

Bladder control training in girls with lower urinary tract dysfunction

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ABSTRACT

Purpose: To evaluate the efficacy of standard and biofeedback bladder control training (BCT) on the resolution of dysfunctional elimination syndrome (primary outcome), and on the reduction of urinary tract infections (UTI) and the use of medications such as antibacterial prophylaxis and/or anticholinergic/alpha-blockers (secondary outcome) in girls older than aged least 5 years.

Materials and Methods: 72 girls, median age of 8 years (interquartile range, IQR 7-10) were subjected to standard BCT (cognitive, behavioural and constipation treatment) and 12 one-hour sessions of animated biofeedback using interactive computer games within 8 weeks. Fifty patients were reevaluated after median 11 (IQR, 6-17) months. Effectiveness of BCT was determined by reduction of dysfunctional voiding score (DVS), daytime urinary incontinence (DUI), constipation, UTI, nocturnal enuresis (NE), post void residual (PVR), and improvements in bladder capacity and uroflow/EMG patterns.

Results: BCT resulted in significant normalization of DUI, NE, constipation, bladder capacity, uroflow/EMG, while decrease of PVR didn't reach statistical significance. In addition, the incidence of UTI, antibacterial prophylaxis and medical urotherapy significantly decreased. There were no significant differences in DVS, DUI, NE, bladder capacity and voiding pattern at the end of the BCT and at the time of reevaluation. The success on BCT was supported by parenteral perception of the treatment response in 63.9% and full response in additional 15.3% of the patients.

Conclusion: Combination of standard and biofeedback BCT improved dysfunctional elimination syndrome and decreased UTI with discontinuation of antibacterial prophylaxis and/or anticholinergic/alpha-blockers in the majority of the patients. Better training results are expected in patients with higher bladder wall thickness as well as in those with vesicoureteral reflux, while presence of nocturnal enuresis may be a negative predictor of the training effect.

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INTRODUCTION

Lower urinary tract dysfunction (LUTD) includes a wide spectrum of voiding dysfunction in the absence of neurological, structural, or medical causes (1). LUTD is an important problem in childhood due to its relatively high prevalence (2-4) and

the fact that it may cause upper urinary tract deterioration with renal scarring (5).

LUTD is commonly associated with constipation, urinary tract infections (UTI) and vesicoureteral reflux (VUR) (1). The pathophysiology of combined bladder and bowel dysfunction known

as dysfunctional elimination syndrome (DES) has been extensively studied, but still remains unexplained (6). It is certain that anatomically close relationship of bladder, urethra and rectum and pelvic floor muscles, as well as similar inervation (S2-S4) of urethral and anal sphincters are predisposing factors for lower urinary tract and bowel dysfunctions to occur simultaneously. It has been suggested and already accepted that bladder instability and bowel dysfunction may lead to over--training of pelvic floor, resulting in a high tone of pelvic floor muscles, which can cause functional outlet obstruction (7). If left untreated, dysfunctional elimination of urine and faeces maintains, and even aggravates bladder and bowel dysfunction, leading to further incontinence, urinary tract infections (UTI) and upper urinary tracts deterioration (8). McKenna et al. suggested that pathophysiology of pelvic floor dysfunction might be related to a phenomenon known as "neuroplasticity". They proposed that long-term pelvic floor hyperactivity results in neural remodeling, causing end organ histological changes, and resulting in clinical symptoms (9). Therefore, it is very important to recognize and treat DES as early as possible.

Advances in the understanding of the pathophysiological process of DES have resulted in biofeedback therapy and pelvic floor muscle retraining (PFMR) to become the first line therapy after failure of simple conservative measures (10). Biofeedback is a technique by which information about a normally unconscious physiological process is presented to a patient as a visual, auditory or tactile signal (11,12). Recently, animated electromyography (EMG)-based biofeedback using interactive computer games has become the preferred biofeedback method in children to obtain PFMR, strengthen/coordinate detrusor function, teach the guarding reflex and retrain central nervous system (10,13,14).

