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Biofeedback pelvic floor muscle training and posterior tibial nerve electrostimulation for treatment of faecal incontinence: monotherapy versus combined therapy: a prospective randomized trial

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Abstract

Background: Faecal incontinence is a common anorectal medical trouble among adult population. The aim was to compare the efficacy of biofeedback pelvic floor muscle training versus posterior tibial nerve electrical stimulation versus combination of both of them in treatment of patients with faecal incontinence. The study included 71 randomly selected patients with faecal incontinence. Eleven patients had one or more exclusion criteria were excluded from the study. Sixty patients were included in the trial. They were randomly assigned to receive biofeedback pelvic floor muscle training (biofeedback group), posterior tibial nerve electrostimulation (posterior tibial nerve electrostimulation group) or combined therapy (combined group). Primary outcome measure was Wexner Faecal Continence scale. Secondary outcome measures were maximal squeezing anal pressure, maximal voluntary anal contraction time and patient global assessment of effect of faecal incontinence on quality of life. The outcome measures were recorded twice, before treatment and after treatment by six weeks.

Results: No statistical significant differences were present between the three groups regarding different baseline clinical characteristics. Significant differences were present between the initial and follow-up assessment of the outcome measures within the three groups. However, there were significant differences between the three groups regarding the outcome measures within follow-up assessment. There were 14 patients (70%) showed successful outcome in the combined group versus 11 patients (55%) in the biofeedback group and 6 patients (30%) in the posterior tibial nerve electrostimulation group.

Conclusions: Combination therapy of biofeedback pelvic floor muscle training and posterior tibial nerve electrostimulation in the treatment of patient with faecal incontinence is quantitatively better than biofeedback pelvic floor muscle training therapy alone and superior to posterior tibial nerve electrostimulation therapy alone, as well as biofeedback pelvic floor muscle training therapy is superior to posterior tibial nerve electrostimulation therapy. This combination could be recommended as an effective treatment for faecal incontinence. It increases the anal sphincter squeezing pressure with improvement in the patients' quality of life.

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Keywords: Biofeedback, Biofeedback pelvic floor muscle training, Faecal incontinence, Posterior tibial nerve electrostimulation

Background

Faecal incontinence (FI) is defined as involuntary loss of flatus, liquid or solid stool that occurs at a socially inappropriate time or place for at least three months, in an individual with a developmental age of at least 4 years (Norton et al. 2008). FI results in considerable embarrassment and anxiety in patients who have it (Norton et al. 2008). The prevalence of FI in adults is about 8%, and it occurs equally in women and men. However, females are 50% more likely to complain of FI than males (Whitehead et al. 2009). FI is usually associated with pudendal neuropathy and neuropathic changes in the different muscles of the pelvic floor (Sultan et al. 2013; Saba and Elsawy 2019).

The treatment of FI includes a wide range of available options (Prichard and Bharucha 2014). It should be tailored according to the cause and severity of the condition. However, a wide variety of strategies are usually used. All of them aim to improve the symptoms of the patient and improve patient's quality of life (QoL) (Scott 2014). The treatment includes conservative and surgical treatment (Norton et al. 2010). The conservative treatment includes biofeedback pelvic floor muscle training (BF) therapy and posterior tibial nerve electrostimulation (PTNS) (Norton et al. 2003; Findlay et al. 2010). In case of failure of the conservative therapy, surgical restoration of normal anatomy can be used (Bartolo and Paterson 2009).

There were several studies that assessed the efficacy of BF training in treating FI (Rao et al. 1997). Also, PTNS was assessed in FI in many studies (Findlay et al. 2010; Knowles et al. 2015; Zbar 2014). Both of them showed good results. However, there was no study compared the efficacy of one method against the other and the efficacy of the combined therapy in the improvement of FI. This issue was not assessed previously. Study aim was to compare the efficacy of BF versus PTNS versus combination of both of them in treatment of patients suffering of FI.

Methods

This was a prospective clinical trial included 71 randomly selected patients with FI. They were recruited from those attending the Pelvic Floor Rehabilitation clinic between July 2018 and September 2020. Patients with idiopathic FI, postoperative FI, postpartum FI, traumatic FI and patients with rectal prolapse were included. Inclusion criteria included patients older than 18 years, duration of FI of not less than six months and failure of conservative treatment in the form of dietary modifications, life style modifications and pelvic floor exercises for at least 3 months. Regarding patients with postoperative FI and traumatic FI, if there was a localized anal defect, it should not extend to more than 25% of the circumference of the anal orifice. The exclusion criteria are shown in Fig. 1 (Madbouly et al. 2017; Ibrahim et al. 2015). Eleven patients had one or more exclusion criteria were excluded from the study. Sixty patients were included in the trial.

