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Original Article

Effectiveness and durability of parasacral transcutaneous electrical nerve stimulation in children with dysfunctional voiding

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ABSTRACT

Objectives: The aim of this study was to compare the effectiveness of biofeedback (BF) treatment, parasacral transcutaneous electrical nerve stimulation (PTENS), and dual combination in pediatric dysfunctional voiding (DV).

Patients and methods: Between July 2018 and July 2021, a total of 42 participants diagnosed with DV were included in the prospective phase and divided into three groups: the BF group (1 male, 12 females; mean age: 9 ± 3.28 years; range, 6 to 13 years), the PTENS (PT) group (2 males, 12 females; mean age: 8.85 ± 2.14 years; range, 6 to 11 years), and the biofeedback and PTENS (BFPT) group (2 males, 13 females; mean age: 9.6 ± 2.29 years; range, 5 to 16 years). Patients with DV were randomly selected for BF, PT, and BFPT. Standard urotherapy was applied to all patients. Patients were evaluated with uroflowmetry, residual urine levels, and an objective symptom scoring system, the International Consultation on Incontinence Questionnaire Pediatric Lower Urinary Tract Symptoms, before and after treatment. Late follow-up evaluations were also done.

Results: No difference was observed in uroflowmetric data. Although the symptom scores decreased significantly in all groups after treatment (p for BF: 0.005, p for PT: 0.0001, p for BFPT: 0.001), the posttreatment score after PT was significantly lower when compared to the score after BF (17.46 ± 3.23 *vs*. 14.5 ± 3.59, $p = 0.018$). Long-term follow-up was 23.11 ± 0.78 months for the BF group and 17.6 ± 1.51 months for the PT group. These scores remained similar in long-term follow-up.

Conclusion: Parasacral TENS seems to be more effective as a primary treatment in patients with DV in the short and long-term compared to BF treatment. It may be more advantageous in patients who cannot cooperate, have inadequate motivation, or have mental retardation. Thus, PT should be kept in mind in patients with DV.

Keywords: Biofeedback, children, dysfunctional voiding, electrostimulation.

Bladder dysfunction in children is an important clinical condition in daily pediatric urology practice.[1] Detrusor dysfunction occurs in the filling phase, whereas sphincter dysfunction is questioned in the emptying phase and defined as dysfunctional voiding (DV). These two entities can be seen together, but each dysfunction can be observed alone, as well. Dysfunctional voiding is an important cause of incontinence, which is defined as habitual contraction of the urethral sphincter or pelvic floor muscles during voiding and is manifested by an intermittent or staccato flow pattern in uroflowmetric studies.[2]

According to the International Children's Continence Society (ICCS), specific urotherapy is recommended in all patients with DV who do not respond to standard urotherapy. Biofeedback (BF) treatment and pelvic floor rehabilitation are the leading approaches that are defined in specific urotherapy.[3]

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In recent years, electrical stimulation and neuromodulation have been used more commonly for the treatment of bladder dysfunction in children. Reflex activation of the hypogastric inhibitory neurons and central inhibition of the bladder's efferent neurons are thought to be responsible for the beneficiary effects of electrostimulation.[4] Current literature on electrostimulation in children mostly involves studies on parasacral transcutaneous electrical nerve stimulation (PTENS) and posterior tibial nerve stimulation (PTNS).[5-8] In 2020, ICCS recommended PTENS for the treatment of detrusor overactivity.[3] The most important problem in studies on neuromodulation in children is that patient groups are not homogeneous, and different bladder dysfunction subtypes with combined treatment modalities are evaluated together. This makes it difficult to interpret the results and extrapolate any recommendations for clinical use. There is no clear information about the use of electrostimulation in DV in the literature except for some clinical observations.[4,9,10]

To the best of our knowledge, there is no previous study comparing BF treatment with PTENS as the primary approach in children with DV in the literature. The aim of this prospective, randomized, clinical study was to compare the effectiveness of BF treatment, PTENS therapy, and dual-combination treatment in these patients.

