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Long-Term Outcome of Biofeedback versus Transcutaneous Posterior Tibial Nerve Stimulation in The Treatment of Functional Non-Retentive Fecal Incontinence

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ABSTRACT

Background: Faecal incontinence lowers children's quality of life (QoL) and is a psychologically distressing and unpleasant problem. **Objective:** The aim of the study was to compare the outcomes of biofeedback training versus bilateral transcutaneous posterior tibial nerve stimulation (BTPTNS) in the management of children's functional no retentive faecal incontinence (FNRFI) and how it affects quality of life (QoL).

Subjects and methods: The present study included 112 Children with FNRFI and received one of two modalities of treatment either BTPTNS or biofeedback training. Eligible patients were followed up for 24 months for the clinical outcomes and the QoL. **Results:** Upon first evaluation, all QoL dimensions, incontinence episodes, incontinence score, and manometric findings showed no significant difference between the two groups. The anal pressures were significantly increased in both groups in comparison with the initial findings with a significant increase in group B more than in group A. There was a significant decrease in the IE and incontinence score (IS) in both groups after 24 months when compared to the initial values. All QoL parameters were significantly within each group throughout the follow-up period however, there was a significant improvement in group B when compared to group A.

Conclusion: Biofeedback and BTPTNS offered a beneficial line of treatment of FNRFI with a positive impact on QoL.

Keywords: Fecal incontinence, BTPTNS, Quality of life.

INTRODUCTION

Any involuntary passage of gas or stool is classified as anal incontinence by The International Continence Society into two categories: gas incontinence (GI) and fecal incontinence (FI), which occurs at least once per month for two consecutive months [1, 2]. Fecal continence is preserved by normal anal sphincter, intact pelvic floor muscles, local sensory and motor neurons, and cortical and spinal connections. Fecal incontinence is a more complex and multifaceted disorder since it can arise from the failure of any of these tissues [3].

Based on Rome IV criteria, functional FI is divided into two categories: retentive and non-retentive FI (FNRFI), the underlying pathophysiological mechanisms of which are still unknown [4]. FNRFI is defined by the Rome III classification as FI in a child who is 4 years of age or older and does not show signs of an inflammatory, metabolic, or anatomical cause [5].

The clinical evaluation provides the basis for the FNRFI diagnosis. Colonic Transit Time (CTT) measurement is the sole test that can help in diagnosis. Additionally, normal CTT values are necessary for the confirmation of the FNRFI-specific entity [6].

Establishing in the child the importance of using the toilet regularly and resisting the urge can help parents and kids be ready for a long course of therapy, knowing that there will be many highs and lows [7]. There is considerable debate on the long-term effects of biofeedback, although many studies view it as a straightforward, easy, noninvasive technique that can enhance anal pressure and rectal feeling in an appropriate amount of time [8, 9]. **Shafik *et al.*** [10] reported effective posterior tibial nerve stimulation (PTNS) for FI. Subsequent studies [11, 12] revealed that percutaneous PTNS (PPTNS) and BTPTN were efficacious therapies for FI, resulting in a 50–80% reduction in incontinence episodes. The stimulating electrode had a greater effect than BTPTN because of its proximity in PPTNS [13]. The long-term effect of TPTNS and biofeedback training is still questionable and this has motivated the authors to conduct this study.

PATIENTS AND METHODS

Study design: This retrospective study was conducted at the Colorectal Surgery Unit, Benha University Egypt through the period from January 2020 to December 2023.

The data of 112 children who had FNRFI (i.e., FI and normal bowel habits, stool consistency, and frequency of bowel movements) were reviewed in the current study, taking into account a 1:1 ratio for the allocation of the eligible children into two groups. Group A consisted of 56 children who received BPTNS, whereas group B comprised 56 patients who received biofeedback training.

Exclusion criteria: Children under 4 years old, traumatic sphincter injuries, anorectal malformations, and spinal illnesses that cause FI. A minimum of 24 months of follow-up were scheduled, and data from the 78 children who finished the follow-up were analyzed.

Prior to enrolling eligible patients, a medical history regarding the patient's bowel habits and level of

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incontinence was acquired. To rule out sphincteric damage, a transanal ultrasound and physical examination were conducted. The diagnosis of FNRFI was established using CTT, which was essential in assessing the segmental and overall intestinal transit times. [14]. All eligible children's initial incontinence score was recorded using the Vaizey score [15] which ranges from 0 (perfect continence) to a maximum score of 24 (complete incontinence). All of the included children had baseline manometric assessment utilizing high-resolution manometry, which was done in accordance with the same technique described by **Banasiuk *et al.*** [16] to measure anal pressure and rectal sensations.

