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Comparison of the Efficacy of 2% Diltiazem gel versus Lateral Sphincterotomy in the Management of Fissure-in-Ano

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ABSTRACT

Introduction: Fissure-in-ano is a common anorectal condition characterized by severe pain, bleeding, and impaired bowel performance. While lateral internal sphincterotomy remains the standard surgical treatment, topical calcium channel blockers such as 2% Diltiazem gel have emerged as a promising non-invasive alternative.

Objectives: To compare pain relief, fissure healing, and treatment-related complications between 2% Diltiazem gel and lateral internal sphincterotomy.

Methods: This prospective interventional study was conducted from April 2024 to September 2025 in the Department of General Surgery, SRMS IMS, Bareilly. Sixty-six patients fulfilling inclusion criteria were randomized into two groups: Group A received 2% Diltiazem gel, and Group B underwent lateral internal sphincterotomy. Outcomes were assessed weekly for four weeks using the Visual Analogue Scale (VAS), Victoria Bowel Performance Scale, DREss score, bleeding status, anal tone, and complications. Statistical analysis was performed using independent-samples t-test, Fisher's exact test, and repeated-measures ANOVA.

Results: Both groups were comparable in baseline demographic and clinical characteristics ($p>0.05$). Pain scores progressively improved in both groups during follow-up. However, at week 4, patients undergoing lateral internal sphincterotomy had significantly lower mean VAS pain scores compared with the diltiazem group (0.12 ± 0.33 vs. 0.74 ± 1.02; $p=0.002$). Bleeding resolved completely in all patients by week 4. Complete fissure healing was achieved in 87.9% of patients in the lateral internal sphincterotomy group compared with 60.6% in the 2% diltiazem group ($p=0.010$). No major complications were observed in either group.

Conclusion: Both topical 2% diltiazem gel and lateral internal sphincterotomy significantly improved symptoms and promoted fissure healing in patients with chronic fissure-in-ano. However, lateral internal sphincterotomy achieved significantly higher healing rates and lower week-4 pain scores. Despite its comparatively lower healing rate, topical 2% diltiazem remains a safe and effective first-line conservative treatment option for patients wishing to avoid surgical intervention.

Keywords: Fissure-in-ano; Diltiazem gel; Lateral internal sphincterotomy; Pain relief; Anal tone; Anorectal disorders.

INTRODUCTION

Fissure-in-ano/anal fissure is one of the most common and distressing anorectal disorders encountered in surgical practice. It is defined as a longitudinal ulcer in the distal anal canal, typically located in the posterior midline, and is characterized by severe pain during and after defecation, often accompanied by rectal bleeding. The condition is commonly seen in young and middle-aged adults and can significantly affect the quality of life due to its chronic and recurrent nature. The underlying pathophysiology involves a cycle of mucosal injury, increased internal anal sphincter tone, reduced blood flow to the anoderm, and impaired healing, ultimately leading to chronic fissure formation.[1]

Anal fissure (fissure-in-ano), a common acute or chronic anorectal condition, is an oval or linear anal canal tear extending to the anal verge, starting below the dentate line. It is associated with elevated pressures of internal anal sphincter; however, its exact etiology is not clear. It results from anal canal / anoderm trauma during the hard or large bowel movements passage, ano-receptive intercourse, local irritation from diarrhea, and anorectal surgery.

Healing with nonoperative management (sitz baths, high fiber diet, and pharmacological agents) can be there in half the fissure patients. Lateral internal sphincterotomy (LIS) has a high success rate, when nonoperative management fails. Chronic fissure-in-ano results primarily from persistent hypertonia of the internal anal sphincter, which compromises ano-dermal blood flow and prevents spontaneous healing. While acute fissures may resolve with conservative care, chronic fissures often present with characteristic features such as sentinel pile, hypertrophied anal papilla, and exposed internal sphincter fibers, necessitating targeted therapy. Pharmacological agents including topical nitrates and botulinum toxin offer minimally invasive options aimed at reducing sphincter spasm, though their effectiveness may be limited in long-standing disease. Lateral internal sphincterotomy remains the gold-standard surgical treatment, providing predictable pain relief and high healing rates when conservative measures fail. Overall, individualized management focusing on sphincter relaxation and restoration of tissue perfusion is essential for successful treatment of chronic anal fissures.[2]