Since the year 2000, children with LUTD have been treated in our clinic with bladder control training (BCT). At first, behavioural modification and pharmacological therapy have been used, but later on uroflow biofeedback has been performed. Animated EMG-based biofeedback using interactive computer games was introduced in 2008. The primary outcome of this study was to

evaluate the efficacy of a combination of standard and computer game assisted PFMR on achieving resolution of DES (LUTD and constipation), while the secondary outcome was to asses the effect of the BCT on the reduction of UTI and medications such as prophylaxis and anti-cholinergic/alpha-blockers in girls older than 5 years.

MATERIALS AND METHODS

All girls with LUTD and/or reccurent UTI treated by biofeedback with interactive computer games between 2008 and 2010 were recruited to participate in the study. The screening consisted of history, clinical, neurological and psychological examination, uroflow study and ultrasonography of the urinary tract. A voiding cysto-urethrography (VCUG) and dimercaptosuccinic acid (Tc-99m DMSA) scan were optional in patients with recurrent UTI. At the presentation, 64 patients were taking drugs such as prophylaxis, and/or anticholinergic/alpha-blockers during at least the last 3 months.

Patients with neurological abnormalities and/or complex urinary tract abnormalities, as well as those younger than 5 years or unable to cooperate fully, were excluded from the study. DES was graded using dysfunctional voiding score (DVS, 0 = normal), as reported by Kramer et al. (15). In addition, daytime urinary incontinence (DUI) was evaluated as recommended by Mulders et al. (16). Functional constipation was defined according to ROME-III diagnostic criteria (17). Urinary flow shape and pelvic EMG were analysed. Bell-shaped urinary flow curves without increased EMG activity during voiding were considered normal.

Post-void residual volume (PVR, mL) was assessed by ultrasound following uroflowmetry. It was considered abnormal if it was greater than 10 mL, unrelated to age, sex or bladder capacity (18). Bladder wall thickness was measured by ultrasound in mid-transverse plane of the voided bladder at three points: anterolaterally, laterally and posterolaterally when the bladder was nearly empty (< 10% of prevoid volume). The mean of three measurements was used for further analysis. Estimated bladder capacity (EBC) was calculated using the following formula: 30 x age (years)+30

(19). After the age of 12 years, EBC of 390 mL was considered normal. The EBC was compared to the maximum voided volume plus the PVR. Values below 65% or greater than 150% of EBC were considered pathological.

BCT included intensive inpatient 5-days course followed by outpatient clinic protocol during 7 weeks. During intensive course the patients underwent: a) an education about urinary tract physiology and dysfunction, b) a psychologist consultation, c) behavioural training, d) physiotherapy, and e) daily one-hour biofedback sessions which combined uroflow-biofeedback and animated EMG-based biofeedback (UrostymTM Behavioral Therapy System, Laborie Medical Technologies) during five consecutive days.

Education of patients was done with patience using understandable words and drawings. Behavioural training consisted of completing a frequency-volume voiding and drinking charts, instruction on proper toilet posture and constipation treatment (high-fiber diet and/or laxative). Aim of behavioural training was to learn to correct maladaptive drinking, voiding and bowel habits. In patients with recurrent UTI, prophylactic antibiotics were given as indicated.

After intensive course, patients continued with pelvic floor exercises of 15 min. three times a week and outpatient clinical protocol consisting of one 60 min. biofedback session per week during 7 weeks. Voiding and drinking charts, as well as uroflow/EMG curves were reviewed at each visit.

The study was approved by the Ethics Committee of University Children's Hospital. Written informed consent from parents and written assent from children were obtained.

Treatment outcome

Effectiveness of biofeedback treatment was determined by improvement reduction in the three DES as primary outcomes (expressed by normalization of DVS, DUI, NE, PVR, uroflow/ EMG curves, and constipation) and the secondary outcome (reduction of UTI, antibacterial prophylaxis and/or anticholinergic/alpha-blockers). For primary outcome there were four measurement points: the first was baseline, the second was at the end of intensive course, the third measurement point was

at the end of the training course, and the fourth one was at the end of follow-up. For secondary outcome there were two measurements points: the first was baseline and the second was at the end of follow-up. Both primary and secondary measurements outcomes were expressed by the increasing percentage of the total patients who normalized elimination habits, and/or were free of UTI and medications. In addition, for primary measurement outcome, the sum of values of the scoring systems that graded severity and numbers of DES (DVS and DUI) accidents per week at baseline were compared with those at other three measurements points. The cure were categorized on a scale of 0 to 100%, with 0-48% indicating non response, 50-99% response and 100% full response. The same categorization was used for the parenteral perception of the BCT success. Intend to treat analysis was used in success rate analysis of primary and secondary outcomes for all phases of treatment.