Procedure:

Group A (**BTPTNS):** Applying the technique described by **Queralto *et al.*** [17]**.** A +ve auto-adhesive electrode was positioned 1.5 inches above the medial malleolus. Below the same malleolus, a 2nd -ve electrode was positioned nearby. An electrical stimulation device was attached to each electrode. The big toe was brought into flexure or fanning of the other toes by progressively increasing the intensity of the electrical current. In order to stop the toes from responding mechanically, the intensity was then lowered once more to 10 AMP. The therapy lasted for 20 to 30 minutes, twice a week, for three months.

Group B: Strength training was conducted using a (MMS U-72210) catheter and sensory training was conducted using a 24-channel water-perfused catheter with a latex balloon. For three months, there were two sessions per week of 20–30 minutes each for biofeedback. All patients underwent biofeedback while facing the monitor and in a crouching position. There were two parts to the biofeedback therapy protocol: (1) Strengthening exercises: Teach the kid to tighten their anal sphincter without inflating a balloon and then try different ways to adjust this contraction. (2) The patients were expected to retrain the rectal sensory threshold through the sequential inflations and deflations of a balloon in stepwise increments of 5 ml of air or saline, typically with a target to distinguish and react to decreasing balloon volumes.

For both groups, dietetic regulation including bulk-forming diet, fruits, and vegetables, while avoiding fast and spicy food and drinks was applied.

Evaluation and follow-up:

Primary outcome was a decrease in the number of incontinence episodes (IE) and QoL improvement.

Secondary outcome was an improvement of the manometric findings.

The Faecal Incontinence Quality of Life (FIQL) scale was utilized to evaluate the influence on the Quality of Life [18]**.** Two elements pertaining to sexuality were eliminated from the FIQL, and the parameter "depressed" was changed to "sad." Therefore, the updated survey consists of 27 items covering the following four major areas: behavior, depression, lifestyle, and embarrassment [19]**.**

After 3 months the clinical response was classified into A full continent. B, decrease in IE > 75%. C, decrease in IE < 75%. D, no improvement or deterioration than before therapy. Group D was excluded from the long-term follow-up.

Ethical approval: This study was ethically approved by The Institutional Review Board of the Faculty of Medicine, Benha University. Written informed consent was obtained from each participant' parent. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical analysis

The study's primary endpoint, IE was utilized to calculate the sample size. 34 or more in each group was considered using the G*power 3.1 program (Universities, Dusseldorf, Germany) with a power of 80%, P value of 0.05, and an effect size of 0.7. Version 20 of SPSS Statistics was used to conduct the statistical analysis. A two-way mixed ANOVA was performed to compare the measured variables across the two groups and across different time periods. The participant's demographic data was subjected to the ANOVA test. While number and percentage were employed to show nominal data, mean and standard deviation were utilized to express numerical data. $P \leq 0.05$ was set as the significance level.

RESULTS

In the current study, 112 children with FNRFI were included and divided into 2 equal groups. 56 patients were included in Group A and B However only 39 patients in Group A and 41 patients in Group B completed 24 months follow-up and underwent analysis. Group A included children with a mean age of 9.72 ± 4.1while in group B was 9.16 ± 3.56 years as shown in table (1).

Table (1): Socio-demographic data of the two groups

Variable		Group A (N=56 patients) BTPTNS	Group B (N=56 patients) biofeedback	P-value
Age	M ±SD	9.72 ±4.1	9.16 ±3.56	0.17
Sex	Boys	18(47.3%)	19(47.5%)	0.091
	Girls	20(52.7%)	21(52.5%)	

Upon first evaluation, all QoL dimensions, incontinence episodes, incontinence score, and manometric findings showed no significant difference between the two groups (Tables 2 & 3). Short-term manometric follow-up showed that the anal pressures were significantly increased in both groups in comparison with the initial findings with a significant increase in group B more than in group A. There was a statistically significant improvement in rectal sensation in both groups but more in group B. (P<0.001*) as presented in table (2).

