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Original Article

Clinical evaluation of the effectiveness of interferential current therapy in the treatment of children with pelvic floor dyssynergia-type constipation: a randomized controlled study

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ABSTRACT

Background. Despite several treatment modalities being described for pelvic floor dyssynergia-type constipation, the clinical evaluation of interferential current therapy (IFC) has not been examined. We aimed to examine the clinical effects of IFC therapy in the treatment of children with pelvic floor dyssynergia-type constipation.

Methods. Between May 2018 and July 2019, this randomized controlled study included sixty-two children (46 boys and 16 girls) with pelvic floor dyssynergia-type constipation; their ages ranged between 7 and 15 years. The children were randomly divided into either the IFC group (n = 31) who received an active IFC therapy to stimulate the pelvic floor and external anal sphincter muscles, three times per week for four successive weeks, or the control group (n = 31) who received sham IFC stimulation. Stool-incontinence frequency per week, stool type, pelvic floor excursion, and myogenic activity of external anal sphincter were evaluated at the baseline, post-treatment, and three months after treatment termination.

Results. The baseline evaluation showed non-significant differences between the IFC and control groups ($p>0.05$). The post-treatment results showed a statistically significant difference between both groups regarding all variables, favoring the IFC group ($p<0.05$). Further, the favorable effect of IFC on all variables continued at the follow-up, three months later.

Conclusions. IFC therapy appears to improve stool-incontinence frequency, stool type, pelvic floor excursion, and myogenic activities of the external anal sphincter in children with pelvic floor dyssynergia-type constipation. These results suggest that adding IFC therapy to the medical treatment could improve the main features of pelvic floor dyssynergia-type constipation.

Key words: interferential current therapy, constipation, pelvic floor dyssynergia, electromyography.

Constipation is a frequent complaint in children, with an estimated worldwide prevalence varying from 0.3% to 8%.[1] Constipation is a symptom that is generally associated with infrequent defecation, abdominal pain, and fecal incontinence, causing significant distresses to children and their families, and impacting the health-care cost.[2]

Constipation can be categorized as primary or secondary. Primary constipation is also referred to as functional constipation, where no organic reasons are established. It accounts for 90% of children with constipation, and can be further classified into slow-transit, normal-transit and obstructed defecation.[3] While, secondary constipation is a consequence of other health problems such as diabetes mellitus,

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an underactive thyroid, hyperparathyroidism, drug, or other organic disorders such as Hirschsprung disease, or due to anatomical disorders.[4,5]

Pelvic-floor dyssynergia (PFD) is a form of obstructed defecation (primary constipation), which has also been identified as dyssynergic defecation, anismus, puborectalis paradoxes or spastic pelvic floor. PFD is described as a disorder in the capability to discharge feces from the rectum, induced by paradoxical contraction or failure to coordinate the abdominal muscles contraction and relax the pelvic floor musculatures during trying to defecate, leading to inadequate propulsive force, paradoxical anal sphincter contraction or insufficient loosening of the anal sphincter.[6,7]

There are several treatment options for PFD such as regimented eating plan, improved toileting behaviors, laxatives, behavioral therapy, surgery, and physical therapy modalities like biofeedback training of pelvic floor muscles and electrical stimulation (ES).[8,9] Although comprehensive medical and behavioral therapy for PFD, long-standing follow-up trials have shown that more than 50% of children still complain from constipation 5 years later.[10] Over the past years, different procedures of ES of the neuromuscular system have been utilized as an optional therapy for pelvic floor disorders such as urinary and fecal incontinences and overactive bladder with high improvement rates.[11,12]

Interferential current (IFC) is a kind of ES utilizing medium-frequency currents, creating low skin resistance and permitting profound tissue penetration.[13] IFC has previously been applied to improve the strength of the pelvic musculature in involuntary urination induced by overactive bladder and nocturnal enuresis.[14,15] Recently, it has been discovered to be efficient in a few clinical trials in treating chronic transit constipation in adults[16] and children.[17] It is a non-invasive, cost-efficient, and comfortable physical therapy modality that can be used safely at home.[18]

Despite some prior studies examining the effect of IFC therapy on constipation, to our knowledge, the therapeutic effectiveness of IFC has not been evaluated to treat children with pelvic floor dyssynergia-type constipation. Thus, the aim of this study was to evaluate the clinical effects of IFC therapy in the treatment of children with pelvic floor dyssynergia-type constipation by assessing the stool-incontinence frequency, stool type, pelvic floor muscles excursion, and myogenic activities of the external anal sphincter.

