Effect of Pelvic Floor Interferential Electrostimulation on Urodynamic Parameters and Incontinency of Children With Myelomeningocele and Detrusor Overactivity

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OBJECTIVES To evaluate safety and efficacy of transcutaneous interferential (IF) electrostimulation on voiding symptoms and urodynamic variables in children with myelomeningocele (MMC)-induced refractory neurogenic detrusor overactivity.

METHODS Thirty MMC children (18 girls, 12 boys; mean age 5.6 ± 2.7) with moderate to severe intractable incontinency, detrusor overactivity, and high maximal detrusor end-fill pressure were enrolled and then randomly allocated to treatment (IF stimulation, 20 children) and control (sham stimulation, 10 children) groups. They underwent urodynamic study (UDS) before and after IF and 6 months later, with attention to mean maximal detrusor pressure (MMDP), maximum bladder capacity (MBC), mean detrusor compliance (MDC), postvoiding residue (PVR), and detrusor sphincter dyssynergia (DSD). Daily incontinence score, voiding frequency, and enuresis were also assessed. Eighteen courses of pelvic floor IF electrostimulation for 20 minutes 3 times per week were performed with low-frequency current, duration of 250 microseconds, and repetition time of 6.6 seconds.

RESULTS Of the UDS parameters in the treatment group immediately after IF implication, MMDP, PVR, and DSD significantly improved compared with sham stimulation and pretreatment measures ($P < .05$). In the treatment group, 78% patients gained continence immediately after IF therapy and 60% had persistent continence for 6 months ($P < .05$). Immediately after IF treatment, urinary frequency and enuresis also improved ($P < .05$), with a statistically significant difference between the 2 groups.

CONCLUSIONS This study demonstrated that noninvasive IF therapy is effective in improving voiding symptoms including incontinence and UDS parameters of MMC children with neurogenic detrusor overactivity. The clinical beneficial implication of this modality is yet to be determined in larger studies. UROLOGY 74: 324–331, 2009.

Myelomeningocele (MMC) is part of neural tube defect spectrum arising from posterior neuropore closure failure during gestation, with an incidence of 1.6 per 1000 live births in Iran.[1] Urologic management of children who are suffering is of paramount importance because renal failure continues to be the leading cause of death in patients after the first year of life.[2] Neurogenic detrusor overactivity (NDO) is a primary urodynamic diagnosis in these children, with the overall incidence of 57% in newborn period (22%-75%, depending on the level of spinal involvement) and, along with high probability of sphincter detrusor dyssynergia in affected children, could lead to incontinency, high intravesical pressure, hydronephrosis, and ultimately upper urinary tract deterioration.[3] Anticholinergic medication along with clean intermittent catheterization (CIC) and infection prophylaxis are the mainstay of treatment in these patients.

For several decades, numerous methods of electrostimulation (ES) of nerves or muscles have been used as an alternative treatment option for urinary complaints, with as high as 50%[4] clinical improvement.[5-9] Interferential (IF) current, a form of electrical stimulation using

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medium-frequency currents with a sinusoidal waveform,[10] has already been used to strengthen the pelvic floor to treat urinary incontinence caused by overactive bladder,[11] especially in females with stress incontinence, and also for pain control and wound healing in adults.[12]

In spite of some previous studies evaluating IF therapy on voiding dysfunction,[12,13] to our knowledge, therapeutic efficacy of this modality has not been investigated to manage patients with bladder complaints mainly consequent to structural abnormality of spinal cord exclusively in pediatric population. Herein, we present the results of a clinical trial using IF current in patients with MMC and refractory NDO to evaluate safety and its efficacy on incontinence and urodynamic study (UDS) variables of these children for a minimum of 6 months after the procedure.

