Botulinum Toxin Injection versus Lateral Internal Sphincterotomy in Management of Chronic Anal Fissure

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Introduction: Anal fissure (AF) is a longitudinal break in the anal mucosa that extends from the anal margin to the dentate line. The internal anal sphincter seldom relaxes on its own, and patients usually have a high resting anal sphincter pressure. For chronic anal fissures, lateral internal sphincterotomy has been the gold standard plan of care. Botulinum toxin injections intrasphincterically appear to be a dependable method for temporarily reducing sphincter spasm and promoting healing of the fissure.

Aim of work: This study aimed to evaluate the duration of surgery, length of hospital stay, and postoperative complications between lateral internal sphincterotomy (LIS) and botulinum toxin (BT) in the treatment of chronic anal fissure (CAF).

Patients and methods: 82 patients with a CAF who were admited to the Menoufia University Hospital's Surgical Department for treatment between January 2024 and March 2025 participated in this prospective randomized clinical research. 82 patients were divided into two groups: Group 1 (n=41): underwent intrasphincteric BT injection (BT group). Group 2 (n=41): underwent a conservative LIS (LIS group).

Results: While incontinence was substantially lower in group I (Botox group) (P=0.042) than in group II (LIS group), bleeding and urine retention were significantly greater in group II (LIS group) than in group I (Botox group) (P=0.021, 0.048). The incidence of constipation and stenosis varied insignificantly between the two groups.

Conclusion: BT injection and LIS are both effective treatment options for CAF. BT injection patients had shorter operative times and hospital stays compared to LIS, making it a less invasive option with quicker recovery. Additionally, pain relief occurred earlier and was more pronounced in the BT group.

Key words: Botulinum toxin injection, lateral internal sphincterotomy, chronic anal fissure.

Introduction

Anal fissure (AF) is a longitudinal break in the anal mucosa that extends from the anal margin to the dentate line. Acute fissures are distinguished from chronic ones, as the latter last more than eight weeks.[1]

The pathogenesis is still not fully understood, although it is becoming more and more clear that localized ischemia enhanced by internal anal sphincter (IAS) hypertonicity plays a role in the process. The finding that 85% of AFs occur in the posterior midline, a region with weak vascular anastomotic network, stands up for this theory. This hypertonicity–ischemia loop has been broken by therapeutic alternatives.[2]

According to a number of worldwide standards, the initial step in treating chronic anal fissures (CAF) is advised to be a medical therapy trial.[3]

Eisenhammer originally suggested internal anal sphincterotomy in 1951, and it was subsequently changed to lateral internal sphincterotomy (LIS). With recovery rates ranging from 88 to 100%, it is still the gold standard surgical method today.[4]

In the early 1990s, intrasphincteric treatment of botulinum toxin (BT) for CAF became a common sphincter-sparing option. By preventing acetylcholine from being released at the presynaptic terminal, BT encourages sphincter complex relaxation and permits fissure healing.[3]

This study aimed to compare BT vs LIS in management of CAF as regards the operation time, hospitalization and postoperative complication.

Patients and methods

This was a prospective randomized study which included 82 patients with CAF who received treatment at Surgical Department at Menoufia University Hospital from junuary 2024 to March 2025. Patients fulfilled an informed written consent. Approval from the Ethics Committee of the Faculty of Medicine, Menoufia University Hospital was obtained before starting the study (Approval code: 3/2024 SURG1).

Inclusion criteria were patients aged 18-80 years, had CAF and tried medical treatment for 8 weeks with no improvement.

Exclusion criteria included atypical fissures including those that were off midline, or fissures due to an underlying systemic illness such as inflammatory bowel disease, immunosuppressive diseases or cancer, more than one fissure, history of previous anal surgery, and patients refusing sphincterotomy.

82 patients were divided into two groups:

Group 1 (n=41): Underwent intrasphincteric BT injection (BT group).

Group 2 (n=41): Underwent a conservative LIS (LIS group).