Material and Methods

This was a randomized placebo-controlled, double-blind, two-parallel group study conducted between May 2018 and July 2019. The Cairo University Hospitals Ethics Committee approved the study protocol (PT-018-031) at 25/2/2018. Research procedures were carried out according to ethical guidelines of the Helsinki Declaration 1964. After a full explanation of the experimental procedures, written consent was obtained from children's parents before commencement of the study.

Children included in this study were referred from the pediatric gastroenterologist to the outpatient clinic of the physical therapy department, New Kasr El-Aini Teaching Hospital. A total of 62 children (46 boys and 16 girls), aged 7-15 years, and diagnosed by a pediatric gastroenterologist with idiopathic constipation as PFD, were enrolled in the present study. Children were considered to have pelvic floor dyssynergia-type constipation if they had all of the succeeding criteria: inappropriate contraction of the pelvic floor muscles (i.e., anal sphincter or puborectalis) or less than 20% relaxation of basal resting sphincter pressure by manometry; past history of too much strain during excretion; lack of secondary reasons of constipation; lack of surgically repairable sources of PFD, like rectal prolapse; and lack of colorectal diseases representing constipation, like colorectal cancer. Children with Down syndrome, Hirschsprung disease, endocrine &

metabolic disorders such as hypothyroidism, diabetes mellitus, and neurologic & psychiatric disorders such as spina bifida, cerebral palsy, epilepsy, autism were excluded from the study.

Before commencing the study, the sample size was estimated that 27 children would be required in each group to achieve success rate differences of at least 30 % in the proportion recording acceptable power of 80%. To achieve a significant change in the myogenic activities of external anal sphincter with a standard deviation of 0.5 and a margin of error of 0.05 is 70% with 27 children in each group for two-sided equality. Therefore, the present study included a total of 66 children to account for the dropout rate of 20% because one child did not meet the inclusion criteria of the study and three children declined to participate in the study.

Enrolled children were randomized by a blinded investigator, who was not in control of the present study at any time utilizing SPSS software version 25 (IBM Corp., Armonk, NY, USA) to obtain two equal-sized groups, following a simple random allocation method. They were randomized into the IFC group (active stimulation, 31 children) or the control group (sham stimulation, 31 children). The CONSORT flow diagram of the study is presented in Figure 1.

All children underwent an initial assessment which included; lumber, pelvic, and hip range of motion, lower limbs and pelvic floor muscle strength, and generalized posture screening. In addition, a pelvic floor evaluation was performed in the form of resting muscle tone, presence or absence of anal reflex, pelvic floor muscle contraction, relaxation, and lump.[19,20]

The treatment procedures (IFC or control groups) were blinded; neither the children nor their parents were aware of the study groups. Children in both groups followed the same treatment procedures. A rechargeable battery-operated, three-in-one electrical stimulator (NexWave, Zynex Medical, Inc., USA) that delivers IFC, transcutaneous electrical nerve stimulation (TENS) or neuromuscular electrical stimulation (NMES) was used for the application of IFC therapy to the study groups.

