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Fecal incontinence responses to anal electrical stimulation

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Fecal incontinence is a common problem and is defined as the intermittent automatic excretion of flatus, liquid or solid stool in unseemly places or at improper occasions that is a hygienic or social problem. Physical therapy management is considered as the first-line treatment because it is a non-invasive nature and simple method to use.This study was designed to evaluate the effect of anal electrical stimulation in a randomized, clinical trial for the treatment of patients with fecal incontinence.66 patients were included in the study, out of a total of 74 patients who were screened for eligibility. The patients were randomized to group (1) received electrical stimulation and pelvic floor muscle training, while group (2) received pelvic floor muscle training only. The outcome measures were the Vaizey incontinence score and fecal incontinence quality of life scale.The current study showed that there were significant differences between pre and post intervention in group (1) ($P< 0.05$) in terms Vaizey incontinence score and QOL questionnaires while, group (2) revealed that there were an improvement but not statistically significantly ($P> 0.05$). Comparing the two groups, there was statistically significant difference between patients in both groups in favor of group (1) ($P< 0.05$) in terms of Vaizey incontinence and FIQOL ($P> 0.05$). The study revealed that 4 weeks of anal electrical stimulation improves patients with fecal incontinence. Anal electrical stimulation is considered as a non-invasive, cheap and simple to use and could be offered to treat fecal incontinence.

Keywords: Fecal incontinence; Electrical stimulation; Quality of life; Vaizey incontinence score; Pelvic floor muscle training.

INTRODUCTION

Faecal incontinence (FI) is primarily defined as the unintentional, involuntary and recurrent passage of liquid or solid stools (Bharucha et al., 2015). It is estimated that FI primarily affects 2-24% of the adult population with approximately half of all nursing home residents and is considered as a major health problem which affects the quality of life (Nelson et al., 1995; Ho et al., 2005). It is eight times more common in females due to the side effects of obstetric trauma on anal sphincter and pelvic floor, in addition to the postmenopausal neuromuscular degeneration effects (Healy et al., 2006).

The first line of treatment for FI is usually conservative and includes dietary modification, laxatives and physiotherapy ((Bols et al., 2007; Schwandner et al., 2010).

Physiotherapy interventions are simple, inexpensive, non-invasive and, require simple equipment and mostly without any side effects. Moreover, it does not exclude any other type of intervention (Miner et al., 1990). Physiotherapy treatment for FI includes biofeedback (BF), pelvic floor muscle training (PFMT), and electrical stimulation (ES). The main aim of PFMT is to restore muscle strength, coordination and timing of contractions while ES is used to increase

awareness and isolated contraction of the anal sphincters (Miner et al., 1990; Madoff et al., 2004).

Anal electrical stimulation (AES) is an option for treating chronic FI by stimulating the pudendal nerve the anal sphincter and which leads to increased circulation, reduced synaptic resistance, increased motor unit size, conduction rate of the pudendal nerve, and reduced fatigability Norton, 2006; Schwandner et al., 2011).

The mechanism of AES effect is still unknown whether is due to muscle strengthening, or sensitization (Swash, 2002; Rowedder, 1984). To the best of the authors' knowledge, there is a shortage of studies examined AES on FI and therefore the aim of the study was to investigate the effect of AES in patients with FI

MATERIALS AND METHODS

Participants

A total of 66 participants were included in the study out of 74 patients (excluded (n= 8): not meeting the inclusion criteria (5), refuse to participate (3), and other reason (1) with chronic FI were assessed for eligibility as demonstrated in Fig (1). Inclusion criteria were patients with FI for at least six months, age ranged between 20- 50 years, with normal colon, and intact anal sphincters as confirmed by preliminary colonoscopy and endo-anal ultrasonography, respectively. The exclusion criteria were presence of a severe systematic disease including metabolic and neurological conditions and with severe liver, lung, renal, hematological, malignancies or other comorbidity. Patients diagnosed with external/internal hemorrhoids including anal fissures, previous usage of an ES for the treatment of urinary or fecal incontinence, patient's unwillingness or inability to provide informed consent, and pregnant or lactating females were excluded

Study design

This is a randomized control trial conducted at Cairo University Hospitals and performed in accordance with the principles of the Declaration of Helsinki. Eligible subjects were invited and screened by an experienced physiotherapist. Information provided regarding the objectives and the different phases of the study. Written informed consent provided once they agreed to participate in the research.

