Original Article

Outcome of Endo-anal Ultrasound Guided Injection of Botulinum Toxin Type-A Therapy in Puborectalis Muscle in Patients with Anismus

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Abstract

Background: Anismus is a functional disorder characterized by dyssenergia and incoordination of pelvic floor muscular contractions at defecation. Despite normal propulsive power used when attempting to defecate, a hypertonic pelvic floor dysfunction results in non-relaxation or even paradoxical contraction of puborectalis muscle, resulting in failure to straiten the ano-rectal angle, hence impaired stool evacuation. This study aims at evaluating The Outcome of Injection of Botulinum Toxin Type A in Puborectalis Muscle in Patients with Anismus.

Methods: The study included 50 patient presented with symptoms of obstructed Defecation (OD) and were diagnosed as Anismus and failed conservative treatment and biofeedback training. Ultrasound-guided Botulinum Toxin Type A injections into Puborectalis Muscle were done. All patients were followed up for 6 month duration for obstructed defecation symptoms and manometric findings

Results: The current study included 50 with the mean age of 36.6±11.9 presented with Anismus for a mean duration of 6.8±2.64.

There was a statistically significant improvement at Longo score of obstructed defecation at 1,3,6 months when compared to the initial values ($p<0.001$*) while there was no statistically significant difference was noticed in the defecation frequency at 3,6 months when compared with the initial records

There was a statistically significant decrease in both resting and squeeze pressures after 3, 6 months when compared with the initial records ($P <0.001$*)

The overall satisfaction was significantly increased to be 68% and 64% after 3 and 6 months respectively when compared to 0% satisfaction reported at the initial assessment

Conclusion: According to the current results, Injection of Botulinum Toxin Type-A Therapy in Puborectalis Muscle in Patients with Anismus is assumed to be effective for short term with good overall satisfaction

Keywords: Anismus, Botulinum Toxin Type-A, Obstructed defecation.

Introduction

A combined prevalence of 14% in the community indicates that chronic constipation is a frequent condition [1,2]. Pathophysiology can be roughly categorized into cases of rectal evacuation problems, colonic dysmotility, or both [3].

Anismus is a functional defecation problem, which is a subtype of disorders of rectal evacuation without anatomical abnormalities [4]. Anismus is characterised by incorrect pelvic floor muscular contraction or non-relaxation, despite normal propulsive power used when attempting to defecate, resulting in a blocked anal canal and impaired stool evacuation [5]. Anismus as well as other terms like "pelvic floor dyssynergia," "spastic pelvic floor syndrome," "paradoxical puborectalis contraction," and "puborectalis syndrome" have mainly been replaced by the term "dyssynergic defecation" (DD) [6].

Between 20% and 81% of patients suffering from chronic constipation who are referred for the specialised examination have anismus [5]. Biofeedback therapy is currently the recommended course of treatment for anismus. This mode of treatment has reportedly been found to be more effective than diazepam, sham, and laxatives based on low-quality evidence, and it is preferred over surgical procedures like partial division of the puborectalis muscle, which have a high risk of incontinence in spite of its effectiveness [1,7].

Problems develop when biofeedback is unavailable, the patient is not committed, or when biofeedback is unsuccessful [6]. Botulinum toxin type A (BTXA) injection into the puborectalis and/or external anal sphincter muscles is a relatively new method. Before new synaptic proteins are produced, the effect on striated muscle starts to take effect after 2–5 days and lasts for 2-3 months [8]. In 1988, a small case study of seven patients [9] first revealed the use of BTXA

injection for the treatment of DD. Despite variations in delivery method, efficacy, and side effects, more trials have since been described [6,10].

The authors were inspired to undertake this study because of the debate about the effects of boutilinium toxin injection.

Patients and Methods

Study design

The current prospective study was conducted following the consideration of the ethical perspectives of Helsinki where research and ethical committees, Benha University approved the conduction of the study.

The study included 50 patients who were presented to the colorectal unit, General surgery department, Faculty of Medicine, Benha University with Anismus are unresponsive to conservative treatment and biofeedback training throughout the period from March 2021 till March 2023. Follow-up was designed for 6 month duration.

