

EFFECT OF MANOMETRIC VERSUS ELECTRICAL STIMULATION BASED BIOFEEDBACK FOR THE TREATMENT OF FAECAL INCONTINENCE AMONG ADULT PATIENTS

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Abstract:

Fecal incontinence (FI) is a common health problem, affecting 1-10% of the adult population experiencing significant impact on daily activities; Fecal incontinence was considered as a distressing condition, resulting in physical, psychological, social and economic implications therefor we must study biofeedback techniques with pelvic floor strengthening exercises as the first line of treatment for patients with fecal incontinence. The aim of this study was to compare the effects of manometric and electrical stimulation biofeedback on improving bowel function control for the treatment of FI in adult. This study was conducted at the gastroenterology motility unit of gastroenterology center, Mansoura University using a quasi-experimental design. The study included 60 adult patients divided into 30 subjects in manometric group and 30 subjects in ES group. Two tools used for data collection in this study, patient's assessment interview sheet used to collect data about patients socio-demographic characteristic, past history, patients complains and general examination. Biofeedback assessment questionnaire sheet, this instrument consisted of BF questionnaire and anorectal manometry assessment at referral, after BF& after 6 months. The present study results concluded that there was no significant difference between two methods of biofeedback on Storage capacity (soiling, urgency, use of pad, and Life style alterations), anal sphincter pressure (resting pressure and squeeze pressure), rectal sensation (initial sensation, urge to defecate, max volume), wexner score and severity & frequency of fecal incontinence at post biofeedback and follow up except at Squeeze pressure the manometric based biofeedback group are more improved immediately post training and at follow up. The study recommends that further studies with a large number of patients are needed to confirm these findings and these studies should include other outcome measures, such as the cost benefits of home training program.

Key words: Anorectal manometry, Biofeedback, Electrical stimulation, Fecal incontinence.

Introduction:

Fecal incontinence is a debilitating condition affecting up to 1.7 percent of the general population. FI is a health problem that involved the unwanted loss of liquid or solid feces. It is serious and

demoralizing problem. Although FI occur in peoples of different years old, but was frequently in older persons and women, Individuals who have incontinent are emotionally load of embarrassment and

shame as well as the physical distress and disturbance of their life that happen with incontinence episodes. ⁽¹⁾ The Nurses can be very proactive for patients with FI, Many different treatment modalities have been used for treatment of fecal incontinence in the name of 'biofeedback'. ⁽²⁾ The term bio-feedback training refers to the use of various devices (mechanical, electrical) that are supposedly able to increase the awareness of a biological response, so that patients can learn through a process of "trial and error" to improve their voluntary control of this response. ⁽³⁾ BF has been extensively used in clinical practice to treat fecal incontinence and has been advocated to be 'the treatment of choice' for FI because it is painless, inexpensive, non-invasive, and has few to no side effects. ⁽⁴⁾

Significance of the Study

Because fecal incontinence is a particularly embarrassing and distressing condition with significant medical, social and economic implications therefor we must study biofeedback techniques with pelvic floor strengthening exercises as the first line of treatment for patients with fecal incontinence since it is minimally invasive, painless, and safe. However, this study was undertaken to compare the physiologic benefits of manometric based biofeedback and electrical stimulation based biofeedback therapy as reflected by noninvasive electromyography parameters.

Aim of the study

The aim of the present study is to compare the effects of manometric based biofeedback and electrical stimulation based biofeedback on improving bowel function control for the treatment of faecal incontinence in adults.

Research Hypothesis

Adults' faecal incontinence Patients who receive manometric based biofeedback will have improved in bowel function control than those receive electrical stimulation based biofeedback as

evidenced by: anal sphincter pressure, rectal storage capacity, established regular bowel habits and rectal sensation,.

methodology

Research design

Quasi-experimental design was conducted.

Research Setting

This study conducted at the gastroenterology motility unit, of gastroenterology center Mansoura University.

Sample

A purposive sample of 60 adult patients who met sampling criteria aged from 20 up to 60 years suffering from fecal incontinence and accepted to participate in the study, Pediatric patients, Patients not accepted to participate in the study, mentally retarded patients were excluded from the study. All subjects were randomized into two groups (N = 30) subjects in manometric based biofeedback group and (N = 30) subjects in electrical stimulation based biofeedback group.