Patients interviewed at baseline and at the end of treatment .The investigator recorded demographic data and collected the questionnaires, assessed patient compliance by inquiring about adherence to treatment instructions, inspection for adverse effects of treatment, and confirmed complete responses to the questionnaire items. By using a number generating table, patients were randomly assigned to a group (1) included 33 patients received endo-anal electrical stimulation (ES) in addition to PFMT training (2 drop out; due to irregular attendance (1) and due to other reason (1), while group (2) included 33 patients received PFMT only (1 drop out; due to health problem (1). The study was conducted over 4-week period.

Procedure

Patients for both treatment groups were treated by experienced physiotherapists. At the beginning of the study, all enrolled participants were asked to complete a self-administered demographic questionnaire, Vaizey incontinence score and The Fecal Incontinence Quality of Life (FI-QOL).

Vaizey incontinence score is used to evaluate the severity of FI and ranges from 0 (complete continence) to 24 (complete incontinence) (Vaizey et al., 1999). It is a widely used and considered as a reproducible score. Recently, it has also been reported that higher Vaizey scores are accompanied with more problems in general health domains (Deutekom et al., 2005).

FIQL is consisting of four scales: lifestyle (10 items), coping/behavior (9 items), depression/self-perception (7 items), and embarrassment (3 items). It has shown to be reliable and valid (Rockwood et al., 2000).

Intervention

Pelvic floor muscle training

PFMT is offered to all patients in both groups and consists of selective voluntary contractions and relaxations of the pelvic floor muscles (PFMs) and the anal sphincter. It is very necessary to make awareness of these muscles, to avoid of the use of other muscles like the abdominals or adductors. PFMT aims to maximize strength, improve strength, timing and coordination of contractions (Bols et al., 2007).

The patients were instructed to feel comfortable and relaxed during the treatment session.