Informed written consent was obtained from all included patients

Inclusion criteria were patients with age between 16 and 50 years old, with a clinical history of obstructed defecation (OD) or sense of anal obstruction during attempted defecation **In addition to at least three positive tests of the following:**

- -ve Balloon expulsion test (BET) for a 50-mL water-filled balloon within 1min during attempted straining.
- High-resolution anal manometry (HRAM): paradoxical increase or failure to decrease anal pressures during attempted straining, sphincter relaxation 20%, and defecation index 1.5.
- Echodefecography to assess patients with OD because of its ability to detect the same anorectal dysfunctions and ano-rectal angel.
- MRI Defecography: failure of increase or even a decline in the anorectal angle with lack of pelvic floor descent during straining and defecation.

Exclusion criteria were age more than 50 or less than 16 years old, patients with Sphincteric injuries, colonic inertia, +ve Defecography for abnormalities other than anismus., pregnancy, and known sensitivity to Botulinum toxin

Preoperative Assessment

The patients who were included in the study underwent history taking for OD symptoms, previous surgery or chronic illness. Inquiries were directed to assess the cause of OD.

Clinical examination: all patients will be assessed for obstructive defecation through longo score for constipation.

Original Longo score (0-40) is 8 points scale. Recently Longo modified this scoring system and added a lifestyle change parameters. Modified Longo score is the most commonly used scoring system for treatment strategy for ODS patients (11)

Table 1: Longo score for obstructed defecation:

Defecation frequency	1-2 def\1-2day	0	2 def\wk or 3 def or attempts \day	1	1 def\wk or 4 def or attempts \ day	2	<1 def\wk or >4 defor attempts\ day	3	
Straining: - intensity - extension	No or light short time	0 1	Moderate	1	Intensive prolonged	2 2			

Sensation of incomplete evacuation	Never	0	< 1x\wk	1	2x\wk	2	> 2x\wk	3	
Rectoperineal pain	Never	0	< 1x\wk	1	2x\wk	2	> 2x\wk	3	
Activity reduction per week	Never	0	<25% of activity	1	25-50% of activity	4	>50% of activity	6	
Laxatives	Never	0	<25% of defecation	1	25-50% of defecation	3	>50% of defecation	5	Always 7
Enemas		0		1		3		5	7
Digitations		0		1		3		5	7

Table 1 **Longo score for obstructed defecation**

All patients will be subjected to all the following:

Transanal ultrasonography Using **(BK Medical Flex Focus 400 with 2052 colorectal transducer)** uses a 3D ultrasound scanner with a 7 or 10 MHz rotating endo probe to assess the pathophysiologic status of the anal sphincter.

Endo anal ultrasound will be used to assess the anatomy of the anal canal and anal sphincter to exclude sphincteric defects or abscesses. **It can be c**onsidered as one of the diagnostic tests for

animus by Echodefecography. US can guide the injection of Botox in the puborectalis muscle and follow up patients after injection of Botox.

Anorectal Manometry: Physiological parameters well be evaluated by high resolution anorectal manometry by **(Solar GI HRAM MMS)** using a 24-channel water-perfused catheter with latex balloon.

Full manometric examination will be done including resting anal pressure,

Mean squeeze pressure &assess muscle relaxation during push.

Balloon expulsion test: 3 attempts for expulsion of a 50-mL water-filled balloon within one minute of straining.

MRI Defecography

When there is a failure to rise or even a fall in the anorectal angle without pelvic floor descent after attempted straining and defecation, dynamic MRI defecography was used to demonstrate animus. Anismus was characterised as a non-relaxing anal sphincter during a defecation effort, a positive balloon expulsion test, and a non-relaxing puborectalis on an MRI defecography together with a prolonged evacuation time or a failure to expel the barium paste in the presence of a normal perineal descent. Before receiving an injection of botulinum toxin type A therapy, every patient with anismus will undergo four sessions of biofeedback therapy.

