



A COMPARATIVE STUDY OF TOPICAL 2% DILTIAZEM AND LATERAL INTERNAL SPHINCTEROTOMY IN THE MANAGEMENT OF CHRONIC FISSURE-IN-ANO.

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Abstract

Background: Chronic fissure-in-ano is a common anorectal condition characterized by severe pain, bleeding, and sphincter spasm, significantly affecting quality of life. While lateral internal sphincterotomy (LIS) is considered the gold standard treatment, it carries a risk of incontinence. Topical agents such as 2% diltiazem offer a non-surgical alternative by reducing sphincter tone. This study compares the efficacy and safety of topical diltiazem with surgical sphincterotomy in chronic fissure management. **Aims:** To compare the effectiveness, safety, and outcomes of topical 2% diltiazem with lateral internal sphincterotomy in the management of chronic fissure-in-ano. **Materials and Methods:** This prospective comparative study was conducted over a period of 10 months and included 45 patients diagnosed with chronic fissure-in-ano. Patients were divided into two groups: Group A (n=24) received topical 2% diltiazem applied twice daily for 6–8 weeks, and Group B (n=24) underwent LIS. Patients were followed up regularly to assess pain relief, fissure healing, recurrence, and complications. Pain was evaluated using a visual analog scale, and healing was assessed clinically. Data were analyzed using appropriate statistical tests, with $p < 0.05$ considered significant. **Results:** The mean age of patients was 39.2 ± 9.8 years, with a slight male predominance. Pain relief was observed earlier in the sphincterotomy group, with significant reduction noted within the first week compared to the diltiazem group ($p < 0.05$). Complete fissure healing was achieved in 22 (91.7%) patients in the sphincterotomy group and 17 (70.8%) patients in the diltiazem group. Recurrence was higher in the diltiazem group (6; 25.0%) compared to the surgical group (1; 4.2%). However, complications such as minor incontinence were observed only in the sphincterotomy group (2; 8.3%), while no major complications were noted in the diltiazem group. Overall, patient compliance was better with conservative management, although surgical treatment demonstrated superior efficacy in terms of faster symptom relief and higher healing rates. **Conclusion:** Topical 2% diltiazem is an effective and safe non-surgical option for the management of chronic fissure-in-ano, particularly in patients unwilling or unfit for surgery. However, LIS remains superior in terms of faster pain relief and higher healing rates, with a lower recurrence rate. The choice of treatment should be individualized based on patient factors and risk of complications.

Keywords: Chronic fissure-in-ano, Diltiazem, Lateral internal sphincterotomy, Pain relief, Recurrence.



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INTRODUCTION

Chronic fissure-in-ano is a common and distressing anorectal condition characterized by a longitudinal tear in the anoderm distal to the dentate line, typically located in the posterior midline.¹ It is associated with severe pain during and after defecation, bleeding per rectum, and sphincter spasm, which significantly impairs the quality of life.² The pathophysiology of chronic fissure involves a cycle of trauma, internal anal sphincter hypertonia, reduced anodermal blood flow, and impaired healing. Persistent sphincter spasm leads to local ischemia, thereby preventing resolution and promoting chronicity.³

The management of chronic fissure-in-ano has evolved considerably over time, with the primary goal being the reduction of internal anal sphincter pressure to improve blood flow and facilitate healing.⁴ Traditionally, lateral internal sphincterotomy (LIS) has been regarded as the gold standard treatment, offering high healing rates exceeding 90%. It effectively relieves sphincter spasm and provides rapid symptomatic relief.⁵ However, this surgical intervention is not without complications, the most concerning being varying degrees of fecal incontinence, which may be temporary or, in

some cases, persistent. This risk has led to increasing interest in non-surgical alternatives that can provide comparable outcomes with fewer adverse effects.⁶

Among conservative therapies, topical calcium channel blockers such as 2% diltiazem have gained prominence due to their ability to induce chemical sphincter relaxation.⁷ Diltiazem acts by inhibiting calcium ion influx into smooth muscle cells, resulting in reduced sphincter tone and improved anodermal perfusion. This promotes healing of the fissure while avoiding the risks associated with surgical intervention.⁸ Topical diltiazem is generally well tolerated, with minimal side effects such as mild perianal irritation or headache. It offers a non-invasive, cost-effective, and patient-friendly treatment option, especially suitable for individuals who are unwilling or unfit for surgery.⁹

Despite the advantages of medical therapy, concerns remain regarding its comparatively lower healing rates, slower onset of symptom relief, and higher recurrence rates when compared to surgical management.¹⁰ On the other hand, while LIS provides definitive treatment with rapid healing, the potential risk of incontinence continues to be a significant limitation.¹¹ Therefore, there is a need to balance efficacy with safety when selecting the appropriate treatment modality for chronic fissure-in-ano.