MATERIAL AND METHODS

The investigation protocol was approved by the local ethics committee at Tehran University of Medical Sciences. Details of the project were explained to children's caregivers and patients (when possible), and written informed consent was obtained from all participants. Children with additional neurologic abnormalities other than MMC consequences, as evaluated by our pediatric neurosurgeon, were excluded. All patients were assessed by a pediatric urology specialist before and during the follow-up sessions, and children with underlying medical conditions (metabolic diseases, anorectal and urogenital malformations, previous urogenital surgery) were excluded before the initiation of the project. Children with new onset signs of upper urinary tract compromise on routine urologic evaluation (kidney ultrasonography, urinary sediment test) were addressed promptly and were considered as failure in the final analysis. They were all instructed on how to compile a voiding diary; daily incontinence score was assessed and data were gathered on each visit during the follow-up period. Frequency was defined as the number of wetting episodes between 2 consecutive CICs, and enuresis was the number of nights that the child involuntarily micturates during sleep in a 1-week period. The daily incontinence score was recorded on a scale of 0-3, as described by Schurch et al.[14]: score 0, completely dry; 1, wet once a day, usually at night (mild); 2, wet for $<$50% of the time between CIC (moderate); and 3, wet for $>$50% of the time between CIC (severe). A decrement of 2 or more degrees in the daytime incontinence score was considered as "improvement."

Patients

Children with MMC between 3 and 16 years of age, with moderate to severe incontinence resistant to conventional treatment (demonstrating adverse effects or unsatisfactory success rate), requiring CIC every 3 to 4 hours were recruited for this single-center prospective study. All children had urodynamically proven detrusor overactivity (spontaneous detrusor contraction during the filling phase causing detrusor pressure increase to $>$15 cm H_2O from baseline)[15] and high maximal detrusor end-fill pressure $>$40 cm H_2O.[16]

The children were randomly allocated to treatment (IF stimulation, 20 children) and control (sham stimulation, 10 children) groups with a 2:1 ratio, respectively (balanced block randomization).

Patients were unaware of the group assignment and so was the urodynamic nurse practitioner. They were followed up for the next 6 months on a regular basis. Most are still under observation at our center at the time of publication.

Urodynamic Measurement

The UDS evaluations were complied with International Children's Continence Society (ICCS) recommendations.[15] Pretreatment cystometry (F.M. Wiest Medizintechnik, GmbH, Unterhaching, Germany) was performed, with patients in supine position, measuring the intravesical and abdominal pressures simultaneously with a double-lumen catheter and rectal balloon. Special attention was given to mean maximal detrusor pressure (MMDP), maximum bladder capacity (MBC), mean detrusor compliance (MDC), postvoiding residue (PVR), and detrusor sphincter dyssynergia (DSD). The same protocol was used for the UDSs performed within 2 weeks after ES courses, and 6 months later. Patients were asked to discontinue their anticholinergic medication intake at least 7 days before all 3 UDS sessions.

Although considered a limitation, success was defined as any significant reduction in each of these UDS parameters compared with our sham stimulation group or pretreatment values regardless of whether they are in the safe zone for that age ($<$30 cm H_2O) or accompany clinical improvement. Subjective success was assessed using a voiding diary and was eventually compared with UDS success.

Interferential Electrical Stimulation

After pretreatment UDS, conventional treatment (anticholinergic and CIC) was resumed and children in the treatment group received 18 courses of pelvic floor IF electrical stimulation for 20 minutes in each session 3 times per week, whereas children in the control group underwent the identical setting of procedure but without the IF stimulation performed by an expert physiotherapist.

The same IF current device (model 510 A, double-channels NOVIN, Isfahan, Islamic Republic of Iran) was used for all patients. Two rectangular self-adhesive (2.5 $\times$ 3.5 cm) electrodes, one from each channel, were used. Two electrodes were placed bilaterally on the skin of the symphysis pubic, and 2 electrodes from the other channel were crossly placed on the skin under the ischial tuberosity. With this approach, the current from each channel would cross within the bladder and pelvic floor muscles. Stimulation was delivered with adjustable amplitude (0-50 mA).