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Complete history was taken from every patient: This included demographic details (Age, sex, and occupation), medical history included pertinent comorbidities like hypertension, diabetes mellitus, chronic obstructive pulmonary disease, coronary disease and heart failure. Family history was also taken past medical history or hospitalization history. Physical examination included general and local examination, anorectal manometry to assess resting pressure and sqeeze pressure. Routine laboratory tests (Complete blood count, blood coagulation function, renal function tests, liver function tests, and random blood sugar), imaging (Including chest x-ray and colonoscopy, were done for suspected cases. Bowl preparation (Including enema the day before surgery, prophylactic antibiotics, and liquid for three days prior to surgery) was performed.

The visual analog scale (VAS)

Hayes and Patterson introduced the visual analog scale (VAS), a pain assessment measure, in 1921. A single handwritten mark is placed at one point along a 10-cm line that represents a continuum between the two ends of the scale, with "no pain" at the left end (0 cm) and the "worst pain" at the right end (10 cm). Scores are based on self-reported measures of symptoms.[5]

Operative technique

Group I (Botulinum toxin injection (BT group)):

The patients received spinal anesthesia, only selected cases had general anesthesia if needed for example failed spinal anesthesia and put in lithotomy position, PR examination was done for all patients with dilatation of sphincter, and proctoscope were used if needed.

Then patient was injected with BTX type A (Botox, Allergen). An insulin syringe and a (26 G) needle were used for injection. After dilution in 1ml isotonic saline a total dose of 10–20 U was injected on both sides of the anus at 3 and 9 o'clock in the internal anal sphincter. **(Fig. 1).**

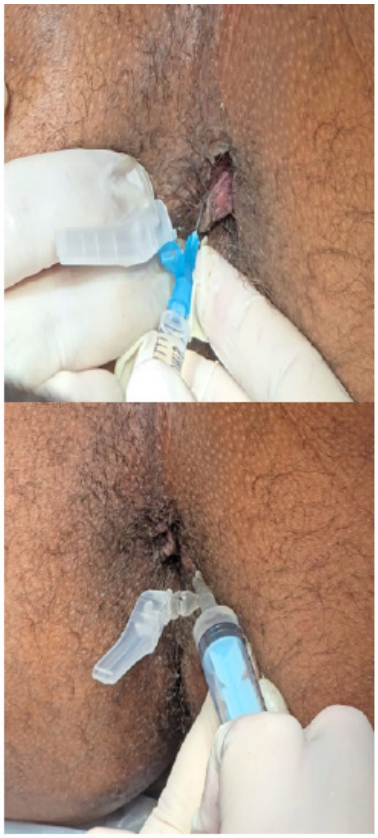

Fig 1: Botulinum toxin injection at 3 and 9 o'clock.

Group II (Lateral internal sphincterotomy (LIS) group):

Patients received spinal anesthesia, only selected cases had general anesthesia if needed (For example failed spinal anesthesia) and were put in the lithotomy position. PR examination was done for all patients, and the proctoscope was used if needed.

Patients in this group had open LIS. In the open approach, the internal sphincter muscle fibers were exposed by making a little incision on the left or right side of the anal skin.

Using a knife or thermal cautery, the surgeon cut the internal anal sphincter muscle after lifting it up. By severing the muscle, the anus's pressure was

released, promoting the healing of the fissure. **(Fig. 2).**

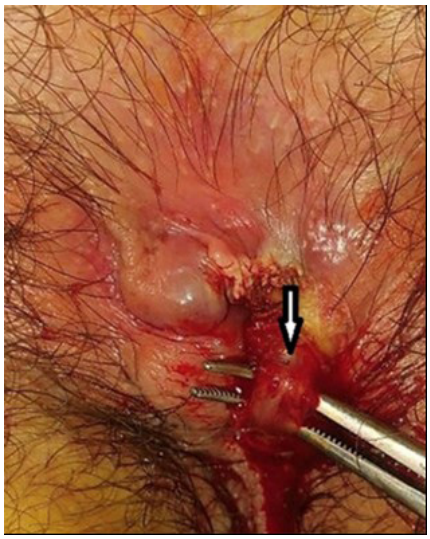

Fig 2: Internal anal sphincter (white arrow).

