



Cohort Study

Biofeedback therapy for anorectal functional disorder: Malaysian colorectal tertiary centre experience



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ABSTRACT

Background: Anorectal functional disorder encompasses arrays of conditions including Obstructive Defecation Syndrome (ODS) and Fecal Incontinence (FI). Biofeedback Therapy (BFT) serves as first line therapy to re-train pelvic floor coordination, rectal sensation and strengthening pelvic floor muscle. The aim of this study is determining the efficacy of BFT in our centre.

Methods: This is a retrospective observational cohort study of patients attended biofeedback therapy session from January 2013 to December 2018. Descriptive statistic was used to analyse the data.

Result: Total 99 patients with mean age of 44.6 ± 18.1 with female 56% ($n = 55$) and male 44% ($n = 44$) attended BFT session. Overall, 77 had CC (77%) and 23 (23%) had FI. Mean number of sessions was 11.8. Overall improvement rate 42 (42%), no improvement 32 (32%) and defaulted 26 (26%). In patients with CC, 32 (41.6%) had improvement in symptoms, 23 (29.9%) had no improvements, 22 (28.6%) defaulted BFT.

Patients with FI, 7 (30.4%) had Obstetric Sphincter Injury, 7 (30.4%) had traumatic anal injury, 3 (13.0%) has Low Anterior Resection Syndrome, 2 (8.7%) had sphincter injury following anal sepsis, 2 (13.0%) had rectocele repair and 1 (4.3%) were idiopathic. 9 patients (39.1%) had stoma created. Overall response rate was: 10 patients (43.5%) had improvement in symptoms, 9 patients (39.1%) had no improvement, 4 patients (17.4%) defaulted therapy.

Conclusion: Our outcome rate is lower compared to published due the limited access and logistic restrictions. This issue should be given great consideration such as broadening the service and training.

1. Introduction

Pelvic floor dysfunction includes an array of conditions including faecal incontinence, chronic constipation, and obstructed defecation syndrome, is a common referral to a colorectal surgeon.

Adults suffer from chronic constipation at a rate of 2–27%^{1,2}. As a result of westernisation of diet and an ageing population, these issues are becoming more prevalent especially among Asians. Patients with chronic constipation have also reported to have co-existent of mild to anxiety or depression [1]. This cohort has the obsession to have bowel movement everyday and they are often caught in a vicious cycle and unaddressed psychological issue will lead to worsening symptoms.

Faecal incontinence affects 2%–17% of the population and is linked to gender, age, and disability. According to a report estimate, women account for 50% of FI sufferers [2,3]. Denervation and stretched Pelvic floor during vaginal childbirth has been proposed as the main aetiology of pelvic floor weakness in women [3].

These problems pose great social and psychological issues that sometimes halt health seeking behaviour. In a local study, only 9.6% of patients sought treatment for faecal incontinence⁴. Social taboo is second cause of such behaviour (5.3%) perceiving FI does not affect one's daily life (88.0%).

Physiologic test modalities for diagnosing Functional Anorectal Disorder are available but the established test are Anorectal Manometry, Rectal Balloon Expulsion test and rectal sensitivity [4]. However not all centres are equipped with such facilities and there is lack of trained personnel to perform these tests.

Biofeedback therapy is effective for constipation by pelvic floor dyssynergia with the success rates of 60–80% [5,6]. It is a non-surgical therapy that act as first line in Anorectal dysfunction disorder that involves rehabilitation program by means muscle contraction and relaxation exercises with the aid of verbal, visual and auditory guidance [6–13]. This study aimed to analyse the clinical efficacy of biofeedback therapy offered in our centre against published data.

Abbreviations: Biofeedback, therapy; anorectal, functional disorder.

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2. Materials and methods

2.1. Subjects

This is a retrospective observational cohort study of all the patients who attended the biofeedback therapy session from 2013 til Dec 2018 in Hospital Sultanah Bahiyah, Alor Setar, Malaysia. Any improvement of symptoms after BFT defined as 'Improved'. Descriptive statistic was used to analyse the data (deleted).

2.2. Methods

Patients referred for faecal incontinence and chronic constipation were assessed in details regarding the bowel habit and relevant history. Further investigations taken depending on the problem to ascertain the cause.

- Colonoscopy

Colonoscopy is mandatory especially in patients 45 years and above, to rule out colorectal malignancy.

