

Unilateral Botox injection, tailored Sphincterotomy in treatment of Chronic Anal Fissure :A Randomized comparative trial

Original
Article

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ABSTRACT

Background: Anal fissures, longitudinal tears in the anal canal, can become chronic if unhealed after 8–12 weeks. Treatment options for chronic fissures include Botulinum toxin (Botox) injections and tailored lateral internal sphincterotomy (LIS).

Objective: This study aimed to compare the effectiveness and safety of unilateral Botox injection versus tailored LIS for treating chronic anal fissures.

Patients and Methods: A single-blinded, randomized, controlled trial was conducted on patients with chronic anal fissure at Mansoura University Hospital from September 2021 to February 2023. Patients were randomly assigned to receive either unilateral Botox injection (group A, n=35) or tailored LIS (group B, n=35). Pre- and postoperative assessments included clinical examination, manometry, and evaluation of incontinence and recurrence rates.

Results: The mean operative time was significantly longer in group B (11.46±1.82 min) compared with group A (6.11±1.59 min, $P<0.001$). Wound healing was faster in group A (5.43±1.70 days) versus group B (10.83±2.20 days, $P<0.001$). Recurrence rates were lower in group B (22.9%) compared with group A (42.9%, $P=0.075$). Incontinence to flatus was lower in group B (22.9%) than in group A (40%, $P=0.122$). Incontinence to solid stool was absent in group B but present in 11.4% of group A ($P=0.039$).

Conclusion: Tailored lateral internal sphincterotomy showed superior long-term outcomes in recurrence and incontinence compared with unilateral Botox injection. Despite a longer healing period, tailored LIS should be preferred for managing chronic anal fissures.

Key Words: Anal fissure, anal incontinence, Botox injection, chronic anal fissure treatment, tailored lateral sphincterotomy.

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INTRODUCTION

An anal fissure is typically defined as a longitudinal tear in the anal canal, extending from the dentate line to the anal verge. Despite being a prevalent benign anorectal condition, population-level incidence data are scarcely available^[1,2].

The occurrence of anal fissures varies significantly by age and sex, with constipation, obesity, and hypothyroidism being common comorbidities. Although topical treatments are frequently prescribed, many patients do not follow through with these prescriptions. Surgical options, such as botulinum toxin (Botox) injections and lateral internal sphincterotomy, are less commonly utilized^[3,4].

Botox injections offer an effective nonsurgical alternative for treating uncomplicated idiopathic anal fissures, showing an 89% success rate in patients with chronic fissures^[5]. However, minor incontinence, like fecal soiling, was observed in two patients but resolved subsequently^[6].

Tailored lateral sphincterotomy is both safe and effective, preserving more of the anal sphincter. While a controlled trial comparing this technique to standard incision methods with pre and postprocedure manometry could provide more insights, the significant reduction in incontinence rates already supports the tailored approach^[7].

This study aimed to compare the effectiveness and safety of unilateral Botox injection versus tailored LIS for treating chronic anal fissures.

PATIENTS AND METHODS:

Trial design

This trial was designed as a single-blinded, controlled, and randomized study to ensure objective and reliable results.

Trial population

The trial included patients presenting with chronic anal fissure. These patients were admitted to the Colorectal Surgery Unit and Department 8th General Surgery at Mansoura University Hospital from September 2021 to February 2023.

Inclusion criteria

Patients aged between 18 and 65 years of both genders, with midline posterior and anterior chronic anal fissures and symptoms lasting 2 months or longer were included in the study.

Exclusion criteria

Patients were excluded if they were younger than 18 or older than 65 years, had symptoms for less than 2 months, had associated anal pathologies such as malignancies and piles, had inflammatory bowel disease, had a history of any anal surgery, or had lateral anal fissures.

Preoperative assessment

History taking

A comprehensive history was taken to identify causes of the anal fissure, risk factors contributing to its formation, comorbidities, past medical history, any previous surgical procedures in the perianal region, previous management attempts, family history of anal fissures, and any acute anal fissure episodes and the treatments prescribed for them.

