

## Clinical Efficacy of Supervised Pelvic Floor Muscle Training - assisted Biofeedback on Quality of Life and Functional Outcomes in patients with Fecal Incontinence

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### Abstract

**Background:** Fecal incontinence (FI) is a prevalent, and embarrassing condition that drastically affects the quality of life (QOL). Pelvic floor muscle training (PFMT) is the first-line therapy in FI either alone or combined with biofeedback (BF). Little trials investigated the effectiveness of PFMT together with BF in improving FI and QOL. **Aim:** To investigate the efficacy of supervised PFMT -assisted BF in improving FI, quality of life, and strength of the rectal muscle in adults with FI. **Methods:** A quasi-experimental design was conducted on 60 patients with FI attending the gastrointestinal motility unit affiliated to gastroenterology center Mansoura University Hospitals and referred for biofeedback and Pelvic Floor exercise. The Fecal Incontinence Quality of Life Questionnaire and the Cleveland Clinic Florida Fecal Incontinence scale were filled out at the first visit and then at follow-up after six months. The patients were directed to perform daily pelvic floor exercise at home. Data were analyzed using SPSS (version 20). **Results:** There was a significant improvement in fecal incontinence severity and quality of life domains post 8-sessions of PFMT -assisted BF  $P < 0.001$ . A strong negative correlation was found between fecal incontinence severity and improvement in fecal incontinence quality of life. Strong positive correlation existed between improvements in quality-of-life domains. **Conclusion:** PFMT-assisted BF has proven to be an effective method for improving FI, QOL, and increasing the strength of the anal sphincter. **Relevance to clinical practice:** PFMT-assisted BF can be recommended as a safe, painless approach and a key element in the comprehensive management of patients with FI. It should be considered as a feasible option by healthcare providers.

**Key Words:** Biofeedback, Fecal incontinence, Quality of life, Pelvic muscle training

## Introduction:

Fecal incontinence (FI) is the involuntary loss of fluid, gases and/or solid stool <sup>[1]</sup>. It is a particularly embarrassing and distressing condition, that drastically affects the patient's quality of life (QOL) and markedly diminishes the activity of daily living, with significant medical, social, and economic implications <sup>[2]</sup>. It is reported that FI affects 2% to 22.3% of the population but the actual prevalence has not been fully assessed due to the social stigma attached to the condition <sup>[3]</sup>.

There are many causes of fecal incontinence, the most common of which is a weakness of the anal sphincter. This can occur secondarily to trauma, degeneration, connective tissue disease, and neuropathy. Other precipitating causes are, inability to perceive rectal filling "Known as *rectal hyposensitivity*", and rectal hypersensitivity sometimes called "the *inability to delay a bowel movement*" <sup>[4,5]</sup>. The severity of FI is described as a combination of stool type, frequency, use of dipper, and severity of urgency. This condition affects both women and men, regardless of their occupational, social, or financial status <sup>[6]</sup>. Fecal incontinence is divided into three subtypes: 1. Passive fecal incontinence; when stool leaks without any prior sense of pressure, 2.

Urge fecal incontinence; when the patient is alert to push but can't wait to go to the bathroom, and 3. Exercise fecal incontinence; which occurs when increased intra-abdominal pressure due to coughing, laughing, sneezing and heavy lifting <sup>[7,8]</sup>.

There are different treatment modalities for (FI) depending on the cause and severity. The recommended first-line therapy for mild and moderate conditions consists of a multi-modal track such as knowledge, anti-motility and antidiarrheal drugs, laxatives, dietary fiber supplements, PFMT, and /or BF <sup>[9,10]</sup>. On the other hand, the surgical option is chosen for patients who do not respond to conservative treatment and who have defects in the anal sphincter muscle <sup>[11]</sup>. The PFMT is regular training of the anal sphincter and pelvic floor muscles with the goal of enhancing muscle strength, coordination and/or endurance. However, BF provides positive reinforcement for patients who perform PFMT. Biofeedback guides the patient to perform PFMT correctly and motivates him to practice this correct response repeatedly through visual, auditory, and tactile means. So as to improve the capacity of anal sphincter muscle, thus improving FI and their quality of life <sup>[12]</sup>. In most recent studies, PFMT is

the first step in treating FI either alone or in combination with BF. However, standard treatment is still not available, and the purported benefits have not yet been determined [11,12]. Interestingly the details of when and how PFMT should be combined with BF have not been examined, and few recent studies has evaluated the efficacy of biofeedback associated with pelvic floor rehabilitation training [13]. Thus,

#### **The Study Aims to**

Evaluate the efficacy of supervised pelvic floor muscle exercise combined with biofeedback on reducing fecal incontinence severity, improving quality of life and strength of rectal muscle as measure by anorectal manometry in adults with fecal incontinence.

#### **Study Hypotheses:**

We considered the following hypotheses.