Procedure

Each patient was given a 50 mg of pethidine and 5 mg of midazolam to put them to sleep before to their injection. With the patient in the lithotomy posture, the anal canal will be cleansed with povidone iodine before the injection process begins. Two fingers will be used to widen the anal canal before an injection is administered using a 90°-bent 23-g needle in a l-ml insulin syringe. Endo anal ultrasound-guided injection will be given to patients at random for the lateral

puborectalis muscle. Each side of the puborectalis muscle will receive an injection of 10 units of BTX-A (Allergan, Irvine, CAT) or the posterior angle (puborectalis sling) will receive an injection of 20 units. (12)

At each follow-up, the necessity for more injections will be evaluated. A second attempt will be provided to any patient who fails the initial injection. The identical researcher will administer each shot.

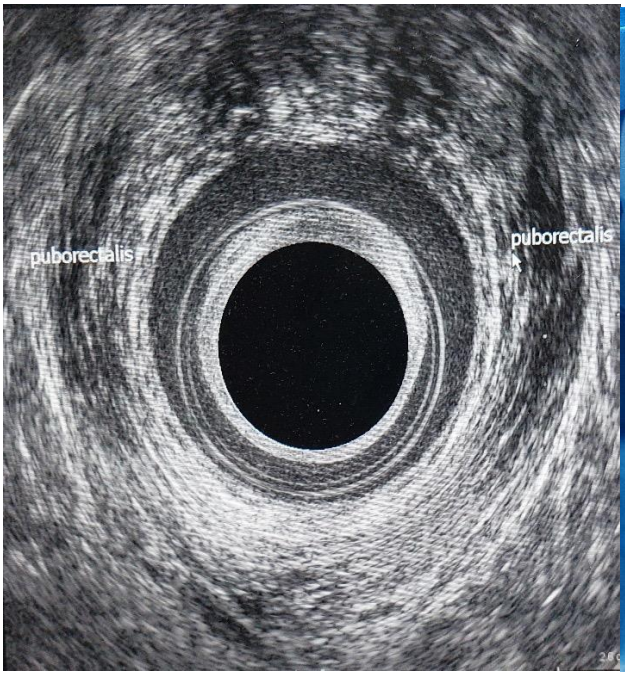

Fig 1: identification of puporectalis

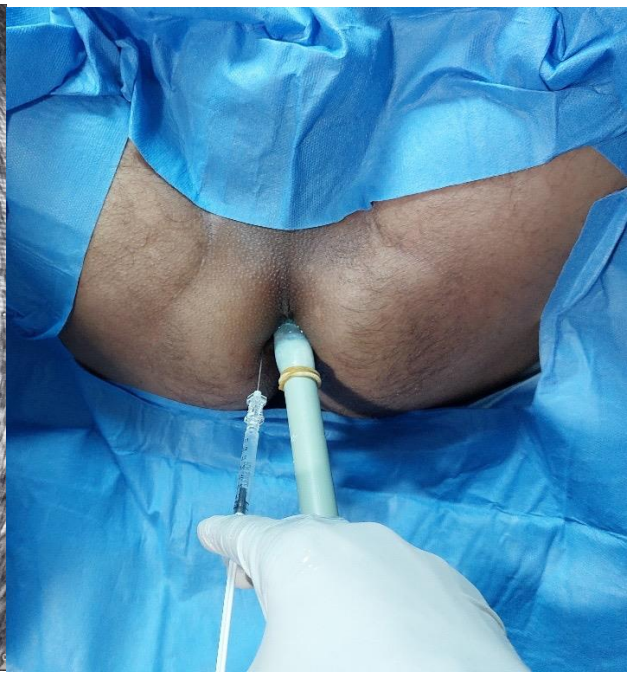

Fig 2 : U/S guided injection of BTXA

Outcomes

The main goal was to examine how BTXA was administered to individuals with DD, including the route, method of administration, dosage, and frequency.

Evaluation of the treatment's rate of adverse events, short- and long-term efficacy, and overall effectiveness were the secondary goals.

Follow-up will be conducted after 1, 3 & 6 months

The patient filled out a symptom questionnaire using the Longo score for constipation & potential complaint at each session. The severity of the straining, anorectal pain, the frequency of bowel movements each week, and any adverse effects will be noted. At 1, 3, and 6 months, anorectal manometry with a balloon expulsion test and echodefecography will be carried out. There will always be a clinical review. Our objectives are to achieve anal sphincter manometric relaxation and effective ejection of a 50-ml water-filled rectal balloon.