Clinical examination

A thorough clinical examination was performed to detect any major organ disorders, psychological disorders, or malignancies. The perianal region was examined to assess the site, extent, and type of anal fissure, as well as to detect any perianal disorders such as suppuration or fistulas.

Investigation

Routine investigations were conducted to ensure anesthetic fitness, including complete blood count, liver function tests, renal function tests, coagulation profile, virology, and blood grouping. Additional investigations were performed based on the patient's medical history, such as random blood glucose and HbA1c for diabetic patients, and echocardiography for cardiac patients or those above 60 years old. Manometry was conducted to detect resting and squeezing pressures and the rectoanal inhibitory reflex pre and postoperatively to assess anal continence outcomes.

The procedures

Unilateral Botox injection

Botox is typically injected either bilaterally at the 3 and 9 o'clock positions, unilaterally at 3 or 9 o'clock, or three sites (3, 9, and 12 o'clock), with a total of 30 units administered. This procedure was performed under spinal anesthesia with the patient in the lithotomy position.

Method of reconstitution of Botox vial

Each Botox vial (Allergan type) containing 100 units of powdered Botox was reconstituted with 3 ml of normal sterilized saline (0.9%). This solution yielded ~30 units per 1 ml, which was the required amount for each injection. The solution was drawn into a 100-unit insulin syringe for precise administration (Fig. 1).



Fig. 1: Vial of Botox 100 Units Allergan Type A.

Preparation and positioning

Patients were prepared for the procedure with colorectal preparation, including clear fluids and enemas. They were positioned in the lithotomy position under spinal anesthesia.

Sterilization of field

The surgical field was sterilized with a betadine solution, and sterilized towels were used to cover unsterilized areas.

Steps of the procedure (Fig. 2)

(a) A thorough examination under anesthesia and per-rectal examination was conducted to identify any abnormalities.

(b) An anal retractor or proctoscope was inserted to inspect the anal canal and dentate line for abnormalities such as skin tags, which were excised if present.

(c) The proctoscope was removed, and the internal anal sphincter (IAS) was palpated with the thumb outside the anal canal and the index finger inside the canal.

(d) The prepared 30 units of Botox were injected into the IAS unilaterally at the 3 o'clock position using an insulin syringe.

(e) A gauze dressing was applied to the injection site without postoperative anal packing.

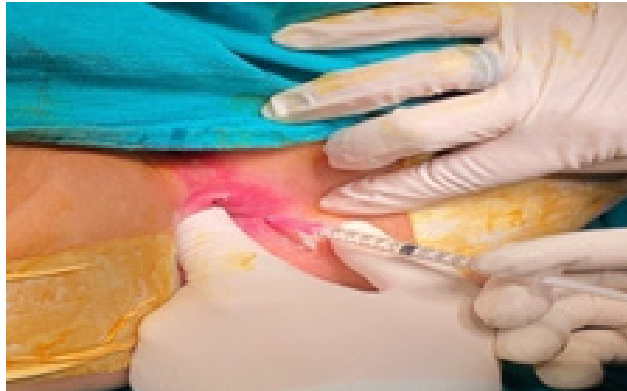


Fig. 2: Unilateral injection of botox in internal anal sphincter at 3 o'clock.

Tailored lateral internal sphincterotomy

The tailored lateral internal sphincterotomy was performed under spinal anesthesia with the patient in the lithotomy position.

Preparation and positioning

Patients were prepared for the procedure with colorectal preparation, which included the administration of clear fluids and enemas. They were then placed in the lithotomy position under spinal anesthesia.

Sterilization of field

The surgical field was sterilized using a betadine solution, and sterilized towels were used to cover unsterilized areas to maintain sterility.

Steps of the procedure

(a) Examination: An examination under anesthesia and per-rectal examination were initially performed to identify any abnormalities.

(b) Inspection: An anal retractor or proctoscope was inserted to inspect the anal canal and dentate line for any abnormalities, such as skin tags, which were excised if present.

(c) Palpation: The proctoscope was removed, and the IAS was palpated with the thumb outside the anal canal and index fingers inside the canal (Fig. 3).