Statistical analysis

Descriptive and analytical statistics were done by SPSS 19.0 software. Data are expressed as median (interquartile range) unless otherwise stated. To compare groups at different time points paired sample t test was used for parametric and Wilcoxon test for non-parametric data. Multiple regression analysis with backward selection was performed to identify independent variables of DVS cure rates. A value of p < 0.05 was considered statistically significant.

RESULTS

Seventy-two girls, median age of 8 years (IQR 7-10) with median DVS of 4 (IQR, 2-6) and median DUI of 2 (IQR, 0-6) were included in the study. Their characteristics are presented on Table-1. All patients had normal glomerular filtration rate, but arterial hypertension was found in 5.5%. Renal ultrasound showed normal finding in 65.3% of the patients. The most common renal ultrasound abnormality was pyelic dilatation which was found in 26.4% of the total number of patients. Dimercaptosuccinic acid (DMSA) scan was done in 51 patient demonstrating renal scarring in 72.5%, while ve-

Table 1 - Characteristics of 72 patients at the entry to the study.

Variables	% of the total number
Age in years, M (IQR) = 8 (7-10)	
Normal estimated glomerular filtration rate	100
Arterial hypertension	5.5
Renal ultrasound abnormalities	34.7
Increased bladder wall thickness	45.8
Renal scarring †	72.5
Vesicoureteral reflux††	28.6
Recurrent urinary tract infections	97.1
Antibacterial prophylaxis	88.9
Anticholinergic and/or alpha blocker	50.8
Abnormality of bladder capacity	
Decreased	20.3
Increased	17.4
Increased post voiding residual	64.1
Non- bell shaped flow pattern	65.7
Tower	11.4
Plato	2.9
Staccato	5.7
Intermittent	45.7
Increased pelvic EMG activity during voiding	52.2

 \mathbf{M} = Median; \mathbf{IQR} = Interquartile range; $\mathbf{\uparrow}$ = Tc99m DMSA was done in 51 patients; $\mathbf{\uparrow\uparrow}$ = Voiding ureterocystography was done in 42 patients.

sicoureteral reflux (VUR) was discovered in 28.6% of 42 patients. Majority of the patients had history of recurrent UTI (97.1%), increased post-void residual volume (PVR, 64.1%), abnormal voiding curve (VC, 65.7%) and increased pelvic EMG activity

during voiding (52.2%). Half of the patients had constipation. DUI was reported in 43.7% patients, nocturnal enuresis (NE) in 30.0%, while combined DUI and NE was found in 19% of the patients. Third of the patients (30.5%) had a combination of DUI, UTI, and constipation.

Of 72 patients 71 (98.6%) were compliant with 5 weeks of BCT, 67 (93%) patients finished 6 weeks, while 55 (76.4%) and 29 (40.3%) patients completed 7 and 8 weeks of BCT, respectively (Figure-1). Long duration of treatment was an important cause of low compliance. Patients stopped treatment due to family issues (38.9%), improvement of LUTD (8.3%), UTI (4.2%), or some other disease (8.4%), while remaining 29 patients (40.3%) completed the treatment. Overall, BCT resulted in significant normalization of DVS, DUI, NE, constipation, bladder capacity, voiding curve and EMG during voiding, while decrease of PVR didn't reach statistical significance (Table-2). Fifty patients were reevaluated after median 11 (IOR, 6-17) months. During that period the number of patients who had UTI, as well as those with antibacterial prophylaxis and medical urotherapy, significantly decreased compared to the period before BCT (Figure-2). There were no significant differences between DVS, DUI, NE, bladder capacity and voiding pattern at the end of the BC and those at the time of reevaluation (Figure-3). Using the ICCS definitions of the treatment outcome, more than half of the patients showed full response in DVS and DUI (Table-2). The success on BCT was supported by parenteral perception of the treatment response in 79.2% (response in 63.9% and full response in additional 15.3%) of the patients (Table-2).