Conventional management of fissure-in-ano aims to break this vicious cycle by reducing sphincter spasm, improving ano-dermal perfusion, and promoting healing. Conservative measures, including sitz baths, dietary fiber supplementation, stool softeners, and topical analgesics, are usually the first line of treatment, but many patients with chronic fissures fail to achieve satisfactory relief with these approaches. This has led to the development of pharmacological agents that target the hypertonicity of the internal anal sphincter. Topical calcium channel blockers, particularly 2% diltiazem, have emerged as effective non-invasive options, providing chemical sphincter relaxation, pain relief, and fissure healing without the risk of permanent sphincter damage.[3]

Surgical management, on the other hand, has long been considered the definitive treatment for chronic fissure-in-ano. LIS, the gold standard surgical procedure, involves controlled division of the internal sphincter fibers to relieve spasm and restore normal ano-dermal blood flow. LIS is associated with high healing rates and rapid symptomatic relief; however, its major concern lies in the risk of postoperative complications, particularly varying degrees of anal incontinence, which may compromise long-term outcomes. As a result, the choice between pharmacological and surgical therapy remains an important subject of clinical debate.[4]

In recent years, several randomized controlled trials and comparative studies have evaluated the efficacy of 2% diltiazem ointment against lateral sphincterotomy, with varying results. While LIS shows superior healing rates and quicker symptom resolution, diltiazem offers a non-invasive,

safe, and well-tolerated alternative that avoids surgical morbidity. The balance between efficacy, safety, recurrence rates, and patient satisfaction forms the basis for ongoing research in this field.[5]

Because both treatments have distinct advantages and drawbacks, there is a continued need to generate robust comparative evidence. Understanding differences in healing, symptom resolution, recurrence, and complications is essential for guiding appropriate clinical decision-making and tailoring treatment to individual patient needs. This shows the importance of systematically evaluating and comparing diltiazem therapy and sphincterotomy in the modern therapeutic landscape. The lack of uniform conclusions across existing studies creates a gap in evidence regarding comparative effectiveness, safety, recurrence, and patient satisfaction. Given the clinical and therapeutic importance of fissure-in-ano, this study has been undertaken with following:

Objectives

1. To compare the symptomatic pain relief in patients of fissure in ano using 2 % Diltiazem gel and patients undergoing lateral internal sphincterotomy.
2. To compare healing in patients of fissure in ano using 2 % Diltiazem gel and patients undergoing lateral internal sphincterotomy.
3. To evaluate the complications in patients of fissure in ano using 2 % Diltiazem gel and patients undergoing lateral internal sphincterotomy.

MATERIALS & METHODS

Study Design and Setting

This prospective, randomized, open-label interventional study was conducted in the Department of General Surgery, Shri Ram Murti Smarak Institute of Medical Sciences (SRMS-IMS), Bareilly, Uttar Pradesh, India, from 1 April 2024 to 30 September 2025. The study included patients presenting to the outpatient and inpatient departments with clinically diagnosed chronic fissure-in-ano.

Eligibility Criteria

The inclusion criteria were:

- Patients aged ≥18 years with clinically diagnosed chronic fissure-in-ano.
- Duration of symptoms greater than six weeks.
- Patients willing to participate and provide written informed consent.

The exclusion criteria were:

- Children and mentally incapacitated patients.
- Fissures associated with hemorrhoids, fistula-in-ano, or other anorectal pathologies.
- Fissures secondary to malignancy, tuberculosis, Crohn's disease, or other specific diseases.
- Pregnant women.
- Patients receiving medications other than the study interventions for fissure treatment.
- Patients unwilling to participate or provide consent.
- Patients who were lost to follow-up.

Sample Size Estimation

Sample size was calculated using G*Power software for comparison of two independent groups. Assuming an effect size (d) of 0.90, a two-sided significance level (α) of 0.05, and a statistical power (1−β) of 95%, the minimum required sample size was estimated to be 66 participants. Accordingly, 66 eligible patients were enrolled and randomized equally into two treatment groups.

Randomization and Allocation Concealment

Eligible patients were enrolled consecutively and randomly allocated into two treatment groups in a 1:1 ratio using a computer-generated random number sequence. Allocation concealment was achieved using sealed, opaque, sequentially numbered envelopes prepared before study

initiation. Following informed consent, the next envelope in sequence was opened to determine treatment allocation.
Group A received topical 2% Diltiazem gel, whereas Group B underwent lateral internal sphincterotomy (LIS).

Blinding
The study was conducted as an open-label randomized controlled trial. Blinding of participants and treating surgeons was not feasible because of the obvious differences between topical medical therapy and surgical intervention. However, outcome assessment was performed using predefined objective criteria and standardized scoring systems to minimize assessment bias.

