urinary dysfunction [6]. Study patients with a history of UTI underwent voiding cystourethrograms.

Treatment program results were documented as subjective (reported clinical improvement) and objective (changes in urodynamic parameters evaluated by the renal and

bladder dynamic US). Patients were considered successfully treated ("cured") if there were no wetting episodes over a 4-week period and "improved" if there was at least a 50% reduction in the number of incontinence episodes.

Variables evaluated through renal and bladder dynamic US were BC, appropriate by age, PVR, bladder wall thickness, and detrusor and pelvic floor contractions during bladder filling. Maximum BC was estimated using the following formula: $BC\,(milliliters) = [age\,(years) \times 30] + 50$ [7] while minimum BC was estimated using the following formula: $BC = [16 \times age\,(years) + 70]$ [8]. BC was considered abnormal when it was 10% above maximum BC or 10% under estimated minimum BC. PVR was considered abnormal when it was more than 10% above predicted maximum BC or more than 20 ml. As part of secondary outcome measures, pelvic floor millivoltage recordings were obtained from surface electrode electromyography patches linked to a biofeedback device. The recordings were taken before beginning treatment and 1 month (M1) after the last session.

At first presentation, all patients underwent a urine analysis and culture and a neurological examination that focused on perineal sensitivity, lower-limb reflexes, and anal tonus. All 56 patients completed a voiding diary, underwent a 24-h home pad test, and were psychosocially assessed. The voiding diary was maintained by each child during and after the treatment program. In this diary, the child recorded the number of incontinence episodes, voiding frequency, and BC, which was considered to be the largest voided volume with the exception of the early morning micturition [9]. The randomization procedure was computerized using the Epitable program (Epi-info version 6,04b), which generated a list of random numbers used to designate the potential participants' questionnaires. These questionnaires were filled out at enrollment.

Data were analyzed using standard statistical software (SPSS, version 12.0), with statistical significance considered to be $p<0.05$. Continuous variables were compared using the Student's t test and were expressed as mean ± 1 standard deviation (SD) unless otherwise specified. A chi-square test or Fisher's exact test was employed to analyze categorical data between the groups. The Mann–Whitney test was used when comparing nonparametric data. A McNemar test was conducted to determine the significant differences between pretreatment symptoms' prevalence and the same symptoms' prevalence at each of the three after treatment evaluations (M1, M6, and M12).

Results

No child showed neurological abnormality. All patients had normal plasma creatinine levels. The 19 boys and 37 girls who completed the program were between 5.9 and 15.2 years old, with a mean age of 10.5±2.3 years. Table 1 presents pretrial clinical evaluation data.

Follow-up clinical evaluations showed that the percentage of patients with urinary incontinence decreased significantly in both groups after treatment. The prevalence of constipation did not significantly decrease at M12 compared with before treatment. The follow-up status of various symptoms is shown in Fig. 1.

The great majority of patients with UTI prior to entry into the training program did not relapse during the study period. In group 1, only one (3.8%) out of eight (30.8%) patients with recurrent UTI showed a relapse (p=0.023). In group 2, three (10%) out of 13 patients (43.3%) with UTI relapsed (p=0.004).

Cure rates for the 21 patients in group 1 with diurnal urinary incontinence were as follows: nine (42.8%) by M1, 13 (61.9%) by M6, and 15 (71.4%) by M12. Improved rates for the same 21 patients were as follows: 5 (23.8%) by M1, three (14.3%) by M6, and two (9.5%) by M12. Cure rates for the 20 patients in group 2 with diurnal urinary incontinence were as follows: six (30%) by M1, 12 (60%) by M6, and 15 (75%) by M12. Improved rates for the same 20 patients were as follows: six (30%) by M1, four (20%) by M6, and three (15%) by M12.

Cure rates for the 24 patients in group 1 with nocturnal urinary incontinence were as follows: six (25%) by M1, 10 (41.7%) by M6, and 14 (58.3%) by M12. Improved rates for the same 24 patients were as follows: 10 (41.7%) by M1, six (25%) by M6, and four (16.7%) by M12. Cure rates for the 24 patients in group 2 with nocturnal urinary incontinence were as follows: two (8.3%) by M1, four (16.7%) by M6, and nine (37.5%) by M12. Improved rates for the same 24 patients were as follows: 13 (54.1%) by M1, ten (41.7%) by M6, and 11 (45.8%) by M12.

