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Original Research Article

Comparison of the Results of Lateral Anal Sphincterotomy vs Botox Injection in Patients with Chronic Anal Fissure in Terms of Pain

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Abstract: *Chronic anal fissure is a common and painful proctologic condition that significantly impairs quality of life. While lateral internal sphincterotomy (LIS) has been the traditional gold standard treatment, concerns about complications such as faecal incontinence have prompted interest in less invasive options like botulinum toxin (BTX) injection.* ***Objective:*** *To compare the effectiveness of lateral internal sphincterotomy versus botulinum toxin injection in terms of pain relief among patients with chronic anal fissure.* ***Methods:*** *This quasi-experimental study was conducted in the Department of General Surgery at the Combined Military Hospital, Hyderabad, from October 2024 to March 2025. A total of 189 patients meeting the inclusion criteria were enrolled and divided into two groups using an odd-even number allocation method: Group A (LIS; n = 95) and Group B (BTX; n = 94). Baseline pain scores were recorded using the Visual Analogue Scale (VAS). Patients were followed up on day 7, at 1 month, and at 3 months post-intervention to evaluate pain resolution, recurrence, and faecal incontinence. Data were analyzed using SPSS version 25, and p-values <0.05 were considered statistically significant.* ***Results:*** *The median (IQR) age of patients in Group A was 37 (13) years, and in Group B was 38.5 (10) years. At 3 months post-intervention, pain persisted in 5 (5.3%) patients in Group A and in none (0%) in Group B (p = 0.024). Recurrence was observed in 1 (1.1%) patient in Group A compared to 13 (13.8%) in Group B (p = 0.001). Fecal incontinence occurred in 7 (7.4%) patients in Group A and 1 (1.1%) patient in Group B (p = 0.031).* ***Conclusion:*** *Botulinum toxin injection demonstrated superior outcomes compared to lateral internal sphincterotomy in terms of pain relief and reduced risk of fecal incontinence, although LIS was more effective in preventing recurrence. BTX may be considered a safer, less invasive alternative in the management of chronic anal fissure.*

Keywords: Anal Fissure, Botulinum Toxins, Fecal Incontinence, Pain Measurement, Sphincterotomy, Subcutaneous Injections

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Introduction

Chronic anal fissure (CAF) is a prevalent anorectal disorder, affecting approximately 10–15% of patients presenting with anorectal complaints globally (1). It is characterized by a longitudinal tear in the anoderm distal to the dentate line, often accompanied by intense pain during defecation, bleeding, and internal anal sphincter spasm. The condition significantly impacts quality of life, with sufferers frequently experiencing difficulty performing daily activities due to persistent pain (2). In Pakistan, exact prevalence rates are not well-documented; however, anecdotal evidence suggests that CAF is a frequent concern in general surgery and gastroenterology outpatient departments, with a disproportionate burden in low-resource settings due to delayed healthcare-seeking behavior (3).

The pathophysiology of CAF is strongly linked to increased resting pressure in the internal anal sphincter, which leads to ischemia of the anal canal and delays healing (4). Treatment modalities for CAF focus on reducing this pressure to alleviate symptoms and promote fissure healing. Lateral internal sphincterotomy (LIS) is considered the gold standard surgical treatment, with success rates exceeding 90% globally (5). However, concerns about complications such as fecal incontinence, which affects up to 45% of patients in some studies, have prompted exploration of alternative treatments (6).

Botulinum toxin injection (Botox) has gained traction as a minimally invasive treatment option for CAF. It reduces resting anal pressure by inducing temporary paralysis of the internal anal sphincter, providing pain relief and promoting fissure healing. Globally, Botox (BTX) has demonstrated healing rates ranging from 60% to 80%, with minimal adverse effects. (7) In Pakistan, however, the high cost and limited availability of Botox injections pose significant challenges to its widespread adoption. Additionally, limited local studies on its efficacy and safety further complicate its integration into routine clinical practice (8).

The debate surrounding the choice between Botox injections and other modalities persists, with each having distinct advantages and limitations. In Pakistan, economic constraints, healthcare accessibility, and cultural factors heavily influence treatment decisions (9). While LIS is widely practiced in tertiary care hospitals, the fear of complications often deters patients from opting for surgery. Conversely, although Botox is less invasive, its efficacy in achieving long-term healing remains variable, and its accessibility in lower-tier healthcare settings is limited.

