**Title:**

**Effect of preoperative biofeedback on anal continence after fistula in ano surgery**

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**Abstract**

Objective: The aim of the present prospective study was to evaluate the role of preoperative prophylactic biofeedback therapy on the anorectal continence of patients with high anal fistula who will be subjected to fistulectomy operation.

Methods: This was a randomized control study which included 40 patients who presented to the Out Patient Department (OPD) of Kasr-al ainy Hospitals, from March 2015 to September 2016. All patients (40) have been presented with high complex anal fistulae. They were divided into two equal groups; group (A) has twenty patients who had undergone prophylactic preoperative anorectal biofeedback and group (B) has the other twenty patients who didn`t receive the prophylactic preoperative anorectal biofeedback therapy.For group (A) patients, six sessions of biofeedback were done two weeks. All patients were assessed postoperatively (0, 3 and 6 months) for continence by Cleveland Clinic Score for incontinence.

Results***:*** Among these forty patients only four (10%) had developed anal incontinence with variable degrees (two of them gas incontinence and another two developed frank stool incontinence), these four patients belong to the group (B), on the other hand, none of group (A) patients had developed incontinence.

Conclusion:

In conclusion, we can rely on preoperative prophylactic biofeedback has an important role to minimize incontinence post high anal fistula surgery.

Key words: (Fistula in ano, Fecal Incontinence, Biofeedback).

**Introduction:**

Surgery of perianal fistulas remains a challenge because of potential sequences including fecal incontinence (FI) that may impair quality of life. [1]

Reported incidences of incontinence following fistulas surgery range from 5% to 60%.Sphincter preserving approaches such as core fistulectomy or mucosal advancement flap are recommended for high complex fistulas as better approaches to preserve continence. [2-4]

About 70% of the resting tone is achieved by internal anal sphincter (IAS). This is supported by the finding lateral internal sphincterotomy could be complicated by fecal incontinence. [5]

The external anal sphincter (EAS), similar to the IAS, is in a state of tonic contraction even at rest and the activity is reflexly raised when intra-abdominal pressure is increased e.g. when coughing, laughing or lifting. Activity is maximally raised when the EAS is contracted voluntarily but contraction. [6]

Both American College of Gastroenterology and the American Gastroenterological Association recommend anorectal biofeedback for the treatment of FI. Biofeedback treatment protocols for FI aim to strengthen pelvic floor muscles, to increase the ability to sense rectal filling and to teach patients to perceive and react even if the rectum is dilated slightly. [7-9]

**Aim of work**

The aim of this article was to describe a standardized biofeedback anal exercises protocol as a prophylactic measure prior to complex anal fistulas surgery to minimize the incidence of postoperative fecal incontinence***.***

**Material and Methods:**

**Patients:**

Our study included **40** patients who came to the Out-Patient Department (OPD) of Kasr-el Ainy Hospital, from ***March 2015*** to ***September 2016***.

After agreement from the Scientific and Ethical Committee of General Surgery Department and Faculty of Medicine Cairo University, the procedure and the study were explained to all individuals participating in the study and informed written consents were taken.

Forty patients who were candidates for high anal fistulas surgical treatment were randomized into two equal groups (A and B) using closed envelope. Neither patients nor physicians were blinded to the group assignment because of the nature of the study. Group (A) included 20 patients who had preoperative biofeedback program while group (B) included 20 patients that were not undergone biofeedback program. Patients’ selection was done using the closed envelope method.

Patients, not fit for surgery didn’t accept treatment modality, at extreme ages, and/or those with low anal fistulas were excluded from the study

**Methods:**

Pre-operative:

All patients were underwent proper history taking (age, presentation, occupation, presence of previous abscess, contributing factors, continence assessment by Cleveland Clinic Score for incontinence and previous anal surgeries) and full general and local examination (P/R examination) to determine: External fistulous opening, Internal fistulous opening ,primary , secondary tract, sphincter tone , scars and presence of abscess cavity.

Anatomical assessment of the fistula tract, its relation to the anal canal and muscular complex were studied by magnetic resonant imaging (MRI) and / or Endoanal Ultrasonography (EUS).