In lack of consensus over the best electrical parameters for IF current in urologic practice, we used a beat frequency sweep covering 1-20 Hz (to cover irritative and obstructive symptoms and stimulate afferent sacral nerve fibers in pelvic floor muscles and bladder), duration of 250 microsecond, and repetition time of 6.6 seconds in the treatment group. The intensity was increased until the child reported a strong but comfortable level of sensory awareness with no visible muscle contractions. In smaller children, an intensity setting of $<$20 mA was administered. Maximum current intensity was below the pain threshold and well tolerated by the child.[12]

Within 2 weeks after the 18-session course of ES, all patients underwent UDS, which was repeated 6 months later.

Statistical Analysis

Statistical analysis was performed with Statistical Package of Social Science software (version 16; SPSS, Inc., Chicago, IL).

Table 1. Demographic and clinical characteristics of children in the case and control groups

	Case[19]	Control([10])
Age (y)*	5.7 ± 2.8	5.6 ± 2.4
Sex		
Female	12 (63%)	6 (60%)
Male	7 (37%)	4 (40%)
MMC† level No. (%)		
Sacral	10 (52%)	4 (40%)
Lower lumbar	8 (42%)	4 (40%)
Upper lumbar	1 (6%)	2 (20%)
Movement disorder No.		
Paraplegia	6 (31%)	4 (40%)
Proximal weakness	4 (22%)	2 (20%)
Distal weakness	5 (26%)	3 (30%)
Normal	4 (21%)	1 (10%)
Follow-up (mon)*	18.9 ± 1.4	17.4 ± 1.1
History of concurrent disability		
Club Foot	6 (26%)	3 (30%)
Hydrocephalus	7 (40%)	5 (50%)
Hip disorder	1 (10%)	—
VUR‡	1 (10%)	—
None	4 (14%)	2 (20%)
Drug		
Oxybutynin	17 (89%)	9 (90%)
Baclofen	2 (11%)	1 (10%)
Incontinency score before study (0-3)		
Score 3	15 (79%)	7 (70%)
Score 2	4 (21%)	3 (30%)

* Mean ± standard deviation.
† Myelomeningocele.
‡ Vesicoureteral reflux.

The paired Student's *t*-test was carried out and Wilcoxon signed-rank test was executed for nonparametric statistical comparisons before and after treatment in both cohorts. The Mann-Whitney *U* test, Student's *t*-test, and Fisher exact test were performed wherever applicable to compare the values between the treatment and control groups. Data are expressed as mean ± SD, and $P < .05$ was considered statistically significant.

RESULTS

In this study, 30 MMC children were enrolled between March 2005 and August 2007. One child in the treatment group required invasive intervention at early stages of the study because of upper tract signs and hence was excluded from the study and regarded as a treatment failure. Children were 3 to 12.5 years old (mean ± SD: 5.6 ± 2.7 years) comprising 18 girls and 11 boys. The demographic features of the patients are shown in Table 1. All children were followed up for a mean of 18.4 ± 1.2 months (range: 6-36 months). Comparing the information with regard to age, sex, and preintervention voiding diary and urodynamic variables, both treatment and control cohorts were similar ($P > .05$).

Of UDS parameters (Table 2), immediately after the procedure, MMDP, PVR, and DSD significantly reduced after IF therapy in the treatment group compared with sham stimulation ($P < .05$). Comparing the 2 cohorts, mean MBC and MDC also improved in the IF group, although this increase was statistically insignificant.

Regarding pre- and posttreatment comparison IF has been accompanied with significant improvement in all UDS parameters, except for maximum bladder capacity. This effect was not observed in the sham stimulation group.

Of voiding diary parameters (Table 2), compared with pretreatment measures, 15 of 19 (78%) patients ($P = .00$) gained continence immediately after IF therapy, of which 9 of the 15 (60%) children ($P = .03$) remained continent after 6 months. Comparing IF and sham stimulation also demonstrated significant difference between the 2 groups ($P = .002$ immediately, $P = .01$ after 6 months). In the treatment group, urinary frequency and enuresis followed the same pattern after IF therapy but only statistically significant immediately after the treatment ($P < .05$).

Fifteen patients in the IF group reported diarrhea the day after the procedure; none has been severe enough to seek medical care. No patient reported any adverse effect during and after the stimulation.