Cure rates for the 11 patients in group 1 with constipation were as follows: five (45.4%) by M1 and four (36.4%) by M6 and M12. In group 2, cure rates for the 11

Table 1 Description of 56 children before the training program entry

Characteristics	Group 1 (26) *n* (%)	Group 2 (30) *n* (%)
Daytime incontinence	21 (80.7)	20 (66.7)
Nocturnal incontinence	24 (92.3)	24 (80.0)
Urge/urge incontinence	23 (88.5)	25 (83.3)
Pelvic withholding maneuvers	16 (61.5)	21 (70.0)
UTI	8 (30.8)	13 (43.3)
Constipation/soiling	11 (42.3)	11 (36.7)
VUR	5 (19.2)	4 (13.3)

UTI urinary tract infection, *VUR* vesicoureteral reflux

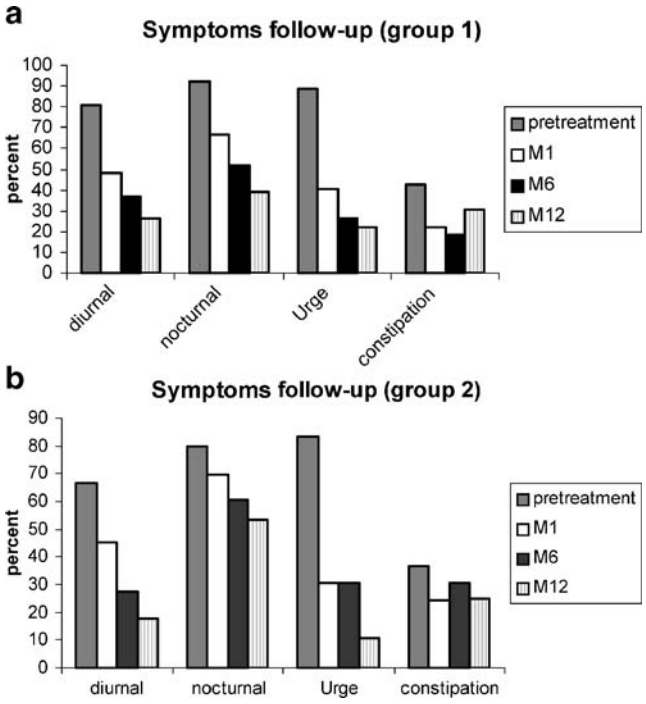

Fig. 1 Follow-up status of nocturnal incontinence, diurnal incontinence, urgency, and constipation prevalences before the training program entry, in month 1 (M1), month 6 (M6), and month 12 (M12). **a** group 1; **b** group 2

patients with the condition were as follows: four (36.4%) by M1 and two (18.2%) by M6 and by M12.

Differences in the effectiveness of the two training programs were not statistically significant for any parameters analyzed. Table 2 shows the renal and bladder dynamic US parameters by group before and after completion of the training program. There were no differences in group 1 parameters. Group 2 showed a significant decrease in the proportion of patients with inadequate BC, excessive PVR urine, and pelvic floor contractions after treatment.

Table 2 Ultrasonography parameter prevalence for the 56 patients before and after the training program

	Group	Before *n* (%)	After *n* (%)	*p* value
Inadequate	G1	7 (26.9)	4 (15.4)	0.25
BC	G2	15 (50)	9 (30)	0.04
PVR urine	G1	5 (19.2)	4 (15.4)	1.0
	G2	7 (23.3)	2 (6.7)	0.023
Bladder wall	G1	5 (19.2)	2 (7.7)	0.25
Thickness	G2	6 (20)	4 (13.3)	0.48
Detrusor	G1	8 (30.8)	5 (19.2)	0.25
Contractions	G2	11 (36.7)	8 (26.7)	0.25
Pelvic floor	G1	22 (84.6)	17 (65.4)	0.07
Contractions	G2	29 (96.7)	19 (63.3)	0.004

BC bladder capacity, *PVR* postvoiding residual

The frequency of incontinence episodes registered in both groups' voiding diaries decreased significantly after treatment was completed: in group 1, the median was three per diary before treatment and 0.5 after treatment (p=0.004); in group 2, the median was two per diary before treatment and one after treatment (p=0.002). The two groups' voiding diaries showed that estimated BC was unchanged by treatment (p>0.05).