The study was discussed with the patients. Each of them gave an informed consent. The study was approved by the Institutional Ethics Committee. The research was registered in Pan African Clinical Trials Registry (a trial registry) with an identifier number of PACTR202008862941254. The study adhered to CONSORT guidelines.

Patients were assessed with the collection of demographic data and history taking. Body mass index (BMI) was assessed (Agu et al. 2019). Assessment of FI severity was done by Wexner Faecal Continence scale (Jorge and Wexner 1993). The scale consists of five variables which are the type of incontinence (gas, liquid, or solid), information about wearing pads, lifestyle alteration; and the frequency of occurrence for each item. The global score was obtained by adding each individual score. The scoring system ranges from 0 to 20 where 0 means normal while 20 means complete incontinence (Jorge and Wexner 1993). The patient global assessment of effect of FI on QoL was assessed by visual analogue scale (VAS) which ranged from zero (negligible effect) to ten (very severe effect) (Boer et al. 2004).

Clinical evaluation was performed to all patients including assessment of the pelvic floor muscle strength by the use of Modified Oxford Scale (MOS) (Mitchell et al. 2012). Anal manometry assessment of maximal squeezing anal pressure and maximal voluntary anal contraction time were done (Mitchell et al. 2012). Anal manometry assessment was done using the manometric biofeedback device (Myomed 632-equipment, Enraf Nonius, B.V. Rotterdam, The Netherlands).

Instructions to stop all medications and to maintain recommended diet during the study were given to the participants. The patients were instructed to fill a bowel diary aiming to report any FI episodes.

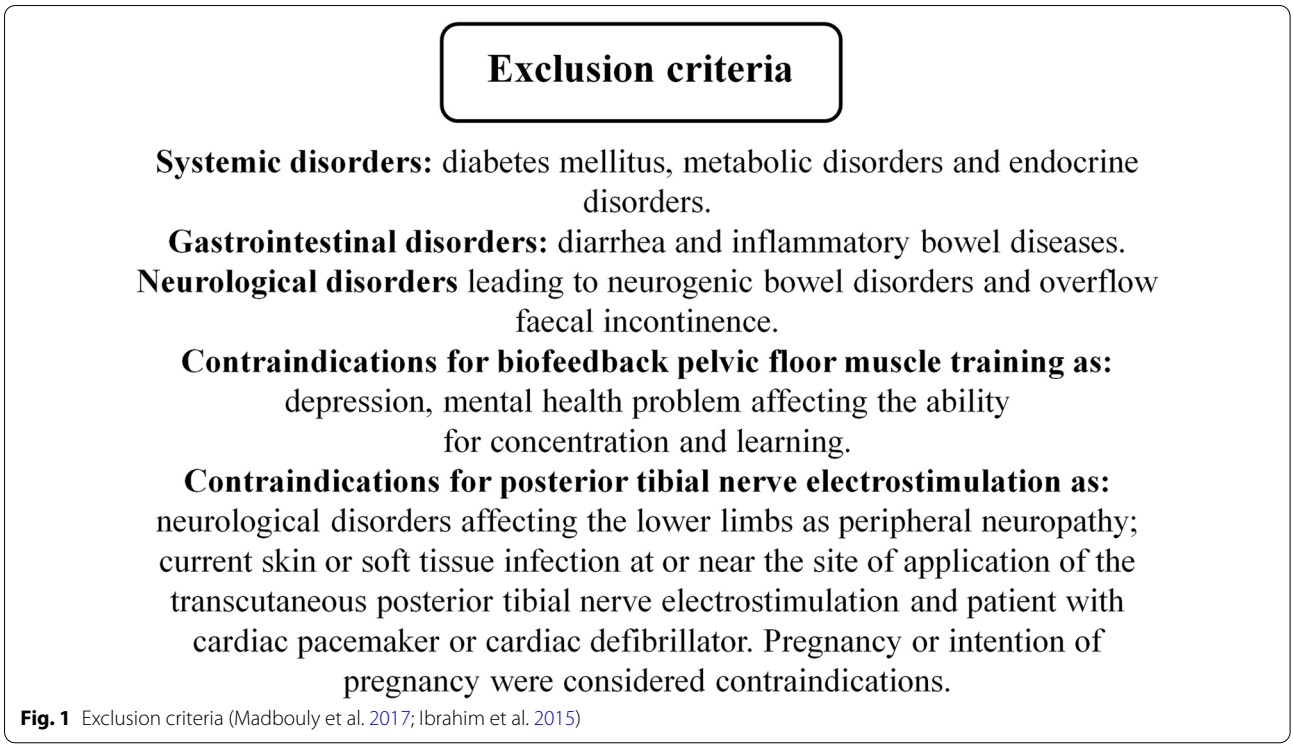

Fig. 1 Exclusion criteria (Madbouly et al. 2017; Ibrahim et al. 2015)