The patient started liquid diet four hours after the operation and anal dressing was removed eight hours after the operation with application of local anesthetic cream before defecation. In this group, the patients weren't discharged till the next postoperative day with instructed high residue diet and good analgesics.

Postoperative follow-up: All patients were prescriped stool softener and advised postoperative Sitz baths for three weeks to reduce pain, bleeding, and infection and to avoid constipation. The patients in group I were discharged from the hospital after 6 hours and patients in group II after 24 hours. Outpatient follow-up involved 1day (Specially group I), 3 weeks, 12 weeks, 24 weeks and 1 year after surgery to asses for healing of fissure and post operative compications including short term complications as: hypersensitivity reaction,bleeding, infection, urinary retention and postoperative pain (Evaluated by the visual analog score(VAS)), and long term complications as recurrence, stenosis (With constipation) and incontinence whether to gas, liquid or faeces. Anorectal manometry to assess resting pressure and sqeeze pressure was performed during the 3 weeks, 12 weeks and 1 year postoperative follow-up visits.

Postoperative complications

Short term complications: Hypersensitivity response, hemorrhage, urinary retention and postoperative pain; the pain was scored by VAS after 1 day, 3 months, and 6 months following surgery. There were four VAS scores: patient checked zero if there is no pain, checked one to three if experienced mild pain, checked four to six if moderate pain, and checked seven to ten if experienced shocking pain. Pain lasting longer than three months were deemed chronic (Zayed & Essa, 2020).

Long term complications: The presence of anal fissure discovered during follow-up period, with or without the brief improvement of symptoms after the original surgery, was referred to as recurrence. Incontinence was defined as the loss of voluntary control of defecation process whether to gas, liquid, or feces during 6-week postoperative visit. Incontinence that continued at the 12-month follow-up was considered long-term. Incontinence data was examined and scored by the validated Wexner scoring system, whereby solid, liquid and gas incontinence were independently scored on a 5-point grading scale.

Statistical analysis

SPSS v28 was used for the statistical analysis (IBM Inc., Armonk, NY, USA). The two groups were compared using the unpaired Student's t-test, and quantitative data were shown as mean and standard deviation (SD). Repeated measures ANOVA tests were used to assess differences across various time periods or circumstances with the same subjects.

The Chi-square test or Fisher's exact test, as applicable, was used to examine the qualitative variables, which were expressed as frequency and percentage (%). Statistical significance was defined as a two-tailed P value < 0.05.

Results

After assessment, there were 116 eligible patients. 8 patients left the study and 26 patients were excluded according the criteria. Random allocation of the remaining 82 patients into two equal groups (41 patients in each) was done. All patients (82) were analyzed statistically after follow-up. **(Fig. 3).**

The baseline characteristics including age, sex and the symptom duration didn't significantly differ between both groups. **(Table 1).**

Group II (LIS group) had a significantly longer operational duration than group I (Botox group) (P<0.001). Group II (LIS group) had a significantly longer hospital stay than group I (Botox group) (P<0.001). Group I (Botox group) had a much greater cost than group II (LIS group) (P<0.001). Group II (LIS group) returned to everyday work much longer than group I (Botox group) (P<0.001). Group II (LIS group) experienced a considerably greater rate of full healing than group I (Botox group) (87.8% vs. 60.98%, P=0.005). **(Table 2).**

In group I (Botox group), the different measurements recording pain showed a significant difference (P<0.001). Pain significantly decreased at 1 day, 3 months and 6 months compared to preoperative pain (P<0.05), significantly decreased at 3 months

and 6 months compared to 1 day (P<0.001, <0.001) and significantly decreased at 6 months compared to 3 months (P<0.001).