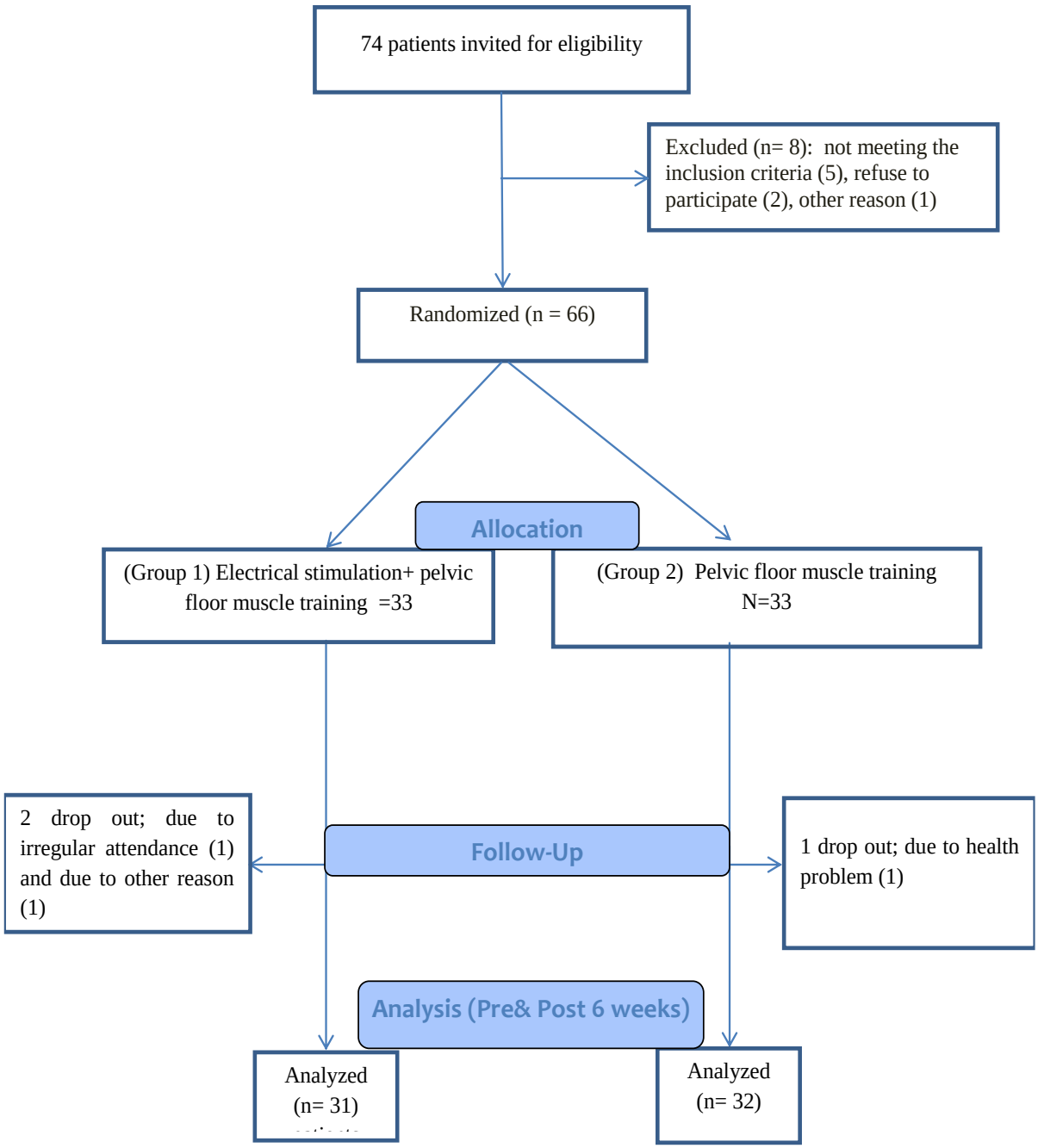

Fig. 1 Study flow chart

Each patient was prepared and taught a program of pelvic floor exercises to be performed in daily sessions in lying, sitting, and standing positions consisting of 10 seconds of contractions followed by 10 seconds of relaxation and repeating the exercises 15 times each session. The contraction and relaxation times were continuously expanded by 1 second every week as training for the slow twitch muscle fibers. While, fast twitch muscle fibers can be trained through asking the patient to contract as if he controls his urine by quick contraction and relaxation of the levator ani muscles 20 times, rest for ten seconds, and then repeat again for a total of 2 to 4 "sets" of contractions (Tantawy et al., 2019; Elgohary& Tantawy, 2017) .

Anal electrical stimulation

AES was offered only to patients in group (1) and performed by using endo-anal electrode at 50 Hz with biphasic pulse duration of 200 microseconds (Myomed 932, Enraf-Nonius NV, Delft). ES was applied for 20 minutes, 3 times per week for 2 months (in cycles which involving; 5 sec contractions and 8 sec rest). After 4 weeks, Vaizey score, fecal incontinence quality of life questionnaire.

Sample Size

Initially, the sample size estimation was performed to avoid type II error. calculation of means and a common standard deviation were obtained from a pilot study included five patients with fecal incontinence who underwent similar intervention for same period using the measure of Vaizey incontinence score (mean1= 11.7, mean2= 8.3, and SD=4.4). Unpaired t-test, power of 80% and α=0.05 created a sample of 27 individuals for each group. The study included 33 individuals in each group to account for the dropout rates of 20 %.

Statistical analysis

Descriptive statistics were calculated as the mean and standard deviation. Inferential statistics measured the changes Vaizey incontinence and FIQOL scores, using the unpaired t-test between the two groups. A paired analysis was used to compare pre-treatment and post-treatment values of effect measurement. All data were analyzed using SPSS version 23.0 (SPSS, Chicago, IL, USA), with statistical significance set at $p \leq 0.05$.

RESULTS

56 patients were included in the study, out of a total of 64 patients who were screened for eligibility. The trial started on 12 January 2018 and ended on 3 September 2018. The patients were randomized to receive both AES and PFMT for group (1) or PFMT only for group (2) as presented in Figure 1.

59 (77%) of the patients were female. At baseline, 9 (11%) had grade I incontinence, 61 (80%) grade II, and 6 (8%) grade III. 36% were incontinent of both urine and stool.

The demographic and baseline characteristics of each group of study participants are given in (Table 1).

At the beginning of the study, before treatment, there were no statistically significant differences between patients in both groups in terms of age, BMI, duration of incontinence, Vaizey incontinence score and QOL questionnaires (P> 0.05) as presented in (Table 1 and 2).

The results of the current study showed that there were significant differences between pre and post intervention in group 1 (P< 0.05) in terms Vaizey incontinence score and QOL questionnaires while, group (2) revealed that there were an improvement but not statistically significantly (P> 0.05) as demonstrated in (Table 2).

Comparing the two groups, there was statistically significant difference between patients in both groups in favor of group 1 (P< 0.05) in terms of Vaizey incontinence and FIQOL (P> 0.05).