(d) Incision: A small perianal incision was made beside the anus using a scalpel, followed by the dissection of the IAS.

(e) Sphincterotomy: A small part or length of the IAS below the dentate line was divided. This procedure is referred to as tailored or minimal sphincterotomy, as it involves dividing only a part of the internal sphincter, unlike previous procedures that divided the entire length.

(f) Hemostasis and Dressing: Surgical hemostasis was meticulously performed to prevent bleeding. Finally, a gauze dressing was applied over the wound, and anal packing was placed postoperatively to ensure proper healing.



Fig. 3: Cutting part of internal anal sphincter (Tailored Sphincterotomy) by using a monopolar diathermy.

Follow-Up

Patients were followed up in the outpatient clinic postoperatively at the 1st week, 4th week, 12th week, and 24th week. During these visits, patients were assessed clinically for the healing of the perianal wound, recurrence of the fissure, and incontinence to stool or flatus. Additionally, postoperative manometry was conducted to evaluate continence to stool and flatus. The tailored lateral sphincterotomy was associated with a lower rate of incontinence.

Outcome measures

The primary outcome measures of this trial were the differences between the two techniques in terms of fecal incontinence and recurrence rates. Secondary outcome measures included operation time, hospital stay duration, and any postoperative complications.

Ethical considerations

The study was done after being accepted by the Research Ethics Committee, Mansoura University (Approval no: MS.21.08.1606). All patients provided written informed consent before their enrolment. The consent form explicitly outlined their agreement to participate in the study and for the publication of data, ensuring protection of their

confidentiality and privacy. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

Statistical analysis was performed using IBM SPSS version 27 (Chicago, USA) for Windows. Qualitative data were displayed in frequency tables showing numbers and percentages. Quantitative data were first tested for normality using the Shapiro–Wilk test. Normally distributed data were summarized as mean±standard deviation (SD), while non-normally distributed data were presented as median (minimum–maximum) and interquartile range (IQR).

RESULTS:

This table show the mean operative time by (min) in both techniques, in group A 6.11±1.59 and group B 11.46±1.82, with *P* value <0.001 (Table 1).

This table describe time of wound healing in two groups by (days), in group A 5.43±1.70, and group B 10.83±2.20, with a *P* value <0.001 (Table 2).

This table show pain score in two groups, from previous statistics pain feeling was more obvious in group B than A at 6 h after procedure, then by time and with close follow-up, we found that no significant difference between two groups as follow: Pain score at 1 month in group A 2 (0–3) but in group B 2 (1–6), with *P* value less than 0.001 (Table 3).

This table summarizes the key complications observed in the trial. The recurrence rate in group B was eight (22.9%), lower than the 15 (42.9%) in group A, with a *P* value of less than 0.075. The incidence of incontinence to flatus was also lower in group B (8, 22.9%) compared with group A (14, 40%), with a *P* value of 0.122. Similarly, the percentage of nocturnal soiling and incontinence to liquid stool was 11 (31.4%) in group B and 14 (40%) in group A, with a *P* value of 0.545. Notably, there were no cases of solid stool incontinence in group B, whereas group A had 4 (11.4%) cases, with a *P* value of 0.039 (Table 4).

Preoperative resting pressure in group A 98.71±9.95, group B 85.14±10.95 with *P* value less than 0.001, Postoperative resting pressure in group A 86±10.56, group B 66.86±11.12 with *P* value less than 0.001, Percent of change in group 12.5 (-5.88:30.43), group B 18.75 (6.25:50) with *P* value less than 0.001, So we found that percent of change in group B is more than group A but still within normal range (Table 5).

We also compared the pre and postoperative squeezing pressures in both groups. The preoperative squeezing pressure was 115±14.25 in group A and 105.14±18.6 in group B, with a *P* value of 0.015. Postoperative squeezing pressure was 95.14±13.64 in group A and 87.29±16.10 in group B, with a *P* value of 0.031. The percent change in squeezing pressure was 13.64 (4.55:33.33) in group A and 15 (4.55:27.78) in group B, with a *P* value of 0.676 (Table 6).