Statistical analysis

The sample size of 1- β =0.80 (80%) for the spearman's correlation at level α =0.05 (5%), under these assumptions, amounts to 50 (G*power, version 3.1).

The collected data and results will be tabulated in suitable figures. Quantitative data will be summarized using mean and Standard Deviation while qualitative data will be summarized using frequency and percentage. Data will be analyzed by the aid of software package of SPSS using suitable statistical tests (Version 25). P value less than 0.05 were considered statistically significant.

Results

The current study included 50 with the mean age of 36.6±11.9 presented with Anismus for a mean duration of 6.8±2.64. Other sociodemographic data are illustrated in Table 2

Table 2 demonstrated the clinical presentation and the ODS in the studied group where the mean defecation frequency/ week was 2.63±o.while the mean sensation of incomplete evacuation/ week was 1.02±0.97. There was reduction of activity by about 27.23±6.24. Other clinical presentations are shown in table 3

The initial manometric assessment for the included patients showed increased mean Resting pressure and Squeeze Pressure when compared with the normal values to be 89.2 and 211.8 respectively (Table 4). None of the included patients had +ve Balloon expulsion test at the initial Assessment with 0% overall satisfaction.

There was a statistically significant increase in the defecation frequency at 1,3,6 months when compared to the initial values ($p<0.001$*) while there was no statistically significant difference was noticed in the defecation frequency at 3,6 months when compared with the recorded values after 1 month (Table 5). Other symptoms including Straining score, Sensation of incomplete evacuation/week or Rectoperineal pain or discomfort/week showed a statistically significant decrease throughout 1,3,6 months follow-up compared to the initial presentation

There was a statistically significant decrease in the resting and squeeze pressure after 3, 6 months when compared with the initial records ($P <0.001$*) with no significant change between the 3 and 6 months reports (Table 6) and Figure 1. The balloon expulsion test was successful in 68% and 62% of patients at 3 and 6 months none of those patients showed +ve balloon expulsion test at the initial assessment Table 6. The overall satisfaction was significantly increased to be 68% and 64%

after 3 and 6 months respectively when compared to 0% satisfaction reported at the initial assessment Table 6 and Fig 2

Table 2: Sociodemographic data

Variable		N=50
Age (years)	Mean±SD	36.6±11.9 (16–55)
Disease duration (years)	Mean±SD	6.8±2.64
Sex Female Male	 N(%) N(%)	 37(74%) 13(26%)

Table 3: Initial ODS symptoms

Variables		N=50
Defecation frequency/week	Mean±SD	2.63±o.76
Straining score	Mean±SD	0.87±0.21
Sensation of incomplete evacuation/week	Mean±SD	1.02±0.97
Rectoperineal pain or discomfort/week	Mean±SD	1.24±0.82
% of Activity reduction per week	Mean±SD	27.23±6.24
Laxatives use score	Mean±SD	2.89±0.68
Enemas use score	Mean±SD	2.66±1.02
Digitations use score	Mean±SD	1.22±0.29
Time: minutes in lavatory per attempt	Mean±SD	38.23±11.23
Failure: unsuccessful attempts for evacuation/24h	Mean±SD	1.03±0.84

Table 4: Initial manometric assessment, defecography, Longo score and overall satisfaction

	N=50
Variable	
Resting pressure (Normal mean resting pressure is 69 ± 14 mmHg) [13,14]	89.2 ± 12.5
Squeeze Pressure (Normal mean squeeze pressure is 191 ± 64 mmHg) [13.14]	224.8±65.3
Functional length of anal sphincter (cm)	4.76±0.72
Balloon expulsion test success rate	0%
Constipation score	13.64±2.37
Positive defecography	78%
Overall satisfaction	0%