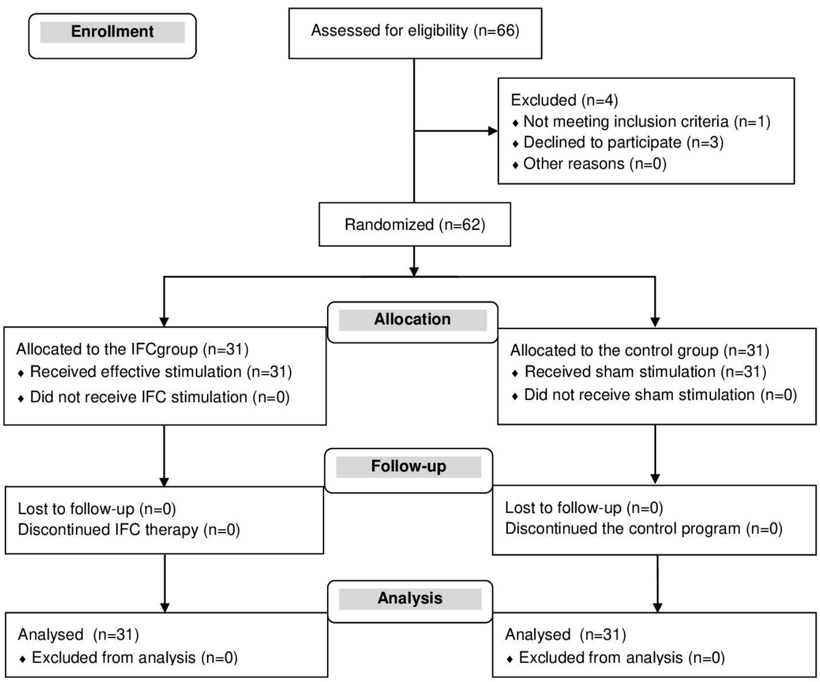

Fig. 1. The CONSORT flow diagram of the study (IFC: interferential current therapy).

In the IFC group (active stimulation)

The stimulator was adjusted to the IFC mode (symmetrical biphasic waveform). While each child was comfortably positioned on his/her back, two self-adhesive, 2.5×3.5 cm electrodes were attached to the skin over the symphysis pubis and on the opposite side over the ischial tuberosity (channel 1; delivered a frequency of 4000 Hz), and two other electrodes were put in a cross path on the skin over the other symphysis pubis and on the contralateral ischial tuberosity (channel 2, delivered a frequency of 4001-4128 Hz, drags every 15 sec). The currents produced from both channels crossed diagonally and were concentrated on the pelvic floor muscles and external anal sphincter. The currents were increased gradually until each child felt a strong comfortable sensation. The IFC stimulation was applied for a duration of 30 min/session, 3 sessions per week for 4 consecutive weeks (12 sessions). Children were instructed to immediately report any itching, burning, or other adverse effects during the treatment.

Control group (sham stimulation)

The same device and electrodes placement applied in the IFC group were used without stimulation for 30 min/session, 3 sessions per week for 4 consecutive weeks (12 sessions).

Children in both groups were instructed to try to move bowels for 5 min, two times per day, half-hour prior to eating time, regardless of their urge to stool. Also, each child was instructed to facilitate his/her pushing attempt by utilizing diaphragmatic breathing exercises and postural corrections as home exercises program for 15 min, 3 times per day.[21] During defecation, the child should be in a comfortable squat position on the toilet by putting footstool as high as from 20 to 30 cm with both feet 45-60 cm apart to assist in enhancing the angle of the rectum within the pelvis and making it easier to pass stool. All children were required to follow a balanced dietary regimen with enough calorie intake. They were instructed to have diets that were rich in vegetables & fruits, and have frequent meals. The dietary regimen secured a consumption of about 25 grams of natural dietary fibers every day for each child.[22]

The clinical evaluations of this study were the stool-incontinence frequency per week, stool type, pelvic floor muscles excursion, and myogenic activities of the external anal sphincter. These outcome measures were assessed at the baseline, post-treatment, and were followed after three months of the treatment termination.

The stool-incontinence frequency was defined as the total number of defecations in one week. The findings of the stool incontinence frequency were categorized as excellent (perfect control), good (more than 50% decline in stool frequency), fair (not deteriorating but less than 50% advancement), and poor (more frequent stool incontinence). Both excellent and good findings were classified as desirable, while fair or poor findings were classified as being undesirable. This categorization was established mainly on a recommendation from experts that a ≥ 50% decrease in stool incontinence frequency is a clinically significant result.[23]

The type of stool was reported per week, using the Bristol stool chart which was reported by parents. According to the Bristol Stool Chart, seven types of stool are reportable; types 1 and 2 indicate constipation, types 3 and 4 mean best stools because stools are easy to pass, and types from 5 to 7 indicate diarrhea.[24]

The pelvic floor muscles excursion was used to assess the coordination and relaxation of the pelvic floor muscles and external anal sphincter. Children were positioned in crook-lying and asked to contract their pelvic floor musculatures and squeeze their external anal sphincter, loosen them and then bearing down and loosen again. The caudal lengthening and external sphincter loosening throughout the tried were visually inspected during the tried bulge. The range of pelvic floor muscles excursion was categorized as: absent (0%), poor (1%-25%), fair (26%-50%), good (51%-75%), and excellent (76%- 100%).[20]

According to this test, poor and fair indicate PFD, while good and excellent mean clinical improvement.