**H1:** Patients with fecal incontinence who completed eight- sessions of PFMT along with BF will have a significant improvement in FI severity post-training compared with FI pre-training.

**H2:** Fecal incontinence participants who completed eight- sessions of PFMT associated with BF will have a marked improvement in manometric parameters' mean scores post-training compared with pre-training mean scores.

**H3:** There are statistically significant changes in fecal incontinence quality of life' mean score after eight- session of PFMT combined with BF among FI patients who completed the study when compared to the mean score before training.

**H4:** Fecal incontinence is inversely proportional to patients' quality of life.

#### **Study variables:**

##### ***Independent variables/ Interventions:***

Include pelvic floor muscle training (PFMT) combined with Biofeedback (BF).

##### ***Dependent variables /Main Outcome***

***Measures:*** Fecal incontinence severity, fecal incontinence quality of life and anorectal manometry were used to measure anal sphincter strength.

#### **Operational definitions:**

***Functional outcomes:*** According to the study tools, functional outcomes described to include 1. Fecal incontinence severity index measured by Wexner scale and 2. Strength of rectal muscle that measured by biofeedback manometric parameters.

#### **Significance of the study:**

Fecal incontinence is an embarrassing and disturbing condition for patients. It has a negative impact on their quality of life and increases financial burdens on the individual and the government. Several studies investigated the effectiveness of

biofeedback alone on fecal incontinence, and other studies uses PFMT to improve QOL and bowel function. So far, few well controlled studies in Egypt evaluated the effect of biofeedback in combination with supervised PFMT on FI severity and QOL. The evidence from these studies was inconclusive and the researchers point to, the need for additional studies in this field [14]. Therefore, there is an urgent need to relieve these symptoms by using biofeedback along with pelvic floor muscle exercise as a safe and painless maneuver. Therefore, the decision was made to carry out this study.

#### **Subjects and Method:**

##### **Research design:**

A quasi-experimental pre/post design was utilized.

##### **Setting:**

This study was conducted at gastrointestinal motility investigation unit in gastroenterology center at Mansoura University Hospitals, Egypt.

##### **Study sample:**

A purposive sample of sixty patients with FI, attending the previously mentioned setting, diagnosed by gastroenterology team, and referred for BF and Pelvic Floor rehabilitation training.

##### **Sample Size Calculation**

The sample size for studying the efficiency of biofeedback in the management of FI was calculated using DSS research.com software. At alpha error 1% (significance 99%) and  $\beta$  error 2% (study power 98%) and mean resting anal pressure =  $33.3 \pm 14.19$  before intervention (Santos et al., 2018) [15]. with 25% expected improvement (increase) in this pressure after intervention. The sample size is 56 by adding (10%) to compensate for drop out. Thus, the calculated sample size is 60 patients.

##### **Inclusion criteria**

Sixty adult patients aged from 20 to 60 years, both sexes, with a history of FI defined as involuntary leakage of gas, solid and/or liquid stool more than 3 episodes / week for more than 24 weeks that impairs quality of life. Underwent biofeedback treatment, psychologically stable, ready to adhere to a strict follow-up schedule, unsuccessful conservative treatment and can read and write.

##### **Exclusion criteria**

Patient using other treatment methods, with acute or inflammatory bowel disorders, those with neurological conditions or patients who missed a treatment session. A history of laxative abuse, fecal impaction, implanted pacemaker, or bleeding disorders and pregnant women were excluded.

### **Study tools:**

The following four tools were used to collect data pertinent to the study after extensive literature review.

#### **1. Structured interview questionnaire**

##### **1.1 Demographic and physical examination data form**

Was constructed by the researcher to assess demographics as age, sex, marital status, occupation, and educational level, complete medical history, and causes of FI. Abdominal examination, inspection of perineum, endorectal ultrasound, pelvic MRI, and barium enema.

##### **1.2 Patient-reported outcomes (Daily Bowel Diaries)**

Used to calculate the frequency of fecal incontinence per week.

#### **2. Anorectal Manometric Parameters**

This tool was developed Elhemaly and modified by the researcher [16]. Two categories of anorectal manometric parameters were measured at referral and after 6 months of PFMT-assisted BF, it composed of 1. Anal sphincter pressure that assesses resting pressure & Squeeze pressure, and 2. Rectal sensations that determine initial sensation, urge to defecate and maximum tolerable volume.

**Scoring system:** Normal range of resting pressure in adults (40:80 mmHg), squeeze

pressure (90:200 mmHg), and rectal sensation classified into three categories, 1. Initial sensation (20:50 cc), 2. Urge to defecate (75:150 cc), 3. Maximum tolerable volume (150:350 cc).