A study conducted in Lahore highlighted that nearly 70% of CAF patients initially present to general practitioners or homeopathic healers, leading to delays in diagnosis and management (10). These delays often result in chronicity, making effective treatment crucial for preventing complications and improving patient outcomes.

This study seeks to bridge the gap in knowledge by comparing the outcomes of LIS and Botox injections in Pakistani patients with CAF, with a focus on pain relief as a primary outcome. While international studies have demonstrated varying success rates for both treatments, the lack of robust local data limits the applicability of these findings to Pakistan. By incorporating statistical analysis of pain scores, this research would provide evidence-based insights tailored to the Pakistani healthcare system. The novelty of this study lay in its focus on addressing the unique challenges faced by CAF patients in Pakistan, including healthcare accessibility and economic constraints. Findings from this research would not only guide clinical decision-making but also contribute to the

development of national guidelines for the management of CAF, ensuring better outcomes for patients across diverse healthcare settings.

Methodology

The present study employed a quasi-experimental design and was conducted over six months, from December 2024 to May 2025, at the Department of General Surgery, Combined Military Hospital (CMH), Hyderabad. Before commencement, ethical approval was obtained from the Ethics Review Committee. The study aimed to assess the outcomes of two interventions for chronic anal fissure. A total of 189 patients diagnosed with chronic anal fissure were enrolled. The sample size was determined based on an expected frequency of post-treatment pain at three months: 4% for patients undergoing lateral internal sphincterotomy (LIS) and 0% for those receiving botulinum toxin (BTX) injection. Using a 95% confidence level and 80% power of the test, the sample size was calculated to be sufficient to detect meaningful differences between groups. Patients were recruited using a non-probability consecutive sampling technique.

Eligible participants were adults between the ages of 18 and 60 years, of either gender, who had a confirmed diagnosis of chronic anal fissure and had previously undergone unsuccessful conservative treatment, which included warm sitz baths, analgesics, and a high-residue diet. Patients were excluded from the study if they had any form of inflammatory bowel disease, a history of anorectal surgery for non-fissure conditions, coexisting hemorrhoidal disease or fistula, or a known or suspected malignancy.

Chronic anal fissure was defined by the presence of pain with or without bleeding, during or after defecation for at least 3 months, and fissure confirmation on digital genital examination, i.e., presence of a confined ulcer, including a big skin sentinel tag, edge indurations, and the internal anal sphincter's horizontal fibers being visible. The primary outcome measure assessed was the presence of pain (VAS pain score more than 3) during or after defecation at 3 months following the intervention. The secondary outcome measure assessed was faecal incontinence and recurrence of anal fistula. An anal fissure discovered during a follow-up physical examination, with or without the brief improvement of symptoms after the initial treatment, was considered a recurrence. The involuntary loss of gas, liquid, or feces was referred to as fecal incontinence.

After obtaining written informed consent from all patients who met the selection criteria, the study was conducted. The pain score at baseline was assessed using a visual analog scale (VAS) for pain. Patients were evaluated on a scale of 10 points, ranging from 0 to 10. No pain was labeled if the score was 0, mild pain was labeled if the VAS score was 1-3, moderate pain if the score was 4 to 6, severe pain if the score was 7 to 9, and worst pain if the score was 10. The patients were divided into two groups, based on odds and even numbers, with 95 patients in Group A (lateral anal sphincterotomy) and 94 patients in Group B (Botox injection). In Group A, under general or spinal anesthesia, a lateral internal sphincterotomy was carried out in the lithotomy posture using a procedure that involved making a circumferential incision laterally to the skin outside the anal margin. The sphincter was separated under direct vision after the anoderm and intersphincteric groove were dissected. Either interrupted sutures were used to seal the wound, or it was left open. In Group B (Botox injection), by using a so-called insulin syringe with a short, thin needle (10 mm, 26 needle), each patient got 20 units of botulinum toxin, which was supplied as split doses through the internal anal sphincter at 3, 9, and 12 o'clock and injected in equal volumes on both sides of the fissure. Neither local anesthetic nor sedation was applied throughout the surgery. Conservative methods, such as sitting baths and/or anal tampons, were advised during the first few weeks following the injection to promote recovery. The surgery was hidden from the surgeons who were assessing the results. Patients were followed up after 1 week, at 1, 2, and 3 months, and the outcome was evaluated. The findings were then subjected to statistical analysis.