Millivoltage recordings taken during pelvic floor relaxation showed a significant difference between the groups (p=0.03): there was a voltage decrease in 16 of the 26 group 1 patients (61.5%) and in 26 of the 30 group 2 patients (86.6%).

Discussion

Advances in the understanding of pathophysiological processes over the last 25 years have caused a change in techniques used to evaluate and treat patients with voiding dysfunction. Recently, several authors have reported effective treatment programs based on the theory of pelvic floor dysfunction [10–12]. Etiologically, dysfunctional voiding can be the consequence of overtraining the pelvic floor muscles brought about by excessive squeezing of the urethral sphincter and pelvic floor muscles in an attempt to prevent loss of urine due to detrusor instability [13]. This pelvic floor overactivity could be the major cause of dysfunctional voiding [14].

Two treatment modalities used to treat children with voiding dysfunction, Kegel pelvic muscle exercises and the same exercises with the addition of biofeedback, have a common goal: to make children aware of their pelvic floor musculature and to teach them functional ways of using these muscles. In our trial, we evaluated the efficacy of these two protocols.

Pelvic-floor muscle exercises (Kegel) were the primary behavioral technique used to treat adult urinary incontinence [15]. Although originally developed to treat stress incontinence through strengthening of the pelvic floor muscles, Kegel exercises can also be effective in the treatment of urge incontinence [16]. Wennergren and Oberg [17] introduced voluntary contractions of the pelvic floor for urge incontinence treatment in order to increase patient awareness of this musculature.

The use of biofeedback to manage urinary incontinence in children was initially described by Maizels et al. in 1979 [18], introducing urodynamic biofeedback. Since then, the technique has become less invasive, and strategies such as the use of computer games have been developed to maintain a high level of patient motivation [12, 14]. Through the use of visual, auditory, and/or tactile signals, biofeedback teaches the child to recognize and then change

or influence unconscious physiologic processes [13]. As the Kegel exercises provide the musculature stimulation that biofeedback monitors, in our study, biofeedback was employed in conjunction with Kegel exercises.

Our study showed no statistically significant efficacy difference between the two techniques for treating DES in any of the subjective outcomes (symptoms). These results correspond with conclusions from some randomized, controlled trials performed on adults. Studies have also suggested that with the use of biofeedback, patients may learn more rapidly how to correctly contract and relax the pelvic floor muscles [19, 20]. In this vein, of the two training programs implemented in our study, the one that included biofeedback was of shorter duration.

We noted a significant decrease in the incidence of incontinence episodes (diurnal, nocturnal, and urgency) after both training programs. As all patients had previously undergone other types of treatment without success, we believe that this reduction was due to the training programs instituted through our study. We consider that normal maturation contributed very little to the observed decrease in the number of incontinence episodes because the treatment provided usually lasted less than 4 months in this study.

Our study results showed that both programs were more successful in the resolution of diurnal urinary incontinence than in the resolution of nocturnal urinary incontinence. The prevalence of nocturnal urinary incontinence was significantly reduced only after M6 while diurnal incontinence was significantly reduced at M1. This indicates that the training programs more rapidly improved control of diurnal urinary incontinence than nocturnal urinary incontinence, an effect noted in other studies [14], and suggests that daytime and nocturnal urinary incontinence have a different pathogenesis, even when, both symptoms, occur in the same patient [21].