Table (2): Short-term manometric follow-up within and between the two groups after 6 months

		Group A (N=39 patients) BTPTNS	Group B (N=41 patients) biofeedback	P-value
Resting pressure	**Before treatment**	31.12±4.23	30.18±3.43	**0.12**
	After 6 months	35.11±4.82	40.24±2.71	**0.01***
	P- value	**<0.001***	**<0.001***	
Squeeze pressure	**Before treatment**	97.11±14.26	96.92±16.62	**0.19**
	After 6 months	121.12±11.92	142.32±11.51	**<0.001***
	P- value	**<0.001***	**0.671**	
First sensation	**Before treatment**	99.62±32.28	98.1±37.12	**0.18**
	After 6 months	86.58±27.34	56.4±17.4	**<0.001***
	P- value	**0.06**	**0.14**	
First Urge sensation	**Before treatment**	161.21±46.84	159.14±49.14	**0.19**
	After 6 months	131.82±39.54	122.8±29.41	**0.037***
	P- value	**<0.001***	**0.092**	
Intense urge sensation	**Before treatment**	192.56±33.14	196.8±34.62	**0.08**
	After 6 months	171.36±29.24	146.4±23.1	**0.01***
	P- value	**0.012***	**0.092**	

Table (3) reported a significant decrease in the IE and incontinence (IS) in both groups after 24 months when compared with the initial values. Significant decrease in the IS and IE were reported in group B when compared to group A at 6, 12 & 24 months follow up (P**<0.001*).** All QoL parameters were significantly within each group throughout the follow up period however, there was significant improvement in group B when compared to group A.

Table (3): Comparison between the two groups regarding the changes in incontinence score, incontinence episode and QoL parameters

		Group A BTPTNS	Group B Biofeedback	P-value
Incontinence score	**Before treatment**	14.1±2.7	14.5±3.4	**0.14**
	After 6 months	6.2 ±1.9	3.8±2.5	**<0.001***
	After 12 months	3.9 ± 2.6	1.9±2.6	**<0.001***
	After 24 months	4.1±1.9	1.7±2.3	**<0.001***
	Post 24 months V initial report (P-value)	**<0.001***	**<0.001***	
Incontinence episodes	**Before treatment**	32.1±5.1	32.8±7.2	**0.12**
	After 6 months	11.6±3.6	8.7±7.1	**<0.001***
	After 12 months	7.1±2.5	2.9±1.9	**<0.001***
	After 24 months	5.7±2.1	2.4±1.9	**<0.001***
	Post 24 months V initial report (P-value)	**<0.001***	**<0.001***	
Life style	**Before treatment**	1.8±0.3	1.8±0.4	**0.39**
	After 6 months	2.8 ±0.5	3.2±0.6	**<0.01***
	After 12 months	3.1±0.6	3.4±0.4	**<0.01***
	After 24 months	3.6±0.5	3.5±0.6	**<0.01***
	Post 24 months V initial report (P-value)	**<0.001***	**<0.001***	
Emotion (Depression)	**Before treatment**	1.9±0.4	1.95±0.3	**0.18**
	After 6 months	2.9±0.5	3.4±0.5	**<0.01***
	After 12 months	3.3±0.3	3.4±0.5	**<0.001***
	After 24 months	3.6±0.4	3.5±0.5	**<0.001***
	Post 24 months V initial report (P-value)	**<0.001***	**<0.001***	
Behavior	**Before treatment**	1.96±0.4	1.9±0.3	**0.17**
	After 6 months	3.1±0.4	3.3±0.6	**<0.001***
	After 12 months	3.3±0.3	3.4±0.5	**<0.01***
	After 24 months	3.5±0.5	3.5±0.5	**<0.001***
	Post 24 months V initial report (P-value)	**<0.001***	**<0.001***	
Embarrassment	**Before treatment**	2.1± 0.54	2.2±0.4	**0.19**
	After 6 months	3.2±0.45	3.4±0.5	**<0.001***
	After 12 months	3.6 ±0.32	3.6±0.4	**<0.001***
	After 24 months	3.7±0.41	3.8±0.4	**<0.01***
	Post 24 months V initial report (P-value)	**<0.001***	**<0.001***	

Table (4) reported the clinical outcomes, both groups showed that decrease in the IE > 75% in 74.3% and 85.4 % of patients in group A and B respectively after 6 months. The effect was maintained in group A in 68.2% and 66.7% after 12 and 24 months respectively (Figure 1). In group B, the effect was maintained in 82.9% by the end of the study (Figure 2).