In group II (LIS group) results showed significantly lower pain at 3 months and 6 months compared to preoperative pain (P<0.001, <0.001), with no significant difference between 1 day and preoperative pain. Pain decreased significantly at 3 months and 6 months visits compared to 1 day (P<0.001, <0.001) and decreased significantly at 6 months than that at 3 months (P<0.001).Group I (Botox) experienced considerably less pain at 1 day and 3 months than group II (LIS) (P<0.001, <0.001), although both groups didn't significantly differ at preoperative and 6-month points. **(Table 3).**

There was an insignificant difference between both groups regarding the preoperative and postoperative maximal resting pressure. In both groups, the postoperative maximal resting pressure was significantly lower compared to preoperative maximal resting pressure (P<0.001, <0.001).

The postoperative maximal squeeze pressure was significantly lower in group I (Botox group) compared to group II (LIS group) (P=0.003), and both groups showed no significant difference regarding the preoperative maximal squeeze pressure. In both groups, the postoperative maximal squeeze pressure significantly decreased than preoperative maximal squeeze pressure (P<0.001, <0.001). **(Table 4).**

Group II (LIS group) experienced significantly more short-term problems, such as bleeding and urine retention, than group I (Botox group) (P=0.021, 0.048). Hypersensitivity showed insignificant differentence between both groups (7.32% vs. 0%, P=0.075). Incontinence, recurrence and the incidence of stenosis and constipation were among the long-term consequences. Incontinence was significantly high in group II (LIS group) (P=0.042). The incidence of constipation and stenosis varied insignificantly between the two groups. Group II (LIS group) saw a considerably reduced rate of recurrence than group I (Botox group) (P=0.042). **(Table 5).**