Interventions
Group A: Topical 2% Diltiazem Gel
Patients allocated to Group A were instructed to apply approximately 1.5–2 cm of 2% Diltiazem gel into the anal canal twice daily, extending at least 1.5 cm beyond the anal verge. Patients were advised to wash their hands before and after each application. Treatment was continued throughout the four-week follow-up period. All patients were managed on an outpatient basis and reviewed weekly.

Group B: Lateral Internal Sphincterotomy
Written informed consent for surgery was obtained from all patients. Preoperative bowel preparation was carried out, and the operative field was prepared using an antiseptic solution. Patients were positioned in the lithotomy position; however, prone jackknife or lateral decubitus positions were used when clinically indicated.

Open Technique
Under appropriate anesthesia, the intersphincteric groove was palpated at the anal verge. A 1–2 cm circumferential incision was made over the free edge of the internal sphincter. Blunt dissection was performed to identify the internal sphincter. The distal portion of the internal sphincter was isolated, grasped, and divided under direct vision.

Closed Technique
A No. 11 blade was introduced between the internal sphincter and the anoderm and advanced parallel to the anal canal. The blade was rotated outward and gentle pressure was applied against the distal internal sphincter while it was maintained under tension using a bivalve retractor. The blade was subsequently withdrawn, and digital palpation was performed to confirm adequate sphincter division. Any remaining sphincter fibers were released by gentle digital pressure. Associated sentinel skin tags or fibroepithelial polyps, when present, were excised. Surgical wounds were left open to heal by secondary intention. Postoperatively, patients were monitored for bleeding, hematoma formation, wound infection, and continence status. Patients were discharged between the third and seventh postoperative day and subsequently reviewed weekly for four weeks.

Outcome Measures
Primary Outcome
The primary outcome measure was complete fissure healing at four weeks following initiation of treatment.

Secondary Outcomes
The secondary outcome measures included:
1. Reduction in pain severity assessed by the Visual Analogue Scale (VAS).
2. Improvement in anal sphincter tone assessed by Digital Rectal Examination Severity (DREss) score.
3. Improvement in bowel function assessed by the Victoria Bowel Performance Scale (BPS).
4. Resolution of bleeding per rectum.
5. Occurrence of treatment-related complications and adverse events, including headache, dermatitis, infection, and incontinence.

Assessment Tools

Visual Analogue Scale (VAS)

Pain intensity was assessed using a 10-cm Visual Analogue Scale ranging from 0 (no pain) to 10 (worst imaginable pain). Patients recorded their pain scores at each follow-up visit.

Victoria Bowel Performance Scale (BPS)

Bowel function was assessed using the Victoria Bowel Performance Scale, which evaluates bowel frequency, urgency, continence, and ease of stool passage. Lower scores indicated improved bowel performance.

Digital Rectal Examination Severity (DREss) Score

Local clinical findings, including sphincter tone, fissure tenderness, induration, and associated sentinel tags, were evaluated using the DREss score during follow-up visits.

Data Collection and Follow-up

Baseline demographic characteristics, medical history, duration of symptoms, and baseline VAS, BPS, and DREss scores were recorded at enrollment. Patients were followed weekly for four weeks. During each visit, pain severity, bowel function, anal sphincter tone, fissure healing status, bleeding, and treatment-related complications were assessed and documented.

To maintain consistency and reduce observer variability, digital rectal examinations were performed by the same consultant surgeon or by a trained senior resident under supervision.

Ethical Considerations

The study was approved by the Institutional Ethics Committee of Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly (Ref. No. SRMS/IMS/ECC/2024/89). Written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 20.0. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Baseline continuous variables between groups were compared using the independent-samples t-test, whereas categorical variables were compared using the Fisher's exact test, as appropriate.

Between-group comparisons at individual time points were performed using independent-samples t-tests, while longitudinal changes within groups were assessed using repeated-measures ANOVA. A p-value <0.05 was considered statistically significant.

RESULT

A total of 120 patients were assessed for eligibility during the study period. Of these, 54 patients were excluded due to failure to meet the inclusion criteria or refusal to participate. The remaining 66 eligible patients were randomized equally into two treatment groups: Group A (2% Diltiazem gel, n=33) and Group B (lateral internal sphincterotomy, n=33). All randomized participants received the allocated intervention, completed the four-week follow-up period, and were included in the final analysis. The participant flow through the study is presented in Figure 1 (CONSORT flow diagram).