Table (4): Clinical Outcomes of both groups

Follow up			Fully Continent	Decrease IE>75%	Decrease IE>75%
6 months	Group A n=39	N (%)	9 (23%)	8 (20.5%)	8 (20.5%)
	Group B n=41	N (%)	12 (29.3%)	12(29.3%)	11 (26.8%)
	P value		0.01*	0.01*	0.01*
12 months	Group A n=39	N (%)	20 (51.3%)	19 (48.7%)	18 (46.2%)
	Group B n=41	N (%)	22 (53.6%)	23 (56.1%)	23 (56.1%)
	P value		0.072	0.046*	0.34*
24 months	Group A n=39	N (%)	10 (25.7%)	12 (30.8%)	13 (33.3%)
	Group B n=41	N (%)	7 (17.1%)	6 (14.6%)	7 (17.1%)
	P value		0.01*	0.01*	0.01*

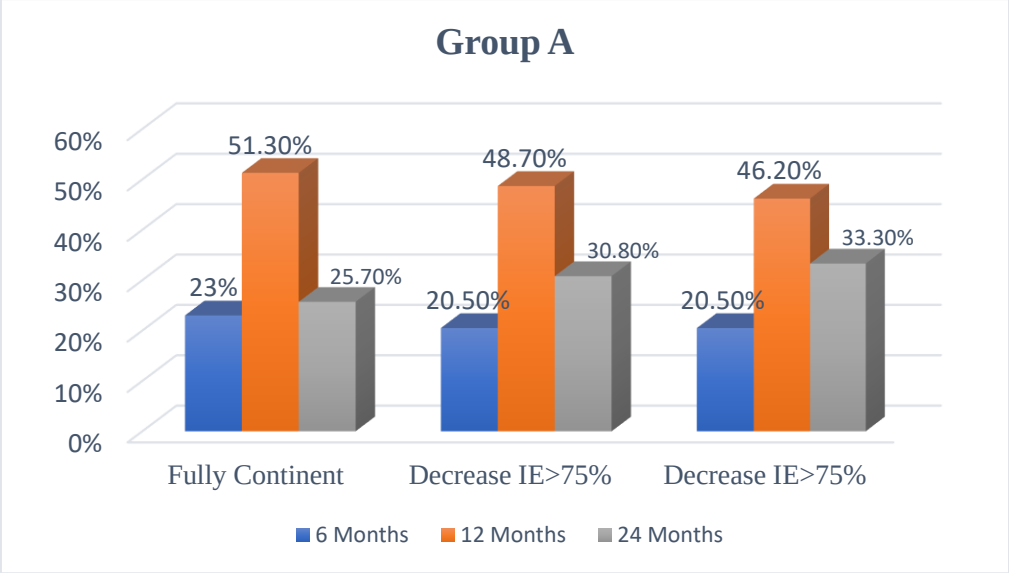

Figure (1): Clinical outcomes in group A.

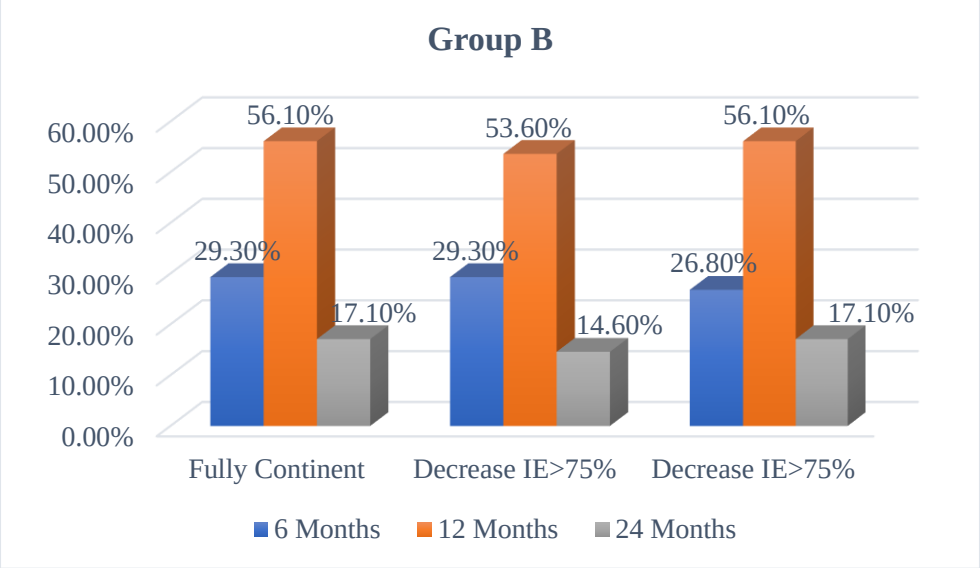

Figure (2): Clinical outcomes in group B.