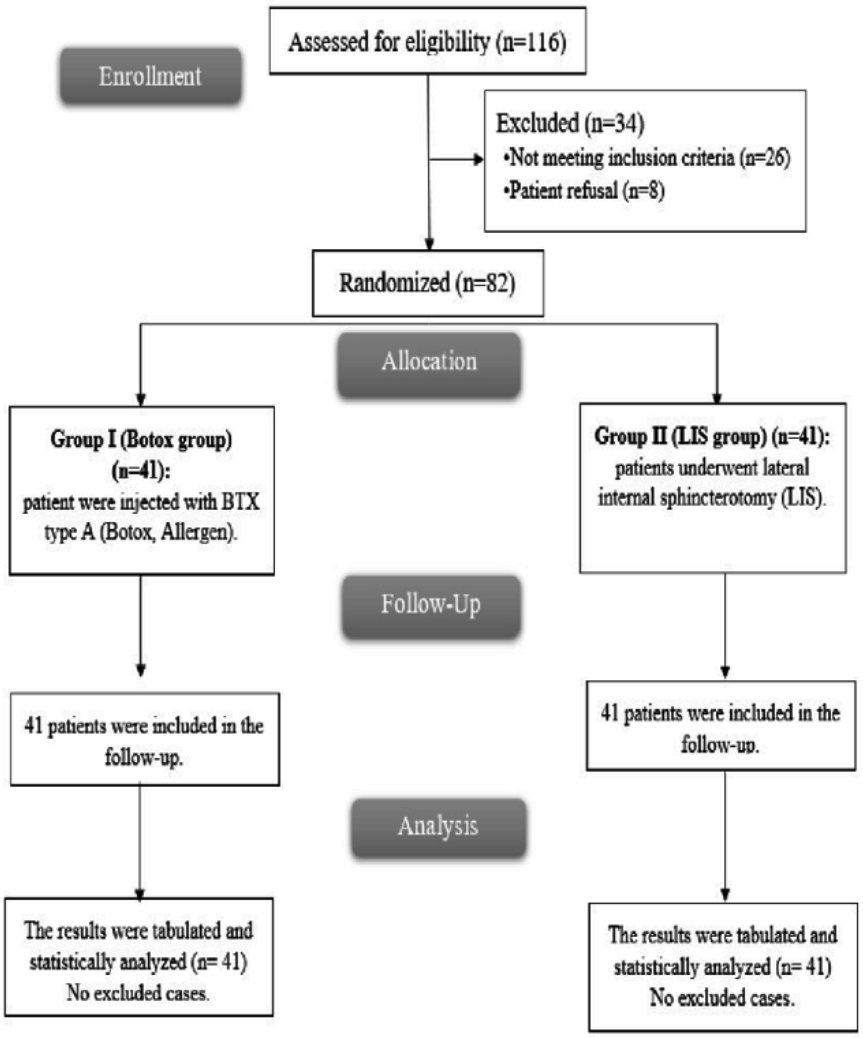

Fig 3: CONSORT flowchart of the enrolled patients.

Table 1: Baseline characteristics and symptom duration of the studied groups

			Group I (Botox group) (n=41)	Group II (LIS group) (n=41)	P value
Baseline characteristics	**Age (years)**		46.32± 12.62	49.44± 14.36	0.299
	Sex	**Male**	15 (36.59%)	19 (46.34%)	0.369
		Female	26 (63.41%)	22 (53.66%)	
Symptom duration (months)			12.17± 3.79	12.07± 4.29	0.913

Data presents as mean ± SD or frequency (%). LIS: lateral internal sphincterotomy, BMI: Body mass index. HTN: Hypertension, DM: Diabetes mellitus, COPD: chronic obstructive pulmonary disease.

Table 2: Operative time, length of hospital stays, cost, return to daily activity and complete healing of the studied groups

	Group I (Botox group) (n=41)	Group II (LIS group) (n=41)	P value
Operative time (min)	30.73± 6.18	50.51± 6.36	<0.001*
Length of hospital stays (hrs.)	9.02± 2.27	21.39± 1.83	<0.001*
Cost	5.53 ± 0.51	4.8 ±0.50	<0.001*
Return to daily activity	4.48 ±0.50	17.46 ±1.73	<0.001*
Complete healing	25 (60.98%)	36 (87.8%)	0.005*

Data presents as mean ± SD or frequency (%). LIS: lateral internal sphincterotomy, *: statistically significant as p value <0.05.

Table 3: Pain in group I (Botox group) and group II (LIS group)

		Pain in group I	Pain in group II	P value
Preoperative		7.12± 1.5	6.88± 1.36	0.44
Postoperative	1 day	4.05± 0.77	6.44± 1.23	<0.001*
	3 months	2.46± 0.95	3.24± 0.89	<0.001*
	6 months	1.39± 1.09	1.46± 1.21	0.75
P value with in group		P1 <0.001*,P2<0.001*, P3<0.001*, P4<0.001*, P5<0.001*,P6<0.001*,	P1 <0.001*, P2<0.001*, P3<0.001*, P4<0.001*, P5<0.001*,P6<0.001*	0.005*

Data presents as mean ± SD or frequency (%). *: statistically significant as p value <0.05. P1: p value of preoperative compared to 1 day, P2: p value of preoperative compared to 3 months, P3: p value of preoperative compared to 6 months. P4: p value of 1 day compared to 3 months e, P5: p value of 1 day compared to 6 months, P6: p value of 3 months compared to 6 months.

Table 4: Maximal resting pressure and maximal squeeze pressure (mmHg) of the studied groups

		Group I (Botox group) (n=41)	Group II (LIS group) (n=41)	P value
Maximal resting pressure	Preoperative	102.59± 14.21	100.39± 12.57	0.461
	Postoperative	84.49± 14.19	82.83± 12.62	0.578
	P value within group	<0.001*	<0.001*	--
Maximal squeeze pressure	Preoperative	98.02± 13.74	109.39± 36.4	0.065
	Postoperative	73.1± 14.24	91.66± 36.07	0.003*
	P value within group	<0.001*	<0.001*	--

LIS: lateral internal sphincterotomy, *: statistically significant as p value <0.053.