Table 1- Demographic characteristics for both groups

Category	Group (1) N=31	Group (1) N= 32	P-value
Age (years)	39.03 (6.8)	38.52 (7.87)	0.77
BMI (kg/m^2)	27.22 (4.21)	26.94 (5.18)	0.80
Incontinence (months)	15.4 (9.2)	16.7 (10.1)	0.58

Significance p-value<0.05

Table 2- Vaizey score and Fecal Incontinence Quality of Life (FIQL) before and after intervention in both groups

Category	Vaizey score			FIQOL		
	Pre	Post	p-value	Pre	Post	p-value
Group (1)	12.71(4.12)	7.9 (5.44)	0.0001	12.58 (3.6)	14.75 (4.1)	0.02
Group (2)	11.9 (3.9)	10.4 (2.9)	0.07	12.63 (3.71)	12.84 (3.7)	0.8
p-value	0.41	0.02		0.95	0.04	

Significance p-value<0.05; FIQOL: Fecal Incontinence Quality of Life

DISCUSSION

The results of the current study showed that there were significant differences between pre and post intervention in group (1) in terms Vaizey incontinence score and QOL questionnaires (P< 0.05) while, group (2) revealed that there were an improvement but not statistically significantly (P> 0.05)

Comparing the two groups, there was statistically significant difference between patients in both groups in favor of group (1) in terms of Vaizey incontinence QOL questionnaires scores (P< 0.05).

The results of the present study showed that there was an improvement of fecal incontinence before and after treatment which might be due to increase muscle strength and squeezing pressure of the external sphincter muscle. The squeeze pressure is the main measure of the external sphincter muscle (Smith and Blatchford, 2007). The variations in PFM strength are not the only ES effect. Additional perspectives of muscle action that were not assessed in the current study, as abdominal muscle contraction and its effect on PFM strength in patients with FI (Kamel et al., 2013).

The improvement might be due to several factors. ES improves the strength and endurance of striated muscle contraction which is directed to the external anal sphincter in patients with FI. In addition, ES increases the muscle contraction voluntarily by enhancing hyperplasia and hypertrophy of the external anal sphincter muscle fibers (Coffey et al., 2002). The sphincter muscle passive exercises by ES help the patient to have awareness of his body which can lead to good muscle recruitment correction and achievement ((Healy et al., 2006, Yamanishiet al., 2010, Pucciani et al., 2008).

It has been reported that ES transforms fast-twitch muscle fibers to slow-twitch muscle fibers, which is helping to improve endurance (Salmons and Vrbová, 1969). In addition, ES is helping to increase capillary density, improving circulation to the oxidative slow-twitch fibers (Hudlická et al., 1982).ES can be applied to the anal sphincter and pelvic floor in various forms, involving surface electrodes or endo-anal probes and with various protocols (Schwandner et al., 2010**).**

Healy et al., (2006) studied 24 patients with FI by applying endo-anal ES and reported that endo-anal ES improved continence scores significantly after intervention. Another study concluded that the amplitude-modulated medium-frequency ES combined with biofeedback reduce FI (Schwandner et al., 2010).

Furthermore, Zakaria et al., (2009) concluded that the posterior tibial nerve stimulation is considered as an effective modality in the treatment of FI caused by partial spinal cord injury.

A Cochrane systematic review showed that biofeedback with exercises is more effective than exercise alone; furthermore, biofeedback with ES is more effective than ES alone in the treatment of patients with fecal incontinence (Norton& Cody, 2012).

The results of the current study contradict with Naimy et al., (2007**)**, who studied 40 females' patients with FI and found that both biofeedback and ES cannot improve continence scores, QOL, or FI QOL scores. Furthermore, Mahony et al., (2004) compared the combination of biofeedback and ES versus biofeedback. They reported that significant improvement of Wexner and FIQL scores within groups, but no significant differences were showed between the groups.

The results of group (2) in which patients received pelvic floor muscle training, showed an improvement of all measurements but did not reach the statistical significant level which may be

due to duration of the study was restricted to 4 weeks only. It is recommended that initial training be followed by maintenance PFMT to ensure duration of effect in the longer term (Bø 2004; Mørkved 2014).

Limitation of the study

The long-term effect of AES was not measured. In addition the role of the abdominal muscle contraction and its influence on PFM was not measured. The current study used two questionnaires. It would be interesting to re-evaluate the FI with more objective measures like manometric function and anal pressure after a period of time to ensure if patient regresses without AES.

CONCLUSION

The current study indicates that 4 weeks anal electrical stimulation significantly improves continence scores and quality of life in patients with fecal incontinence. Anal electrical stimulation is considered as a non-invasive, cheap and simple to use and could be offered to treat fecal incontinence

CONFLICT OF INTEREST

The authors declared that present study was performed in absence of any conflict of interest.

ACKNOWLEGEMENT

Authors would like all subjects who participated in this study.

Ethical approval

All the study procedures which carried out including human participants were based on the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

AUTHOR CONTRIBUTIONS

Tantawy SA designed this study, fulfilled data curation, and analysis, wrote the original draft, revised and approved the final manuscript.

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