Recent clinical practice has increasingly emphasized individualized patient management based on disease severity, patient preference, and risk factors. Comparative studies evaluating both conservative and surgical approaches are essential to guide evidence-based decision-making. Assessing parameters such as pain relief, healing rate, recurrence, and complications can help determine the most suitable treatment strategy for different patient populations.

AIMS AND OBJECTIVES

- To compare the effectiveness, safety, and outcomes of topical 2% diltiazem with lateral internal sphincterotomy in the management of chronic fissure-in-ano.

MATERIALS AND METHODS

This prospective comparative study was conducted in the Department of General Surgery at Sree Mookambika Institute of Medical Sciences over a period of 10 months from March 2025 to December 2025. A total of 45 patients diagnosed clinically with chronic fissure-in-ano were included in the study. Written informed consent was secured from all participants prior to enrollment.

Inclusion criteria comprised patients aged between 18 and 65 years with clinically diagnosed chronic fissure-in-ano (symptoms persisting for more than 6 weeks), presence of sentinel pile or hypertrophied anal papilla, and those willing to participate in the study and comply with follow-up.

Exclusion criteria included patients with acute fissure-in-ano, previous anorectal surgery, associated anorectal conditions such as hemorrhoids, fistula-in-ano, or malignancy, inflammatory bowel disease, pregnancy, immunocompromised status, and patients unwilling to provide consent or adhere to follow-up.

A detailed clinical history was obtained, and thorough local anorectal examination was performed in all cases to confirm the diagnosis. Patients were divided into two groups based on the treatment modality.

Group A consisted of 24 patients who were managed conservatively with topical 2% diltiazem ointment, applied twice daily for a duration of 6–8 weeks. All patients in this group were also advised dietary modifications, including a high-fiber diet, adequate fluid intake, and use of stool softeners where necessary.

Group B included 24 patients who underwent LIS under appropriate anesthesia. The surgical procedure was performed using a standardized open technique, ensuring division of the internal anal sphincter up to the level of the fissure apex. Postoperative care included analgesics, sitz baths, and dietary advice similar to the conservative group.

Patients were followed up at regular intervals to assess clinical outcomes, including pain relief, fissure healing, recurrence, and complications. Pain was assessed using a visual analog scale (VAS), and healing was determined based on complete epithelialization of the fissure on clinical examination. Any adverse effects such as headache, perianal irritation, infection, or incontinence were noted and recorded. Recurrence was defined as the reappearance of symptoms or fissure after initial healing during the follow-up period.

The collected data were entered into a structured proforma and analyzed using appropriate statistical methods. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were expressed as percentages.

Statistical significance was determined using suitable tests, with a p-value of less than 0.05 considered statistically significant.

RESULTS

Majority belonged to 31–50 years (54.2%). No significant difference between groups ($p = 0.84$). Male predominance observed. Distribution comparable ($p = 0.76$). Most patients presented within 6–12 weeks. No significant difference ($p = 0.91$). (Table 1)

Table 1: Distribution of age, gender and duration of illness

		Group A n (%)	Group B n (%)	Total n (%)
Age Group (years)	21–30	5 (20.8%)	4 (16.7%)	9 (18.8%)
	31–40	7 (29.2%)	6 (25.0%)	13 (27.1%)
	41–50	6 (25.0%)	7 (29.2%)	13 (27.1%)
	51–60	4 (16.7%)	5 (20.8%)	9 (18.8%)
	>60	2 (8.3%)	2 (8.3%)	4 (8.3%)
Gender	Male	15 (62.5%)	16 (66.7%)	31 (64.6%)
	Female	9 (37.5%)	8 (33.3%)	17 (35.4%)
Duration	6–8 weeks	10 (41.7%)	9 (37.5%)	19 (39.6%)
	9–12 weeks	8 (33.3%)	9 (37.5%)	17 (35.4%)
	>12 weeks	6 (25.0%)	6 (25.0%)	12 (25.0%)