Data Collection Tools

Two tools will be utilized for data collection in this study based on reviewing the related literature ⁽⁵⁾⁽⁶⁾

Tool I "Patients' Interview Assessment Sheet"

Part 1:- Socio-demographic characteristic data of patients such as age, sex, marital status, occupation, and educational level...etc.

-Past history, medical history, surgical history, obstetric history, congenital malformation, and dietary habits.

- Patient complains such as change bowel habits, abdominal pain, rectal bleeding, and or passage of mucus.

Part 2: General examination includes (abdominal examination, laboratory data, inspection of perineum, endorectal ultrasound, pelvic MRI, barium enema, and anorectal manometry)

Tool II:-biofeedback sheet:-

Biofeedback assessment Questionnaire sheet was adopted from (Elhemaly, 2011)

⁽⁵⁾ and modified by researcher, this instrument consisted of two parts:

The 1st Part includes; Biofeedback assessment questionnaire and the 2nd composed of Anorectal manometry assessment at referral, after BF& after 6 months. Four categories of Anorectal manometry parameters were assessed in this study at referral, after BF& after 6 months (Resting pressure, Squeeze pressure, recto anal inhibitory reflex RAIR and rectal sensations) and Symptoms changes at referral, after BF (After one month &6 months) entailed knowledge about patient complains.

Methods

- Official permissions were obtained from the managers of Mansoura gastroenterology center; and also from the managers of gastroenterology motility unit to facilitate data collection of the study, Official written permission will obtained from ethical committee in faculty of nursing Mansoura University, The agreement of participants in the research was taken after explanation of the study aim to them
- Validity of the tool, it was submitted to a jury composed of six experts from faculty of nursing and faculty of medicine, Mansoura University. They were asked to judge completeness, accuracy, and relevance of the tool and the modifications were done.
- Reliability of tools, alpha cronbach's test was done to measure reliability of proposed tool.
- Pilot study it was applied on 6 patients 10% of total sample; to examine the clarity and applicability of the tool, and to calculate the time needed for data collection.

Data collection phase

Once the necessary approvals were granted to proceed with the proposed study, the subjects who met sampling criteria and agreed to participate in the study, were interviewed by the researcher

to collect the necessary data after explanation of the purpose of the study. According to the previous mentioned study criteria. The patients attending the settings of the study (gastroenterology motility unit) during a period of data collection were divided randomly and alternatively to two equal groups; the one group (30 patients) who received the Manometric based biofeedback and another group (30patients) who received electrical stimulation based biofeedback. Data collections take approximately 12 months from 3/5/2014 to 5/5/2015.

The data was collected through three phases:

1. Phase of assessment

- The approval consent for participation was verbally obtained from each patient
- Before patients' inclusion into the study, clarification of the study purpose and nature was done at the patient interview.
- The participation in study was absolutely confidential and voluntary.
- Privacy, safety, confidentiality and Anonymity were absolutely assured during the whole study, also the patient has right to withdraw at any time from the study.
- The researcher perform initial assessment (Tool I: - Patients assessment interview sheet) include Socio demographic data from the patients.
- Medical history should be taken to exclude contributing or exacerbating factors, such as neurologic or gastrointestinal disorders.
- Complete history about previous anorectal surgery perineal trauma, or obstetric surgery; the perianal area should be inspected for surgical scars, excoriation, or fistulas and spreading the buttocks to inspect and examine the anus gape. Valsalva maneuver to detected Full thickness or mucosal prolapse.

- Diet history assessment taken into consideration as a predisposing factor and part of treatment.
- The researcher used Wexner score for assessment type and scoring of incontinence before and after biofeedback.
- Manometric examination provides accurate measures of squeeze and resting pressures and is helpful to evaluation before and after biofeedback.

2. Implementation phase

Pressure based biofeedback group:

The study protocol for patients received Pressure based biofeedback training included of pelvic floor exercises with verbal and visual feedback. At the initial session of training, the clients received a session of PFE training and then learned how to do this exercises at house the session lasted for about 20 minutes. The clients had advised to isolate the puborectalis muscles of anal sphincter and improve its strengthening. Clients received 6 :8 training session once or twice per week and after finishing of whole session manometric examination performed to assess anal sphincter pressure (resting and squeeze), rectal Storage capacity, rectal sensation, and regular bowel habits. Patients received instructions on PFE. Clients were advised to continue PFE at home per day, for period of 6 months. However, clients had asked to attend to the motility lab after 6 months for follow up.

