



MANAGEMENT OF CHRONIC FISSURE IN ANO-LATERAL INTERNAL SPHINCTEROTOMY VERSUS 2% DILTIAZEM GEL LOCAL APPLICATION: A PROSPECTIVE COMPARATIVE STUDY

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Received: January 10, 2026**Revised:** January 15, 2026**Accepted:** February 09, 2026**Published:** February 23, 2026**Abstract**

Background: Chronic fissure-in-ano is a painful anorectal condition resulting from internal anal sphincter hypertonia and impaired anodermal perfusion. Lateral internal sphincterotomy (LIS) is considered the gold standard treatment, while topical 2% diltiazem gel offers a sphincter-preserving alternative. This study compared the efficacy and safety of these two modalities. **Material and Methods:** A prospective comparative study was conducted at Mamata Medical College and Hospital, Khammam, from October 2023 to October 2025. Fifty patients aged 20–60 years with chronic fissure-in-ano were equally divided into two groups. Group A (n=25) received topical 2% diltiazem gel twice daily for six weeks, and Group B (n=25) underwent lateral internal sphincterotomy under spinal anesthesia. All patients received adjunct conservative measures. Follow-up was conducted weekly for four weeks and monthly for two additional months. Primary outcomes included fissure healing and pain relief assessed using the Visual Analog Scale (VAS). Complications were also recorded. Statistical analysis was performed using the Chi-square test. **Results:** At 3 months, healing was observed in 76% of patients in the diltiazem group and 84% in the LIS group. Pain relief was achieved in 80% and 88% of patients, respectively. Although the surgical group demonstrated slightly higher healing and pain relief rates, the differences were not statistically significant ($p > 0.05$). Minor complications were noted in both groups. Transient flatus incontinence occurred in the LIS group, while mild perianal irritation was reported in the diltiazem group. **Conclusion:** Both treatments are effective for chronic fissure-in-ano. LIS provides slightly superior outcomes, whereas topical diltiazem is a safe and effective non-surgical alternative.

Keywords: Chronic fissure-in-ano; lateral internal sphincterotomy; diltiazem; pain relief; healing rate.



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INTRODUCTION

Chronic fissure-in-ano (CAF) is defined as a longitudinal tear in the anoderm distal to the dentate line persisting for more than six weeks and is commonly associated with severe post-defecatory pain, bleeding per rectum, and internal sphincter spasm (1,2). Chronic fissures are often accompanied by secondary changes such as a sentinel pile, hypertrophied anal papilla, and exposure of internal sphincter fibers (2,4). The pathophysiology of chronic fissure is primarily attributed to internal anal sphincter hypertonia leading to reduced anodermal blood flow and local ischemia, which perpetuates the cycle of pain, spasm, and impaired healing (3,5). Manometric studies have demonstrated elevated resting anal pressure in patients with chronic fissure, and reduction in sphincter pressure has been shown to restore perfusion and promote healing (3).

Initial management includes conservative measures such as high-fiber diet, stool softeners, sitz baths, and avoidance of straining (1,5). However, chronic fissures often require interventions aimed at reducing internal

sphincter tone. Medical management includes topical nitrates, calcium channel blockers, and botulinum toxin injection (6). Among these, topical 2% diltiazem gel acts by inhibiting calcium-mediated smooth muscle contraction, thereby reducing sphincter tone and improving anodermal blood flow (6,7). Compared to glyceryl trinitrate, topical diltiazem has shown similar healing rates with significantly fewer adverse effects such as headache, improving patient compliance (6).

Lateral internal sphincterotomy (LIS) remains the gold standard surgical treatment for chronic fissure-in-ano (1,8). It works by dividing a portion of the internal anal sphincter, thereby reducing resting anal pressure, relieving spasm, and enhancing blood flow to facilitate healing (3). Multiple studies and meta-analyses have demonstrated superior healing rates with LIS compared to medical therapy (8). However, concerns remain regarding postoperative complications, particularly fecal incontinence, which may range from minor flatus incontinence to occasional seepage (9). Long-term

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follow-up studies have shown that although LIS offers high healing rates, a small but significant proportion of patients may experience continence disturbances (9,10).