COMMENT

Management of urinary complications in patients with neurogenic bladder overactivity caused by MMC remains challenging. Therefore, treatment for preservation of the upper urinary tract and bladder continence should be started at an early age. Of all the factors predisposing to renal destruction, it has been shown that elevated storage pressure, as a result of either low bladder compliance or detrusor overactivity, is of remarkable importance[17] and if left untreated, the risk of upper urinary tract deterioration with NDO, especially in the face of DSD, approaches 80%, with a decline to 10% with appropriate treatment.[18] Therefore, bladder treatment should address low-pressure urine storage and low-pressure emptying of the bladder.[19] In addition, elevated storage pressure, urinary tract infection, and its associated complications are the most significant causes for renal deterioration in MMC children.

Currently, detrusor relaxation by oral anticholinergic treatment along with clean intermittent catheterization is regarded as the standard first-line treatment in patients with neurogenic detrusor overactivity[20]; however, indwelling catheters carry the risks of chronic urinary tract infection, impairment of renal function, and bladder cancer development,[21] and not all patients tolerate and/or respond effectively to anticholinergics. If the above-mentioned medical and/or minimally invasive treatments such as botulinum toxin A injection[22] fails, these patients may undergo aggressive surgical treatments, such as sphincterotomy, bladder neck reconstruction, enterocystoplasty with or without Mitrofanoff,[23] or autoaugmentation.

Since their first therapeutic implication on urinary incontinence in 1963,[5] pelvic and sacral nerve electrical

Table 2. Urodynamic and voiding diary parameters of children before, immediately after, and 6 months following interferential (treatment) and sham (control) stimulation

Variables	Groups	Pre IF	Post IF	6 Mon After IFT	P^* Pre vs Post	P^* Pre vs 6 m
Urodynamic Study Parameters						
Mean maximal detrusor pressure (cm H_2O)	Treatment	97.2 ± 40.3	60.4 ± 18.03	82.5 ± 40.3	**.01**	**.01**
	Control	97.1 ± 38.6	94.8 ± 30.4	92 ± 34.1	.3	.4
	$P^{†,‡}$	.9	**.001**	.55		
Maximum bladder capacity (mL)	Treatment	209.6 ± 73.2	210.5 ± 55.6	222.9 ± 88.5	.1	.3
	Control	276.4 ± 57.7	191.4 ± 93.1	251.4 ± 248.5	.8	.3
	$P^{†,‡}$	.3	.5	.7		
Mean detrusor compliance (ml/cm H_2O)	Treatment	9.7 ± 5.8	12.7 ± 7.1	9.4 ± 6.5	**.001**	.8
	Control	9.3 ± 6.1	9.5 ± 5.7	8.6 ± 5.2	.6	.4
	$P^{†,‡}$	.8	.2	.8		
Post voiding residue (mL)	Treatment	113.1 ± 79.2	50.8 ± 51.7	48.8 ± 41.5	**.00**	**.00**
	Control	97 ± 52.2	96.5 ± 51.6	91.5 ± 49.6	.7	.1
	$P^{†,‡}$	.5	**.03**	**.02**		
Detrusor-sphincter dyssynergia (No.)	Treatment	18/19	7/19	8/19	**.01**	**.05**
	Control	9/10	8/10	9/10	.2	.7
	$P^§$	.9	**.01**	**.005**		
Voiding diary parameters						
Continent (No. patients)	Treatment	0/19	15/19	9/19	**.00**	**.03**
	Control	0/10	0/10	2/10	.3	.9
	$P^§$		**.002**	**.01**		
Frequency (times/week)	Treatment	8.4 ± 3.3	4.4 ± 2.2	7.8 ± 3.1	**.00**	.5
	Control	7.3 ± 2.4	7 ± 1.8	7.4 ± 2.1	.25	.7
	$P^{†,‡}$		**.04**	.7		
Enuresis (nights/wk)	Treatment	5 ± 2.5	2.8 ± 2.8	4.6 ± 1.1	**.002**	.2
	Control	4.3 ± 2.5	4.4 ± 2.3	5.2 ± 2.3	.31	.6
	$P^{†,‡}$		.24	.8		