Table 5: Comparison between the initial ODS symptoms and 1,3,6, months after Botox injection

	initial	Post 1 month	Post 3 months	Post 6 months	P value					
					Initial Vs Post 1 month	Initial Vs Post 3 months	Initial Vs Post 6 months	Post 1m vs post 3 m	Post 1m vs post 6 m	Post 3m vs post 6m
Defecation frequency/week	2.63±o.76	5.22±1.05	5.02±0.86	4.67±0.54	<0.001*	<0.001*	<0.001*	0.45	0.49	0.78

Straining score	0.87±0.21	0.38±0.19	0.41±0.26	0.51±0.27	<0.001*	<0.001*	<0.001*	0.62	0.67	0.72
Sensation of incomplete evacuation/week	1.02±0.97	0.65±0.32	0.63±0.26	0.74±0.25	<0.001*	<0.001*	<0.001*	0.37	0.29	0.93
Rectoperineal pain or discomfort/week	1.24±0.82	0.89±0.32	0.83±0.41	0.95±0.34	<0.001*	<0.001*	<0.001*	0.06	0.16	0.88
% of Activity reduction per week	27.23±6.24	17.45±3.87	17.65±4.01	18.94±3.21	<0.001*	<0.001*	<0.001*	0.19	0.34	0.12
Laxatives use score	2.89±0.68	1.75±0.42	1.76±0.47	1.91±3.65	<0.001*	<0.001*	<0.001*	0.54	0.29	0.66
Enemas use score	2.66±1.02	1.68±0.76	1.71±0.68	1.82±0.78	<0.001*	<0.001*	<0.001*	0.07	0.09	0.27
Digitations use score	1.22±0.29	0.85±0.12	0.87±0.19	0.92±0.16	<0.001*	<0.001*	<0.001*	0.82	0.92	0.28
Time: minutes in lavatory	11.23±6.23	4.98±2.24	4.86±2.66	5.02±2.56	<0.001*	<0.001*	<0.001*	0.18	0.22	0.59

per attempt										
Failure: unsuccessful attempts for evacuation/24h	1.03±0.84	0.67±0.49	0.65±0.51	0.72±0.53	<0.001*	<0.001*	<0.001*	0.75	0.23	0.81

Table 6 comparison between the initial manometric assessment, defecography, Longo score and overall satisfaction and 3, 6 months post Botox injection .

Variable	Initial	Post 3 months	Post 6 months	P value		
				Initial Vs Post 3 months	Initial Vs Post 6 months	Post 3m vs post 6m
Resting pressure	96.2 ± 12.5	63.26±11.53	69.21±12.23	<0.001*	<0.001*	0.092
Squeeze Pressure	224.8±65.3	192.2±54.6	196.7±57.6	<0.001*	<0.001*	0.16
Functional length of anal sphincter (cm)	4.76±0.72	3.56±0.46	3.64±0.49	<0.001*	<0.001*	0.056
Balloon expulsion test success rate	0%	68%	62%	<0.001*	<0.001*	0.082

Constipation score	13.64±2.37	7.98±2.61	8.22±2.54	<0.001*	<0.001*	0.32
Positive defecography	78%	58%	60%	<0.001*	<0.001*	0.89
Overall satisfaction	0%	68%	64%	<0.001*	<0.001*	0.72