At 1-week follow-up, a significantly higher proportion of patients in the sphincterotomy group (83.3%) experienced significant pain relief ($\geq 50\%$ reduction in VAS score) compared to the diltiazem group (50.0%). Moderate and mild relief were more commonly observed in the diltiazem group, indicating a slower response to medical therapy. The difference in pain relief between the two groups was statistically significant ($p = 0.02$), suggesting that surgical intervention provides more rapid symptomatic improvement in chronic fissure-in-ano.

Table 2: Pain Relief at 1 Week Based on VAS Score Reduction

VAS Reduction Category	Definition (Reduction in Score)	Group A (Diltiazem) n (%)	Group B (Sphincterotomy) n (%)	Total n (%)	p-value
Significant relief	$\geq 50\%$ reduction	12 (50.0%)	20 (83.3%)	32 (66.7%)	0.02*
Moderate relief	25–49% reduction	8 (33.3%)	3 (12.5%)	11 (22.9%)	
Mild relief	<25% reduction	4 (16.7%)	1 (4.2%)	5 (10.4%)	
No relief	No change	0 (0%)	0 (0%)	0 (0%)	

Pain reduction was significantly faster and more pronounced in the surgical group at follow-up. Baseline pain scores were comparable between the two groups ($p = 0.79$). However, the sphincterotomy group demonstrated a significantly greater reduction in VAS scores at 1 week and 4 weeks ($p = 0.01$). (Table 3).

Table 3: Mean VAS Score Comparison (Follow-up).

Time Interval	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	p-value
Baseline	8.4 $\pm$ 1.1	8.5 $\pm$ 1.0	0.79
1 week	5.2 $\pm$ 1.3	3.1 $\pm$ 1.2	0.01*
4 weeks	2.8 $\pm$ 1.2	1.2 $\pm$ 0.8	0.01*

A significantly higher proportion of patients in the sphincterotomy group achieved healing within ≤ 4 weeks compared to the diltiazem group ($p = 0.01$). Early healing was significantly higher in the sphincterotomy group. (Table 4)

Table 4: Time to Complete Healing

Duration to Healing	Group A n (%)	Group B n (%)	Total n (%)	p-value
≤ 4 weeks	6 (25.0%)	15 (62.5%)	21 (43.8%)	0.01*
5–8 weeks	11 (45.8%)	7 (29.2%)	18 (37.5%)	
Not healed	7 (29.2%)	2 (8.3%)	9 (18.8%)	

Sphincterotomy showed significantly better outcomes in terms of early pain relief, higher healing rates, and lower recurrence ($p < 0.05$). (Table 5).

Table 5: Outcome Variables

Parameter	Group A n (%)	Group B n (%)	p-value
Early pain relief	12 (50.0%)	20 (83.3%)	0.02*
Healing	17 (70.8%)	22 (91.7%)	0.04*
Recurrence	6 (25.0%)	1 (4.2%)	0.04*
Complications	2 (8.3%)	3 (12.5%)	0.07

Satisfaction was significantly higher in the surgical group. A significantly greater proportion of patients in the surgical group reported high satisfaction compared to the diltiazem group ($p = 0.04$). Lower satisfaction levels were more frequent in the conservative group, reflecting comparatively slower symptom relief and healing. (Table 6).

Table 6: Post-Treatment Patient Satisfaction

Satisfaction Level	Group A n (%)	Group B n (%)	Total n (%)	p-value
Highly satisfied	14 (58.3%)	20 (83.3%)	34 (70.8%)	0.04*
Moderately satisfied	7 (29.2%)	3 (12.5%)	10 (20.8%)	
Not satisfied	3 (12.5%)	1 (4.2%)	4 (8.3%)	

DISCUSSION

The present study evaluated 48 patients with chronic fissure-in-ano, equally distributed between topical 2% diltiazem therapy and LIS, with comparable baseline characteristics in both groups. The majority of patients belonged to the 31–50 years age group (54.2%), indicating that chronic fissure predominantly affects the middle-aged, economically active population. A male predominance (64.6%) was observed, and most patients presented after 6–12 weeks of symptom onset (75.0%), reflecting delayed healthcare-seeking behavior and chronicity of symptoms. These demographic findings are consistent with several comparative studies. Wadhokar P et al.12 reported that most patients were between 30 and 60 years of age, with a mean age of 42 years, and demonstrated a marked male predominance (88.3%), which is higher than that observed in the present study but supports the trend of male preponderance. Similarly, Varshney PM et al.13 observed that the majority of patients were in the 28–38 years age group, with a male predominance (57.5%), closely aligning with the present findings.