Multiple regression analysis with backward variable selection (R 2 0.557%, p < 0.005) demonstrated (Table-3) that improvement of DVS at the end of the training was inversely dependent on NE (β = -5.137; p < 0.001) and directly dependent on age (β = 2.045; p < 0.05), bladder wall thickness (β = 3.623; p < 0.005) and finding of VUR on VUCG (β = 3.944; p < 001).

DISCUSSION

Epidemiological studies reported LUTD symptoms in 21.8% school-age children (3). Mo-

A Assed for eligibility Enrollement (A) E Excluded patients (n=25); Male gender; With neurological abnormalities; With complex urinary tract abnormalities; Younger than 5 years; Unable to cooperate fully. Entry of the study Baseline (A) n = 72 5 days inpatient treatment Intensive course (B) n = 72 Outpatient clinical protocol End of the 1 weeks 2 weeks 3 weeks 4 weeks 6 5 weeks 6 weeks 87 training (C) weeks Follow-up Reevaluation median 11

Figure 1 - Flow chart describing the progress of the patients through the trial.

(IQR, 6-17) months

End of the follow-up

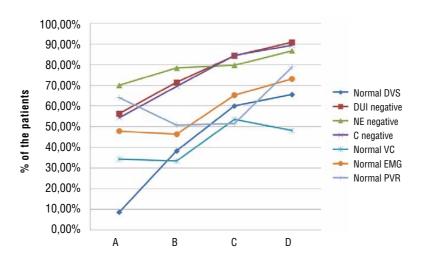
Table 2 - Bladder control training response rate according to dysfunctional voiding score (DVS), daytime urinary incontinence score (DUI), and parents' impression.

n=50

Result	DVS (%)				DUI (%)1		Parents' impression (%) ²
	В	С	D	В	С	D	D
Full response	42.9	56.9	64.3	52.5	67.5	81.0	19
Response	18.3	27.7	16.1	22.5	17.5	8.1	79.3
No response	38.8	15.4	19.6	25.0	15.0	10.8	1.7

DVS = Dysfunctional voiding score; **DUI** = Daytime urinary incontinence score; ¹ Analysis involved 39 patients with daytime urinary incontinence; ² 14 parents didn't give response; **B** = intensive course; **C** = at the end of training; **D** = end of the follow-up.

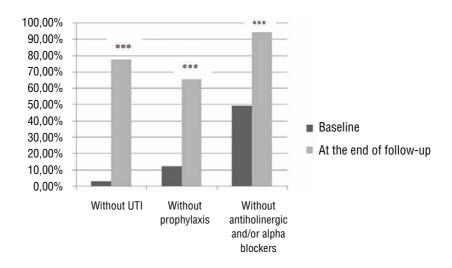
Figure 2 - Primary outcome.



Legends: A, baseline; B, after intensive course; C, at the end of the training, D, at the end of follow-up; DVS, disfunctional voiding score; DUI, daytime urinary incontinence; NE, nocturnal enuresis; C, constipation; VC, voiding curve; EMG, electromiography; PVR, postvoid residual

	DVS	DUI	NE	С	VC	EMG	PVR
	p	р	р	р	р	p	р
A vs. B	0.000	0.000	0.014	0.002	ns	ns	ns
A vs. C	0.000	0.000	0.008	0.000	0.004	0.016	ns
A vs. D	0.000	0.000	0.001	0.000	ns	0.008	ns
C vs. D	ns	ns	ns	ns	ns	ns	ns

Figure 3 - Secondary outcome.



UTI = Urinary tract infections; *** = p = 0.000

Table 3 - Multiple linear regression analysis for dysfunctional voiding score (DVS) determinants with backward selection.