Table 1: Operative time in the two study groups

Items	Group A (Botox injection) (n=35)	Group B (lateral internal sphincterotomy) (n=35)	Test of significance
Operative time (min)	6.11±1.59	11.46±1.82	t=-13.091 P<0.001*

Table 2: Time of wound healing in the two study groups

Items	Group A (Botox injection) (n=35)	Group B (lateral internal sphincterotomy) (n=35)	Test of significance
Time of wound healing (days)	5.43±1.70	10.83±2.20	t=-11.222 P<0.001*

Table 3: Follow-up of pain scores in the two study groups

Items	Group A (Botox injection) (n=35)	Group B (lateral internal sphincterotomy) (n=35)	Test of significance
Pain score at 6 h	7 (3–9)	8 (5–9)	z=-4.096 P<0.001*
Pain score at 12 h	5 (2–7)	7 (3–9)	z=-4.834 P<0.001*
Pain score at 24 h	4 (1–6)	5 (3–8)	z=-4.283 P<0.001*
Pain score at 1 week	2 (0–5)	4 (1–6)	z=-3.266 P=0.001*
Pain score at 1 month	2 (0–3)	2 (1–6)	z=-4.988 P<0.001*

Table 4: Analysis of complications in the two study groups

Items	Group A (Botox injection) (N=35) [n (%)]	Group B (lateral internal sphincterotomy) (N=35) [n (%)]	Test of significance
Recurrence	15 (42.9)	8 (22.9)	$\chi^2=3.173$ $P=0.075$
Incontinent to flatus	14 (40)	8 (22.9)	$\chi^2=2.386$ $P=0.122$
Nocturnal perineal (underwears) soiling	14 (40)	11 (31.4)	$\chi^2=0.560$ $P=0.545$
Incontinent to liquid stool	14 (40)	11 (31.4)	$\chi^2=0.560$ $P=0.545$
Incontinent to solid stool	4 (11.4)	0	FET=4.242 $P=0.039^*$

Table 5: Analysis of preoperative and postoperative resting pressure in the two study groups

Items	Group A (Botox injection) (n=35)	Group B (lateral internal sphincterotomy) (n=35)	Test of significance
Preoperative resting pressure	98.71±9.95	85.14±10.95	t=5.427 $P<0.001^*$
Postoperative resting pressure	86±10.56	66.86±11.12	t=7.368 $P<0.001^*$
Percent of change	12.5 (-5.88:30.43)	18.75 (6.25:50)	z=-3.437 $P=0.001^*$
P1	<0.001*	<0.001*	

Table 6: Analysis of preoperative and postoperative squeezing pressure in the two study groups

Items	Group A (Botox injection) (n=35)	Group B (lateral internal sphincterotomy) (n=35)	Test of significance
Preoperative squeezing pressure	115±14.25	105.14±18.6	t=2.488 $P=0.015^*$
Postoperative squeezing pressure	95.14±13.64	87.29±16.10	t=2.203 $P=0.031^*$
Percent of change	13.64 (4.55:33.33)	15 (4.55:27.78)	z=-0.417 $P=0.676$
P1	<0.001*	<0.001*	

DISCUSSION

Recently, the most popular techniques for treating anal fissures are Botox injections and sphincterotomy^[5,8]. Botox injection is an effective alternative to surgery for uncomplicated idiopathic anal fissures^[9]. Surgery should be offered to patients who do not improve with Botox injections and to those with complicated anal fissures^[6].

Currently, LIS is a common surgical method for treating chronic anal fissures. In the studies by Arroyo *et al.*, after LIS, minor incontinence was found in 5% of patients, healing occurred in 93–100% of patients, recurrence occurred in 0–25% of patients, and incontinence occurred in 0–38% of patients^[10]. No recurrence rates were reported in studies related to Botox injections, although one study reported that 30% of patients had nonhealing fissures but with symptomatic improvement^[11]. LIS has shown the best healing rates with low recurrence rates (6.7%). Both open and closed techniques are described in the literature, with similar rates of efficacy^[12].