PATIENTS AND METHODS

This prospective randomized clinical study was conducted at İstanbul Medeniyet University, Department of Pediatric Surgery between July 2018 and July 2021. A total of 42 participants diagnosed with DV were included in the prospective phase and divided into three groups using simple randomization: the biofeedback (BF) group (1 male, 12 females; mean age: 9 ± 3.28 years; range, 6 to 13 years), the PTENS (PT) group (2 males, 12 females; mean age: 8.85 ± 2.14 years; range, 6 to 11 years), and the biofeedback and PTENS (BFPT) group (2 males, 13 females; mean age: 9.6 ± 2.29 years; range, 5 to 16 years). New patients with DV aged above five years were included in the prospective phase based on the presence of at least two of the following conditions: uroflowmetry showing disrupted urine flow (plateau, staccato, interrupted voiding), electromyography showing increased external sphincter activity, or ultrasonography showing significantly increased post-void residual urine. Conversely, patients were excluded from the study if they had neuropathic bladder dysfunction, detrusor overactivity without DV, primary bladder neck dysfunction, or active urinary tract infections. Written informed consent was obtained from all individual participants included in the study. The study protocol was approved by the İstanbul Medeniyet University Göztepe Training and Research Hospital Clinical Research Ethics Committee (Date: 10.04.2018, IRB No. 2018/0010), and the research was conducted in accordance with the ethical principles of the Declaration of Helsinki.

In the next prospective phase, 45 new patients with the diagnosis of DV, who did not receive any urotherapy or pharmacotherapy before (BF n = 15, PT n = 15, BFPT n = 15), were included. In the BF group, one patient who was later diagnosed as having neurogenic bladder and another patient as having brain tumor were excluded. In the PT group, one patient, who did not continue treatment due to the COVID-19 pandemic, was not included. Thus, prospective evaluation was performed in a total of 42 patients (37 girls and 5 boys), as shown in Table 1. Details of the study are summarized in the CONSORT diagram, as shown in Figure 1.

Before the onset of this prospective study, a preliminary evaluation was done. Patients who received standard urotherapy and BF in the last 15 months for DV were searched for their clinical outcomes and factors influencing treatment success, like constipation, stool incontinence, and deep sleep, retrospectively. Constipation was evaluated according to Rome IV criteria, and stool incontinence was defined as the inability to hold stool with involuntary passage either as a piece or as soiling. Deep sleep was defined as difficulty in waking up during sleep with external stimuli like verbal and physical cues.

The ICCS standards were adopted in the urodynamic examinations and in the

terminology.[2] A residual urine volume greater than 10% of the expected bladder capacity or greater than 20 mL was considered a significant residual urine volume.

After the diagnosis of DV, standard urotherapy was applied to all patients throughout the treatment period. This included bladder education, control of fluid intake, behavioral

Table 1. Demographic and clinical data of the study groups

	BF group	PT group	BFPT group	
	Mean ± SD	Mean ± SD	Mean ± SD	*p*
Age (year) post treatment normal	9 ± 3.28	8.85 ± 2.14	9.6 ± 2.29	0.423*
Sex (abnormal**)				0.85
Male	1	2	2	
Female	12	12	13	
Sphincteric EMG activity abnormal	10	11	9	0.557
UF pattern before	11	12	8	0.229
UF pattern after	4	4	5	0.288
Constipation before	6	3	4	0.607
Constipation after	-	-	-	N/A

EMG, electromyography; BF, biofeedback; PT, parasacral TENS; BFPT, biofeedback and TENS groups; SD, standard deviation; UF, uroflowmetry; * Kruskal Wallis test; ** Abnormal UF patterns described as plateau, tower, interrupted, staccato. N/A, not applicable. Sphincteric EMG activity was abnormal in all patients before treatment. Chi-square test.

