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Comparative Study between Botulinum Toxin and Lateral Sphincterotomy in the Treatment of Acute Anal Fissure

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Abstract: ***This prospective observational study compared the efficacy, safety, and tolerability of botulinum toxin (BTX) injection and lateral internal sphincterotomy (LIS) in treating acute anal fissure (AAF) in 50 patients at Alluri Sitaramaraju Academy of Medical Sciences, Eluru, from January 2021 to August 2022. Patients were randomly allocated into two groups: Group A (n=25) received BTX (20 units), and Group B (n=25) underwent open LIS under general anesthesia. Outcomes assessed included pain (using the Visual Analogue Scale [VAS]), healing rates, incontinence, recurrence, patient satisfaction, and hospital stay duration. At 24 hours post - treatment, Group A reported significantly lower pain (p=0.005), with 88% experiencing VAS ≤3 compared to 20% in Group B. Healing was achieved in all Group A patients by 2 weeks, versus 60% in Group B (p=0.04). Incontinence occurred in 5 Group B patients (20%) but none in Group A (p=0.05). Recurrence at 6 months was higher in Group A (20%) than Group B (4%). Patient satisfaction was significantly higher with BTX (88%) than LIS (56%) (p=0.02), and hospital stay was shorter with BTX. BTX emerges as a safe, effective first - line treatment for AAF, though recurrence rates warrant addressing precipitating factors.***

Keywords: Acute anal fissure, Botulinum toxin, Lateral internal sphincterotomy, Pain, Healing, Incontinence

1. Introduction

The association between anal fissure and anal sphincter hypertonia has been recognized for decades, with the hypertonia of the internal anal sphincter (IAS) contributing to ischemia and delayed healing of the anoderm [1, 2]. While most acute anal fissures (AAF) heal spontaneously or with conservative measures like stool softeners, a subset progresses to chronicity, necessitating advanced interventions. Lateral internal sphincterotomy (LIS) is the gold standard for chronic anal fissure (CAF), achieving over 90% efficacy but with risks of incontinence (8–30%) [3 - 6]. Botulinum toxin (BTX) injection, a reversible sphincter - relaxing therapy, has emerged as a less invasive alternative, initially described by Jost and Schimrigk [7], with superior efficacy to topical nitrates [8].

This study aimed to compare the morbidity and effectiveness of BTX versus LIS in treating uncomplicated AAF. The hypothesis was that BTX, by reducing sphincter pressure temporarily without surgical intervention, might offer comparable healing rates with fewer complications. Previous studies on CAF suggest BTX has a higher recurrence rate but lower incontinence risk compared to LIS [17 - 21]. However, data on AAF are limited, prompting this investigation to evaluate these treatments in an acute setting.

2. Methodology

This prospective, observational, open - label study was conducted at the Department of General Surgery, Alluri Sitaramaraju Academy of Medical Sciences, Eluru, over 20 months (January 2021 to August 2022), with 18 months of data collection. Following Institutional Ethics Committee approval, 50 patients with AAF were enrolled after providing written informed consent. Sample size was calculated using the formula, based on a 17.8% prevalence of AAF [22], with a 9% error and 90% confidence level, yielding 50 participants.

Inclusion Criteria:
Patients aged >18 years of both sexes with AAF, willing to consent.

Exclusion Criteria:
Patients with hemorrhoids, fistula - in - ano, inflammatory bowel disease, rectal malignancy, prior anal surgeries, chronic fissures, or hypersensitivity to BTX; those on aminoglycosides, baclofen, dantrolene, diazepam, or anticoagulants were excluded.

Preoperative assessment included history (pain, bleeding, constipation), clinical examination (anorectal evaluation), and laboratory tests (hemoglobin, bleeding/clotting times, INR, serum creatinine, SGPT, FBS). Pain was categorized using the Visual Analogue Scale (VAS: 0–10). Patients were randomized into two groups: Group A (n=25) received BTX (20 units diluted in saline, 10 units per side injected into the IAS under local anesthesia), and Group B (n=25) underwent open LIS under general anesthesia. Group B patients started a liquid diet 4 hours post - operation, with anal dressings removed after 8 hours and local anesthetic cream applied before defecation, followed by discharge on postoperative day 1 with instructions for a high - residue diet, analgesics, and sitz baths.