The myogenic activities of pelvic floor musculatures and external anal sphincter were measured by electromyography Neuroscreen plus system® (EMG, Jaeger-Toennies, Hochberg, Germany) to explore muscular contradictory through assessing amplitude per turn (A/T) in mV. Children were positioned in crook-lying, skin was cleaned with alcohol to decrease skin resistance while capturing the EMG signals, surface EMG electrodes were applied as follow: the active electrode placed on the anal skin over the external anal sphincter and the reference electrode was placed at an electrically neutral area like the thigh. Each child was informed to repeatedly contract the external anal sphincter for 10-sec flowed by relaxation for 10-sec, repeated for 10 times without bearing down to relax the pelvic floor musculatures. EMG activities (A/T in mV) were measured during relaxation of the pelvic floor musculatures and external anal sphincter, in an attempt to defecate.[25] A continuous increase in myogenic activity of external anal sphincter and failure to relax the pelvic floor muscles is attributed to PFD.[26]

Statistical analysis

Data were demonstrated and analyzed in the form of means ± standard deviations. The descriptive analysis measured the differences of the mean values of the continuous variables (myogenic activities of external anal sphincter and stool incontinence frequency) between the two groups of the study using unpaired t-test while the intragroup changes were assessed using the repeated-measure ANOVA test. Categorical variables (pelvic floor excursion and stool type) were analyzed using Fisher's exact test. Statistical analysis was performed using SPSS software version 25 (IBM Corp., Armonk, NY, USA) and was assessed with the Kolmogorov-Smirnov test for normality. The significance level was set at $p < 0.05$.

Results

As revealed in Table I, baseline characteristics showed non-significant differences between both groups in gender, age, body mass index (BMI), stool-incontinence frequency per week, stool type, pelvic floor muscles excursion, and myogenic activities of the external anal sphincter ($p > 0.05$). The findings of the mean values of the amplitude per turn (A/T) in mV and the stool-incontinence frequency per week showed statistically significant differences in the IFC group ($p < 0.001$). On the other hand, the mean values of both measures in the control group revealed that there were statistically non-significant differences ($p > 0.05$) as described in Table II. The comparison between the mean values of both measures immediately after treatment and after 3-month follow-up period disclosed that there were statistically significant differences ($p < 0.001$) in favor of the IFC group (Table III).

There were statistically significant differences in numbers and percentage of children in the pelvic floor muscles excursion in the IFC group ($p < 0.05$) while, there were statistically non-significant differences in the control group ($p > 0.05$) as described in Table II. There were statistically significant differences in all numbers and percentage of children immediately after treatment, and after 3-month follow-up period in the IFC group compared to the control group ($p < 0.05$) in favor of the IFC group (Table III).

There were statistically significant differences in the number and percentage of children in stool type per week in the IFC group ($p < 0.05$) with non-significant changes in the control group ($p > 0.05$) immediately after treatment and after 3-month follow-up period (Table II). There were statistically significant differences in all numbers and percentage of children immediately after treatment, and after 3-month follow-up period in the IFC group compared to the control group ($p < 0.05$) in favor of the IFC group (Table III).

Table I. Baseline characteristics of the participants.

Measures	IFC group (n=31)	Control group (n=31)	P-value
Male/female, n/n	24/7	22/9	0.920
Age (years)	12.5 ± 4.23	13.2 ± 4.51	0.531
Body mass index (kg/m^2)	24.33 ± 2.72	25.21 ± 2.84	0.217
A/T (mV)	0.31 ± 0.14	0.33 ± 0.18	0.627
Stool frequency/week	2.3 ± 0.5	2.4 ± 0.6	0.478
PFE*, n (%)			
Excellent	0 (0)	0 (0)	0.781
Good	0 (0)	0 (0)	
Fair	23 (74.2)	21 (67.7)	
Poor	8 (25.8)	10 (32.3)	
Stool type**, n (%)			
1-2	31 (100.0)	31 (100.0)	1.000
3-4	0 (0)	0 (0)	
5-7	0 (0)	0 (0)	

A/T (mV): amplitude per turn in millivolt, IFC: interferential current, PFE: pelvic floor excursion.
*: The range of pelvic floor muscles excursion was categorized as: absent (0%), poor (1-25%), fair (26-50%), good (51-75%), and excellent (76-100%).
**: Stool types according to the Bristol Stool Chart: type 1 and 2 indicate constipation, type 3 and 4 indicate best stools because stools are easy to pass, and types from 5 to 7 indicate diarrhea.