- Anal manometry

Physiological parameters of the anal sphincter complex are obtained preferably before starting the biofeedback therapy. Patient given appointment date with rectal enema given upon arrival on the day of anal manometry study. Patient will lie on left lateral position and balloon probe will be inserted at level of 0 cm, 1 cm or 2 cm from anal verge, which ever gives the best resting pressure. All the parameters will be tested namely, resting anal pressure, anal squeeze pressure, balloon expulsion and rectal sensation to different balloon volumes.

- Colon transit study

This is a pertinent tool in assessing global colonic transit disorder. Patients were given single capsule containing radio-opaque markers and instructed not to take any form of laxative 2 weeks prior to study. Patients were instructed to ingest the markers and supine abdominal x-rays were taken on Day 3 and Day 5 of markers ingestion. Delayed colonic transit is defined as > 20% markers retention.

- Endo Anal Ultrasound

Patients with faecal incontinence will be assessed with endoanal ultrasound to look at the anal sphincter complex for any defects and its' integrity. A 3D ano-rectal axial transducer was used when patient in left lateral position.

2.3. Biofeedback therapy

Biofeedback therapy device consists of generator and monitor displaying real-time Electromyography (EMG) signal of pelvic floor muscle work done by the patient. Patient is required to attend the therapy as outpatient in clinic twice a week, for a total of 12 cycles for each cycle.

2.4. Statistical methods

Data are presented as numbers and percentage for categorical data and as means \pm standard deviations. Chi-square test used to analyse response rate to therapy. P-value of less than 0.05 considered to be statistically significant. Data were analyzed using SPSS software (version 22.0 for Windows; IBM- SPSS, Chicago, IL).

3. Results

3.1. Characteristics of patients

Total 99 patients with mean age of 44.6 ± 18.1 with female 55.5% (n = 55) and male 44.5% (n = 44) attended the BFT session. Of all the patients, 76 had CC (76%) and 23 (23%) had FI. Mean number of sessions was 11.8. Overall improvement rate 42 (42%), no improvement 32 (32%) and defaulted 26 (26%)(Table 1).

4. Constipation

In the constipation group, 56% (n = 42) of the patients are women and men were 44% (n = 34). The mean duration of symptoms in constipation group is 57 ± 18 weeks. Mean number of biofeedback therapy sessions attended is 10.9 ± 7.2 . 42.1% (n = 32) of patients in Constipation group had improvement in symptoms after BFT, 28.9% (n = 22) had no improvement in symptoms and 28.9% of patients (n = 22) had defaulted follow up. 13% (n = 10) of patients have Diabetes Mellitus, 26% (n = 20) with hypertension, 10% (n = 8) are smokers, 14% (n = 11) have ischaemic Heart Disease and 5% (n = 4) have chronic lung disease.

5. Faecal incontinence

In the Faecal incontinence group, 57% (n = 13) of the patients are women whereas 43% (n = 10) are men. Mean age of patients in this group is 46 ± 19.2 . the mean duration of symptoms is 16 ± 15.5 months. Mean number of sessions attended is 12.2 ± 8.4 . 43.5% (n = 10) had improvement in symptoms after BFT, 39.1% (n = 9) had no improvement in symptoms and 17.4% (n = 4) had defaulted follow up. 26% (n = 6) of patients have DM, 30%(n = 7) have hypertension, 17%(n = 4) are smokers, 4%(n = 1) has ischaemic heart disease and 13%(n = 3) have chronic lung disease.

6. Constipation

Among the responder in Constipation group, 53% are men (n = 17) and 47% are women (n = 15), where in the non-responder group 27% are men (n = 6) and 73% are women (n = 16). The mean age in the responder group is slightly younger (44.2 ± 19.3) than the non-responder group (48.8 ± 14.5) but it is not statistically significant (Table 2). When compared the physiological parameters obtained via anal manometry test, mean resting anal pressure in the responder group (65.6 ± 36.3) is lower than non-responder group (76.9 ± 45.1). Same

Table 1
Clinical characteristics of patients in both group.

	Constipation (n = 76)	Faecal Incontinence (n = 23)
Age (mean \pm SD)	44 \pm 17.9	46 \pm 19.2
Gender		
Male	34 (44%)	10 (43%)
Female	42 (56%)	13 (57%)
Co-morbid	10 (13%)	6(26%)
Diabetes Mellitus		
Smoker	8 (10%)	4 (17%)
Hypertension	20(26%)	7(30%)
Ischaemic Heart Disease	11(14%)	1(4%)
Chronic Lung Disease	4(5%)	3(13%)
Symptom duration in months (mean \pm SD)	57 \pm 18	16 \pm 15.5
No of sessions (mean \pm SD)	10.9 \pm 7.2	12.2 \pm 8.4
Response to therapy		
Improved	32 (42.1%)	10 (43.5%)
Not improved	22 (28.9%)	9 (39.1%)
Defaulted	22 (28.9%)	4 (17.4%)

Legend: (SD): Standard Deviation.