Follow - up occurred at 1 week, 2 weeks, 1 month, 2 months, and 3 months, assessing pain, healing (complete re - epithelialization), incontinence (soiling or flatus loss), recurrence, and satisfaction. Data were analyzed using MS Excel 2019 and Epi Info version 26, with chi - square tests for

categorical variables, t - tests for numerical data, and $p<0.05$ considered significant

3. Results & Discussion

The study included 50 patients (28 females, 22 males; female: male ratio 1.27), with mean ages of 38.5±7.6 years (Group A) and 38.9±10 years (Group B), showing no significant age difference (p=0.8). Most fissures (60%) were posterior, with no gender - location association. Pain at 24 hours was significantly lower in Group A (88% VAS ≤3) than Group B (20% VAS ≤2) (p=0.005), though no difference was noted at 2 weeks. Healing was universal in Group A by 2 weeks, versus 60% in Group B (p=0.04). Incontinence affected 20% of Group B patients but none in Group A (p=0.05). Recurrence at 6 months was 20% in Group A and 4% in Group B. Patient satisfaction was higher with BTX (88%) than LIS (56%) (p=0.02), and hospital stay was prolonged in 72% of Group B versus 8% of Group A patients.

Table 1: Subjects categorisation

Treatment	Frequency	Percent
Botulinum toxin (group A)	25	50.00%
Lateral Sphincterotomy (group B)	25	50.00%
Total	50	100.00%

These findings align with prior studies. Nasr et al. [19] reported higher healing with LIS (p=0.0086) but increased incontinence (p=0.0338) compared to BTX in CAF, with higher recurrence in the BTX group (p=0.0111). Mentes et al. [18] noted a 98% healing rate with LIS at 2 months versus 73.8% with a single BTX injection, though incontinence was significant with LIS ($p<0.001$). The current study's focus on AAF highlights BTX's rapid pain relief and healing, likely due to its reversible sphincter relaxation, avoiding surgical trauma. However, the 20% recurrence rate with BTX reflects its 3 - month action duration, necessitating correction of precipitating factors (e. g., constipation). LIS's higher incontinence rate (20%) is consistent with literature (8–30%) [5, 6], though transient in most cases. The shorter hospital stay with BTX underscores its feasibility Limitations include the small sample size and single - center design, potentially limiting generalizability. The lack of long - term follow - up beyond 6 months and absence of manometric data on sphincter pressures are additional constraints. Future multicenter trials with larger cohorts and extended follow - up are warranted.

Groups	Minimum	Median	Maximum	Mode
Group A	20	37	48	36
Group B	20	41	54	32

Table 2: Age of the study subjects.

Method	Variances	P value
Pooled	Equal	0.8749
Satterthwaite	Unequal	0.8749

Group	No: of subjects	Mean	Std Dev
Group A	25	38.52	7.6492
Group B	25	38.92	10.0537

Table 3: Age & Gender distribution in the study.

Age Category	Gender		Total
	Females	Males	
20 to 30	4	6	10
31 to 40	12	6	18
41 to 50	11	9	20
51 to 60	1	1	2
Total	28	22	50

Table 4: Position of fissure

Position of fissure	Gender		Total
	Females	Males	
Anterior	13	7	20
Posterior	15	15	30
Total	28	22	50

Table 5: Duration of stay

Duration of stay	botulinum toxin	lateral sphincterotomy	Total
Increased	2	18	20
Normal	23	7	30
Total	25	25	50

Table 6: Patient satisfaction at 1st month

Patient satisfaction at 1st month	Treatment		Total
	botulinum toxin	lateral sphincterotomy	
No	3	11	14
Yes	22	14	36
Total	25	25	50

Table 7: Pain at 24 hrs

Pain at 24 hours	Treatment (p=0.05)		Total
	Botulinum toxin	Sphincterotomy	
2	12	5	17
3	10	11	21
4	3	9	12
Total	25	25	50

Table 8: Pain at 2 weeks

Pain at 2 Weeks	Treatment (p=0.13)		Total
	Botulinum toxin	Sphincterotomy	
1	6	2	8
2	9	7	16
3	10	13	23
4	0	3	3
Total	25	25	50

4. Conclusion

Botulinum toxin injection offers a safe, effective first - line treatment for acute anal fissure, providing rapid pain relief, high healing rates (100% at 2 weeks), no incontinence, and greater patient satisfaction compared to lateral internal sphincterotomy. However, its higher recurrence rate (20% at 6 months) suggests the need to address underlying causes. Lateral sphincterotomy, while effective (60% healing at 2 weeks), is associated with incontinence (20%) and longer hospital stays. These findings support BTX as a preferable initial therapy for AAF, with LIS reserved for non - responders or recurrent cases after optimizing conservative measures.

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