



A COMPARATIVE EVALUATION OF TOPICAL 2% DILTIAZEM AND LATERAL INTERNAL SPHINCTEROTOMY IN THE MANAGEMENT OF CHRONIC ANAL FISSURE: A PROSPECTIVE CLINICAL STUDY

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ABSTRACT

Background: Chronic anal fissure is a painful and debilitating condition of the anal canal, commonly presenting with severe pain during defecation, rectal bleeding, and discomfort that significantly impairs quality of life. It is primarily caused by hypertonia and spasm of the internal anal sphincter, which hinders healing. Management strategies aim to relieve sphincter spasm and promote mucosal recovery. Both conservative medical therapies and surgical options like lateral internal sphincterotomy are employed based on severity and patient response. **Methods:** A prospective clinical study was conducted over 23 months (Nov 2019 – Sep 2021) including 60 patients with chronic anal fissure. Patients were randomized into two groups: Group A received 2% Diltiazem topical gel (n=30), and Group B underwent LIS (n=30). Primary outcome was fissure healing; secondary outcomes included pain relief, bleeding, anal incontinence, and recurrence. **Results:** Fissure healing was higher in Group B (96.7%) than in Group A (73.3%) (p=0.026). Pain relief was significantly better in Group B (final VAS 0.56 vs 2.26, p=0.001). Anal incontinence occurred in 33.3% of Group B (1 permanent), while Group A had only temporary incontinence in 3.3%. Recurrence occurred in 20% of Group A and 0% of Group B (p=0.024). **Conclusion:** LIS provides faster and more complete healing with better pain and bleeding relief but carries a higher risk of temporary incontinence. 2% Diltiazem is a safe, non-invasive alternative, suitable as first-line therapy in compliant patients.

KEYWORDS : Anal fissure, Diltiazem, Lateral internal sphincterotomy, pain, incontinence.

INTRODUCTION:

Chronic anal fissures are painful longitudinal ulcers of the anoderm, usually located at the posterior midline, and are commonly associated with hypertonia of the internal anal sphincter. The resulting sphincter spasm reduces blood flow, impeding healing. Conservative treatment includes dietary fiber, sitz baths, and topical agents such as calcium channel blockers and nitrates. Lateral internal sphincterotomy (LIS) is considered the gold standard for chronic or refractory cases, offering rapid symptom relief and healing. However, concerns over complications like fecal incontinence have prompted the evaluation of less invasive alternatives. This study compares topical 2% Diltiazem with LIS for efficacy, safety, and recurrence.

MATERIALS AND METHODS:

Study Design and Setting:

A prospective clinical trial was conducted at KIMS AND RF, Amalapuram from November 2022 to September 2024.

Participants:

60 patients with chronic anal fissures (>6 weeks duration) were enrolled. Exclusion criteria included pregnancy, IBD, TB, malignancy, immunosuppression, prior anal surgery, or bleeding disorders.

Randomization:

Patients were assigned alternately: odd-numbered patients to Group A (2% Diltiazem) and even-numbered to Group B (LIS).

Interventions:

- Group A (n=30):** 2% Diltiazem gel applied twice daily for 6 weeks.
- Group B (n=30):** Open LIS performed under spinal anesthesia.

Follow-Up and Outcome Measures:

Patients were reviewed at 2, 6, and 10 weeks. Outcomes assessed:

- Primary outcome:** Fissure healing (visual resolution).
- Secondary outcomes:** Pain (VAS), bleeding per rectum, anal incontinence (Wexner Score), and recurrence.

Statistical Analysis:

SPSS v16.0 was used. Chi-square and t-tests compared outcomes between groups. Significance set at p < 0.05.

RESULTS

Demographics:

Mean age: 37 years; Female: Male = 55:45. Posterior midline fissures predominated (91%).

Healing Rates:

- Group A: 73.3% healed by week 10.
- Group B: 96.7% healed by week 10. (p = 0.026)

Pain Relief:

- Group A: VAS reduced from 7.66 to 2.26.
- Group B: VAS reduced from 7.93 to 0.56. (p = 0.001)

Bleeding Per Anum:

- Group A: 73.3% recovered.
- Group B: 96.7% recovered. (p = 0.026)

Anal Incontinence:

- Group A: 1 patient (3.3%) temporary.
- Group B: 10 patients (33.3%) initially; 1 permanent case. (p = 0.003)

Recurrence:

- Group A: 6 patients (20%)
- Group B: None. (p = 0.024)

Outcome	Diltiazem (n=30)	LIS (n=30)	p-value
Healing Rate	73.3%	96.7%	0.026
Final VAS Score	2.26	0.56	0.001
Bleeding Resolved	73.3%	96.7%	0.026
Incontinence	3.3% (temporary)	33.3% (1 permanent)	0.003
Recurrence	20%	0%	0.024

DISCUSSION

Lateral internal sphincterotomy (LIS) continues to be the gold standard in the surgical management of chronic anal fissures due to its consistently high healing rates and prompt symptom relief. Our study corroborates these findings, with LIS

demonstrating a healing rate of 96.7% compared to 73.3% in the 2% Diltiazem group. Additionally, patients who underwent LIS reported significantly greater pain relief and a more rapid resolution of bleeding symptoms. These results highlight the effectiveness of LIS in addressing the underlying pathophysiology of chronic fissures—internal sphincter hypertonia.

However, despite its clinical efficacy, LIS is associated with a notable risk of postoperative complications, particularly fecal incontinence. In our study, 33.3% of patients in the LIS group experienced temporary incontinence, and one patient (3.3%) had persistent incontinence at final follow-up. This aligns with existing literature that emphasizes the need for careful patient selection when considering surgical intervention. Patients who are young, female, or have a history of obstetric trauma may be particularly vulnerable to continence-related complications.

In contrast, topical 2% Diltiazem, a calcium channel blocker that induces chemical sphincter relaxation, offers a non-invasive treatment option with a much lower incidence of side effects. In our study, only one patient (3.3%) reported transient incontinence with Diltiazem, and no cases of permanent incontinence occurred. Previous studies by Rithin-Suvarna et al. and Madhusudhan et al. have similarly reported Diltiazem healing rates ranging from 60% to 89%, suggesting its utility in managing early or mild cases.

Though the recurrence rate was higher with Diltiazem (20% vs. 0% in LIS), its safety profile and ease of use make it a viable first-line treatment. Surgical management should be reserved for patients who fail to respond to conservative therapy or who present with severe, debilitating symptoms.



CONCLUSION

Lateral internal sphincterotomy (LIS) proves to be a highly effective treatment for chronic anal fissure, offering superior healing rates, rapid symptom relief, and zero recurrence in our study. However, it carries a higher risk of morbidity, particularly postoperative incontinence, which warrants careful consideration. Topical 2% Diltiazem gel emerges as a safe, non-invasive, and effective first-line therapy, especially suitable for patients at risk of incontinence or those preferring to avoid surgery. While LIS remains the definitive treatment for refractory cases, initiating management with medical therapy is advisable, reserving surgical options for non-responders or those with severe, persistent symptoms.

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