The patients were enrolled randomly to receive BF (BF group), PTNS (PTNS group) or BF combined with PTNS (combined group). They were enrolled by one of the investigators. The allocation was performed on an equal basis of 1:1:1 ratio with randomly permuted block sizes of variable length (three and six). This was performed to preserve allocation concealment. It was performed by the same investigator who enrolled the patients. (I) BF group: it included 20 patients. Each one received 12 sessions (twice weekly) of BF pelvic floor muscle training over a period of six weeks. (II) PTNS group: it included 20 patients. Each one received 18 sessions of transcutaneous PTNS (trice weekly) over a period of six weeks. (III) Combined group: it included 20 patients. Each one received 12 sessions (twice weekly) of BF pelvic floor muscle training and 18 sessions of transcutaneous PTNS (trice weekly) over a period of six weeks. All the sessions were done on an outpatient bases. Patients were instructed to perform strengthening Kegel exercises at home (Ibrahim et al. 2015).

Before starting therapy, the patients received a session of health education. It included illustration of the pelvic floor anatomy, defecation physiology, advice about diet modification and instructions to practice pelvic floor exercises (strengthening Kegel exercises) (Ibrahim et al. 2015).

The pressure-based BF pelvic floor muscle training was done using Myomed 632-equipment. The anal pressure probe with its connection hose were used. The BF session lasted 20–30 min. The sessions were performed by the same researcher. The anal pressure probe was inserted in the anus till its base. The session included the following: (i) First part: the patient contracted maximally their anal sphincter and hold for 10 s then relax completely for another 10 s. This was associated with increasing the duration of contraction. This was done for a period of 10–15 min. (ii) Second part: the patient practiced flicks exercises several times for up to 10–15 min. The BF session was done with continuous reinforcement by the performing investigator in conjunction with visual and auditory feedback. The patients were instructed to visualize the changes in the pressure tracing monitor to recognize pelvic floor muscles contraction during anal squeezing (Ibrahim et al. 2015). Female patients—during menstruation—were temporally withdrawn from the BF sessions. The patients were instructed to avoid contraction of the glutei and adductors muscles of both lower limbs during the BF session (Ibrahim et al. 2015).

The transcutaneous PTNS was done bilateral in both lower limbs. It was done by using surface stimulation electrodes (flexible rubber electrodes) connected to electrode cable using Myomed 632-equipment. The surface negative electrode was attached just above and behind the medial malleolus. The surface positive electrode was attached 10 cm proximally on the medial surface of the leg. The current parameters were set at pulse width of

200 μs; current frequency of 10 Hz and intensity of the electrical current was slowly increased till eliciting tingling sensation in the foot and/or plantar flexion of the toes. It was maintained at a comfortable level for the patient. PTNS session lasted 30 min (Madbouly et al. 2017).

The pretreatment assessment was done before initialization of therapy. Post-treatment assessment was done at the end of the 6 weeks' intervention. The assessed outcome measures included: (i) Primary outcome measure: Wexner Faecal Continence scale. (ii) Secondary outcome measures: maximal squeezing anal pressure, maximal voluntary anal contraction time and patient global assessment of effect of FI on QoL. The outcome measures were qualified as the following: (i) Improvement: the outcome measure had at least 50% improvement after therapy. (ii) No improvement: the outcome measure had less than 50% improvement after therapy (Heywood et al. 2018).

It was not a blinded study. The study profile is illustrated in Fig. 2. The initial assessment and therapy were done by one of the investigators while the post-treatment assessment was done by another one to avoid bias.

Statistical Package of Social Science (SPSS version 17) software was used. Analytic measures included Mann Whitney test, Kruskal–Wallis test, Wilcoxon Signed Ranks test, Chi-square test and Fisher's Exact test (if indicated). For any P value at < 0.05, statistical significance was proved.