In contrast, some studies have reported a more balanced or female-predominant distribution. Dua M et al.14 noted a nearly equal gender distribution with a slight female predominance (54.3% females), suggesting that gender distribution may vary depending on population characteristics and healthcare access. Likewise, Pangtey S et al.15 reported a slight female predominance (53.3%) with a mean age of 34.17 years, which still falls within the young to middle-aged group, consistent with the current study's age profile. Pain relief was significantly superior in the surgical group. At one week, 83.3% of patients in the LIS group experienced significant pain relief compared to 50.0% in the diltiazem group ($p = 0.02$). Furthermore, the reduction in mean Visual Analog Scale (VAS) scores was significantly greater in the LIS group at both 1 week and 4 weeks, demonstrating faster symptomatic improvement. These findings are in agreement with Dua M et al.14 who reported significantly better pain relief in the LIS group (94.3%) compared to the diltiazem group (68.6%). Similarly, Wadhokar P et al.12 observed higher rates of early pain relief in patients undergoing sphincterotomy, although long-term pain control was comparable between groups.

Healing outcomes in the present study also favored the surgical approach. Early healing (≤ 4 weeks) was achieved in 62.5% of patients in the LIS group compared to 25.0% in the diltiazem group. Overall healing rates were significantly higher in the surgical group (91.7% vs 70.8%; $p = 0.04$). These findings are consistent with Bansal AR et al.16 who reported healing rates of 96% in the LIS group compared to 72% in the diltiazem group. Likewise, Siripurapu S et al.17 demonstrated higher healing rates with LIS (82%) compared to diltiazem (68%). Varshney PM et al.13 also reported faster healing and superior outcomes with surgical intervention compared to topical therapy. Recurrence rates were significantly lower in the surgical group (4.2%) compared to the diltiazem group (25.0%), indicating the durability of surgical treatment. This observation is supported by Acar T et al.18 who highlighted that LIS provides the best long-term outcomes with minimal recurrence. In contrast, conservative therapy, although effective in selected cases, is associated with higher recurrence rates. Kavya P et al.19 also suggested that while diltiazem is effective as a first-line therapy, recurrence and incomplete healing may necessitate surgical intervention.

Complication rates were low and comparable in both groups. In the present study, minor side effects such as headache and perianal irritation were observed in the diltiazem group, whereas a small proportion of patients in the LIS group developed minor incontinence (12.5%), which was not statistically significant. These findings are in line with Wadhokar P et al.12 and Siripurapu S et al.17 who reported occasional flatus incontinence following sphincterotomy but no major complications. The safety profile of diltiazem was also supported by Pangtey S et al.15 who demonstrated minimal adverse effects with topical therapy. Patient satisfaction was significantly higher in the LIS group (83.3%) compared to the

diltiazem group (58.3%), reflecting better symptom resolution and quality of life. This observation is consistent with multiple studies emphasizing the superior efficacy of surgical management. However, topical diltiazem remains a valuable alternative, particularly in patients unwilling or unfit for surgery, as highlighted by Bansal AR et al.¹⁶ and Kavya P et al.¹⁹.

CONCLUSION

LIS is a highly effective treatment for chronic fissure-in-ano, providing faster pain relief, earlier healing, and significantly lower recurrence rates compared to topical 2% diltiazem. Although topical diltiazem is safe and non-invasive with minimal side effects, it demonstrates slower symptomatic improvement and higher rates of non-healing and recurrence. Surgical management, despite a small risk of minor complications, offers superior overall outcomes and higher patient satisfaction. Therefore, sphincterotomy should be considered the preferred treatment in suitable patients, while topical diltiazem may be reserved for those unfit or unwilling for surgery.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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