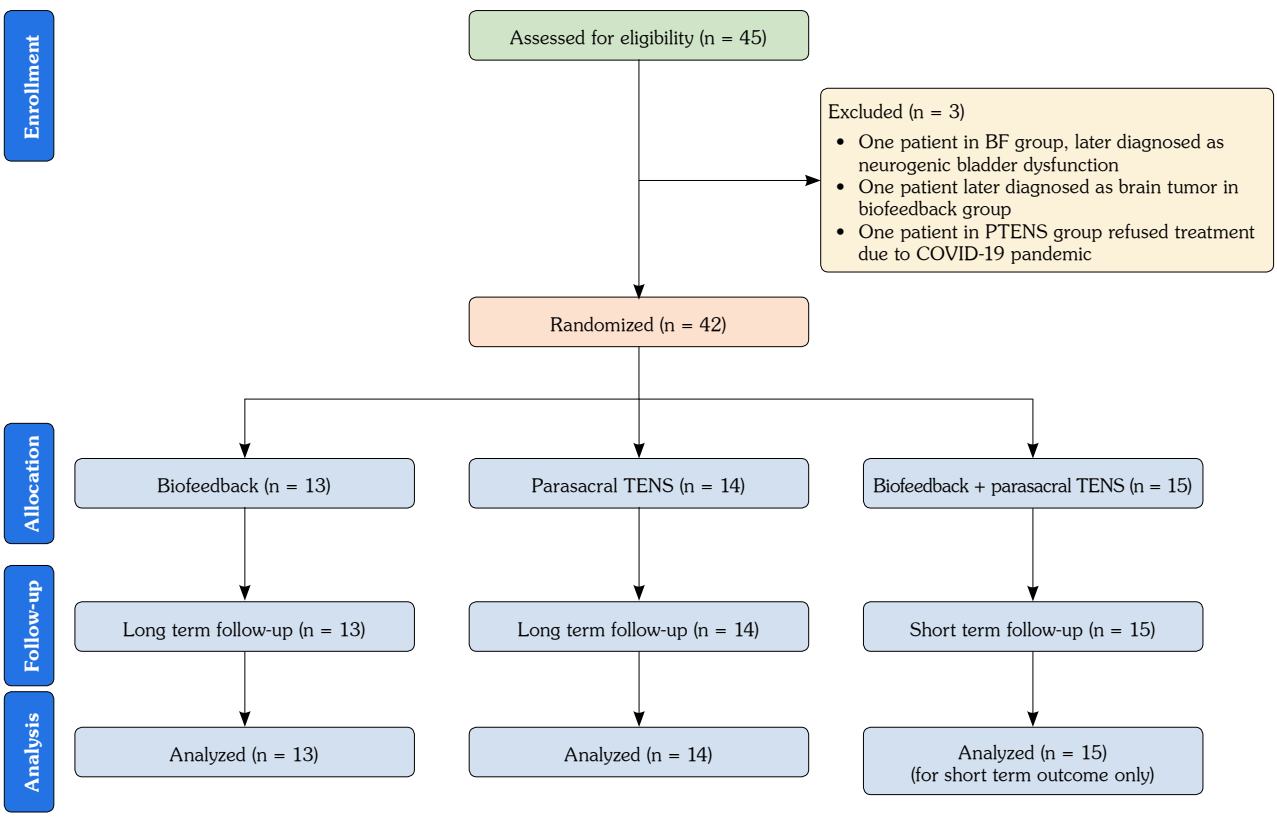


Figure 1. The CONSORT diagram of the study.

BF, Biofeedback; BFPT, biofeedback and PTENS; COVID-19, Coronavirus Disease 2019, PT, Parasacral TENS.

modifications, appropriate voiding position, and treatment of constipation. None of the patients received medical treatment other than urotherapy. Biofeedback and PTENS were applied as the first-line treatment together with standard urotherapy.

Standard urodynamics equipment (MMS Solar Blue Urodynamics, Enschede, Netherlands) was used for BF and uroflowmetric studies. For the BF, electrodes were placed in the 3 and 9 o'clock perianal regions, and a reference electrode was placed on the patella. Patients completed their weekly exercises in 30-min sessions by contracting and relaxing their pelvic muscles with a computerized animation for 10 weeks.