Best model parameters	β	Р
Age	0.246	< 0.05
DUI	-0.220	0.081
NE	-0.629	< 0.001
Constipation	-0.186	0.14
Bladder thickness	0.461	< 0.005
VUR	0.516	< 0.001

Model 1: Independent DVS predictors: age, urinary tract infections (UTI), daytime urinary incontinence (DUI), nocturnal enuresis (NE), NE+DUI, constipation, renal ultrasound, bladder thickness, renal scarring, vesicoureteral reflux (VUR), uroflow, pelvic muscle electromyography (EMG), postvoid residual (PVR), bladder capacity (adj. R2 = 0.394, p < 0.05));

Model 2: Excluded bladder capacity from M1 (adj. $R^2 = 0.419$, p< 0.01);

Model 3: Excluded renal ultrasound from M2 (adj. $R^2 = 0.441$, p < 0.01);

Model 4: Excluded renal scarring from M3 (adj. $R^2 = 0.460$, p < 0.005);

Model 5: Excluded EMG from M4 (adj. $R^2 = 0.477$, p < 0.005);

Model 6: Excluded NE+DUI from M5 (adj. $R^2 = 0.491$, p < 0.005);

Model 7: Excluded Uroflow from M6 (adj. $R^2 = 0.504$, p < 0.001);

Model 8: Excluded PVR from M7 (adj. $R^2 = 0.505$, p<0.001);

Model 9 - The best model: Excluded UTI from M8 (adj. $R^2 = 0.508$, p < 0.001); $\beta = standardized beta coefficient of multiple correlation.$

reover, up to 40% of the patients seen in a pediatric urology clinic have symptoms of LUTD (4). Seventy-five percent of such children are evaluated between 3 and 10 years of age, and about 20% is between 11 and 17 years of age (20). Girls are predominant compared to boys (3). There can be a profound impact of LUTD on the quality of life of the patients and their families (21).

The mainstay of treatment for LUTD in children lies in BCT which may be the only therapy needed in the majority of patients. The combination of standard BCT with biofeedback therapy significantly improves results (21).

We evaluated the success of a combination of standard and biofeedback BCT in 72 girls (age 5-16 years) with various dysfunctional elimination syndrome and/or recurrent UTI. Overall, compliance with BCT was quite satisfactory during 6 weeks of training (93 - 98.6%), but later on it decreased to 76.4% at 7 weeks and 40.3% at 8 weeks of BCT. A decreasing compliance was

mainly caused by non-medical issues. Considering that long duration of treatment, it was an important cause of low compliance, we realized that duration of treatment should be shorter. Therefore, our current protocol involves one week of intensive training followed by outpatient clinic training during 4 weeks instead of 7.

The efficiency of BCT was estimated from decrease in percentage of patients with dysfunctional elimination syndrome, and from increase of those who normalized lower urinary tract and/or bowel function. In addition, grading of response to BCT was done for DVS, DUI, and PVR. The evaluation was performed in 50 patients at the end of training after median 11 months. In general, the results at the end of the training and at reevaluation were similar. Overall, the patients were found to benefit with BCT. When evaluating a percentage of affected patients a significant decrease of DUI (from 43.7% to 9.2 %, p = 0.000), nocturnal enuresis (30% to 13.4%, p = 0.001)

and constipation (from 45.7 to 10.6%, p = 0.000) was observed. Also, the treatment response rates were high for bladder capacity and uroflow/EMG pattern, while the results for PVR were was less satisfactory. Furthermore, BCT resulted in decreased number of the patients with UTI (97.1% to 22.6%, p = 0.000) as well as those treated with antibacterial prophylaxis (88.9% to 11.9%, p = 0.000) and/or medical urotherapy (50.8% to 5.1%, p = 0.000). In addition, parents graded BCT success as response and full response in 79.2% of the cases. According to parent's impression, only 1.4% of the patients had no improvement.