Table 2

Characteristics of patients with constipation based on the response to biofeedback therapy.

	Responder (n = 32)	Non-Responder (n = 23)	p-value
Gender (male/female)	17/15	6/17	0.111
Age (mean ± SD)	44.2 ± 19.3	48.8 ± 14.5	0.196
Symptoms duration (months)	49.2 ± 68.8	70.3 ± 89.4	0.574
BFT sessions	13.2 ± 5.8	12.2 ± 9.0	0.001
Bowel transit study			0.806
No	16	11	
Normal	13	8	
Obstructed defecation	1	1	
Slow transit	0	2	
Suboptimal study	2	0	
Colonoscopy			0.290
No scope done	5	1	
Normal	12	16	
SRUS	10	3	
others	4	5	
Endoanal U/S			0.08
No	32	20	
Normal	0	2	
Defecating proctogram			0.352
None	23	12	
Rectocele	3	0	
Mucosal prolapse	2	1	
Rectal prolapse	3	0	
Spastic pelvis	0	1	
Normal	1	2	
Thyroid function test			0.126
No	14	9	
Normal	18	13	
Serum Calcium level			0.319
No	15	8	
Normal	17	14	

Legends: SD: Standard Deviation.

BFT: Biofeedback Therapy.

SRUS: Solitary Rectal Ulcer Syndrome.

U/S: Ultrasound.

goes to the minimal volume, desire volume, urgent volume and pain volume for the responder group as compared to the non-responder group. However, this result is not statistically significant. The therapy session different between the responder and non-responder group is only 1 session but it is statistically significant (Table 3).

Table 3

Anal physiology parameters of Patients with Constipation Based on the Response to Biofeedback Therapy.

	Responder (n = 32)	Non Responder (n = 22)	p-value
Gender (male/female)	17/15	6/16	0.111
Age (mean ± SD)	44.2 ± 19.3	48.8 ± 14.5	0.205
Symptoms duration (months)	49.2 ± 68.8	62.6 ± 83.3	0.796
BFT sessions	13.2 ± 5.8	12.5 ± 9.0	0.001
Mean Resting anal pressure	65.6 ± 36.3	76.9 ± 45.1	0.865
Mean Squeeze anal pressure	83.1 ± 62.5	103.8 ± 73.9	0.399
Minimum volume	13.0 ± 0	26.5 ± 19.1	0.806
Desire volume	28.0 ± 0	71.0 ± 29.7	0.573
Urgent volume	43.0 ± 0	96.0 ± 36	0.613
Pain volume	57.0 ± 0	131.0 ± 43	0.541

Legends: SD: Standard Deviation.

BFT: Biofeedback Therapy.

7. Faecal incontinence

In patients with FI, 7 (30.4%) had Obstetric Sphincter Injury, 7 (30.4%) had traumatic anal injury, 3 (13.0%) has Low Anterior Resection Syndrome, 2 (8.7%) had sphincter injury following anal sepsis, 2 (13.0%) had rectocele repair and 1 (4.3%) were idiopathic. 9 patients (39.1%) had stoma created.

Overall response rate was: 10 patients (43.5%) had improvement in symptoms, 9 patients (39.1%) had no improvement, 4 patients (17.4%) defaulted therapy (Table 4).

The mean age in the responder group (54.8 ± 19) is slightly higher than the non-responder group (47.6 ± 14) (Table 5). is longer Mean duration of symptoms in the responder group (20.5 ± 20) is longer than the non-responder group (11.8 ± 6). This is because the non-responder group includes largely the patients with traumatic anal injury.

More BFT sessions observed in the responder group (14.9 ± 8) compared to the non-responder group (11.9 ± 8). The physiological parameters obtained via anal manometry test also differs in both groups. The responder group observed to have higher values in minimal, desire, urgent and pain volume when compared to non-responder group. However, these values are of no statistical significance.

8. Discussion

Due to unwillingness in seeking medical attention behaviour among the population and logistic issue in Malaysia generally, the number of Functional Anorectal disorder among men and women are underestimated. Health seeking behaviour has often halted by lack of health awareness and financial burden [14,15]. The general public assumes these conditions are part of ageing and therefore defer medical treatment.

There are many postulated factors for pelvic floor disorders including socioeconomic status, gender, multiparity, medical illness and obesity [16–18]. Women have higher levels of defecative disorder, especially after vaginal deliveries [2,4,16]. This may be associated with Pudendal nerve injury and anal sphincter disruption during vaginal delivery due to overstretching of the pelvic outlet. Women with FI related to birth injury can present as late as decade later.