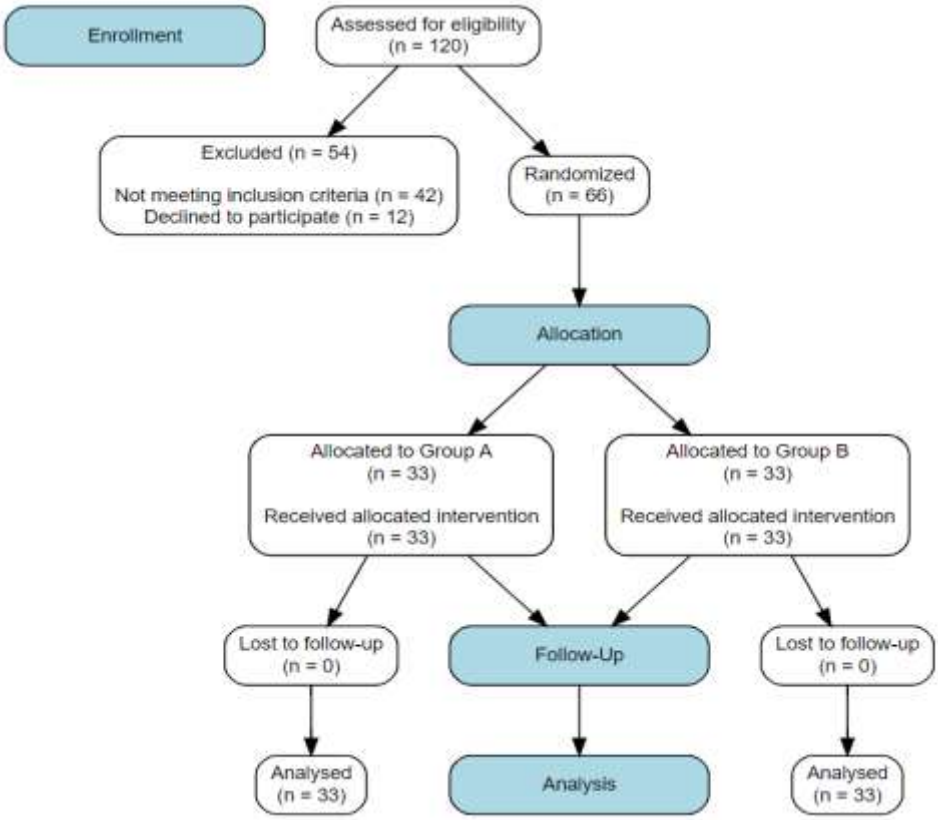

Figure 1: CONSORT flow diagram

The two groups were comparable with respect to age, sex distribution, dietary habits, symptom duration, presenting complaints, comorbidities, and clinical examination findings (all p>0.05). The mean age was 40.39 ± 11.61 years in Group A and 37.46 ± 11.91 years in Group B (p=0.458). Male participants constituted 54.5% and 60.6% of Groups A and B, respectively (p=0.618), indicating no significant baseline differences between the treatment groups. Table 1 shows a progressive improvement in anal tone in both groups over the four-week follow-up period. By week 1, an increase in normal anal tone and a reduction in extremely tight tone were observed in both groups, (p =0.343). At week 2, normal anal tone became predominant in both groups [22 (66.7%) in group A and 24 (72.7%) in group B], while elevated and extremely tight tones markedly declined, (p =0.478). Further improvement was noted at week 3, with normal tone observed in 27 (81.8%) patients in group A and 32 (97.0%) in group B (p =0.66). By week 4, almost all patients had normal anal tone [32 (97.0%) in group A and 33 (100.0%) in group B].

Table 1: Comparison of anal tone changes over four weeks between groups

Time Point	Anal Tone Category	Group A n (%)	Group B n (%)	Total n (%)	P value
At the time of presentation	Mildly decreased tone	2 (6.1%)	8 (24.2%)	10 (15.2%)	0.147
	Normal	6 (18.2%)	3 (9.1%)	9 (13.6%)	
	Elevated tone	13 (39.4%)	9 (27.3%)	22 (33.3%)	
	Extremely tight	12 (36.4%)	13 (39.4%)	25 (37.9%)	
Week 1	Mildly decreased tone	1 (3.0%)	3 (9.1%)	4 (6.1%)	0.343
	Normal	12 (36.4%)	11 (33.3%)	23 (34.8%)	
	Elevated tone	14 (42.4%)	17 (51.5%)	31 (47.0%)	
	Extremely tight	6 (18.2%)	2 (6.1%)	8 (12.1%)	
Week 2	Mildly decreased tone	1 (3.0%)	2 (6.1%)	3 (4.5%)	0.478
	Normal	22 (66.7%)	24 (72.7%)	46 (69.7%)	