Results

Sixty patients [32 females (53.3%) and 28 males (46.7%)] were participated in the research. Their age was 48.76 ± 14.36 years (range: 18–68 years). Duration of FI was 25.18 ± 18.19 months (range: 6 months to 72 months). There were no significant differences between the studied groups regarding demographic, anthropometric and clinical characteristics (Table 1).

Comparison of the three groups regarding outcome measures assessed before and after therapy is shown in Table 2. No statistical significant differences were present between them regarding assessed outcome measures before starting the therapy. Statistical significant differences were found between the initial and follow-up assessment of the outcome measures within the three groups. There were statistical significant differences between the three groups regarding the outcome measures within the follow-up assessment. But, statistical significant differences were present between the PTNS group and combined group regarding all outcome measures within follow-up assessment (Table 2).

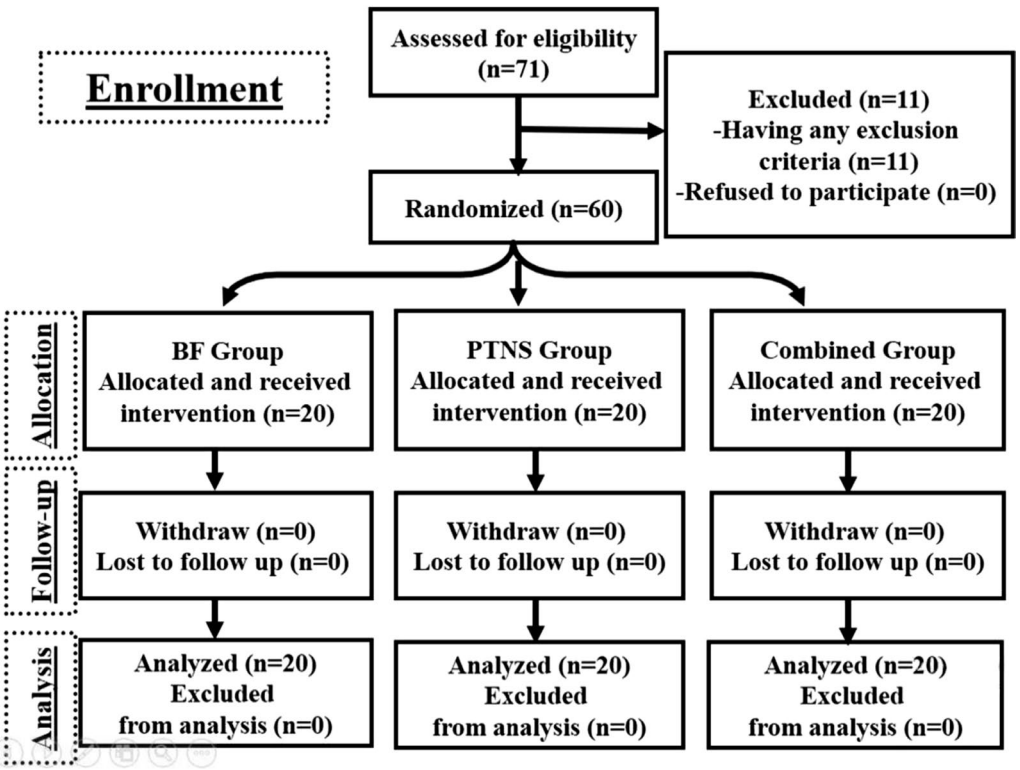

Fig. 2 The study profile

Table 1 Characteristics of the patients in the three groups

Characteristics of the patient	BF Group ($n=20$ patients) n(%)	PTNS Group ($n=20$ patients) n(%)	Combined Group ($n=20$ patients) n(%)	Test of significance	P
Women	11(55.0)	10(50.0)	11(55.0)	$X^2=0.134$	0.935
Age (years)†	49.20 ± 13.82	47.00 ± 14.67	50.10 ± 15.14	$K=0.580$	0.748
Parity‡	1(0–3)	1(0–2)	2(0–4)	$K=0.585$	0.746
Anthropometric measures					
Weight (kg)†	65.20 ± 17.72	62.20 ± 18.67	63.40 ± 15.55	$K=0.320$	0.852
Height (cm)†	160.80 ± 12.60	160.15 ± 14.09	159.05 ± 12.59	$K=0.868$	0.648
BMI (kg/m^2)†	25.02 ± 5.79	23.83 ± 5.66	24.91 ± 5.16	$K=0.745$	0.689
BMI category					
Underweight	1(5.0)	2(10.0)	2(10.0)	$X^2=0.871$	0.990
Normal weight	9(45.0)	10(50.0)	9(45.0)		
Overweight	6(30.0)	4(20.0)	5(25.0)		
Obese	4(20.0)	4(20.0)	4(20.0)		
Duration of symptoms (months)†	20.25 ± 16.22	29.80 ± 20.15	25.50 ± 17.58	$K=2.599$	0.273
Type of FI					
Gas	2(10.0)	5(25.0)	2(10.0)	$X^2=2.486$	0.647
Liquid	8(40.0)	6(30.0)	7(35.0)		
Solid	10(50.0)	9(45.0)	11(55.0)		
Clinical examination					
Patulous anus	8(40.0)	6(30.0)	8(40.0)	$X^2=0.574$	0.750
Localized anal defect	3(15.0)	2(10.0)	2(10.0)	$X^2=0.323$	0.851