Several comparative studies have evaluated LIS versus topical 2% diltiazem in chronic fissure-in-ano. Prospective and randomized studies have demonstrated higher and faster healing rates with LIS, while diltiazem offers a non-operative alternative with fewer immediate risks (11,12). However, variability exists in terms of healing time, recurrence rates, adverse effects, and patient compliance across studies. Many existing studies have relatively small sample sizes, inconsistent follow-up durations, and variable outcome definitions, leading to a lack of uniform consensus regarding optimal first-line definitive management.

Although both lateral internal sphincterotomy and topical 2% diltiazem are established treatment modalities, there remains uncertainty regarding comparative pain relief, healing duration, recurrence rates, and continence outcomes when evaluated prospectively under standardized criteria. Additionally, limited region-specific prospective comparative data with uniform follow-up protocols contribute to variability in clinical decision-making. Therefore, a well-designed prospective comparative study is necessary to provide clearer evidence regarding efficacy, safety, and long-term outcomes.

The present study aims to prospectively compare lateral internal sphincterotomy and 2% diltiazem gel local application in the management of chronic fissure-in-ano with respect to pain relief, fissure healing rate, time to healing, recurrence rate, and treatment-related complications, particularly continence disturbances.

MATERIALS AND METHODS

This prospective comparative study was conducted in the Department of General Surgery at Mamata Medical College and Hospital, Khammam, from October 2023 to October 2025. The study was initiated after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants after explaining the nature and purpose of the study.

RESULTS

Table 1: Baseline Demographic Characteristics of Study Participants (n = 50)

Variable	Number of Patients (n)	Percentage (%)
Gender		
Female	36	72.0
Male	14	28.0
Age Group (years)		
20–30	12	24.0
31–40	18	36.0
41–50	13	26.0
51–60	7	14.0

A total of 50 patients clinically diagnosed with chronic fissure-in-ano were included. Chronic fissure was defined as a fissure persisting for more than six weeks with features such as indurated edges, sentinel pile, or visible internal sphincter fibers.

Inclusion Criteria

- Patients aged 20–60 years
- Both male and female patients
- Clinically diagnosed chronic fissure-in-ano

Exclusion Criteria

- Children and mentally challenged patients
- Fissures associated with hemorrhoids or fistula-in-ano
- Fissures associated with malignancy
- Fissures secondary to tuberculosis or Crohn's disease
- Pregnant women

Patients were divided into two groups of 25 each:

Group A: Treated with topical 2% diltiazem gel, applied twice daily for six weeks.

Group B: Underwent lateral internal sphincterotomy (LIS) under spinal anesthesia.

All patients in both groups were advised a high-fiber diet, adequate fluids, warm sitz baths, and mild laxatives (Cremaffin 15 ml at bedtime).

Patients were followed up weekly for the first 4 weeks and monthly for the next 2 months. At each visit, assessment included pain relief, bleeding, healing of fissure, leakage of flatus or feces, and other complications. Healing was defined as complete epithelialization of the fissure on clinical examination.

Pain Assessment

Pain was assessed using a standardized Visual Analog Scale (VAS) pain score, ranging from 0 (no pain) to 10 (worst imaginable pain). Pain scores were recorded at baseline and at each follow-up visit.

Statistical Analysis

Data collected were entered into Microsoft Excel and analyzed using appropriate SPSS version 23.0. Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as mean $\pm$ standard deviation.

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Mean Age (years)	38.6 ± 9.4	—
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A total of 50 patients with chronic fissure-in-ano were included in the study. Females constituted the majority of the study population (72%), while males accounted for 28%, indicating a female predominance. The age of patients ranged from 20 to 60 years, with a mean age of 38.6 ± 9.4 years. The highest proportion of patients belonged to the 31–40 years age group (36%), followed by 41–50 years (26%) and 20–30 years (24%). Only 14% of patients were in the 51–60 years age group. Overall, the condition was most commonly observed in the third and fourth decades of life.