After the agreement of the scientific and ethical committee of the general surgery department, the procedure and the study were explained for all individuals participating in the study and all of them consented for agreement.

**Biofeedback protocol:**

The biofeedback protocol was explained in details to patients in group (A). It was done in the colorectal unit with the subject in the left lateral position a multi-lumen catheter was placed in the rectum with 8 side holes with varying distances from the anal verge .These were perfused with water and connected to water filled transducers. A 5 cm latex balloon was attached to the catheter and linked to an air filled transducer. Catheter used: with 8 side holes 3,4,5,6,7,8,9 and 10 cm from the balloon and at angles 0, 45, 90,135,180,225,270 and 315 respectively. Recordings were made on a computer using the machine software to be printed when needed.

 Six sessions were performed preoperatively each of which lasting 20 -30 minutes, the sessions are performed every other day with average three sessions per week. First sensation: the balloon of the catheter is inflated until the first sensation is reached at which the patient is asked to contract his sphincters; this is done to improve sensation and coordination. Challenge pressure, the patient is asked to pass the obstacle over a bar (representing the challenge pressure) by maximum squeeze. The muscle response measured by pressure transducers is translated into a visual display so that the patient receives immediate feedback regarding the strength and duration of pelvic floor muscle contraction. Challenge time, during which the patient squeezed. Resting time, during which the patient rested. Challenge pressure, challenge time and resting time could be adjusted through the program before starting the session

Operation:

For all patients general anesthesia without muscle relaxant was used. Patients were operated in lithotomy position. They were received prophylactic antibiotic.

Core fistulectomy was done to all the patients. Its principle was to remove the chronic, epithelialized tract to allow healing by secondary intention of healthier tissue. Dissection was typically carried out from the external opening up to the internal fistulous opening.

Postoperative care:

The patients started oral fluids same day of procedure intake advanced gradually as patient tolerating feeding. Analgesia (usually IV or IM nonsteroidal anti-inflamatory) started immediately postoperative.

Patients were discharged 24 hours postoperative with instruction for frequent dressing. Early assessment for anorectal continence was carried using Cleveland Clinic incontinence score (table 1) 10.

**Table (1): Cleveland Clinic continence score.**

|  |
| --- |
| **The Wexner score** |
| Type of incontinence | Frequency |
| Never | Rarely | Sometimes | Usually | Always |
| Solid | 0 | 1 | 2 | 3 | 4 |
| Liquid | 0 | 1 | 2 | 3 | 4 |
| Gas | 0 | 1 | 2 | 3 | 4 |
| Wears pads | 0 | 1 | 2 | 3 | 4 |
| Lifestyle alteration | 0 | 1 | 2 | 3 | 4 |
| Never, 0; rarely, <1/month; sometimes, <1/week, 1/month; usually, <1/day, 1/week; always, 1/day. 0, perfect; 20, complete incontinence. |

The patients were advised for follow up in outpatient clinic 7-14 days to assess the wound and early postoperative complications. 6 months later, anorectal continence was reassessed after complete wound healing.

**Findings**:

Both groups were matched regarding the age and gender. The mean age for group (A) was 41.35 while that for group (B) was 39.5.

In group A, there were 8 (40 %) with extrasphincteric fistulas, 4 (20 %) with suprasphincteric fistulas and 8 (40 %) with high transphincteric fistulas while in group B, there were 5 (25 %) with extrasphincteric fistulas, 6 (30 %) with suprasphincteric fistulas and 9 (45 %) with high transphincteric fistulas.

There were 4 (20 %) patients with recurrent fistulas in group A and 3 (15 %) in group B.

Four patients in each group had associated abscess collections that had been drained during fistula surgery.

According to Cleveland Clinic incontinence score for postoperative follow up, 4 patients developed incontinence in group B while all patients in group A were fully continents postoperatively (p = 0.038).