#### **3. Cleveland Clinic Florida Fecal Incontinence (CCF-FI) Scale**

This scale was first proposed and described by Wexner et al., and widely used to assess fecal incontinence severity score [17]. The Wexner scale measures accidental leakage of solid stool, liquids and gases, the need to wear a diaper and impact on quality of life. It is a self-administered tool of 5 elements that are distributed as (Never / Rarely / Sometimes / Usually / Always), scored from 0-4". The scale can also be classified into four categorical levels (no incontinence / never =0), (Slight incontinence / Rarely (1 episode in past month), (Moderate incontinence / Sometimes (2-4 episodes) / Weekly (>1 week - <1-day episodes), (Sever incontinence / Daily (1 or more daily episodes). The total CCF-FI score ranged from zero (perfect fecal continence) to 20 (severe fecal incontinence). The higher the score, the more severity anal incontinence [18]. *The construct and discriminative validity* of the Wexner scale was confirmed [19]. *The reliability* of the scale was performed by test-retest method  $r=85$  [20].

#### **4. Fecal Incontinence Quality of Life (FIQOL) Questionnaire**

Fecal Incontinence Quality of Life (FIQL) questionnaire is a disease-specific instrument, constructed and described by Rockwood et al., to investigate the effect of FI on four domains of patients' QOL; lifestyle; coping behavior; depression; and embarrassment. The scale consisting of 29 questions in four domains on a scale of 1-4 score<sup>[21]</sup>. FIQOL questionnaire widely used, *validated* in women & men approved by the American Society of Colorectal Surgeons. *The reliability* of the scale was confirmed and the internal reliability (Cronbach's alpha = 0.8 to 0.96)<sup>[22]</sup>.

##### **Pilot study:**

The pilot study was conducted on 10% of the total sample (6 patients). It has been applied to check the applicability and clarity of the study tools as well as to estimate the time required to fill out the questionnaire. Modifications were made accordingly.

**Ethical considerations and patients' rights** Ethical approval was granted by scientific research ethics committee, Faculty of Nursing Mansoura University. The purpose and nature of the study were clarified to patients who expressed their willingness to participate in the study, and informed consent was obtained from them.

The researcher emphasized that participation is not mandatory. Privacy, security, confidentiality, and anonymity were maintained throughout the whole study. Participating patients have the right to withdraw at any stage of the study without accountability, blame or influence on the care provided to them. The study was conducted in accordance with the Helsinki Declaration and the University's research ethics standards.

##### **Procedure**

Once the necessary approvals were granted to proceed with the proposed study, the patients who met sampling criteria and agreed to participate in the pelvic floor training program at the above-mentioned setting were interviewed individually by an independent researcher to fill in the study questionnaire. The patients were interviewed in a quiet room before stating the program and were briefly informed about the aim and nature of the study. The researcher assistance filled out FIQOL questionnaire and FISFI before the training program and after eight sessions of PFMT-assisted BF (the end of 6<sup>th</sup> months of training).

##### **Data collection**

At the initial interview, the condition of each patient was examined by colorectal physician, to inspect perineum, and

endorectal ultrasound, pelvic MRI, and barium enema was performed before referral for biofeedback using tool (1). The patient who meets inclusion criteria were assigned to receive PFMT-assisted BF. To measure strength of sphincter muscle, the colorectal nurse measured anorectal manometric parameters using tool (2) by using catheter attached with small balloon and the balloon can be inflated in the rectum, the colorectal nurse directs the patient to relax, squeeze and push. The pressure of anal sphincter was measured during each of these maneuvers. The rectal sensations were also measured by gradual inflation of the balloon and explore the maximum tolerable volume, urgency, and initial sensation. Manometric examination provides accurate measurement to squeeze, resting pressures and rectal sensation. Then independent researcher used Wexner scale to assess fecal incontinence severity score by tool (3). To investigate the impact of FI on patients' QOL, the researcher assistant used tool (4). These outcome measures were assessed initially before training, at each follow-up session and at the end of six months of the training program.

***Development of Supervised PFMT-assisted BF***

The training program in the present study was designed for FI adults guided by

previous programs to improve anal sphincter pressure, rectal storage capacity, continence ability and regular bowel habits and practice pelvic floor exercise at home correctly [7,8]. The training program was established and revised in collaboration with the gastrointestinal motility doctors, according to the requirements and capabilities of each patient. The content validity of training program was assured by three professors in gastroenterology unit and two experts in medical surgical nursing.

***Description of Supervised PFMT -assisted BF***

The study was conducted over a period of 6 months from the beginning of November 2020 to the end of April 2021. Informed consent was obtained from participating patients after explaining aim and nature of the study. The study's' questionnaire was assessed pre, at every follow up visit and post 6 months of the program by the colorectal nurse and an independent researcher who don't know the nature of the study to avoid bias. The study's' participants were received eight face -to- face sessions (weeks 0, 2, 4, 6, 10, 16,20 and 26; 60 minutes for the first training session and 45 minutes for subsequent sessions. The previously prepared sessions were delivered by a trained colorectal nurse who has more

than 5 years of experience in gastro-motility unit.