Other authors also showed the beneficial effect of BCT on LUTD and related complications (22-25). However, because of a lack of standardization concerning diagnoses, treatment modalities, intervention program as well as evaluation of outcomes, it is difficult to compare results of various studies (26,27). A scoring system grading the severity of dysfunctional elimination syndrome could improve evaluation methods and enable comparisons among studies. Muddlers et al. presented the first study in which severity and number of daytime wetting accidents per week was used to define the results of BCT (16). This scoring system took into account that change to a lower grade of daytime urinary incontinence indicated improvement. We used the same scoring system for quantitative assessment of DVS and DUI. At the end of the training course more than half of our patients (56.9%) with DUI showed full response is better than the results of Muddlers et al. who reported full response in 42% of the patients. Furthermore, we found no response in 15.0% while Muddlers et al. found no response in 22% of the patients (16). The training programs were similar in both studies but Muddlers et al. did not use animated biofeedback. Therefore, better outcome in our study may be due to introducing animated biofeedback in addition to uroflow/EMG biofeedback.

Nocturnal enuresis was a negative predictor for the DVS improvement, while age, bladder wall thickness and finding of VUR were positive predictors. The positive influence of age on training response may reflect natural maturation of the regulation of bladder function.

CONCLUSIONS

Treatment of girls with a combination of behavioral and biofeedback was associated with improved urinary incontinence, and decreased frequency of constipation and UTI. It enabled improvement of bladder capacity and uroflow/EMG pattern, while decreasing of PVR was achieved only in a one-third of patients. Bladder control training seems to be an important tool in reducing prevalence of UTI in girls with lower urinary tract dysfunction. Better training results are expected in patients with higher bladder wall thickness as well as in those with vesicoureteral reflux, while presence of nocturnal enuresis is a negative predictor of the training effect.

ABBREVIATIONS

BCT: Bladder control training

DES: Dysfunctional elimination syndrome

DVS: Dysfunctional voiding score DUI: Daytime urinary incontinence EBC: Estimated bladder capacity

LUTD: Lower urinary tract dysfunction

NE: Nocturnal enuresis

PFMR: Pelvic floor muscle retraining

PVR: Post-void residual UTI: Urinary tract infections VUR: Vesicoureteral reflux

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CONFLICT OF INTEREST

None declared.

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EDITORIAL COMMENT

This is an interesting study that adds valuable information to the literature regarding the results of biofeedback plus standard urotherapy for children with lower urinary tract dysfunction (LUTD). The authors dealt with a group that is difficult to treat, since about 75% of the patients had renal scars and 97% had recurrent UTI. However I would like to discuss some issues presented in this paper. The authors make the same mistake that is found in most studies published on this subject. They do not separate the outcome of patients with isolated overactive bladder, those with overactive bladder plus dysfunctional voiding (a worse off group) and those with isolated dysfunctional voiding. These 3 groups behave differently and should be considered different groups to better interpret the results. LUTD can be classified with non-invasive methods, such as a voiding diary, uroflowmetry and the measurement of postvoid residual urine. Urodynamic study is not usually necessary.

I would like to keep addressing the terminology issue. The authors use the term dysfunctional elimination syndrome (DES) as synonym of LUTD. Only half of the patients with LUTD had constipation. Then, DES was present in only 50% of the cases. According to the ICCS (1), DES is an imprecise and unspecific term and we should report the data from patients with OAB and dysfunctional voiding with and without constipation, separately.

The ideal protocol for biofeedback therapy is unknown. The authors, like many others, use an intensive inpatient 5-days course. The study's data suggests that this intensive treatment might increase the post-treatment dropout rate. In our experience, biofeedback therapy can be as successful when performed in an outpatient clinic, in a weekly forty minute session (2). However, these two methods should be compared in a randomized clinical trial.

Some notable issues: Biofeedback, on principle, should be indicated for children with dysfunctional voiding. Since 34% of patients had a normal uroflow curve and 48% had no EMG activity, I infer that the authors treated patients with isolated overactive bladder, which can be better managed by electrical stimulation or anticholinergics. Some patients used anticholinergics and alpha-blockers during the biofeedback treatment. This confuse the results since some patients may have improved symptoms due to the mediaction.

I agree that interactive games help the treatment success, although the data presented does not show this. Kaye and Palmer performed a controlled study with 120 children with dysfunctional voiding. Sixty underwent biofeedback with animation and 60 underwent biofeedback without animation. They demonstrated that the outcome was the same but the number of sessions was lower in the group who underwent biofeedback with animation.

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