Increased perineal descend	17(85.0)	18(90.0)	16(80.0)	$X^2=0.784$	0.676
MOS‡	3(3–4)	4(3–4)	3(3–4)	$K=0.525$	0.769
Diagnosis of FI					
Idiopathic FI	3(15.0)	4(20.0)	3(15.0)	$X^2=1.702$	0.989
Rectal prolapse	2(10.0)	2(10.0)	2(10.0)		
Postpartum FI	4(20.0)	3(15.0)	4(20.0)		
Postoperative FI	7(35.0)	9(45.0)	9(45.0)		
Traumatic FI	4(20.0)	2(10.0)	2(10.0)		

BMI body mass index; *kg* kilogram; *cm* centimetre; *m*^{2} metre square; *MOS* Modified Oxford Scale; *FI* faecal incontinence; *BF* biofeedback pelvic floor muscle training; *n(%)*number (percentage) of patients; *PTNS* transcutaneous posterior tibial nerve electrostimulation; *n* number of patients; X^2 value of Chi-square test; *K* value of Kruskal–Wallis test

* Significant $P<0.05$

† Data are mentioned as mean ± standard deviation

‡ Data are mentioned as median (range)

Comparison regarding the frequency of improvement of different measures between the three groups is shown in Table 3. There were 14 patients (70%) showed successful outcome in the combined group in comparison to 11 patients (55%) in the BF group and 6 patients (30%) in the PTNS group. Comparison between the PTNS group versus combined group showed that there were statistical significant differences regarding the frequencies of improvement of different outcome measures. No patients achieved perfect faecal continence as presented by Wexner Faecal Continence scale less than three. No side effects were reported in the three groups.

Discussion

Faecal incontinence is a common medical problem in the community (Norton et al. 2010). The treatment of FI includes a wide variety of conservative and surgical therapies (Norton et al. 2010). These included BF and PTNS. BF and PTNS are methods that are well-established for the treatment of FI patients (Findlay et al. 2010). This could be considered as the initial study that assessed the efficacy of BF alone versus PTNS alone versus combination therapy of both BF and PTNS in the treatment of FI.

There was statistical significant improvement between the follow-up assessment and pretreatment assessment in all outcome measures among the BF group. These included the maximal squeezing anal pressure and

Table 2 Comparison between the initial and follow-up assessments of the three groups and between the three groups in each phase regarding outcome measures