DISCUSSION

For many years, the treatment of FNRFI in children was considered a grey area by medical professionals. Group B in the present investigation received biofeedback. When compared to group A, which received BTPTNS, this group had a considerable improvement in rectal sensation as well as in resting and maximum squeeze pressures, which is consistent with the short-term outcomes described by **Abdelrahman *et al.*** [2]**.** It is believed that the external anal sphincter has directly benefited from biofeedback training, leading to an improvement in squeeze pressure.

It was believed that the direct impact of biofeedback training on the external anal sphincter was partially responsible for the improvement in resting pressure. After evaluating several factors that contribute to resting anal pressure, **Lestar *et al.*** [20] reported that 30% of the variation is caused by external striated tonic activity. This is in line with the significant improvement that was thought to be partly brought about by the external anal sphincter's immediate response to biofeedback training. Following biofeedback therapy, changes in rectal sensations and pressures have been associated with improvements in the pattern of recognition of both the sensory pathway and the cerebellar cortex. This observation led to the current study's finding that patients who received biofeedback therapy had a significant improvement in their incontinence score when compared to their initial scores. **Gadelhak *et al.*** [21] had previously recommended biofeedback as a successful treatment for children's faecal incontinence. Our findings, however, contradicted those of **Van-Tets *et al.*** [22] who disclaimed that biofeedback had any further role in the treatment of faecal incontinence. This may have been because patients with neurological diseases who were not included in our study were included in theirs.

There are both motor and sensory fibers in the posterior tibial nerve, making it a mixed nerve. Preganglionic neurons that directly interact with sacral roots are inhibited by electrical activation of the fibers at the ankle level. Maximum resting and squeezing pressures will rise as a result of this upregulating striated muscle activity and afferent rectal sensory perception [23]**.** At the 6-month follow-up, patients in group A had a significant improvement in their incontinence score, which is consistent with the findings of **Vitton *et al.*** [11] who observed a significant reduction in incontinence events following a 3-month PTNS treatment period.

Many authors [24, 25] reported that children who received TPTNS showed a significant increase in anal pressure after 6 months. This is consistent with the findings of the present study where TPTNS and biofeedback were useful treatment modalities for children with fecal incontinence. According to the results of this investigation, biofeedback works better than TPTNS.

This could be explained by how biofeedback can raise awareness of a biological reaction. The voluntary regulation of this reaction, which is not accomplished in TPTNS, can be improved to achieve this.

Jimenez *et al.* [26] showed statistically significant improvement in all QoL domains, with a noteworthy increase in the total score during the one-year follow-up period for TPTNS, which is comparable to the findings of this study.

The efficacy of BTPTNS decreased over time, in group A the initial decrease in the IE > 75% was reported in 74.3% and maintained in 66.7% after 24 months. These outcomes are better than those of **Ladi Seyedian *et al.*** [27] who found that after six months, 55% of patients had significantly improved.

According to the current study, in 85% of cases, the biofeedback group's incontinence score and episodes were dramatically reduced by more than 75%. This benefit persisted over a 24-month period. Many authors [28, 29] reported nearly identical results at this time, which is highly controversial. However, **Lacima *et al.*** [30] showed that after three years of follow-up, there were more fully continent cases (35%). Many authors [30, 31] have shown that the effect of biofeedback decays with time. When compared to the first encouraging results after a 6-month follow-up, they reported a significant decline in the biofeedback outcome after a 3-year follow-up.

CONCLUSION

In the current study, there was a statically significant improvement in lifestyle, emotion, behavior, and embarrassment domains of QoL in the biofeedback and this can be simply explained by the reflection of a decrease in the incontinence score and episodes on QoL domains. Thus, Biofeedback and BTPTNS offered a beneficial line of treatment of FNRFI with a positive impact on QoL.

Limitations of the study: Long-time for follow-up was faced by obstacles in the commitment of the included children. Also lack of similar articles comparing long-term outcome of both modalities.

- **Declaration of conflicting interests:** NIL.
- **Funding:** NIL.

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