Electrical stimulation based biofeedback group

Anal electrical stimulation included stimulates of anal sphincter muscles to contract by utilization of a mild electrical current, which may strengthening the muscles by the time. using a small intra anal probe to apply The electrical current for a few minutes every session, the patient take six to eight session once or twice per week and after finishing of

whole session manometric examination performed to assess anal sphincter pressure (resting and squeeze), rectal Storage capacity, rectal sensation, and established regular bowel habits. Patients received instructions on PFE. Clients were advised to continue PFE at home per day, for period of 6 months. However, clients had asked to attend to the motility lab after 6 months for follow up.

3. Evaluation phase:

- Each client in the two group had assessed using the study Tool II (Biofeedback sheet) and wexner score before and at end of training sessions and 6 months later to assess the improvement in anal sphincter pressure (resting and squeeze), rectal Storage capacity, rectal sensation, and established regular bowel habits, and compare between the result of the two groups to reach the aim of the study.

Ethical consideration

- Official written permission will obtained from ethical committee in faculty of nursing Mansoura University, The agreement of participants in the research was taken after explanation of the study aim to them, and they told that at any stage of the research can withdraw without giving any explanation. Explanatory form provided to every participant includes confidentiality of information, some instructions and the purpose of the study. All ethical issues were taken into consideration during all phases of the study.

Statistical analysis

- After complete collection of data each sheet had scored manually the data sheet was coded and listed in to numbers for calculation. Data were entered and analyzed by using SPSS (special package for social science) (version 20) software computer packed. Descriptive statistics used in the form of percentages and frequencies for qualitative variables, and standard deviations, means for quantitative variables. (RM ANOVA)

and Paired t-test had utilized to compare between more than two groups. To test correlation between variables we used Chi-square test and Fishers' exact test.

Result

Table 1: shows the socio-demographic characteristics of the study sample (n=60). More than a half of the sample age (55.0%) ranged from 30 to 40 years, while approximately quarter of the study sample (23.3%) more than 40 years, and less than quarter (21.7%) ranged from 20 to 30 years. Male were more prevalent in the studied sample than female they constituted (83.3%). Concerning level of education, the majority of studied sample were reading and writing and Secondary school learning approximately 66.6%, 33.3 for each one.

Table(1):Socio-demographic characteristic of adults Fecal Incontinence patients (n=60)

Socio-demographic characteristic	Adults Fecal Incontinence patients (n=60)	
	No.	%
Age categories:		
<20	13	21.7
20-40	33	55.0
>40	14	23.3
Gender:		
Male	50	83.3
Female	10	16.7
Education:		
Illiterate	16	26.7
Read and write	20	33.3
Secondary school	20	33.3
University	4	6.7

Table (2): shows predisposing risk factors among the study sample it was found that the majority of the sample (96.7%) did not have any medical diseases, and more than a half (66.7%) did not have previous surgery, 83.3% of the study sample did not have anorectal malformation, while regarding diet history 61.7 of the study sample have takeaway diets.

Table (2): Predisposing risk factors of adults Fecal Incontinence patients (n=60)

Predisposing risk factors	Adults Fecal Incontinence patients (n=60)	
	No.	%
Medical disease:		
Yes	2	3.3
No	58	96.7
Previous surgery:		
Yes	20	33.3
No	40	66.7
Anorectal malformation:		
Yes	10	16.7
No	50	83.3
Diet history:		
Fiber and water content	19	31.7
Takeaways	37	61.7
Caffeine containing drinks	4	6.7

Table (3) revealed that there was no significant difference on *Storage capacity (soiling, urgency, use of pad, and Life style alterations) and bowel habits* between two methods of biofeedback immediately post biofeedback and at follow up.