	Elevated tone	8 (24.2%)	7 (21.2%)	15 (22.7%)	
	Extremely tight	2 (6.1%)	0 (0.0%)	2 (3.0%)	
Week 3	Mildly decreased tone	1 (3.0%)	1 (3.0%)	2 (3.0%)	0.66
	Normal	27 (81.8%)	32 (97.0%)	59 (89.4%)	
	Elevated tone	5 (15.2%)	0 (0.0%)	5 (7.6%)	
Week 4	Normal	32 (97.0%)	33 (100.0%)	65 (98.5%)	0.314
	Elevated tone	1 (3.0%)	0 (0.0%)	1 (1.5%)	

Note: Fisher exact test.

Table 2 shows a gradual reduction in mean anal tone scores and a similar pattern of improvement over four weeks in both groups. At presentation, the mean anal tone was slightly higher in group A (4.1 ± 0.9) compared to group B (3.8 ± 1.2), (p =0.360). A similar declining trend was observed at week 1 and week 2 in both groups, (p > 0.05). At week 4, mean anal tone scores were comparable in both groups (3.0 ± 0.2 vs. 3.0 ± 0.0), (p =0.321). Mean anal tone scores decreased progressively throughout follow-up in both treatment groups. Repeated-measures ANOVA demonstrated a significant reduction in anal tone scores over time within both Group A and Group B (both p<0.001). However, the time × treatment interaction was not statistically significant (p=0.114), indicating that the pattern of improvement in anal tone was comparable between the two treatment modalities.

Table 2: Comparison of mean anal tone scores over four weeks between groups

Time Point	**Group A (Diltiazem) Mean ± SD**	**Group B (LIS) Mean ± SD**	**Between-Group p-value**
Baseline	4.1 ± 0.9	3.8 ± 1.2	0.36
Week 1	3.8 ± 0.8	3.5 ± 0.8	0.27
Week 2	3.3 ± 0.6	3.2 ± 0.5	0.208
Week 3	3.1 ± 0.4	3.0 ± 0.2	0.058
Week 4	3.0 ± 0.2	3.0 ± 0.0	0.321
Within-group p-value (RM-ANOVA)	**<0.001**	**<0.001**	
Time × Treatment Interaction			**0.114**

Note: *Between-group comparisons were performed using independent-samples t-test. Within-group changes over time were assessed using repeated-measures ANOVA.*

Table 3 shows that at week 1, both groups experienced comparable baseline pain levels (p =0.413). Over the subsequent weeks, both groups exhibited a steady and marked decline in pain intensity, showing significant clinical improvement. By week 4, mean pain scores had reduced to 0.74 ± 1.02 in group A and 0.12 ± 0.33 in group B. Group B showed marginally greater pain reduction at each follow-up. VAS pain scores decreased significantly over time in both groups (RM-ANOVA, p<0.001 for each group). The significant time × treatment interaction (p=0.021) indicates that the magnitude of pain reduction differed between treatment modalities. Although pain scores were similar during weeks 1–3, patients undergoing lateral internal sphincterotomy achieved significantly lower pain scores at week 4 compared with those receiving topical Diltiazem gel (0.12 ± 0.33 vs. 0.74 ± 1.02; p=0.002).

Table 3: Comparison of VAS scores over four weeks between groups

Time Point	**Group A (Diltiazem) Mean ± SD**	**Group B (LIS) Mean ± SD**	**Between-Group p-value**
Week 1	6.64 ± 1.08	6.39 ± 1.30	0.413
Week 2	5.06 ± 1.30	4.85 ± 1.42	0.528

Week 3	3.46 ± 1.54	3.30 ± 1.45	0.682
Week 4	0.74 ± 1.02	0.12 ± 0.33	0.002*
Within-group p-value (RM-ANOVA)	**<0.001**	**<0.001**	
Time × Treatment Interaction			**0.021**

Note: *Between-group comparisons were performed using independent-samples t-test. Within-group changes over time were assessed using repeated-measures ANOVA.*

Table 4 shows that at week 1, nearly half of the patients in both groups experienced bleeding (p =0.622). By week 2, the proportion of patients without bleeding increased to 78.8% in group A and 81.8% in group B (p =0.757). By week 3, only 6.1% of patients in each group continued to report bleeding, while week 4 showed complete resolution of bleeding in all patients (100%).