In session one, the researcher used a pelvis model and simulated pictures to explain the anatomy and function of PFM. In this session, a background was explained about the causes and prevalence of fecal incontinence, and a brief description of the biofeedback -assisted PFM technique and preparation for it before each session. The principal researcher directed patients to eat a fiber-rich diet of 25 to 30 grams/day to improve consistency and increase stool volume to gradually reduce the potential for gas and bloating. In the same context, they were also instructed to avoid caffeine, carbonated drinks, milk, and alcohol if they caused diarrhea, and drink enough water, 2.5 to 3 liters per day, to prevent constipation. During the training, patients were instructed to maximally squeeze PFM in response to rectal distensions while at the same time minimizing contraction of abdominal wall. This maneuver is referred to as *coordination training*.

#### ***Implementing of Supervised PFMT - assisted BF***

The patients were taught correct pelvic floor contractions and directed" to "squeeze around the anus in an attempt to block the passage of air or stool from the intestines for strengthening pelvic floor muscles. Patients

received instrument-assisted biofeedback during the pelvic floor training with use of catheter attached with a balloon. Patients viewed a computer screen showing intra-rectal pressure and anal canal pressure as line graphs. The patients were asked to isolate the puborectalis muscles of the anal sphincter and asked to contract it for 5-10 seconds and then relax and repeat it 10 times. A catheter connected to balloon was inserted in the rectum, and gradually inflated till the sensation of rectal filling. Re-inflation of the balloon with a smaller volume, to detect rectal distension at the lower volume. The function of PFM was examined by BF.

In the initial visit, a biofeedback assessment was performed when the patient was in the side-lying position, and from the 2<sup>nd</sup> session, the side-lying, sitting, and standing position was used. As well as the ability to contract PFM during walking, coughing, sneezing, and lifting was determined. Based on the results of the BF measurements, individualized home training was developed considering the capabilities of each patient. It consisted of three sets of 10 pelvic floor muscle contractions lasting 10 seconds and two sets of three contractions lasting 30 seconds. The participants were instructed to have a one-minute rest between each set. The patient with reduced muscular



endurance was directed to decrease the number and duration of contraction and gradually increase it to achieve the prescribed training. Patients experiencing difficulties in achieving a correct contraction of the pelvic floor muscles were directed to palpate the perineum and /or anus to achieve a correct contraction. The patients were also taught how to tighten PFM in cases of urgency and increased abdominal pressure. During the performance of pelvic muscle contractions, the participant was instructed to take pursed-lip breathing, ensure that, patients are able to breathe freely without using the abdominal, thigh or gluteal muscles. They also received written training handout with illustrations along with the instructions provided both orally and digitally. The patients were informed to fill out training diaries that were used as a motivational tool and to determine their commitment to the individual home training. At follow-up visits, training diaries were assessed and, accordingly the participants who have made progress were directed to demonstrate PFMT in sitting, standing, walking, while transferring, lifting, sneezing, and coughing.

#### **Statistical Analysis:**

Data for 59 people were analyzed due to the exclusion of one patient who was transferred to another hospital. The collected data were coded, processed, and analyzed using the SPSS (Statistical Package for Social Sciences) version 20 for Windows® (SPSS Inc, Chicago, IL, USA). Qualitative data was presented as number and percent. Comparison between groups was done by Chi-Square test. Wilcoxon signed ranks test was used for comparison within group. Quantitative data was tested for normality by Kolmogorov-Smirnov test. Normally distributed data was presented as mean  $\pm$  SD. Paired t-test was used for comparison within groups.  $P < 0.05$  was considered to be statistically significant.

#### **Results:**

The patient's characteristics are illustrated in table 1. Fifty -eight patients were analyzed. All patients had persisting fecal incontinence with a conservative treatment. The mean age was  $31.02 \pm 12.50$  years. Females were prevalent in the studied sample than males they constituted 86.4% (n= 51). The bowel movement frequency was  $4.8 \pm 2.1$  per day and 100% of Biofeedback sessions were performed by colorectal nurse. Nearly half 45.8% were married and 59.3% read and write. Concerning the occupation, the majority of sample were working and 50.8% lived in rural areas.

Table 2. clarified the causes of fecal incontinence in studied patients. Of 59 patients 33.9% (n=20) complained of idiopathic fecal incontinence. Meanwhile, 33.8% (n=20) suffer from chronic constipation. In the same context, 10.2% (n=6) of the participants had congenital anorectal malformation and 13.6% (n=8) were exposed to anal surgery indicated as the reason for fecal incontinence. Prolapsed hemorrhoids and fistulas accounted for 3.4% (n= 2%) of the causes in the participating patients. Obstetric trauma represented 1.7% (n=1) of the causes. Table 3. illustrates the clinical outcomes of anorectal manometry regarding anal sphincter pressure and rectal sensation before and after the training program. As regards anal sphincter pressure, the table revealed, maximum squeeze pressure and resting anal pressure mean score significantly improved after 6 months of training program ( $p < 0.001$  &  $p = 0.010$ , respectively). Also, regarding sensitivity to rectal sensation there were statistically significant changes pre and post for initial sensation, maximum tolerable volume and urge to defecate ( $p < 0.001$ ). However, anal pressure on staining clinically improved with no statistical significance differences. When comparing the change in fecal incontinence level in the study participants