In our trial, we noticed that the recurrence rate in group B (8, 22.9%) is less than in group A (15, 42.9%), with a *P value* of less than 0.075, which is statistically significant and correlates with most previous trials and

studies showing that sphincterotomy is better in the long term than Botox injections. The incontinence rate reported in one study of Botox injections was 18%, with no permanent incontinence occurring^[11]. The overall incontinence rates (early and late incontinence) for LIS range from 3.3 to 16%, with the incontinence rate beyond 2 months ranging from 3 to 7%^[26].

In our trial, we found that the percentage of incontinence to flatus in group B (8, 22.9%) is less than in group A (14, 40%), with a *P value* of 0.122. The percentage of both nocturnal soiling and incontinence to liquid stool in group B (11, 31.4%) is less than in group A (14, 40%), with a *P value* of 0.545. At the end of the study, we found no cases of solid stool incontinence in Group B, but in Group A, the percentage is four (11.4%), with a *P value* of 0.039.

Limitations of the present trial include it being a single-center trial with a small number of patients in each group. The short follow-up period of patients is another limitation; hence, longer follow-up is needed to ascertain the positive preliminary results of the trial.

CONCLUSION

Tailored (limited) internal sphincterotomy was superior to unilateral Botox injection concerning the recurrence

of anal fissures and incontinence to flatus and stool in the long-term follow-up. Postoperative complications, including operative time, pain, and wound healing time, were comparable in both groups.

Recommendation

Although time-consuming, tailored (limited or minimal) sphincterotomy is preferred for reducing the recurrence of anal fissures and anal incontinence to flatus and solid stool in the long term.

CONFLICT OF INTEREST

There are no conflicts of interest.

REFERENCES

1. Rakinic J. Anal fissure. *Clin Colon Rectal Surg* 2007; 20:133–137.
2. Stewart D, Gaertner W, Glasgow S, *et al.* Clinical Practice Guideline for the Management of Anal Fissures. *Dis Colon Rectum* 2017; 60:7–14.
3. Mapel DW, Schum M, Von Worley A. The epidemiology and treatment of anal fissures in a population-based cohort. *BMC Gastroenterol* 2014; 14:129.
4. Gallo G, Pegoraro V, Trompetto M. Description and management of patients with anal fissure: insights on Italian primary care setting coming from real-world data. *Updates Surg* 2024; 26:10–17.
5. Brisinda G, Chiarello M, Crocco A, *et al.* Botulinum toxin injection for the treatment of chronic anal fissure: uni- and multivariate analysis of the factors that promote healing. *Int J Colorectal Dis* 2022; 37:693–700.
6. Radwan M, Ramdan K, Abu-Azab I, *et al.* Botulinum toxin treatment for anal fissure. *Afr Health Sci* 2007; 7:14–17.
7. Littlejohn D, Newstead G. Tailored lateral sphincterotomy for anal fissure. *Dis Colon Rectum* 1997; 40:1439–1442.
8. Safiyeva K. Results of botox treatment in anal fissures (Our experience); Central Customs Hospital. *Egypt J Surg* 2023; 42:598–602.
9. Brisinda G, Maria G, Sganga G, *et al.* Effectiveness of higher doses of botulinum toxin to induce healing in patients with chronic anal fissures. *Surgery* 2002; 131:179–184.
10. Arroyo A, Pérez F, Serrano P, *et al.* Surgical versus chemical (botulinum toxin) sphincterotomy for chronic anal fissure: long-term results of a prospective randomized clinical and manometric study. *Am J Surg* 2005; 189:429–434.
11. Lindsey I, Jones O, Cunningham C, *et al.* Botulinum toxin as second-line therapy for chronic anal fissure failing 0.2 percent glyceryl trinitrate. *Dis Colon Rectum* 2003; 46:361–366.
12. Abe T, Kunimoto M, Hachiro Y, *et al.* Long-term Efficacy and Safety of Controlled Manual Anal Dilatation in the Treatment of Chronic Anal Fissures: A Single-center Observational Study. *J Anus Rectum Colon* 2023; 7:250–257.