Table 5: Outcome of the studied groups

		Group I (Botox group) (n=41)	Group II (LIS group) (n=41)	P value
Short term complications	Bleeding	0 (0%)	5 (12.2%)	0.021*
	Urine retention	1 (2.44%)	6 (14.63%)	0.048*
	Hypersensitivity	3(7.31%)	0(0%)	0.075
Long term complications	Incontinence	2 (4.88%)	8 (19.51%)	0.042*
	Stenosis and constipation	3 (7.32%)	6 (14.63%)	0.289
	Recurrence	8 (19.51%)	2 (4.88%)	0.042*

Data presents as mean ± SD or frequency (%).

Discussion

Although they can form anywhere around the anus, chronic anal fissures occurs most frequently near the posterior midline of the anal canal as shedding of the squamous epithelium at the muco-cutaneous interface.[6]

Based on demographic data from the groups under examination, the current study found that baseline characteristics like age and sex didn't significanly differ.

Furthermore, these results were consistent with a research by Maurice et al,[7] who found no discernible variations in the distribution of sexes and ages.

There was an insignificant difference between both groups regarding the symptom duration.

Also, a randomized controlled trial of Gandomkar et al.[8] reported no statistically significant difference as regard duration of symptoms.

In our study, we reported significantly longer operative time in group II (LIS group) compared to group I (Botox group) (P<0.001).

According to our results, which agreed with a randomized comparison study by Mohsen et al.[9] group B (LIS group) had a considerably longer mean operative time (11.46±1.82 minutes) than group A (BT injection group) (6.11±1.59 minutes), with P<0.001.

According to our study, group II (LIS group) had a considerably longer hospital stay than group I (Botox group) (P<0.001). Group II (LIS group) had a considerably greater cost than group I (Botox group) (P<0.001). Group II (LIS group) returned to everyday work much longer than group I (Botox group) (P<0.001).

Our results agreed with those of Gandomkar et al.[8] reported that LIS group patients mean hospitalization of 1.2 days, while BTX was performed in an outpatient setting.

Matching with our findings, Mentes et al.[10] reported that BTX patient needed significantly less time to Fully practice daily activities (1vs.14.8±5.7 days; P<0.0001).

In contrast, our findings disagreed with Maurice et al.[7] who reported the need for one day hospital for all patients in both groups.

In the present study, regarding pain in group I (Botox group), the different measurements recording pain showed a significant difference (P<0.001). Pain significantly decreased at 1 day, 3 months and 6 months compared to preoperative pain (P<0.05), significantly decreased at 3 months and 6 months compared to 1 day (P<0.001, <0.001) and significantly decreased at 6 months compared to 3 months (P<0.001).

Our results matched with results of Maurice et al.[7] who found that in Botox group, the different measurements recording pain showed a significant difference (P<0.001). Pain at 1 day, two weeks and 30 days was significantly lower compared to preoperative pain, was significantly lower at two weeks and 30 days compared to 1 day and was significantly lower at 30 days compared to two weeks.

In the present study, regarding pain in group II (LIS group), our results showed significantly lower pain at 3 months and 6 months compared to preoperative pain (P<0.001, <0.001), with no significant difference between 1 day and preoperative pain. Pain significantly decreased at 3 months and 6 months visits compared to 1 day (P<0.001, <0.001) and significantly decreased at 6 months than that at 3 months (P<0.001).

This came in accordance with Maurice et al.[7] who found that in LIS group, the different measurements recording pain showed a significant difference (P<0.001). Pain at 1 day, two weeks and 30 days was significantly lower compared to preoperative pain, was significantly lower at two weeks and 30 days compared to 1 day and was significantly lower at 30 days compared to two weeks.

In the present study, we showed that group I (Botox) experienced considerably less pain at 1 day and 3 months than group II (LIS) (P<0.001,

<0.001), although both groups didn't significantly differ at preoperative and 6-month points.