at baseline and after 6 months of training. It is noticed from table 4. that, the patients with severe incontinence dropped from (83%) pre intervention to (20.4%) post intervention and slight incontinence markedly increased from (1.7%) at baseline to (50.8%) after 6 months of the study. Overall, after 24 weeks of training, there was a considerable improvement in fecal incontinence level in studied patients where ( $P < 0.001$ ). Table 5. presents Wexner components in patients with FI before and after rehabilitation training. In general, according to the findings of the current study, there was a significant difference in Wexner fecal incontinence severity mean score before and after training where  $P < 0.001$ . In particular, the mean incontinence score for solid feces was markedly reduced from ( $0.95 \pm 1.12$ ) pre-program to ( $0.31 \pm 0.77$ ) post program ( $P < 0.001$ ). Before training program, the mean of diluted feces was ( $3.15 \pm 0.98$ ) and dramatically decreased to ( $1.69 \pm 1.15$ ) after pelvic rehabilitation program with significant improvement ( $P < 0.001$ ).

At baseline, the patient's complaint from gas incontinence ( $3.02 \pm 0.68$ ) and only ( $1.78 \pm 1.08$ ) developed these symptoms after training program with a statistically

significant difference ( $P < 0.001$ ). With regard to wearing a pad before the training program, the mean score was high and decreased significantly after the program ( $3.12 \pm 0.97$  and  $1.24 \pm 1.39$ ) respectively ( $P < 0.001$ ). There was a trend toward improvement in mean score QOL of incontinence patients post intervention ( $1.73 \pm 1.24$ ) when compared to QOL at baseline ( $3.24 \pm 0.68$ ) with a statistically significant change ( $P < 0.001$ ). When investigating FIQOL mean scores pre and post 6 months of pelvic floor training, table 6. and figure 1. illustrated that, exercise training improved the four quality of life domains, (lifestyle, behavior, depression, and embarrassment) where there was a statistically significant differences in FIQOL mean score after the training program  $p < 0.001$ . A significant improvement in the severity of fecal incontinence was also observed post training  $p < 0.001$ . In relation to, the mean score of lifestyles was ( $15.75 \pm 4.81$ ) before and ( $26.49 \pm 7.48$ ) after. This is a trend that confirms the improvement of lifestyle of participating patients. In this study only ( $12.05 \pm 3.18$ ) have coping behavior pre-program, improved post training to reach ( $21.47 \pm 6.55$ ) with a statistically significant difference  $p < 0.001$ . With respect to "depression" domain the mean score was

dramatically changed from ( $14.37 \pm 3.3$ ) pre to ( $21.07 \pm 5.86$ ) post completion of the training where  $p < 0.001$ . As regards the mean score of embarrassment domain, there were marked improvement from baseline ( $4.15 \pm 1.14$ ) to ( $7.92 \pm 2.73$ ) after finishing the training with a statistically significant difference  $p < 0.001$ . Interestingly, table 6. and figure 1. showed a significant enhancement in FIQOL and FISCI after 6 months of intervention  $p < 0.001$ . Overall, according to the findings of the present study we can conclude that, there was a significant difference between the studied patients in terms of the quality of life and fecal incontinence severity index before and after training.

When analyzing correlation between fecal incontinence and quality of life domains, table 7. demonstrated that there was a strong negative correlation between FIQL and FISCI scores. As regards FIQOL subdomains, a strong positive correlation was emphasized between lifestyle & coping, depression, and embarrassment domains. Interestingly, Positive correlation appeared between coping behavior and depression & embarrassment. Finally, depression correlated positively with embarrassment where  $P < 0.001$

**Table (1): Characteristics of studied patients with fecal incontinence N= 59**

	No	%
<b>Age (years)</b>		
20- 35	42	71.2%
>35- 45	4	6.8%
> 45	13	22%
<b>Mean ± SD</b>	31.02 ± 12.50	
<b>Gender</b>		
Female	51	86.4%
Male	8	13.6%
<b>Marital status</b>		
Single	32	54.2%
Married	27	45.8%
<b>Educational level</b>		
Read and write	35	59.3%
Secondary School	17	28.8%
Higher education	7	11.9%
<b>Employment status</b>		
Student	8	13.6%
Working	46	78%
Housewives	5	8.4%
<b>Residence</b>		
Urban	29	49.2%
Rural	30	50.8%
<b>Persistence of fecal incontinence with conservative treatment</b>	59	100%
<b>Bowel movement frequency / week</b>	<b>Mean ± SD 4.8 ± 2.1</b>	
<b>Who perform Biofeedback sessions</b>		
Colorectal nurse	59	100%
<b>Preparation</b>		
Enema	59	100%
Laxatives	24	40.7%

Data are shown as mean and standard deviation if applicable.