Outcome measures	BF Group ($n=20$ patients) mean ± SD	PTNS Group ($n=20$ patients) mean ± SD	Combined Group ($n=20$ patients) mean ± SD	Test of significance	*P*
Primary outcome measure					
Wexner Faecal Continence scale					
Initial assessment	10.80 ± 1.962	10.00 ± 1.71	10.00 ± 1.52	$K=2.201$	0.333
Follow-up assessment	6.80 ± 2.83	7.85 ± 2.62	5.15 ± 1.72	$K=10.572$	0.005*
Test of significance	$Z=-3.933$	$Z=-3.658$	$Z=-3.980$		
$P^{\dagger}$	≤ 0.0001*	≤ 0.0001*	≤ 0.0001*		
$P^{\ddagger}$	$P_1=0.196$	$P_2=0.001$*	$P_3=0.065$		
Secondary outcome measures					
Maximal squeezing anal pressure (hPa)					
Initial assessment	58.95 ± 16.55	60.55 ± 17.36	56.90 ± 20.40	$K=0.368$	0.832
Follow-up assessment	78.75 ± 26.17	64.40 ± 16.78	80.75 ± 25.62	$K=4.748$	0.093
Test of significance	$Z=-3.921$	$Z=-3.931$	$Z=-3.922$		
$P^{\dagger}$	≤ 0.0001*	≤ 0.0001*	≤ 0.0001*		
$P^{\ddagger}$	$P_1=0.088$	$P_2=0.046$*	$P_3=0.645$		
Maximal voluntary anal contraction time (seconds)					
Initial assessment	4.20 ± 1.79	4.30 ± 1.94	4.45 ± 1.98	$K=0.133$	0.936
Follow-up assessment	6.50 ± 2.50	5.65 ± 2.20	7.65 ± 2.32	$K=6.963$	0.031*
Test of significance	$Z=-3.872$	$Z=-3.834$	$Z=-3.958$		
$P^{\dagger}$	≤ 0.0001*	≤ 0.0001*	≤ 0.0001*		
$P^{\ddagger}$	$P_1=0.289$	$P_2=0.006$*	$P_3=0.183$		
Patient global assessment of effect of FI on quality of life					
Initial assessment	6.45 ± 1.70	6.60 ± 1.75	6.50 ± 1.46	$K=0.080$	0.961
Follow-up assessment	3.90 ± 2.14	5.45 ± 2.28	3.10 ± 1.33	$K=11.602$	0.003*
Test of significance	$Z=-3.949$	$Z=-2.842$	$Z=-4.018$		
$P^{\dagger}$	≤ 0.0001*	≤ 0.0001*	≤ 0.0001*		
$P^{\ddagger}$	$P_1=0.027$*	$P_2\leq 0.0001$*	$P_3=0.278$		

hPa hectopascal (it is the unit of pressure and it is equal to 100 Pascals); *FI* faecal incontinence; *BF* biofeedback pelvic floor muscle training; *PTNS* transcutaneous posterior tibial nerve electrostimulation; *n* number of patients; *SD* standard deviation; *Z* value of Wilcoxon Signed Ranks test used for comparing between the initial assessment and follow-up assessment in each group; P_1 *P* value for test of significance for comparing between BF group and PTNS group regarding the follow-up assessment; P_2 *P* value for test of significance for comparing between PTNS group and combined group regarding the follow-up assessment; P_3 *P* value for test of significance for comparing between BF group and combined group regarding the follow-up assessment; *K* value of Kruskal–Wallis test used for comparing between the three treatment groups

* Significant $P<0.05$

† *P* value of the Wilcoxon Signed Ranks test

‡ *P* value for the statistical test used for comparing the outcome measures in the follow-up assessment between different two groups of the three groups

maximal voluntary anal contraction time. These findings were in accordance with previous studies regarding BF therapy for FI (Melao et al. 2014; Jodorkovsky et al. 2013; Chiarioni et al. 2009; Damin et al. 2017; Leite et al. 2013; Santos et al. 2018).

There were 55% of the participated patients showed successful improvement in the primary outcome measure in the BF group. This was also applied for the secondary outcome measures of the same group. These were in agreement with previous studies regarding the efficacy of BF in the treatment of FI (Glia et al. 1998; Rao et al. 1996). However, these were not in accordance with other previous studies (Fynes et al. 1999; Norton and Kamm 1999; Sangwan et al. 1995). This might be due to the differences in the demographic characteristics of the included patients, differences in the inclusion criteria of FI patients; and lack of standardized tools for FI assessment and technique for BF therapy (Melao et al. 2014).

The BF is a technique that inform the treated patients about some of their internal physiological events in a

Table 3 Comparison between the three groups regarding frequency of improvement in outcome measures

Outcomes measures	BF Group ($n=20$ patients) n(%)	PTNS Group ($n=20$ patients) n(%)	Combined Group ($n=20$ patients) n(%)	Test of significance (X^2)	P
Primary outcome measure					
Wexner Faecal Continence scale improvement	11(55.0)	6(30.0)[‡]	14(70.0)[‡]	6.541	0.038*
Secondary outcome measures					
Maximal squeezing anal pressure improvement	6(30.0)[†]	0(0)[†‡]	10(50.0)[‡]	12.955	0.002*
Maximal voluntary anal contraction time improvement	13(65.0)	8(40.0)[‡]	17(85.0)[‡]	8.756	0.013*
Patient global assessment of effect of FI on quality of life	9(45.0)	4(20.0)[‡]	15(75.0)[‡]	12.188	0.002*

FI faecal incontinence; *BF* biofeedback pelvic floor muscle training; *PTNS* transcutaneous posterior tibial nerve electrostimulation; *n* number of patients; *n(%)*number (percentage) of patients; X^2 value of Chi-square test