In the PT group, treatment was done using a TENS device (Saneo GmbH Dorsten, Germany) with a setting of 10 Hz frequency and 350 μs in 20-min sessions daily for 10 weeks, at a sensitivity level which the patient could tolerate, using 4 × 4 cm electrodes placed on the S3 dermatome. After training for the first application in the hospital, the rest of the treatment was performed at home. In combined treatment, both BF and PTENS were done together for 10 weeks, as described above. Post-void residual urine was measured by a real-time ultrasonography device (Signos RT, Signostics Ltd., Thebarton, SA, Australia) after each session of BF, at the onset and at the end of PTENS treatment.

Primary outcomes of the study were

- Uroflowmetric parameters and sphincter electromyography (EMG) activity at the beginning and end of treatment
- Post-void residual urine at the beginning and end of treatment
- The score of the International Consultation on Incontinence Questionnaire Pediatric Lower Urinary Tract Symptoms (ICIQ-CLUTS), validated in the local language as an objective symptom scoring system, was reported by the parents at the beginning and end of the study.[11]

The secondary outcomes of the study included the rates of improvement and resolution of the symptoms defined by the ICCS.[2]

Age, sex, presenting symptoms, pre- and post-treatment constipation, encopresis, urinary tract infections, and stool incontinence were also evaluated separately.

Patients were called for long-term outcomes, and reevaluation was performed by filling in ICIQ-CLUTS forms with parents.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Quantitative data were expressed as mean ± standard deviation (SD), and qualitative data were given in frequency. Power calculation was done, and n number in each group was found to be at least 14 cases with a 5% error margin and 90% power. The Kolmogorov-Smirnov test was used to evaluate if the variables had a normal distribution. Quantitative parameters were analyzed using the Kruskal-Wallis and Mann-Whitney U tests. Chi-square test was used for the comparison of qualitative values. The dependent parameters were evaluated using the Student's t-test and the Wilcoxon signed rank test. A p-value of < 0.05 was considered statistically significant.

RESULTS

Regarding the preliminary retrospective evaluation of patients receiving BF treatment, a clinical response was achieved in 28 patients (62.2%). The mean age was found to be 10.6 ± 2.5 years in the patients who responded to BF and 8.3 ± 2.3 years in the patients who did not. When all parameters were evaluated, BF was found to be unsuccessful in patients who had constipation ($p = 0.022$), stool incontinence ($p = 0.007$), and deep sleep ($p = 0.048$).

Long-term symptom scoring could be performed in a total of 27 patients in the BF and PT groups. Major presenting symptoms were daytime/nighttime incontinence and urinary tract infection in these patients, as shown in Table 2. Five patients in the BF group (38.46%), six patients in the PT (42.85%), and six patients in the BFPT group (40%) presented initially with symptoms of detrusor overactivity together with DV.

Post-void residual urine volume was found to be 46.68 ± 64.35 mL before treatment and 26.36 ± 66.14 mL after treatment in

Table 2. The patients' presenting symptoms

	Presenting symptoms
Symptoms	Number of patients
Daytime and nighttime incontinence	24
Urinary tract infection	20
Nighttime incontinence	9
Daytime incontinence	6
Vesicoureteral reflux	5
Constipation	4
Abdominal pain	2
Voiding postponement	1

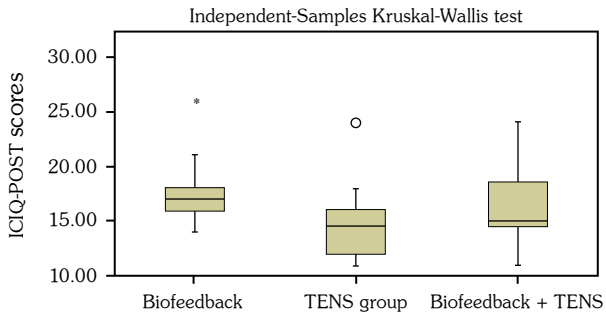


Figure 2. Box plot graph of the ICIQ-CLUTS scores after treatment in the groups.
TENS, transcutaneous electrical nerve stimulation; ICIQ-POST, International Consultation on Incontinence Questionnaire-Postpartum Module; ICIQ-CLUTS, International Consultation on Incontinence Questionnaire Pediatric Lower Urinary Tract Symptoms.

the BF group (p = 0.037). Whereas, in the PT group, this value was 54.5 ± 48.96 mL before and 1.36 ± 5.08 mL after treatment (p = 0.005).