**Table (2): Causes of fecal incontinence in study participants N= 59**

Causes of fecal incontinence	No	%
Idiopathic	20	33.9
Chronic Constipation (CC)	20	33.8%
Congenital anorectal malformation	6	10.2%
Obstetric trauma	1	1.7%
Anal surgery	8	13.6%
Prolapsed hemorrhoids	2	3.4%
Fistulas	2	3.4%

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**Table (3): Changes in anorectal manometric mean scores before and after pelvic floor muscle training-assisted biofeedback in fecal incontinence participants N=59**

Anorectal manometric parameters of bowel function control	Before PFRT-assisted BF Mean ± SD	After 6 months of PFRT-assisted BF Mean ± SD	t	P
	<b>Anal sphincter pressure</b>			
Resting anal pressure	52.63 ± 12.3	55.05 ± 10.76	2.655	0.010*
Maximum Squeeze pressure	100.61 ± 46.63	141.02 ± 41.68	5.246	<0.001*
	<b>Rectal sensation</b>			
Anal pressure on straining	32.88 ± 6.45	33.56 ± 9.96	0.782	0.437
initial sensation	57.54 ± 15.63	41.69 ± 11.47	8.224	<0.001*
Urge to defecate	137.29 ± 43.94	98.98 ± 31.44	8.095	<0.001*
Maximum tolerable volume	229.83 ± 59.06	188.64 ± 51.14	5.799	<0.001*

Paired t-test (t)

\* Significant P < 0.05

Abbreviations: PFRT - assisted BF, Pelvic Floor Rehabilitation Training - assisted Biofeedback; FI, fecal Incontinence

**Table (4): Comparing Fecal incontinence level at baseline and after 6 months of pelvic floor muscle training-assisted biofeedback in studied patients N= 59**

Cleveland Clinic Florida Fecal Incontinence severity CCF-FIS	Baseline		After 6 months of PFRT-assisted BF		Test of significance	
	No	%	No	%	Z	P
Slight incontinence	1	1.7%	30	50.8%	5.961	<0.001*
Moderate incontinence	9	15.3%	17	28.8%		
Sever incontinence	49	83%	12	20.4%		

Wilcoxon sign-rank test (Z)

\* Significant P < 0.05

Abbreviations: PFRT - assisted BF, Pelvic Floor Rehabilitation Training - assisted Biofeedback; CCF-FIS, Cleveland Clinic Florida Fecal Incontinence severity

**Table (5): Improvement in fecal incontinence severity index according to Wexner fecal incontinence scale before and after pelvic floor muscle training-assisted biofeedback in studied sample  
N=59**

Wexner FI components	Before PFRT-assisted BF Mean ± SD	After 6 months PFRT-assisted BF Mean ± SD	t	p-value
Solid feces	0.95 ± 1.12	0.31 ± 0.77	5.584	<0.001*
Diluted feces	3.15 ± 0.98	1.69 ± 1.15	11.752	<0.001*
Gas	3.02 ± 0.68	1.78 ± 1.08	10.828	<0.001*
Using pad	3.12 ± 0.97	1.24 ± 1.39	10.681	<0.001*
Impact on Quality of Life (QOL)	3.24 ± 0.68	1.73 ± 1.24	10.073	<0.001*

t: paired t-test

\* Significant P < 0.05

Abbreviations: PFRT - assisted BF, Pelvic Floor Rehabilitation Training - assisted Biofeedback; FI, fecal Incontinence; QOL, Quality of Life, FISI, fecal incontinence severity index

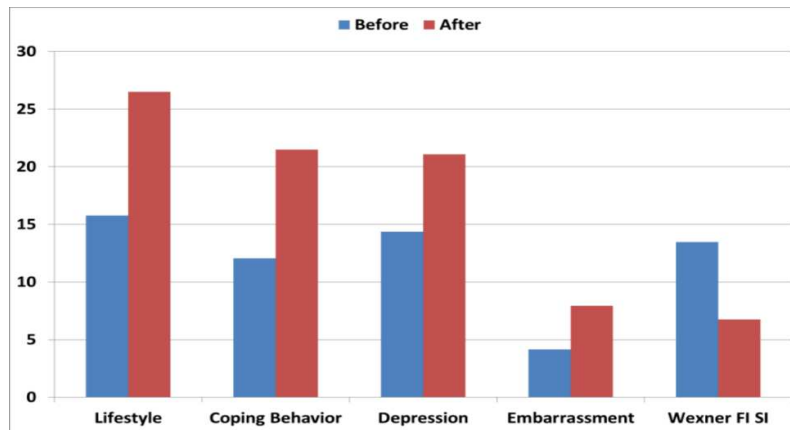
**Clinical efficacy of pelvic floor muscle training-assisted biofeedback on fecal incontinence quality of life.**