Table (3): Comparing effect of electrical stimulation and manometric based biofeedback on Storage capacity and bowel habits among adults Fecal Incontinence patients (n=60):

	Adults Fecal Incontinence patients (n=60)				χ^2 test	P value
	electrical stimulation based biofeedback (n=30)		manometric based biofeedback (n=30)			
	No.	%	No.	%		
Soiling						
Post	10	33.3	7	23.3	0.74	0.39
Follow up	10	33.3	7	23.3	0.74	0.39
Urgency:						
Post	10	33.3	8	26.7	0.32	0.57
Follow up	10	33.3	8	26.7	0.32	0.57
Use of pad:						
Post	9	30.0	6	20.0	0.8	0.37
Follow up	14	46.7	10	33.3	1.1	0.29
Life style alterations:						
Post	10	33.3	6	20.0	1.4	0.24
Follow up	15	50.0	10	33.3	1.7	0.19
Regular bowel habits:						
Post	10	33.3	7	23.3	0.7	0.39
Follow up	12	40.0	17	56.7	1.7	0.19

* Significant, at $p \leq 0.05$

show Comparison between effect of electrical stimulation and manometric based biofeedback on anal sphincter pressure (resting pressure and squeeze pressure), rectal sensation (initial sensation, urge to defecate, max volume), among adults Fecal Incontinence patients

post and follow up; there was no significant difference between electrical stimulation and pressure based biofeedback except at Squeeze pressure the manometric based biofeedback group are more improved immediately post training and at follow up.

Table (4): Comparing effect of electrical stimulation and manometric based biofeedback on anal sphincter pressure and rectal sensation among adults' fecal incontinence patients (n=60):

	Adults Fecal Incontinence patients(n=60)				Independent t-test	P value
	electrical stimulation biofeedback (n=30)		manometric biofeedback (n=30)			
	Mean	± SD	Mean	± SD		
Wexner score:						
Post	4.9	3.7	4.1	2.9	1.0	0.32
Follow up	4.9	3.7	4.1	2.9	1.0	0.32
Resting pressure:						
Post	50.7	13.9	55.7	9.8	-1.6	0.11
Follow up	48.8	12.8	53.3	10.4	-1.5	0.14
Squeeze pressure:						
Post	129.3	34.0	147.0	31.9	-2.1	0.04*
Follow up	116.3	32.9	140.0	24.8	-3.1	0.003*
Initial sensation:						
Post	42.0	12.7	37.3	7.8	1.7	0.09
Follow up	43.0	12.6	40.7	6.4	0.9	0.37
Urge to defecate:						
Post	98.3	31.6	104.3	31.9	-0.7	0.47
Follow up	99.0	33.2	104.3	33.1	-0.6	0.54
Max. volume:						
Post	187.7	48.2	197.8	43.2	-0.8	0.39
Follow up	184.7	46.1	202.0	45.1	-1.5	0.15

Discussion:

The socio-demographic background of the studied sample of present study showed that, More than a half of the sample age ranged from 30 to 40 years. In my study males were more prevalent in the studied sample they constituted the majority of sample, this contradict another study done reported that his subjects were enrolled in the treatment program the female are 90% and male 10%. And the mean age 55 years ranged from 15 to 87 years. Concerning level of education in present study, about two third of studied sample were reading and writing and Secondary school learning approximately one third for each one. ⁽⁷⁾

The symptom details or its severity were incompletely explained in several studies, this lead to difficulty to make comparison analysis. ⁽⁸⁾ In present study, found the number of incontinence episodes decreased in my patients, immediately post training and after 6 months, I found that the patients reported satisfaction about their bowel function. Pre training the mean Wexner score was high, and it's decreased immediately after training and also after 6 months in electrical stimulation group, and also in manometric based biofeedback group. This result confirmed previous observations of **Norton, et al. (2003)**; he report that more than half of his clients feel bowel function satisfaction and no

incontinence episodes. The mean bowel satisfaction score on a VAS was increased both immediately after training and after 1 year. ⁽⁸⁾ Additionally, Norton report that this finding was slightly better and comparable than this observed previously by **Norton, 2010** it may be as result to the utilize of biofeedback treatment program as well as a sessions of reinforcement that was participate to enhance the pathophysiologic parameters involve the rectal sensation, anal sphincter strength, or/and coordination of sensory motor. ⁽⁹⁾