No statistically significant difference was observed in uroflowmetric data between the groups, as shown in Table 3.

Although the symptom scores decreased significantly in all groups, the posttreatment score after PT was significantly lower than the score after BF (17.46 ± 3.23 *vs.* 14.5 ± 3.59, respectively, p = 0.043). The data obtained by the ICIQ-CLUTS scoring system in the groups are summarized in Figure 2 and Table 4.

Complete and partial symptom improvement, as the secondary outcome of the study, was achieved in 85.7% of PT patients, whereas this ratio was 73.3% in BFPT and 69.2% in BF patients, respectively.

Table 3. Comparison of the uroflowmetric parameters between the groups

	Uroflowmetric data			
	BF group	PT group	BFPT group	
Variables	Mean ± SD	Mean ± SD	Mean ± SD	p*
PREVOL (mL)	196.3 ± 65.4	186.14 ± 113.4	209.27 ± 110.5	0.834
POSTVOL (mL)	175.3 ± 58.4	152.71 ± 135.6	218.4 ± 111.9	0.063
PREQMAX (mL/sec)	18.85 ± 5.8	17.79 ± 7.9	20.73 ± 11.5	0.853
POSTQMAX (mL/sec)	18.9 ± 8.6	18.93 ± 8.2	25.8 ± 12.6	0.212
PREQAVE (mL/sec)	12.2 ± 4.4	9.57 ± 4.8	9.8 ± 7.3	0.202
POSTQAVE (mL/sec)	12.2 ± 4.1	8.36 ± 4.6	14.47 ± 8.5	0.080
PREQTIME (sec)	9.15 ± 9.6	9.5 ± 11.9	16.2 ± 23.9	0.883
POSTQTIME (sec)	6.85 ± 5.5	4.79 ± 3.5	8.53 ± 7.6	0.261
PREFLOWTIME (sec)	20.77 ± 9.9	24.21 ± 17.2	29.27 ± 21.5	0.796
POSTFLOWTIME (sec)	18.54 ± 8.8	18.21 ± 10.6	18.73 ± 12.7	0.852
PREVOIDTIME (sec)	25.54 ± 21.1	43.29 ± 45	38.07 ± 34.5	0.655
POSTVOIDTIME (sec)	25.69 ± 18.6	34.14 ± 36.6	20.07 ± 14.2	0.517

BF, biofeedback; PT, parasacral TENS; BFPT, biofeedback and TENS groups; SD, standard deviation; PREVOL, voiding volume before treatment; POSTVOL, voiding volume after treatment; PREQMAX, Q max before treatment; POSTQMAX, Q max after treatment; PREQAVE, mean Q before treatment; POSTQAVE, mean Q after treatment; PREQTIME, time to reach Q max before treatment; POSTQTIME, time to reach Q max after treatment; PREFLOWTIME, flow time before treatment; POSTFLOWTIME, flow time after treatment; PREVOIDTIME, voiding time before treatment; POSTVOIDTIME, voiding time after treatment; * Kruskal-Wallis test.