**Table (6): Comparing fecal incontinence quality of life and fecal incontinence severity mean score before and after 6 months of pelvic muscle training in studied subjects N=59**

FIQL domain/ Wexner FI SI	Before PFRT-assisted BF Mean ± SD	After 6 months PFRT-assisted BF Mean ± SD	t	p-value
Lifestyle	15.75 ± 4.81	26.49 ± 7.48	12.676	<0.001*
Coping Behavior	12.05 ± 3.18	21.47 ± 6.55	11.96	<0.001*
Depression	14.37 ± 3.3	21.07 ± 5.86	8.769	<0.001*
Embarrassment	4.15 ± 1.14	7.92 ± 2.73	11.526	<0.001*
Wexner FI SI	13.47 ± 3.31	6.75 ± 5.03	12.267	<0.001*

Paired t-test (t) \* Significant P < 0.05

Abbreviations: PFRT - assisted BF, Pelvic Floor Rehabilitation Training - assisted Biofeedback; FI, fecal Incontinence; FISI, Fecal Incontinence Severity Index; FIQOL, Fecal Incontinence Quality of life



**Figure 1: Effect of pelvic floor muscle training-assisted biofeedback on fecal incontinence severity and quality of life domains in studied patients pre and post 6 months**

**Relation Between Improvement in fecal incontinence severity index and fecal incontinence quality of life**

**Table (7): Correlation between fecal incontinence quality of life and Wexner fecal incontinence severity post 6 months of pelvic floor muscle training - assisted BF in studied participants  
N=59**

FIQL/ Wexner FI severity	Wexner FI severity	Lifestyle	Coping Behavior	Depression	Embarrassment
Wexner FI severity		-0.520**	-0.648**	-0.662**	-0.610**
Lifestyle			0.807**	0.740**	0.773**
Coping Behavior				0.950**	0.935**
Depression					0.887**
Embarrassment					

Spearman correlation test \*\* Highly Significant P < 0.001

FI, fecal Incontinence; FISi, Fecal Incontinence Severity Index; FIQL, Fecal Incontinence Quality of life

### **Discussion:**

In this observational study, we investigated efficacy of an 8-sessions PFMT along with BF in reducing fecal incontinence, improving quality of life, and increasing strength of anal sphincter. Several causes contribute to fecal incontinence, such as anal surgery, hemorrhoidal fistula, idiopathic, chronic diarrhea/ or constipation and urinary incontinence<sup>[23,24]</sup>. The results of the current study were consistent with these findings. More than one third of the studied patient suffered from chronic constipation and reported idiopathic cause of FI. Meanwhile, rectal surgery and congenital anorectal malformation constituted more than ten percent while prolapsed hemorrhoids and anal fistula accounted for a lower percentage.

The first hypothesis stated that "Fecal incontinence patients who complete eight-sessions of PFMT along with BF will have a significant improvement in fecal incontinence severity post-training compared with FI pre-training ". The findings of the present study confirmed the 1<sup>st</sup> hypothesis and demonstrated a significant improvement in fecal incontinence as evidenced by a reduction in FI severity as shown in table 4. The results indicated that most of the patients experienced moderate to

severe FI before the pelvic training program, and significantly decreased after 8-sessions of PFMT assisted BF with a significant difference where ( $P < 0.001$ ). In the same context, it is noted from the study findings that, there was a trend toward decreasing the number of FI episodes in terms of (solid, liquid and gas), and reduction in using pads as shown in tables 5. The mean score was high at baseline and decreased markedly after the training program with a statistically significant difference ( $P < 0.001$ ). Interestingly, in table 6. and figure 1. there was a significant improvement in fecal incontinence severity index as measured by Wexner scale after 6 months of pelvic training program-assisted BF,  $P < 0.001$ . The likely rationale for improving the severity of FI symptoms can be explained by the fact that this maneuver strengthens the anal sphincter and PFM thus reduces the frequency of fecal leakage in participating patients.

The findings of the current study were consistent with previous trials that reported marked changes in FI severity among studied patients who received supervised BF with PFMT and the patient exhibited less frequency of involuntary loss of stool or



using pads per day <sup>[23,25,26,27]</sup>. It is worth noting that other recent RCT supported the beneficial effect of pelvic floor muscle exercise combined with feedback in reducing incontinence severity based on Wexner FI SI <sup>[28,29]</sup>. In addition, biofeedback combined with pelvic floor exercises is better than pelvic exercises alone, for alleviating FI symptoms in nearly three fourth of patients after 12 sessions of supervised training <sup>[30-32]</sup>. When analyzing the effect of biofeedback-assisted PFMT on strength of anal sphincter, the present study results supported the 2<sup>nd</sup> hypothesis that: "Fecal incontinence participants who complete eight sessions of pelvic floor training associated with Biofeedback will have a marked improvement in manometric parameters' mean scores post-training compared with pre-training mean scores". The results briefly indicated that there were significant improvements in manometric measures regarding anal sphincter pressure and rectal sensation after pelvic floor rehabilitation-assisted biofeedback  $p < 0.001$  table 3. In detail, the findings indicated that, maximum Squeeze pressure and resting anal pressure mean score significantly improved after 8-sessions training program ( $p < 0.001$  &  $p = 0.010$ , respectively). The findings of this study also suggested considerable