* Wilcoxon signed-rank test.
† Mann–Whitney *U* test.
‡ Student *t* test.
§ Fisher Exact Test.
Values in boldface represent statistically significant data.

stimulation have evolved and, with a success rate as high as 50%, has become an alternative for invasive surgical treatments. This development has been toward less invasive and more effective techniques.[8,24] Studies on stimulation of the bladder, pelvic floor, pelvic nerve, spinal cord, sacral root, and detrusor apparatus have led to the development of neuromodulation therapies for urologic disorders,[25] and although mostly safe and effective, the use of some are limited because of surgical implantation requirements. Transcutaneous electrical nerve stimulation, first introduced by Fall et al[9] in 1980, has been accompanied with up to 30% success in treating detrusor overactivity, exclusively stress incontinence in women. Applied for the first time in children, this technique was advocated by promising results reported from different studies conducted by Hoebeke et al[7] and Bower et al[26] on idiopathic urge incontinency in children.

Interferential electrical stimulation, introduced not more than a decade ago, has been implicated in the management of urinary and fecal incontinence to promote fracture healing and pain control.[12] In a recent study, Oh-Oka et al[13] demonstrated IF to be effective in treating stress incontinence caused by overactive bladder in the elderly. Due to lack of published data on the efficacy of IF therapy in voiding problems in children, the findings reported herein represent promising results of this technique in 19 MMC children, wherein 78% experienced significant incontinence improvement after 6 weeks, 42% achieved complete day and night continence between CICs, maintaining for the 6-month follow-up period, and enuresis status significantly improved shortly after treatment.

Unlike our study, in most previous trials evaluating the effect of ES, exclusively IF, the subjects did not have an organic neurological insult as did our patients, and all the gathered data are subjective and via the patient satisfaction questionnaires. Nonorganic malfunction in urination and defecation are very common and some are very sensitive to placebo effect of the procedures and behavioral treatments. Therefore, repeating these heartening outcomes in the setting of an organic insult (MMC) and assessing by more objective measures (UDS), makes the results more to be relied upon. On the other hand, we focused mainly on a single organic symptom (incontinence) and not a general functional "umbrella" of symptoms, where resolution in one or more entities could result in major overall satisfaction of the patients biasing the subjective measurements.

As previously stated, MMDP and MBC significantly improved after application of IF current in our children. In multiple sclerosis patients, van Poppel et al[27] and

Kabay et al[28] have reported subjective and objective improvement in neurogenic detrusor hyper-reflexia.

The exact underlying mechanisms by which ES affects the bladder function are not well known. It is believed that ES will result in reflex inhibition of the pelvic nerve to increase bladder capacity and that afferent pudendal stimulation will activate hypogastric efferents and inhibit pelvic efferents to stop or delay involuntary contractions.[29] Researchers agree that medium and low-frequency (5-10 Hz) and moderate amperage (<20 mA), which is the mainstay of IF therapy, are required to obtain such results.[29] The pelvic floor has an important role in this system of sacral reflexes. As in our method the pelvic floor was stimulated by low frequency of IF current, we hypothesized that the activated efferent fibers of the pelvic floor influences the sacral level of the neural network controlling bladder functioning. Moreover, rhythmic contraction and stimulation of the pelvic floor can result in coordination of voiding reflexes.[5] The latter phenomenon is well demonstrated by significant improvement of DSD and declined PVR in the children in our study, indicating more efficient emptying of the bladder. Theoretically, the inhibitory effect of pelvic nerve after afferent sacral nerve stimulation and sphincter contraction can be observed through an intact reflex arc at S_{2-4}.[29] Therefore, the observation that of our 6 paraplegic patients in the treatment group, known to have more complex and severe neurological deficits, only one regained continence after the treatment can be explained.