Table 4. Changes in symptom scoring between the groups before treatment, after treatment, and in the long-term

	BF group	PT group	BFPT group	
ICIQ-CLUTS	Mean ± SD	Mean ± SD	Mean ± SD	*p**
Before treatment	22.38 ± 5.14	22.5 ± 4.26	20.87 ± 4.47	0.326
After treatment	17.46 ± 3.23	14.5 ± 3.59	16.4 ± 3.56	**0.043**
Long term	17.78 ± 4.52	16.57 ± 5.51		
p value**	**0.005**	**0.0001**	**0.001**	

BF, biofeedback; PT, parasacral TENS; BFPT, biofeedback and TENS groups; SD, standard deviation; ICIQ-CLUTS, International Consultation on Incontinence Questionnaire Pediatric Lower Urinary Tract Symptoms; * Kruskal-Wallis test, inter-group evaluation; ** Chi-square test. The long-term follow-up time was 23.11 ± 0.78 months for the BF group and 17.6 ± 1.51 months for the PT group. In the PT group, the difference between the score in the pre-treatment period and the score in the long-term period was significant ($p = 0.002$, Student's t-test). However, there was no significant difference between the score in the post-treatment period and the score in the long-term period. The ICIQ-CLUTS score was significantly lower after TENS treatment compared to the score after biofeedback treatment (17.46 ± 3.23 vs. 14.5 ± 3.59, $p = 0.018$, Student's t-test). A significant difference could not be found when the scores in the BFPT group were compared with the other treatment groups. There was a significant reduction in the ICIQ-CLUTS score after treatment compared to the pre-treatment period in all groups.

DISCUSSION

Dysfunctional voiding is a clinical condition that is observed in about 2-7% of children. It is usually manifested by nighttime or daytime urinary incontinence and urinary tract infection.[12-14] If not treated, vesicoureteral reflux and recurrent urinary tract infections may occur.[15-18] Classical treatment for DV includes pelvic floor rehabilitation, BF therapy, and alpha agonist treatment in addition to standard urotherapy.[1,3] Biofeedback has been described by Maizels for the first time in patients who had residual urine after staccato or intermittent voiding patterns.[19] Since the use of computer-based programs by McKenna et al.,[20] in 1999, BF has been commonly recommended as the first-line treatment in patients with DV. In the literature, symptom improvement rates of 64.7%-89% have been reported after BF in patients who are resistant to standard urotherapy.[4,6,21,22] In our retrospective evaluation, we found a symptom resolution rate of 62.2% after BF in children with DV. Poor patient motivation, inadequate mental capacity, inadequate patient compliance, social and geographic limitations, and inadequate health coverage have been considered as the factors determining the efficiency of BF.[23] However, there may be difficulties in the interpretation of the studies in the literature, as spontaneous resolution of daytime urinary incontinence per year is commonly ignored, and usually, patients who receive multimodal treatment are also included in the study design. There is also a lack of a clear definition of treatment success, as well as the definition of patient groups and the clinical conditions.[1] Nevertheless, BF therapy is currently accepted as the standard therapy for DV.[3,24]

Neurostimulation has recently been included in the treatment armamentarium for lower urinary tract dysfunction in children after its use in adult patients. Although there are many different electrical stimulation methods, the studies predominate on TENS and PTNS in children.[4-7,25] In a study by Barroso et al.,[5] it was observed that TENS was more efficient compared to PTNS in patients who had bladder dysfunction with detrusor overactivity, and it was interpreted that TENS acts by stimulating the sacral nerve plexus more directly than PTNS. With the clinical experience from these studies, ICCS recommended the use of TENS for children with detrusor overactivity and urge incontinence in their standardization document.[3] Although the exact mechanism of electrical stimulation is not known, it is thought that stimulation of inhibitory sympathetic neurons in the hypogastric nerve, triggering of central inhibition, relaxation of the bladder following contraction with the first stimulation, activation of the inhibitory pelvic plexus with stimulation of the sacral nerve, and a change in the nerve conduction pattern with electrical stimulation may lead to these observed