improvement in urgency, initial sensation, and maximum tolerable volume pre and post rehabilitation training  $p < 0.001$ ). In conclusion, after 6 months of implementing PFMT assisted BF, there was a marked improvement in squeeze and, resting pressure, urge to defecate, and maximum tolerable volume resulting in improved bowel control. These findings come in accordance with Lee and colleagues <sup>[33]</sup> who found that not only the squeeze pressure, but the duration of squeeze also improved and maintained post biofeedback training. This is due to the fact that the external sphincter of the anal canal affects up to thirty percent of resting tone, this means; if external anal sphincter function improved, resting pressure will improve secondary. In the same context, the results of Bols and his associates <sup>[34]</sup> supported our study's findings and reported that resting pressure and squeeze pressure were enhanced immediately after biofeedback training and one year later. It is also worth noting the combination of biological feedback with pelvic floor exercises over 3 months has been recommended by the American College of Gastroenterology as a suggestion for patients with hypotonia and/or impaired rectal sensitivity to achieve the best results. Schwandner et al. <sup>[35]</sup>. A multicenter study confirmed the results of this and previous studies <sup>[36]</sup>

In our study, when considering the clinical efficacy of PFMT -assisted BF on fecal incontinence quality of life. Notably, table 6. and figure 1. illustrated improvement in the FIQOL subdomains, (Coping behavior, lifestyle, depression, and embarrassment) post-8- sessions of pelvic training where there were statistically significant differences in FIQOL mean score after the training program compared to pre-program mean score  $p < 0.001$ . Therefore, the third hypothesis was accepted, which assumed an improvement in FIQOL scores after completing 8- training sessions of biofeedback and pelvic floor exercises. Various studies have confirmed the efficacy of BF plus pelvic exercise in improving FIQOL.<sup>[37]</sup> In addition according to the findings of other studies <sup>[38-40]</sup>. Fecal incontinence has been observed to cause significant changes in quality of life, including patients' embarrassment and low self-esteem. After the training program, it was found that there was a significant improvement in all aspects of patients' quality of life domains. Positive changes in quality of life and symptom severity were observed among both patients with idiopathic FI <sup>[41]</sup>. Fecal incontinence of different causes <sup>[42]</sup>., and FI associated with scleroderma <sup>[43]</sup>. This goes in accordance with. <sup>[44]</sup> who proved that women who received BF-assisted PFMT were significantly more likely to report improvement in FIQOL compared to those who received PFMT alone. Many comparable studies indicated that a supervised rehabilitation program that includes PFMT and biofeedback

can substantially enhance pelvic muscle strength and markedly improve FI and QOL <sup>[ 25,26, 28,45]</sup>. Hypotheses 4. Fecal incontinence is inversely proportional to patients' quality of life. As expected, there was a strong negative correlation between fecal incontinence and the four FIQOL domains after 8- sessions of pelvic floor muscles with the help of feedback as noted in table 7. Remarkably Thus, any improvement in QOL score was associated with decreased fecal incontinence severity, this is in line with some studies that reported strong correlation between FIQOL scores with the scores obtained in FISI scale <sup>[22, 46,47]</sup>. The results of similar study indicated that restoring the strength of the anal sphincter muscle is strongly associated with improved symptom severity and quality of life <sup>[48]</sup>. As regards FIQOL subdomains, a strong positive correlation was reported between lifestyle & coping behavior, depression, & embarrassment domains. Interestingly, Positive correlation appeared between coping behavior and depression & embarrassment

#### **Conclusion:**

Overall, supervised PFMT- assisted BF has proven to be an effective, safe, and low-cost intervention in improving quality of life, fecal incontinence, and strengthening anal sphincter muscle, thus should be presented as first-line therapy for adults with fecal incontinence.

**Strengths and limitations:**

The strengths of this study are that PFME with BF is standardized and structured based on the patients' needs and capabilities. All participants were directed on how to apply PFMT at home regularly. Moreover, patients who missed one of the training sessions were carried out in the nearest week. As regards limitations, recruitment of participants was based on their desire to engage in PFMT training, and thus, there is an inherent selection bias. Also, the non-random design and the small sample size constituted other limitations.

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**Conflict of Interest:**

The author asserts that there is no conflict of interest

**Ethical approval:**

The approval of the Scientific Research Ethics Committee, Faculty of Nursing, Mansoura University was obtained ( Ref No P.0230) Permission was obtained from the Gastroenterology Hospital. The nature of the study was clarified to the participating patients, and written consent was obtained.

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