* Significant $P<0.05$

† Statistical significant difference between BF group and PTNS group ($P<0.05$)

‡ Statistical significant difference between PTNS group and combined group ($P<0.05$)

continuous and instantaneous way through visual and/or auditory signals (Melao et al. 2014). It allows the continuous assessment of the patients' progress through the assessment of the contractile ability of the anal sphincter muscles (Melao et al. 2014). BF improves the awareness and the function of the anal sphincter and other pelvic floor muscles (Santos et al. 2018). The aim of the BF training for the anal sphincter is to teach the patients different skills that could prevent attacks of FI under the usual daily life circumstances (Scott 2014). It should be recommended to all FI patients after failure of conservative treatment, because BF is a safe procedure associated with short- and long-term effectiveness (Ozturk et al. 2004). The best candidates for BF therapy are those patients without severe degree of FI and without indications for surgical intervention (Scott 2014).

There was statistical significant improvement of all assessed outcome measures in the follow-up assessment in comparison to the pretreatment evaluation in the PTNS group. These were in line with literature (Findlay et al. 2010; Knowles et al. 2015; Govaert et al. 2010; Hotouras et al. 2012; Veronique et al. 2010). However, these were not in line with Heywood et al. (Heywood et al. 2018) and Lopez-Delgado et al. (Lopez-Delgado et al. 2014) regarding the effect of PTNS on anal manometry parameters (Heywood et al. 2018; Lopez-Delgado et al. 2014). The PTNS produced successful improvement in 30% of the participated patients who showed improvement in the primary outcome measure in the follow-up assessment. This was similar to previous researches (Knowles et al. 2015; Heywood et al. 2018). However, this was not agreed with other researches (Findlay et al. 2010; Govaert et al. 2010; Portilla et al. 2009). Regarding secondary outcome measures, 40% of the included patients showed improvement in the maximal voluntary anal contraction time and 20% showed improvement in the patient global assessment of effect of FI on QoL. The differences between the present study and these previous studies which were not in agreement with the current study regarding the effects of PTNS might be due to differences in the demographics of the included patients, differences in the aetiologies of FI between different studies, differences in the techniques of application of PTNS due to lack standardization of the technique regarding application, electrical current parameters and the frequency of the sessions. The patients in all previous studies that assessed the effect of PTNS in the treatment of FI included patients who failed conservative treatment including BF treatment (Findlay et al. 2010; Heywood et al. 2018; Govaert et al. 2010; Hotouras et al. 2012; Lopez-Delgado et al. 2014). This was not applied to those included in the current study. The statistical significant improvement between the initial and follow-up assessment regarding the maximal squeezing anal pressure in the PTNS group could be due to the suggested effect of PTNS on the external anal sphincter muscle contractility combined with the effect of Kegel exercises performed by the patients during home exercises (Scott 2014; Shafik et al. 2003; Portilla et al. 2014; Invrati et al. 2016). Future assessment is required to confirm this issue.

The mechanism of action of PTNS in the treatment of FI and in increasing the external anal sphincter muscle contractility is still not well understood. It could act by modulation of the peripheral nerves that share the same innervation of the pelvic floor muscles, as well as central mechanisms by modulation of the ascending neuronal pathways to the sensory cortex (Heywood et al. 2018; Malaguti et al. 2003; Finazzi-Agro et al. 2009). The presence of sensory and motor neuromodulatory effects affect the pelvic floor skeletal muscles activation. This could be via reflex-mediated responses in the faecal continence mechanism through spinal

reflex arcs (Wunnik et al. 2011). These allow the generation of increased maximal squeezing anal pressure by external anal sphincter muscle contraction (Shafik et al. 2003; Portilla et al. 2014; Invrati et al. 2016).

The comparison between BF group versus PTNS group regarding the percentage of improvement in the outcome measures showed that there were no statistical significant differences between both of them except for maximal squeezing anal pressure improvement. BF was significantly better in improvement of the maximal squeezing anal pressure in 30% of the BF group patients in contrast to PTNS group that showed no patient achieved this. These data were not assessed previously in the literature. These should be taken with caution because all previous studies on PTNS in FI included FI patients who failed conservative therapy included BF therapy (Findlay et al. 2010; Heywood et al. 2018; Veronique et al. 2010). This is also the only study that assessed BF therapy versus PTNS therapy as head-to-head assessment. Although there was significant difference between both of them regarding the maximal squeezing anal pressure improvement only, BF therapy is considered superior to PTNS therapy.