Table 2: Baseline Clinical Characteristics of Study Participants (n = 50)

Variable	Number of Patients (n)	Percentage (%)
Duration of Symptoms		
6–12 weeks	21	42.0
>12 weeks	29	58.0
History of Constipation	34	68.0
Bleeding per Rectum	40	80.0
Site of Fissure		
Posterior Midline	44	88.0
Anterior	6	12.0

Among the 50 patients included in the study, the majority (58%) had symptoms persisting for more than 12 weeks, while 42% presented with symptoms between 6 and 12 weeks, indicating a predominance of long-standing disease. A history of constipation was reported in 68% of patients, highlighting its important etiological role in chronic fissure-in-ano. Bleeding per rectum was a common associated symptom, observed in 80% of cases. Regarding the anatomical location, posterior midline fissure was the most common finding, present in 88% of patients, whereas anterior fissures accounted for 12%. These findings are consistent with the classical posterior predominance of chronic anal fissures.

Table 3: Comparison of Healing Outcomes at 3 Months Between Study Groups (n = 50)

Treatment Group	Total Patients (n)	Healed n (%)	Not Healed n (%)	Healing Rate (%)	p-value*
Group A – 2% Diltiazem	25	19 (76%)	6 (24%)	76.0	
Group B – Lateral Internal Sphincterotomy	25	21 (84%)	4 (16%)	84.0	0.48
Total	50	40 (80%)	10 (20%)	80.0	—

At 3 months follow-up, complete healing was observed in 19 out of 25 patients (76%) treated with 2% diltiazem gel and in 21 out of 25 patients (84%) who underwent lateral internal sphincterotomy. Although the surgical group demonstrated a higher healing rate compared to the medical group, the difference was not statistically significant (p = 0.48). Overall, 80% of the total study population achieved complete healing at the end of 3 months. These findings suggest that both treatment modalities are effective, with a modest clinical advantage seen in the surgical group.

Table 4: Comparison of Pain Relief at 3 Months Between Study Groups (n = 50)

Treatment Group	Total Patients (n)	Pain Relief Achieved n (%)	No Significant Relief n (%)	Pain Relief Rate (%)	p-value*
Group A – 2% Diltiazem	25	20 (80%)	5 (20%)	80.0	
Group B – Lateral Internal Sphincterotomy	25	22 (88%)	3 (12%)	88.0	0.46
Total	50	42 (84%)	8 (16%)	84.0	—

At 3 months follow-up, pain relief was achieved in 20 out of 25 patients (80%) in the 2% diltiazem group and in 22 out of 25 patients (88%) in the lateral internal sphincterotomy group. Although a higher proportion of patients in the surgical group experienced pain relief, the difference between the two groups was not statistically significant (p = 0.46). Overall, 84% of the total study population reported significant improvement in pain at the end of the study period. These results indicate that both treatment modalities are effective in relieving symptoms, with a slight clinical advantage observed in the surgical group.

Table 5: Comparison of Post-Treatment Complications Between Study Groups (n = 50)

Complication	Group A – 2% Diltiazem (n=25) n (%)	Group B – LIS (n=25) n (%)	p-value*
Flatus Incontinence	0 (0%)	3 (12%)	0.07
Fecal Incontinence	0 (0%)	1 (4%)	0.31
Perianal Irritation	2 (8%)	0 (0%)	0.15
Wound Infection	0 (0%)	1 (4%)	0.31
Bleeding (Post-procedure)	0 (0%)	1 (4%)	0.31
No Complications	23 (92%)	19 (76%)	—

Post-treatment complications were infrequent in both groups. In the lateral internal sphincterotomy group, transient flatus incontinence was observed in 3 patients (12%), and fecal incontinence in 1 patient (4%). Additionally, 1 patient (4%) developed wound infection and 1 patient (4%) experienced postoperative bleeding. In contrast, no cases of incontinence, wound infection, or bleeding were reported in the diltiazem group. However, mild perianal irritation was noted in 2 patients (8%) treated with topical diltiazem. Overall, 92% of patients in the diltiazem group and 76% in the surgical group had no complications. Although complications were relatively more common in the surgical group, the differences were not statistically significant ($p > 0.05$). These findings indicate that while lateral internal sphincterotomy offers effective treatment, it carries a small risk of transient continence disturbances, whereas topical diltiazem is associated mainly with minor local side effects.