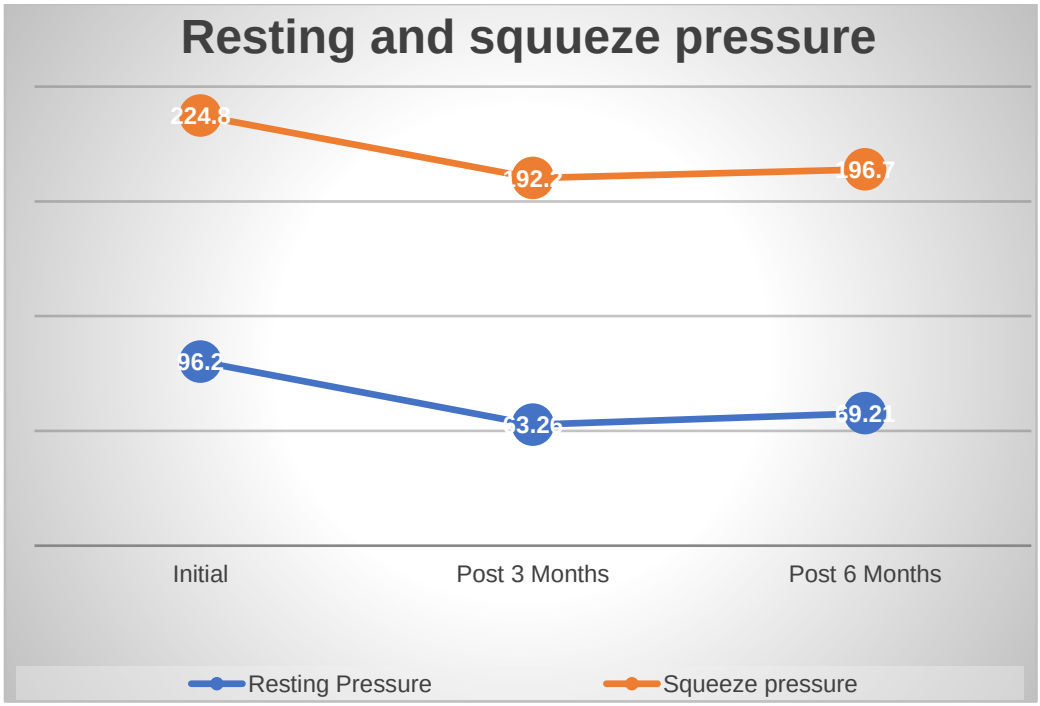

Figure 3: Manometric findings after 3 and 6 Months.

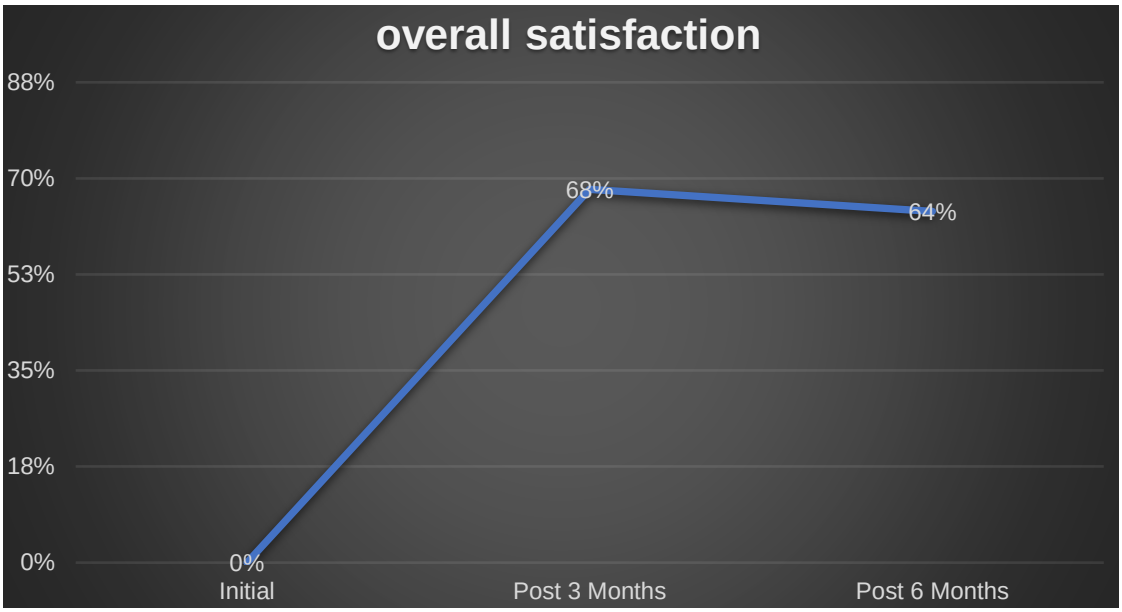

Figure4: Overall patient Satisfaction.

Discussion

The vast majority of patients who experienced constipation had issues with outlet obstruction. Although the cause and frequency of anismus is unknown, it is assumed to be the most likely common cause of OD. Biofeedback treatment generally resulted in higher patient satisfaction among anismus patients[15].