The combined group showed a statistical significant improvement in the outcome measures in the follow-up assessment. However, at this level, there were statistical significant differences between the combined group in comparison to the PTNS group in the post-treatment assessment in which the results were better in the combined group in comparison to the PTNS group. But, this was not found when the combined group was compared to the BF group. The combined group showed a significantly highest percentage of improvement of the primary outcome measure which was 70%. Also, this was applied to the secondary outcome measures. However, this was significantly higher than those of the PTNS group but not BF group. The combination therapy produces better results in comparison to the two modalities utilized as monotherapy. These results are unique and were not mentioned previously in the literature. These results could be due to the presence of a synergistic effect for the combination of BF and PTNS in the treatment of FI patient and due to the combination of the active cooperation between the patients and the performing physician in BF therapy with the subconscious neuromodulative effect of PTNS (Heywood et al. 2018; Melao et al. 2014; Ozturk et al. 2004; Shafik et al. 2003; Portilla et al. 2014; Invrati et al. 2016; Malaguti et al. 2003; Finazzi-Agro et al. 2009).

Although combined therapy was superior to PTNS therapy, it was quantitatively better but not statistically significant than BF therapy alone. The combination therapy of BF and PTNS is effective, safe and applicable.

Rationale for combined therapy is the combination between two completely different physical modalities which had completely different mechanisms of action (Heywood et al. 2018; Melao et al. 2014; Ozturk et al. 2004; Shafik et al. 2003; Portilla et al. 2014; Invrati et al. 2016; Malaguti et al. 2003; Finazzi-Agro et al. 2009). This could be the best choice for treatment of FI especially when it is associated with health education, dietary modifications and pelvic floor muscles exercises. The combined therapy could decrease therapy duration, improve patient satisfaction to the therapy and improve success rate.

No patients reported side effects in the three groups. This was in agreement with previous studies in which BF and transcutaneous PTNS were considered safe physical modalities and not associated with any side effects (Findlay et al. 2010; Glia et al. 1998; Rao et al. 1996; Portilla et al. 2009).

Reviewing the literature, this study was the only study assessed BF and PTNS combined therapy versus BF alone and PTNS alone. Reviewing the hierarchy of conservative treatment of FI is essential to add the combination therapy in the armamentarium of the treatment of FI.

The current study had some limitations which could be summarized as the following: (i) The study included a wide variety of FI aetiologies. Further studies on different aetiologies of FI separately could give different results according to different aetiologies. (ii) There was no long-term follow-up assessment because this study aimed to investigate the short-term effect of both BF and PTNS versus combination of both of them. (iii) Patients who were included in the PTNS did not received BF previously in contrast to previous studies that the inclusion criteria of their patients were the failure of previous therapy with BF (Findlay et al. 2010; Heywood et al. 2018; Govaert et al. 2010; Hotouras et al. 2012). This made the comparison between the results of PTNS group in the current study and previous studies to be taken with caution. (iv) Blinded study was not applied. This was secondary to the differences in the therapeutic modalities between the three intervention groups. This could be a source of bias in the current study. (v) Because the study had been held in one medical institute, the generalizability of the obtained conclusions should be taken with caution.

Conclusions

In conclusion, combination therapy of BF and PTNS in the treatment of patient with FI is quantitatively better than BF therapy alone and superior to PTNS therapy alone, as well as BF therapy is superior to PTNS therapy. This combination could be recommended as an effective

treatment for FI. It increases the anal sphincter squeezing pressure with improvement in the patients' QoL.

Abbreviations
BF: Biofeedback pelvic floor muscle training; FI: Faecal incontinence; MOS: Modified Oxford Scale; PTNS: Posterior tibial nerve electrostimulation; QoL: Quality of life; SD: Standard deviation; VAS: Visual analogue scale.

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Authors' contributions
MSE contributed to the concepts, design, definition of intellectual content, clinical studies, data acquisition and manuscript revision. EKAS contributed to the concepts, design and definition of intellectual content, and did literature search, clinical studies, data acquisition and analysis, manuscript preparation, editing and revision. All the authors read and approved the manuscript.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The local Ethics Committee of Faculty of Medicine, Alexandria University, Egypt (IRB NO:0007555-FWA NO:00018699) approved the study. Date of approval:19/7/2018; Serial number: 0304025; A written informed consent was given by each.

Consent for publication
Consent for publication was given by each participant.

Competing interests
The authors declare that they have no competing interests.

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