**Table (2): Analytical results of the patients with high anal fistulas without preoperative biofeedback who had developed incontinence.**

|  |  |  |
| --- | --- | --- |
| Fistula type | Preoperative Wexner score | Postoperative Wexner score |
| Extrasphincteric with abscess formation | 0 | 8 |
| Suprasphincteric fistulas with abscess  | 0 | 20 |
| Suprasphincteric fistulas with abscess | 0 | 20 |
| Suprashincteric  | 0 | 4 |

**Discussion**

The fecal incontinence is a very frequent pathology, the frequency considered in the general population being 2-3%, although the studies of prevalence in the general population show a great variability 11. Biofeedback training has been regarded as the conservative therapy of choice for fecal incontinence secondary to a variety of medical and surgical disorders in all age groups 12.

The preoperative biofeedback and pelvic exercises improve urinary control and decrease severity of urine incontinence following radical prostatectomy 13.

This was a randomized control study, which included forty patients who presented to the outpatient clinic of the colorectal unit in Kasr Alainy hospital in the period between from March 2015 to September 2016 for colorectal surgery.

The purpose of this study was to assess anorectal biofeedback as a prophylactic measure for fecal incontinence after fistulectomy surgery for patients with complex fistulas.

In 2003, Fernandez et al. studied the effect of anorectal biofeedback on a total of 145 patients with anal incontinence (118 female and 27 male) Four weeks following completion of the sessions, 59 patients (76%) had improved significantly, 13 (17%) had improved slightly and 6 (8%) had not changed 14.

In 2007, Byrne et al. studied 513 patients, 385 (75 percent) completed the treatment program. In those completed the treatment program maximum anal sphincter pressure increased by a mean 12 mmHg (14 percent; from 90 to 102 mmHg) 15.

In 2004, Kairaluoma et al. studied biofeedback therapy in treating 22 patients with anal incontinence; 21 female and one male, with a median age of 57 (range 27–84) years. In this study manometry results suggested that the external sphincter function is improved by biofeedback therapy. However, there is no effect on resting pressure and internal sphincter function 16.

In 2003, Kienle et al. studied a consecutive patient series (N = 70) with anal sphincter deficiency and compare the efficacy of biofeedback and electrostimulation as conservative treatment options. Forty patients were treated by biofeedback therapy; Patients were not specifically selected for one or the other treatment. Resting and squeeze pressure increased significantly after biofeedback training (P < 0.05 and < 0.001) 17.

 In 1994, Keck et al. studied fifteen patients (13 women and 2 men) with incontinence underwent a mean of three (range, 1–7) biofeedback sessions. The cause was obstetric (four patients), postsurgical (five patients), and idiopathic (six patients). Total resolution of symptoms was reported in four patients, favourable improvement in four patients and some improvement in three patients. Manometric measurements showed a mean increase of 15.3 mmHg in resting pressure and 35.7 mmHg in squeezing pressure after biofeedback 18.

In 2006, Dobben et al. studied 266 patients (91% female) and observed that the improvement in incontinence with the use of biofeedback was not associated with results in tests including anorectal manometry 19.

**Conclusion:**

In our study twenty patients with high anal fistulas had received prophylactic biofeedback therapy with mean age of 41.35 years, all of them were completely continent postoperatively; another twenty patients with high anal fistulae had not received prophylactic preoperative biofeedback with mean age of 39.45 years , among them four patients had developed fecal incontinence with varying degrees ( two patients had developed gas incontinence and another two had developed complete incontinence ), so it had been found that preoperative prophylactic biofeedback has an important role to prevent or minimize incontinence post high anal fistula surgery (with P value of 0.038 when comparing both groups using the Wexner score) as it enhances the contraction capacity of the external sphincter muscles and has a role to teach the patients to perceive and react even the rectum is slightly dilated.

Preoperative prophylactic anorectal biofeedback reduces the incidence on anorectal incontinence after anal operations for high anal fistulae.

The use of biofeedback has shown that autonomic functions can be conditioned by training the mind to control them.

Biofeedback enhances the contraction capacity of the external sphincter muscles.

Biofeedback teaches the patient to perceive and react even if the rectum is slightly distended.

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**No Conflict of Interest**

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