Table II. Changes of mean values within each group before, after intervention and 3-month follow-up.

Measures	IFC group (n=31)			P-value	Control group (n=31)			P-value
	Before	After	Follow-up		Before	After	Follow-up	
A/T (mV)	0.31 ± 0.14	0.08 ± 0.01	0.11 ± 0.03	<0.0001	0.33 ± 0.18	0.29 ± 0.16	0.30 ± 0.19	0.653
Stool frequency/week	2.3 ± 0.5	5.2 ± 0.31	4.9 ± 0.37	<0.0001	2.4 ± 0.6	2.6 ± 0.5	2.5 ± 0.6	0.387
PFE*, n (%)								
Excellent	0 (0)	3 (9.7)	1 (3.2)	<0.0001	0 (0)	0 (0)	0 (0)	0.242
Good	0 (0)	24 (77.4)	22 (71.0)		0 (0)	3 (9.7)	1 (3.2)	
Fair	23 (74.2)	3 (9.7)	5 (16.1)		21 (67.7)	23 (74.2)	22 (71.0)	
Poor	8 (25.8)	1 (3.2)	3 (9.7)		10 (32.3)	5 (16.1)	8 (25.8)	
Stool type**, n (%)								
1-2	31 (100.0)	4 (12.9)	6 (19.4)	<0.0001	31 (100.0)	29 (93.5)	26 (83.9)	0.436
3-4	0 (0)	27 (87.1)	25 (80.6)		0 (0)	2 (6.5)	5 (16.1)	
5-7	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	0 (0)	

A/T (mV): amplitude per turn in millivolt, IFC: interferential current, PFE: pelvic floor excursion.
*: The range of pelvic floor muscles excursion was categorized as: absent (0%), poor (1-25%), fair (26-50%), good (51-75%), and excellent (76-100%).
**: Stool types according to the Bristol Stool Chart: type 1 and 2 indicate constipation, type 3 and 4 indicate best stools because stools are easy to pass, and types from 5 to 7 indicate diarrhea.

Discussion

The present study was designed to assess the effects of 4-week IFC therapy in the treatment of children with pelvic floor dyssynergia-type constipation. It was hypothesized that IFC therapy could provide a good prognosis and decrease the symptoms of pelvic floor dyssynergia-type constipation with improvement continued up to three months later. The results of the study confirmed our

Table III. Changes of mean values between groups after intervention and 3-month follow-up.

Measures	After intervention		P-value	3-month follow-up		P-value
	IFC group (n=31)	Control group (n=31)		IFC group (n=31)	Control group (n=31)	
A/T (mV)	0.08 ± 0.01	0.29 ± 0.16	<0.0001	0.11 ± 0.03	0.30 ± 0.19	<0.0001
Stool frequency/week	5.2 ± 0.31	2.6 ± 0.5	<0.0001	4.9 ± 0.37	2.5 ± 0.6	<0.0001
PFE*, n (%)						
Excellent	3 (9.7)	0 (0)	<0.0001	1 (3.2)	0 (0)	0.007
Good	24 (77.4)	3 (9.7)		22 (71.0)	1 (3.2)	
Fair	3 (9.7)	23 (74.2)		5 (16.1)	22 (71.0)	
Poor	1 (3.2)	5 (16.1)		3 (9.7)	8 (25.8)	
Stool type**, n (%)						
1-2	4 (12.9)	29 (93.5)	<0.001	6 (19.4)	26 (83.9)	0.005
3-4	27 (87.1)	2 (6.5)		25 (80.6)	5 (16.1)	
5-7	0 (0)	0 (0)		0 (0)	0 (0)	

A/T (mV): amplitude per turn in millivolt, IFC: interferential current, PFE: pelvic floor excursion.
*: The range of pelvic floor muscles excursion was categorized as: absent (0%), poor (1-25%), fair (26-50%), good (51-75%), and excellent (76-100%).
**: Stool types according to the Bristol Stool Chart: type 1 and 2 indicate constipation, type 3 and 4 indicate best stools because stools are easy to pass, and types from 5 to 7 indicate diarrhea.

hypothesis regarding that IFC therapy provided a significant improvement in the

stool-incontinence frequency per week, stool type, pelvic floor muscles excursion, and myogenic activities of the external anal sphincter without detecting any adverse or side effects.