The training programs did not significantly reduce the incidence of constipation, and the "cure" rates were similar between the two treatment groups at M1, M6, and M12. The management of functional constipation is probably one of the greatest pediatric challenges. The relapses noted in our study were also found in other studies. Defecation problems seem to be a result of an intricate weave of primary, secondary, and psychological factors [22]. Although studies published over the last decade reinforce the role of constipation as a causal or perpetuating factor in voiding dysfunction, constipation cure rates are continually much lower than urinary incontinence cure rates [23]. This cure rate divergence was also found in our study, which reflects the difficulties of achieving patient compliance to constipation treatment. As a hypothesis to explain the divergence, it may be that less emphasis is placed on the maintenance of constipation therapies than on the resolution of urinary incontinence. Urinary incontinence is both inconvenient and socially unacceptable while, to some children and their parents, constipation is less inconvenient and more easily overlooked. In the absence of painful symptoms or encopresis, parents are generally unaware of the bowel habits of children older than 4 or 5 years [1] and ignore the fact that fecal retention actually exists and is pathological.

The prevalence of UTI decreased significantly in both groups after treatment. There were no significant differences between UTI success rates in the two groups. This result reinforces the importance of DES treatment in the resolution of UTI. The UTI cure rate found by our study was greater than reported in other studies [24]. A more prolonged follow-up will be needed to confirm the maintenance of these results.

After treatment, only group 2 patients exhibited a significant reduction of PVR urine, normalization of BC, and an absence of pelvic floor contractions as detected by renal and bladder dynamic US. However, we noted a tendency for improvement in group 1 regarding inadequate BC and pelvic floor contractions although not statistically significant (Table 2). The resolution of PVR urine was better in group 2 (only two out of seven patients persisted with PVR urine compared with four out of five in group 1). The small sample size could be the reason for negative findings in group 1 (type II error) but, the statistical difference, detected after the treatment, in group 2 is real. This finding suggests that the use of electromyography tracings as feedback, as for group 2 patients, can be an important tool for the reduction of PVR when combined with other appropriate therapies.

Pelvic floor exercises combined with biofeedback (group 2) were also more efficacious than pelvic floor exercise alone (group 1) in decreasing relaxation millivoltage. Although some studies have used millivoltage data as a diagnostic tool to measure improvement during treatment, or even as an integral part of biofeedback training [25, 26], these recordings may be considered of limited clinical value, as normal values for relaxation millivoltage are missing.

Our programs' objective results lagged behind the patients' subjective improvement (symptoms). This has also been noted by other authors [14, 27]. McKenna et al. link this lag with collateral neuroplasticity theory and expect that consistent relaxation of the pelvic floor muscles during voiding will eventually improve objective parameters to indicate normal urinary patterns at some point after subjective improvement [14].

There are some limitations to our study, one of which is sample size. This sample gave a 58% power (α=5%) to detect a 25% efficacy difference between the two treatments groups, assuming that 60% would be cured with pelvic

floor muscle training without biofeedback. The small sample size may have been the reason for the negative findings (type II error); however, these figures were based on findings from previous studies performed in adults [20], as we are not aware of published studies in children comparing the two techniques.

Our study was also limited by the lack of a control group. As it was only intended to compare two training programs, applied to patients with voiding dysfunction that had remained unresolved by other therapies, the lack of a control group did not affect the validity of our results. Although there was no control group without the treatment protocol in this multimodal therapeutic study, we are not concluding that each treatment individually was efficient. Actually, the two compared voiding programs represented a complete multimodal therapeutic protocol, including not only Kegel exercises and/or biofeedback but also all procedures of our daily handling of the patients. Besides, we are not aware of published studies comparing the efficacy of a simple behavioral therapy (voiding instructions only) or randomized trials with no therapy. McKenna commented that there is a 10–20% cure rate from the application of a simple behavioral voiding program, depending on the amount of effort parents expend applying the program [28]. The difficulties encountered when attempting to construct a control group, as described in other studies [25, 29], placed such an endeavor beyond our current capabilities.

In conclusion, the two modalities of behavioral treatment employed in our study have been shown to equally reduce symptoms of diurnal and nocturnal urinary incontinence and UTI frequency in patients with dysfunctional voiding. It seems that the training program that included biofeedback was effective in reducing PVR and relaxation millivoltage. It was found that motivating the children with voiding dysfunction to be actively involved in their own treatment was a major challenge, and we hypothesize that the use of apparatus during training might be of help in this regard.

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