actions.[26,27] In a recent study in adults, Netto et al.[28] demonstrated that PTENS stimulates the anterior cingulate cortex in the brain, and increased connectivity between this point and the dorsal lateral prefrontal cortex may be responsible for the effects of PTENS. In the studies on TENS, it is difficult to interpret the results, as patient groups are not homogeneous and harbor different bladder dysfunction types, including patients receiving different treatment modalities like pharmacotherapy.[4,6,8] Barroso et al.[4,10] used PTENS on 19 patients with detrusor overactivity and BF treatment on 17 patients with DV. They used TENS on seven patients who did not respond to BF and reported a complete clinical response in four patients and a partial response in two patients. They commented that TENS was also effective in DV patients who did not respond to BF. Capitanucci et al.[9] applied PTNS to 37 patients who had different bladder dysfunction subtypes; they reported that the efficiency of PTNS could be stronger in DV than in detrusor overactivity, and treatment practices might also be extended to this patient group. In the study by Tugtepe et al.,[6] a total of 27 therapy-resistant patients with bladder dysfunction were evaluated according to their response to TENS. It was reported that 16 of these patients had DV, and these patients received different medical and behavioral therapies with TENS. The effect of TENS treatment in the patient group who had DV was not particularly examined. Besides, due to the heterogeneity of the patient group, it is difficult to interpret the results of this study. De Abreu et al.[29] used standard urotherapy on 20 of 40 patients and standard urotherapy plus PTENS treatment on the other 20 patients, and they found that PTENS treatment was effective in patients who had bladder and bowel dysfunction. Other than these observational studies, we could not find any clinical study comparing the effectiveness of BF and TENS treatment in pediatric patients with a primary diagnosis of DV in the literature.

In the publications on TENS, electrical stimulation has been used with different settings in each study. These different applications make it difficult to compare the differences between the methods. Although the exact effect of protocol differences on clinical results is not known, the good clinical outcome in all studies suggests these differences may not influence the outcome.[4,6,7,25]

The results in this study showed that PTENS treatment with standard urotherapy was more effective in DV as primary treatment compared to BF and urotherapy in the early phase. This efficiency was durable and maintained in the long-term. Bianchi et al.[30] showed in adult patients with voiding dysfunction who were treated with percutaneous tibial nerve stimulation that these patients still considered themselves improved even seven years after the treatment. Neuroplasticity of children may be higher in the central and peripheral nervous system; thus children may respond better to electrical stimulation. However, this action has not been proven yet. This study contributes to the literature in terms of showing both the short-term and long-term effects of TENS treatment in children with DV.

One of the limitations of this study was the relatively low number of patients, but these numbers are comparable with those of similar studies in the literature. Lack of a control group may also be regarded as a limitation. We could not get the late-term result of the BFPT group, as the study had to be stopped for a certain period of time due to the COVID-19 pandemic, despite the fact that both BF and PT treatments were durable after a long period, which may decrease the need for this observation. On the other hand, the effect of electrostimulation in DV patients with detrusor overactivity might positively affect the clinical results, but these effects were evenly observed in the patient groups. As all patients similarly received standard urotherapy and treatment of constipation before the specific treatment, the effects of this approach on the results are not known, but the comparison may not be expected to be influenced. On the other hand, with the parameters of the current study, we can only evaluate the results of the treatment modalities but not their mechanism of action.

In conclusion, it is thought that PTENS treatment may be an alternative as a primary treatment in children with DV in the short and long-term compared to BF treatment. Although

a control group of patients receiving standard urotherapy alone was not included in this study, all three therapies proved to be effective. However, the best results were achieved with PT. This study seems to be the first clinical study on this topic in the literature. PTENS is an easily applicable and cheap method and does not require hospital admission. It may be advantageous in patients who cannot cooperate, who have inadequate motivation for any treatment, and who have intellectual disabilities. Due to these superiorities, PTENS should be kept in mind as an alternative primary treatment option in children with a diagnosis of DV.

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Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Ş.K.Ö.: Type of contribution, contributors, idea/concept, design, literature review, references and fundings materials; N.G., C.C.: Control/supervision; Ş.K.Ö., B.A., M.M.: Data collection and/or processing, analysis and/or interpretation; Ş.K.Ö., Ç.U.D.: Writing the article critical review

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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