Of note is the unsafe level of detrusor pressure after IF treatment in our children (approximately 60 cm H_2O), whereas most believe that <30 cm H_2O is desirable to remain safe in the long term. In light of >40% reduction after the treatment, we could propose that children with not very high detrusor pressures would mostly benefit from this modality or relate this suboptimal result to insufficient IF sessions, although without directed clinical trials in this regard, none can be accurately claimed. Unlike other ES treatments such as sacral neuromodulation, which are considerably effective in these patients,[30] IF therapy is relatively inexpensive, noninvasive, without pharmaceutical side effects, does not need sophisticated technical support, and can be used immediately, with no waiting list for a procedure, making it a feasible option for centers with restrained resources.

Posing the possibility that we may only be observing normal maturation of the nervous system and natural resolution of incontinence, despite our intriguing results, we recognize that weaknesses exist in our study. Apart from small sample size and short duration of follow-up, unsafe level of detrusor pressure also merits further investigations. The fact that the voiding diaries were completed by the patient caregivers also introduces a certain degree of bias. Despite these limitations, our results are encouraging and serve to broaden the role of electrostimulation for voiding dysfunction.

CONCLUSIONS

This study demonstrates that IF therapy, which is a minimally invasive technique, seems effective in improving voiding symptoms including incontinency and UDS parameters of children with NDO caused by MMC. No serious adverse events or side effects were observed during or after treatments. However, to consider this modality in the management algorithm of patients with neurogenic NDO after failed conventional treatments, larger prospective trials with longer-term follow-up are required.

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EDITORIAL COMMENT

This study evaluates 30 children with myelomeningocele (MMC) (mean age 5.6 ± 2.7 years) and refractory neurogenic detrusor overactivity using pelvic floor electrostimulation with interferential (IF) current. The children had moderate to severe retractable incontinence, detrusor overactivity, and a high maximal detrusor end-fill pressure. Each child required anticholinergic therapy (oxybutynin or baclofen) and clean intermittent catheterization. They were randomly allocated to the treatment (IF stimulation, $n = 20$) and control (sham stimulation, $n = 10$) groups with a 2:1 ratio (balanced block randomization). The patients were evaluated with the following: urodynamic studies before treatment, 2 weeks after treatment, and 6 months after treatment, a subjective questionnaire, and measurement of the postvoid residual urine volume. The patients underwent 3 treatment sessions per week for 6 weeks. Immediately after IF therapy, the mean maximal detrusor pressure, postvoid residual urine volume, and detrusor sphincter dyssynergia were significantly reduced in the IF treatment group compared with the sham stimulation group ($P < .05$). The mean bladder capacity did not increase significantly in either group.

I would like to compliment the authors for evaluating a difficult problem. This topic is often studied subjectively. Incorporating repeated urodynamic studies provides an objective outcome to the use of IF therapy. The goal of treatment in this population is to protect the upper urinary tract in a noninvasive manner. Therefore, anticholinergic therapy with clean intermittent catheterization has become the reference standard. Botulinum toxin injections are actively being studied in this population.[1,2] Multiple small studies have shown favorable outcomes. However, many patients have required repeat injections, and the duration of efficacy is still being determined. Also, sacral neuromodulation is being studied in children with and without neurologic abnormalities.[3,4] Augmentation cystoplasty has become a last resort.

The obvious limitations to the present study are the cohort size and long-term achievement of upper tract protection. At 6 months after therapy, improvement in the mean maximal detrusor pressure and postvoid residual urine volume remained significant. Regarding the voiding diary parameters, only continence continued to show improvement. Before IF, none of the 29 patients was continent. Immediately after IF, 15 of 19 patients were continent, and at 6 months, 9 of 19 patients in the treated group were maintaining continence and 2 of the 10 patients in the sham group had developed continence. It appears that long-term application of this therapy will require repeated stimulation at regular intervals and close follow-up of the patients' upper tract system. As noted by the authors, a larger prospective trial with long-term follow-up is required. If the therapy continues to result in significant improvement, practical questions, such as the frequency of retreatment, whether the therapy can be administered at home, and whether home-based therapy is economical, arise. We look forward to the completion of a large, long-term, prospective study that will answer these questions.

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REPLY

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