Our results, however, were in conflict with those of Massoud et al,[11] who reported that BTX patients had pain more frequently (0/5; P<0.05) than the surgery group.

In the present study, we showed that group II (LIS group) experienced considerably more full healing than group I (Botox group) (87.8% vs. 60.98%, P=0.005).

Additionally, Chen et al.'s meta-analysis of randomized control trials,[12] found a significant difference in the healing rate, with faster healing rate in LIS (OR 0.15; 95% CI 0.08, 0.27; Z = 6.26; p<0.00001).

Maurice et al,[7] shown that the healing duration was much longer for the open group and significantly shorter for the Botox group, which is in contrast to the current study.

Regarding outcome, short term complications including bleeding and urine retention were significantly higher in group II (LIS group) compared to group I (Botox group) (P=0.021, 0.048). Hypersensitivity was insignificantly different between both groups (7.32% vs. 0%, P=0.075).

Long term complications including incontinence and the incidence of stenosis and constipation. As the most serious complication, Incontinence; defined as the loss of voluntary control of defecation process whether to gas, liquid, or feces during 6-week postoperative visit. Incontinence that continues at the 12-month follow-up is considered long-term. Due to its practicality, ease of use, and interpretability, the validated Cleveland Clinic Scoring System was used to determine the degree of incontinence. Each type of anal incontinence-gas (1-3), liquid stool (4-6), solid stool (7-9), or the need to wear a pad (1-3)-was assigned a point based on how frequently it occurred (Sometimes, [1/week or daily], respectively.

The total of those points-0 for perfect continence, 1-7 for good continence, 8-14 for moderate incontinence, 15-20 for severe incontinence, and 21 for total incontinence was the Cleveland Clinic incontinence score.

Incontinence was observed in 2 patients in the BTX group that resolved spontaneously after few days, whereas 8 patients in the LIS group experienced incontinence, being significantly lower in group I (Botox group) (P=0.042). There was an insignificant difference between both groups regarding the incidence of stenosis and constipation. Recurrence was significantly lower in group II (LIS group) compared to group I (Botox group) (P=0.042).

Our results are in concordance with Gandomkar et al.[8] who reported significantly higher urinary retention in patients of the LIS group postoperatively (p<0.001).

Chen et al.[12] in their meta-analysis of randomized control trials demonstrate that Botox is better than LIS in terms of incontinence.

According to Chen et al,[12] patients treated with the LIS experienced a significant lower rate of recurrence than those treated with BTX.

Additionally, Nasr et al,[13] recorded higher recurrence rate in the BT group than that in the LIS group (P=0.0111).

In contrast, our findings disagreed with Rashad et al,[14] who revealed that regarding complication after treatment, bleeding, infection, and incontinence, showed insignificant differences between surgical sphincterotomy and BTX injection.

Also, like our study, Maurice et al,[7] showed higher incontinence with open group and lower in BTX group.

The limitations were its single-center study possibly introduced a selection bias, the generalizability of the results, small sample size and limited follow-up period.

Conclusions

Both BT injection (Group I) and LIS (LIS, Group II) are effective treatments for chronic anal fissure, each with distinct advantages and limitations. BT injection was associated with significantly shorter operative times and hospital stays compared to LIS, making it a less invasive option with quicker recovery. Additionally, pain relief occurred earlier and was more pronounced in the BT group at 1 day and 3 months, though both groups experienced significant pain reduction by 6 months. However, LIS demonstrated a higher complete healing rate, reinforcing its efficacy as a definitive treatment. Postoperative complications differed between the groups: LIS patients experienced higher chances of bleeding and urinary retention. Incontinence was significantly lower in BT and recurrence was significantly higher. Preoperative and 6-month pain levels, incidence of stenosis, or constipation showed no difference in both groups.

Therefore, we recommend further research to add to these findings, and long-term follow-up studies for firm results.

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