The data were analyzed using SPSS version 25.0. Normality of data was assessed using the Shapiro-Wilk test. As the data were non-normal, quantitative data, such as age, duration of symptoms, and VAS pain, were presented as medians and interquartile ranges. Qualitative data, including gender, presence of pain, recurrence, and faecal incontinence, were presented as frequencies and percentages. Chi-square test was used to compare the presence of pain, recurrence, and faecal incontinence between both groups, and a p-value of ≤ 0.05 was considered significant. The Mann-Whitney U test was used to compare VAS pain scores between both groups, and a p-value of ≤ 0.05 was considered significant.

Results

A total of 189 patients were enrolled in the study. The median (IQR) age in Group A was 37 (13) years, and in Group B, it was 38.5 (10) years. The median (IQR) duration of symptoms in Group A was 4 (1) months, and in Group B, it was 4 (2) months. The median (IQR) VAS pain score at baseline in Group A was 6 (1) and in Group B was 5 (1) (Z=-0.601, p=0.548). The median (IQR) VAS pain score at 7 days in Group A was 2 (1) and in Group B was 2 (1) (Z=-1.247, p=0.212). The median (IQR) VAS pain score at 1 month in Group A was 0 (0) and in Group B was 0 (0) (Z=-3.222, p=0.001). The median (IQR) VAS pain score at 3 months in Group A was 0 (0) and in Group B was 0 (0) (Z=-2.248, p=0.025).

There were 42 (44.2%) males and 53 (55.8%) females in Group A, and there were 45 (47.9%) males and 49 (52.1%) females in Group B (Figure 1).

Pain at 3 months was present in 5 (5.3%) patients in Group A and 0 (0%) patients in Group B (p = 0.024). Recurrence occurred in 1 (1.1%) patient in Group A and in 13 (13.8%) patients in Group B (p = 0.001). Faecal incontinence occurred in 7 (7.4%) patients in Group A and 1 (1.1%) patient in Group B (P=0.031) (Table II).

Table 1: Comparison of Demographic and Clinical Variables Between Group A (LIS) and Group B (BTX)

Variable	Group A (LIS) *(n = 95)*	Group B (BTX) *(n = 94)*	Z value	p-value
Age (in years)	37 (13)	38.5 (10)	–	–
Duration of symptoms (months)	4 (1)	4 (2)	–	–
VAS pain score at baseline	6 (1)	5 (1)	-0.601	0.548
VAS pain score at 7 days	2 (1)	2 (1)	-1.247	0.212
VAS pain score at 1 month	0 (0)	0 (0)	-3.222	0.001
VAS pain score at 3 months	0 (0)	0 (0)	-2.248	0.025

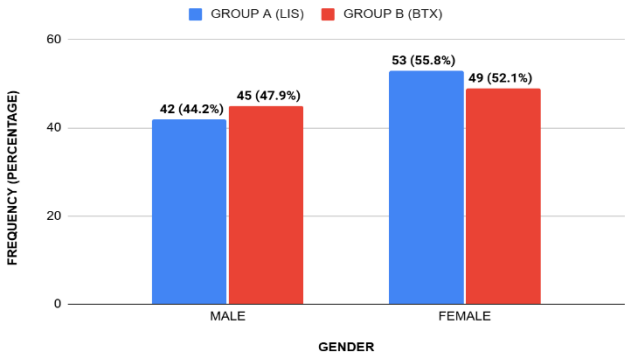

Figure 1: Gender distribution of patients in both groups (n=189)

Table 2: Frequency of clinical findings and their comparison in both groups (n=189)

Variables	Group A (LIS) *(n = 95)*	Group B (BTX) *(n = 94)*	p-value
Presence of pain after 3 months			
Yes	5 (5.3%)	0 (0%)	0.024
No	90 (94.7%)	94 (100%)	
Recurrence			
Yes	1 (1.1%)	13 (13.8%)	0.001
No	94 (98.9%)	81 (86.2%)	
Faecal Incontinence			
Yes	7 (7.4%)	1 (1.1%)	0.031
No	88 (92.6%)	93 (98.9%)	

Discussion

The current study's findings revealed a significant difference between LIS and BTX in terms of pain presence at 3 months, with BTX being associated with a significantly lower frequency of pain. Recurrence of CAF was substantially more prevalent in the BTX group, and faecal incontinence occurred markedly more frequently in the LIS group.