Constipation sufferers seldom associated with psychological disorder; obsessive defecation tendencies [3,5,18]. Management may need to include psychological assessment and cognitive therapy along with biofeedback therapy [5,6,10,12]. A small study from the Netherlands indicated that the effectiveness of biofeedback therapy was indeed when incorporated with initial psychotherapy [8].

When compared to constipation, some studies demonstrated larger number of symptomatic improvement in patients with FI. Patients with chronic constipation typically have combination of delayed transit and obstructive defecation, both have entirely different pathophysiology and

Table 4

Causes of Faecal Incontinence and response to therapy.

Cause of Anal Incontinence n(%)		Response	
		Improved (n = 10)	No improvement (n = 9)
Idiopathic 1 (4.3%)		10%	0
LARS 3(13.0%)		20%	11%
OBSI 7(30.4%)		30%	22%
Perianal Sepsis 2 (8.7%)		20%	0
Prolapse Surgery 2(13.0%)		0	22%
Traumatic 7 (30.4%)		20%	44%

Legends: LARS: Low Anterior Resection Syndrome.

OBSI: Obstetric Sphincter Injury.

Table 5
Characteristics Patients with Faecal Incontinence on response to Biofeedback Therapy.

	Responder (n = 10)	Non Responder (n = 9)	p-value
Gender (male/female)	5/5	4/5	0.693
Age (mean ± SD)	54.8 ± 19	47.6 ± 14	0.303
Symptoms duration (months)	20.5 ± 20	11.8 ± 6	0.469
BFT sessions	14.9 ± 8	11.9 ± 8	0.281
Mean Resting anal pressure	50.7 ± 5.7	32.5 ± 4.9	0.073
Mean Squeeze anal pressure	87.6 ± 23.5	50.5 ± 15.8	0.121
Minimum volume	18.3 ± 7.6	10.6 ± 5.1	0.208
Desire volume	47.0 ± 3.6	37.0 ± 12.1	0.462
Urgent volume	83.0 ± 25.2	62.3 ± 15.0	0.532
Pain volume	90.0 ± 14.1	77.6 ± 6.8	0.421

Legends: SD: Standard Deviation.

BFT: Biofeedback Therapy.

treatment approach [7,8,19].

An important finding from this study is great number of patients defaulted therapy mainly attributed to logistic issue. Our hospital is in the state of Kedah and some of our centre's referrals are from other states. First line of treatment is biofeedback therapy which needs full dedication from patients every week or 2 weekly for at least 6 weeks course. This regime was not able to be adhered to by the majority of patients mainly due to work commitments and logistic issue.

9. Conclusion

We conclude that in both Faecal Incontinence and Obstructive Defecation syndrome, biofeedback therapy is proven to be an effective mode of pelvic floor rehabilitation. Early referral for biofeedback therapy should be made in patients whom are identified to have pelvic floor disorder.

There are numbers of limitations identified in this study in few aspects. 1. With limited cohort and significant proportion of therapy drop-outs, it is insufficient to reflect true outcome of the therapy. 2. There was no standardization of symptoms documentation by using severity grading scoring system for example Wexner Continence Score or Constipation Score that will yield more significant clinical outcome analysis.

Pelvic Floor Disorder and Rehabilitation is not well established in Malaysia. The importance of education among primary care and junior doctors in recognizing patients with Pelvic Floor Disorder should be addressed in all hospitals with surgical capabilities. Resources in our facility were very limited, here is only one trained nurse available and one machine to conduct the therapy for all referred patients. With this study, we hope to inspire Colorectal Surgeons or trainee in this region to engage in this domain of gastrointestinal disorder in order to cater the service to the community.

Ethical approval

Ethical approval were obtained from local administrative, national NMRR ethical committee and this included consent from patient.

Sources of funding

This work had no source of funding.

Author contribution

Saidah Sahid has initiated and conduct the cohort study and did the writing of the manuscript, Nil Amri Bin Mohamed Kamil, Muhd Yusairi Bin Kamarulzaman, Johari Bin Mustafa involve in managing the patient

and follow up, Nik Amin Sahid involve in reviewing and editing the manuscript for publication.

Guarantor

Saidah Sahid.

Consent

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 2013 and its later amendments. Informed consent was obtained from the patients family for being included in this case report prior to submission. Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

This article compliant with the STROCSS 2021 criteria [20].

Declaration of competing interest

All authors declare that they have no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.amsu.2022.103848>.

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