Few anismus patients respond to a regular course of biofeedback training because the pelvic floor muscles cannot be relaxed, a necessary condition for optimal function. Numerous surgical and pharmacological procedures have been used to treat the pressure caused by the spastic puborectalis and anal sphincter[16,17].

According to experts, there is currently no therapy method that has been shown effective for treating anismus. Although surgical attempts to weaken or expand the puborectalis muscle typically fail[18], direct injections of botulinum toxin into the puborectalis muscle have shown encouraging results[12]. Biofeedback training has been found to be an effective treatment for persons with anismus, with efficacy rates varied from 9% to 100%[19].

Direct injection of BTX-A into the puborectalis muscle was documented by Hallan et al. [9]. By inhibiting the release of acetylcholine at the presynaptic area, the neurotoxic BTX-A paralyses muscles[8,10]. The use of injections of BTX-A, which are less expensive and technically simpler than BFB retraining, has shown promise in the treatment of anismus[20]. Contrary to BFB, BTX-A injection is not dependent on the patient's participation or compliance, which are essentially subjective. The BTX-A injectable therapy was deemed successful in terms of short-term symptomatic relief of anismus because the effect of BTX-A is transient and lasts for around three months after delivery. Repeated injections are required for longer-term improvement in order to maintain the achieved clinical improvement[21].

The identification of the injection site and dosage distribution to the proper muscle were made easier by ultrasonography guidance during the injection. By inhibiting presynaptic acetylcholine release and lowering resistance during evacuation, BTX-A instantaneously paralyzed muscles. However, patients with anismus also have a lack of concordance during defecation in addition to puborectalis and external sphincter spasm. Following biofeedback training aims to enhance the puborectalis and external sphincter's motor coordination, which has a long-lasting effect. Several authors have stated that botulinum toxin appears to be a promising treatment for anismus patients[20,21].

In the current study, there was a statistically significant improvement of the clinical symptoms including Defecation frequency/week, Straining score, Sensation of incomplete evacuation/week, and Rectoperineal pain or discomfort/week and the maximum improvement was obtained after 1 month this improvement was slightly decreased after 3 and 6 months respectively but it was not significant

and this matched the results of Emile SH et al (10) who reported a median % of patients who reported initial improvement of symptoms was 77.4% and this declined to a median of 46% (at 4 months after injection of BTX-A and this is assumed to the decrease of spasticity of the puborectalis that was clearly detected by the decrease of both resting and squeeze pressure similar to what was reported by Farid M et al (17) who reported manometric relaxation in 70.83% of patients following botulinum toxin injection, on the contrary, Ron V etal (21) reported only 28.5% manometric relaxation

two studies[12,20] reported a significant decrease in the mean resting and squeeze anal pressures 3 months after injection.

+ve balloon expulsion was reported in many studies[12,17,21,22], with a median rate of 74.6% ranging from 37.5%-80% matching the results of the current study where 68% of patients showed successful balloon expulsion test and this is assumed to be due to relaxation of puborectalis following injection of BTX-A

In the current study a statistically significant improvement signs of anismus in the post-injection defecogram matching the results of several studies [17,18,22,23] that reported improvement of 25%-86.6% of patients in the post-injection defecogram.

The primary criterion for determining if a treatment plan was successful is patient satisfaction. Due to its brief medical efficacy, BTX-A was viewed as a temporary therapy for anismus. According to our research, BTX-A injection and pelvic floor biofeedback training are more effective ways to cure anismus because of its long-lasting effects. Compared to BTX-A or biofeedback training alone, it is a safer and more efficient treatment technique for intractable anismus and this is similar to what was reported by Zhang Y etal [12] and this can be simply explained by the significant improvement of the symptoms of Anismus.

Conclusion: According to the current results, Injection of Botulinum Toxin Type-A Therapy in Puborectalis Muscle in Patients with Anismus is assumed to be effective for short term with good overall satisfaction

Recommendations: Further studies should be conducted to determine the long term effect of Botulinum Toxin Type-A Therapy

Conflicts of interest: NIL

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