Anal fissures are a frequent, painful disorder that primarily affects young individuals and causes severe morbidity (12,13). Acute anal fissures frequently mend on their own or with medical assistance (14,15). If treatment is stopped after the fissure has healed, the recurrence rate may be higher. (16) The choice between Botox injections and LIS is still a matter of dispute, as each procedure has its unique benefits and drawbacks. Keeping this in view, our study compared LIS and BTX in terms of pain relief.

Our study revealed that BTX was significantly associated with a lower frequency of pain at 3 months, specifically 0% compared to 5.3% in the LIS group (p = 0.024). Zngana and Hiwa revealed that in the BTX group, none of the patients had pain, whereas 4% patients in the LIS group had it (11). Rashad et al. revealed that after 3 months, none of the patients who had LIS versus BTX17 experienced pain. Maurice et al. revealed that pain was reported by 6% of patients after a month who had LIS, whereas none of the patients in the BTX group reported pain (18). These findings are consistent with our study findings that BTX was associated with less pain.

In our study, recurrence occurred more commonly in the BTX group compared to the LIS, specifically at a rate of 13.8% versus 1.1%. De Robles and Young revealed that in patients with CAF who underwent LIS, the rate of recurrence was 5% compared to 15% in the BTX group (p = 0.012) .(6) Maurice et al. revealed that recurrence was seen in 4% patients who were treated by LIS compared to 42% who had BTX (p<0.01) (18). Cakir et al. revealed that the recurrence rate was 2.7% in the LIS group and 13.1% in the BTX group (p = 0.041), (19). These findings align with our study's findings that LIS is associated with a lower frequency of CAF recurrence.

Our study findings showed that faecal incontinence was more frequent in the LIS group (7.4%) compared to BTX (1.1%). Maurice et al. reported that incontinence was experienced by 30% of patients in the LIS group, compared to 2% of patients in the BTX group (p = 0.01), a finding consistent with our study results. At the same time, De Robles and Young revealed that faecal incontinence occurred in 7% of patients who underwent LIS for CAF, compared to 6% of patients in the BTX group (p = 1.000). (6) Our study findings are inconsistent with those of De Robles and Young. The discrepancy may be attributed to differences in surgeon experience.

BTX injection is a recognized therapeutic approach. In the treatment of CAF, it is a useful alternative method that is safe, simple to use, and offers quick pain relief without the risk of anesthesia or surgical complications. It has a greater recurrence rate than LIS, but it is comparatively less intrusive than surgery, and the consequences are minimal. Anal incontinence is more common in the surgical group, particularly in older patients. Conversely, when it comes to middle-aged and older individuals, those who have a risk factor for anal incontinence, or those who have recently complained of an anal fissure, BTX injection is suggested. T

he study had certain limitations. The results of this study cannot be generalized because it was a single-center study with a small sample size. Secondly, the follow-up period was brief and patients were not assessed for long-term incontinence.

Conclusion

The current study concluded that in terms of pain, BTX was significantly associated with a lower frequency of pain compared to LIS. Our study findings proposed that BTX injection is a more suitable first-line treatment of choice for CAF, which is not associated with other anal

conditions. It is a simple procedure that is easy to learn and can be performed in an outpatient clinic without the need for sedation or local anesthesia. Thus, BTX injection decreases the use of hospital resources, and therefore, it is less costly. Future studies should be conducted on a larger scale to validate the findings of the current study.

Declarations

Data Availability statement
All data generated or analysed during the study are included in the manuscript.
Ethics approval and consent to participate
Approved by the department concerned. (IRBEC-CMHAHA -039-24)
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Conflict of interest

The authors declared the absence of a conflict of interest.

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All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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