Regarding the effectiveness of biofeedback on bowel function control, the present study showed that, electrical stimulation effect on anal sphincter pressure (resting pressure and squeeze pressure) and rectal sensation (initial sensation, Urge to defecate and Max. volume) revealed highly statistical significant (P= 0.001) between pre and post, and the same between pre and follow up for squeeze pressure and rectal sensations. And also the effect of pressure based biofeedback on anal sphincter pressure included (resting and squeeze pressure), and rectal sensation included (Initial sensation, Urge to defecate and Max. Volume) revealed highly statistical significant (P= 0.001) between pre and post, and the same between pre and follow up for squeeze pressure and rectal sensations, also statistical significant (P= 0.002) between Post and follow up for resting pressure and Initial sensation. This result is in agreement with a study by **Rao, (2006)** ⁽¹¹⁾ who found that, the anal sphincter pressures (resting and squeeze) were improved. Also, he report that the client's ability to maintain the squeeze of the sphincter was improved after BF. **Frenckner & Von Euler, (2015)** ⁽¹²⁾ suggested that not only the power of squeeze but the duration of squeeze also may increase by program of biofeedback and can be maintained. Because the external sphincter of the anal can affect up

to thirty percent of the resting tone, this mean; if external anal sphincter function improved, resting sphincter pressure will improved secondary. **(Bruce, et al., 2007)**. said the resting pressure and squeeze pressure of anal sphincter increased after biofeedback therapy immediately and at 1 year. The squeeze duration also increased (pre vs. post training) and (pre vs. 1 year), and related to Rectal sensation about one third of studied sample have weak rectal sensation and improved after biofeedback therapy, the first sensation and a desire to defecate volumes decreased. ⁽¹³⁾

Regarding the effect of electrical stimulation based biofeedback on bowel function control improving as evidence by storage capacity. Shows that there is a high statistically significant relation at P (0.001) between pre and post, pre and follow up regarding (soiling, Urgency, Use of pad, Severity of incontinence, and Frequency of incontinence). This result confirmed with **(Ryn, et al. 2010)** they said the symptoms of chronic fecal incontinence improver after electric stimulation biofeedback training. ⁽¹⁴⁾

Regarding the effect of electrical stimulation on bowel function control improving, as evidence by storage capacity; Shows that there is a high statistically significant relation at P (0.001) between pre and post, pre and follow up regarding (soiling, Urgency, Use of pad, Severity of incontinence, and Frequency of incontinence). This result confirmed with **chairioni, et al. (2009)** ⁽¹⁶⁾, they said the symptoms of chronic fecal incontinence had improved after electric stimulation biofeedback training.

Regarding the effect of manometric based biofeedback on patients symptoms included (soiling, urgency, use of pad and Life style alteration), revealed highly statistical significant between pre and post, and the same between pre and follow up, but there is no statistical significant between Post and follow up for soiling,

urgency, use of pad and Life style alteration respectively, and also between pre and post, pre and follow up regarding (severity of incontinence, frequency of incontinence, and regularity bowel habits). This result has high significant if compared with other studies, for example the study carried at (2003) by Norton, et al., reported that the incontinence mean of severity are high, before treatment some clients had incontinence episodes per day, the mean episodes of incontinence weekly were high; and after end of initial training the bowel satisfaction score was improved immediately and after one year later and more than a half of clients have no incontinence episodes, and were have a high bowel satisfaction score.⁽¹⁷⁾

Our study revealed that there was no significant difference between two methods of biofeedback according to subjective data and objective measures of fecal incontinence at post biofeedback or follow up, this result presented in our study confirmed with (Neil et al., 2017) suggested that using biofeedback isolated or associated with electrical stimulation in treatment fecal incontinence is effectively for the patients with fecal incontinence treatment. BFT when applied for patients with FI, there was no difference between electrical stimulation and or manometric biofeedback exercises.⁽¹⁵⁾

Finally, BFT is a successful technique for FI people treatment. The most frequently used method in biofeedback training includes anorectal manometry, and electrical stimulation. Other studies have reported positive responses ranging from 70% to 80%.^{(18) & (19)}

Conclusion

Based on the findings of the current study, it can be concluded that, Adults faecal incontinence Patients who received manometric based biofeedback have the same improvement in anal sphincter pressure, rectal sensation, storage capacity, and established bowel

habits similar those received electrical stimulation based biofeedback and there was no significant difference between two methods of biofeedback.

Recommendations:

According to results of this study, the following suggestions are recommended:

-Hand book about biofeedback were essential for all nursing who working at GIT centers, health care practitioners, and clients and their family who need knowledge about the treatment of FI.

- Further studies with a large number of patients are needed to confirm these findings and these studies should include other outcome measures, such as the cost benefits of home training program.

-further research focus on ES + BF to be a combination therapy which would be important for treatment guidelines. and studies with a large number of patients are needed to confirm these findings and these studies should include other outcome measures, such as the cost benefits of home training program.

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