The results of the study confirmed our concept that IFC therapy may improve the performance of pelvic floor musculatures and the external anal sphincter by reducing the hyper myogenic activity of these muscles which was assessed by EMG regarding the reference values. Simultaneously the stool-incontinence frequency per week was increased up to normal values, also the stool type was changed from types 1 and 2 constipations to types 3 and 4 normal defecations. The results of the visual assessment of the pelvic floor excursion after the application IFC therapy showed an increase in the numbers and percentage of children with excellent and good responses than of those with fair and poor responses. The improvements of the study outcomes were continued up to three months later after completing 4-weeks of IFC therapy.

Regarding the control group (sham IFC therapy with the prescribed home routine recommendations), there was no improvement in all outcome measures. Clarifying that both sham IFC stimulation and home recommendations were not enough to improve pelvic floor dyssynergia-type constipation in children.

In consistence with the results of the present study, previous studies confirmed that IFC therapy is efficacious in the treatment of transient constipation.[17,18,27] In the present study, the pelvic floor dyssynergia was assessed by various, easy, non-invasive, and inexpensive methods.

Initially, IFC therapy was used to control pain and reduce the instability of bladder detrusor.[28] The clinical applications of IFC were advanced by Nemec who stated that the intersecting of dual current paths produces maximal stimulation in the tissues.[29] Other suggestions could be recommended to enlighten the detected results of the present study. An improvement of the pelvic floor dyssynergia could also be provided through stimulating various nerve roots through the self-adhesive surface electrodes that are located over symphysis pubic and over the ischial tuberosity. Consequently, the sympathetic and parasympathetic efferent fibers can target directly or indirectly through stimulating afferent fibers. Definitely, the sympathetic stimulation is identified to reduce motor activities. But also, this may cause a direct inhibition or blockade of sympathetic nerve fibers.[30] Moreover, the rhythmic contraction and stimulation of pelvic floor muscles and external anal sphincter can lead to coordination of defecation reflexes.[31]

The underlying mechanism of IFC therapy be may explained by the intersection of two medium-frequency currents which creates a third therapeutic current at the point of intersection. The advantages of utilizing medium frequency current are lowering skin impedance to electrical currents, more deep stimulation with a comfortable tingling sensation. Additionally, the proper placements of electrodes transfer the ES precisely on the target crossover region with the least adverse effects to the nearby regions.[32]

The principle of neuromodulation for applying IFC therapy was accepted for treatment of constipation caused by unknown reason and irritable bowel syndrome.[33,34] IFC therapy is supposed to stimulate somatosensory nervous plexus in the pelvic area with improvement in the voluntary and involuntary processes of defecation; apparent decrease in pain and flatulence with enhancement of bowel-movement.[33,35] IFC therapy has been used previously to treat idiopathic constipation in pediatrics and adults.[34,36] Chase et al.[37] reported that not just evacuation difficulties were decreased, but also a considerable drop in defecation periods in bathroom was noted.

In this study, different clinical evaluation methods were applied to evaluate the effects of IFC therapy in children with pelvic floor dyssynergia- type constipation. The objective evaluation of the myogenic activity of pelvic floor muscles and external anal sphincter was measured by EMG and the subjective evaluation of prognosis of the pelvic floor excursion examination in addition to the parents' evaluation of the stool-incontinence frequency per week, stool type was used to determine the prognosis of constipation in children with PFD.

There are several strengths to the present study. It is the first study to evaluate the impacts of IFC therapy in the treatment of children with pelvic floor dyssynergia- type constipation. The study findings showed that IFC therapy is an effective, save, non-invasive modality without any side or adverse effects for managing pelvic floor dyssynergia in children during the study intervention and 3-month follow-up. Comparatively, IFC therapy is a low-cost, and applicable simply so that it may be considered as a practicable therapeutic modality and recommendable to be used in the treatment of pelvic floor dyssynergia- type constipation.

The limitations of the study were the lack of long follow-up duration after 6-12 months, besides the results of the type of stool were collected by children's parents that may have a certain degree of bias. Finally, we could not be sure that all the children followed the home recommendations. Further studies should be done with longer follow-up periods to explore the efficacy and optimal duration for usage of IFC therapy.

Using IFC therapy may provide improvements of stool-incontinence frequency per week, stool type, pelvic floor muscles excursion, and myogenic activities of the external anal sphincter. Due to the convenient application of IFC therapy, it can be used in the treatment of children with pelvic floor dyssynergia-type constipation.

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