DISCUSSION

Chronic fissure-in-ano is a common anorectal condition characterized by severe pain, sphincter hypertonia, and impaired anodermal healing. The fundamental therapeutic goal is reduction of internal anal sphincter tone to improve perfusion and promote epithelialization. The present prospective comparative study evaluated the efficacy of topical 2% diltiazem gel versus lateral internal sphincterotomy (LIS) in 50 patients over a 3-month follow-up period.

In the present study, females constituted 72% of the study population, indicating a female predominance. Similar female preponderance has been reported in Indian and Asian studies, possibly attributed to higher prevalence of constipation, dietary factors, and postpartum anorectal changes (13,14). The mean age in our study was 38.6 ± 9.4 years, with the majority of patients in the 31–40 year age group. Comparable age distribution has been reported by Mishra et al. and Singh et al., who observed peak incidence in the third and fourth decades of life (13,15). The predominance of posterior midline fissure (88%) in our study is consistent with the classical vascular anatomy and reduced posterior anodermal perfusion described in earlier literature (16).

At 3 months, healing was achieved in 76% of patients treated with 2% diltiazem and 84% of patients undergoing LIS. Although the surgical group demonstrated a higher healing rate, the difference was not statistically significant.

These findings are comparable with the study by Giridhar et al., who reported healing rates of 70–75% with topical diltiazem and approximately 90% with LIS (17). Similarly, Vaithianathan et al. observed healing rates of 73% in the diltiazem group and 88–92% in the

LIS group (18). A meta-analysis by Nelson et al. demonstrated that LIS consistently provides higher healing rates compared to medical therapy, often exceeding 90% (19).

However, it is noteworthy that healing rates with diltiazem in our study (76%) are within the acceptable range reported in global literature (60–80%) (20). This suggests that topical therapy remains an effective first-line treatment in selected patients.

Pain relief at 3 months was achieved in 80% of patients in the diltiazem group and 88% in the LIS group. Although the surgical group showed slightly superior symptomatic improvement, statistical significance was not achieved. Similar trends have been observed in earlier comparative studies where LIS resulted in faster and more complete pain resolution (17,18). The rapid reduction in sphincter pressure following surgical division likely accounts for earlier pain relief. Medical therapy, though slower in onset, still provided substantial symptomatic benefit, supporting its role in patients preferring conservative management.

Post-treatment complications were minimal in both groups. Transient flatus incontinence was observed only in the LIS group, while minor perianal irritation occurred in the diltiazem group. No permanent fecal incontinence was recorded.

Earlier studies have reported minor continence disturbances in 5–15% of LIS patients (21). A long-term follow-up study by Pernikoff et al. documented minor incontinence in a subset of patients following LIS, although major incontinence was rare (22). In contrast, topical diltiazem is associated primarily with local

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irritation or mild headache but carries no risk of sphincter damage (20).

The absence of major incontinence in our study supports the safety of carefully performed LIS while also highlighting the advantage of sphincter-preserving therapy in selected cases.

Although recurrence data were limited to 3 months in the present study, literature suggests higher recurrence rates with medical therapy compared to LIS (19,23). Arroyo et al. demonstrated lower recurrence following surgical treatment during long-term follow-up (23). Therefore, while diltiazem offers a non-invasive approach, LIS remains more definitive in resistant cases.

Strength of Present Study

The study design was prospective with uniform follow-up and standardized pain assessment using VAS. Equal sample distribution between groups allowed direct comparison. Both clinical and symptomatic outcomes were assessed systematically.

Limitations

The relatively small sample size and short follow-up duration (3 months) may limit assessment of long-term recurrence and continence outcomes. Larger multicentric trials with longer follow-up would provide more robust evidence.

CONCLUSION

The present prospective comparative study demonstrates that both topical 2% diltiazem and lateral internal sphincterotomy are effective in the management of chronic fissure-in-ano. Lateral internal sphincterotomy showed a higher healing rate (84%) and superior pain relief (88%) compared to topical diltiazem (76% healing; 80% pain relief), although the differences were not statistically significant. Surgical treatment offers faster and more definitive healing but carries a small risk of transient incontinence. Topical diltiazem provides a safe and effective non-operative alternative with minimal complications. Therefore, topical diltiazem may be considered as first-line therapy, reserving lateral internal sphincterotomy for non-responders or recurrent cases.

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