Table 4: Comparison of bleeding status over four weeks between groups

Week	Bleeding Status	Group A (n=33)	Group B (n=33)	Total (n=66)	p-value [#]
Week 1	Absent	16 (48.5%)	18 (54.5%)	34 (51.5%)	0.62
	Present	17 (51.5%)	15 (45.5%)	32 (48.5%)	
Week 2	Absent	26 (78.8%)	27 (81.8%)	53 (80.3%)	0.76
	Present	7 (21.2%)	6 (18.2%)	13 (19.7%)	
Week 3	Absent	31 (93.9%)	31 (93.9%)	62 (93.9%)	1.00
	Present	2 (6.1%)	2 (6.1%)	4 (6.1%)	
Week 4	Absent	33 (100.0%)	33 (100.0%)	66 (100.0%)	
	Present	0 (0.0%)	0 (0.0%)	0 (0.0%)	-

[#]*Fisher exact test*

Table 5 shows that at week 1, the mean Victoria BPS scores were 1.788 ± 0.820 in group A and 1.970 ± 0.809 in group B, (p=0.368). By Week 2, the scores decreased to 1.364 ±1.113 and 1.697 ± 1.015 for groups A and B respectively, further dropping to 1.091 ± 1.011 and 1.242 ± 0.936 by week 3 (p =0.530). At week 4, both groups achieved low Victoria BPS score levels, with mean scores of 0.818 ± 0.983 in group A and 0.909 ± 0.914 in group B (p =0.698). Mean BPS scores decreased from 1.788 ± 0.820 to 0.818 ± 0.983 in Group A and from 1.970 ± 0.809 to 0.909 ± 0.914 in Group B. Repeated-measures ANOVA demonstrated a significant improvement in bowel performance over time within both groups (both p<0.001). However, no statistically significant differences were observed between the treatment groups at any follow-up assessment (all p>0.05). Furthermore, the time × treatment interaction was not statistically significant (p=0.742), indicating that the pattern of improvement in bowel performance was comparable between the two treatment modalities.

Table 5: Comparison of mean Victoria BPS scores over four weeks between groups

Time Point	Group A (Diltiazem) Mean ± SD	Group B (LIS) Mean ± SD	Between-Group p-value
Week 1	1.788 ± 0.820	1.970 ± 0.809	0.368
Week 2	1.364 ± 1.113	1.697 ± 1.015	0.208
Week 3	1.091 ± 1.011	1.242 ± 0.936	0.53
Week 4	0.818 ± 0.983	0.909 ± 0.914	0.698
Within-group p-value (RM-ANOVA)	**<0.001**	**<0.001**	
Time × Treatment Interaction			**0.742**

Note: *Between-group comparisons were performed using independent-samples t-test. Within-group changes over time were assessed using repeated-measures ANOVA.*

Across the four-week follow-up period, the occurrence of perianal dermatitis showed a declining pattern in both groups, with no statistically significant differences at any time point. During the first week, dermatitis was noted in 24% of patients in group A and 12% in group B. By the second week, the prevalence further decreased to 15% in Group A and 9% in group B. In the third week, only 9% of group A and 3% of group B patients had dermatitis. By the fourth week, dermatitis had almost completely resolved in both groups, with only one patient (3%) in each group showing persistence.

At week 1, headache was reported by an equal proportion of participants in both groups, with 18.2% in each group experiencing headache, (p = 1.000). In week 2, headache was reported by 12.1% of participants in group A and 9.1% in group B (p = 0.689). By week 3, headache was reported only in group A (6.1%), (p = 0.151). In week 4, headache further declined, with only 3.0% of participants in group A reporting headache and none in group B, (p = 0.314). Overall, a progressive reduction in headache prevalence was observed over time in both groups, with no significant differences between the study groups at any follow-up point.

Table 6 shows that at week 1, incontinence was observed only in 3 group B participants (9.1%), while none in group A; (p = 0.076). In Week 2, incontinence was noted, in only 1 participant (3.0%) in group B and none in group A, (p = 0.314). From Week 3 onwards, 100% continence was reported in both groups. By the end of the fourth week, complete healing was achieved in 87.9% of patients in group B, compared to 60.6% in group A. Conversely, non-healing was observed in 39.4% of patients treated with topical Diltiazem and only 12.1% in the surgical group (p =0.010).

Table 6: Comparison of incontinence between groups over four weeks

Week	Status	Group A n (%)	Group B n (%)	Total n (%)	p-value
Week 1	**Present**	0 (0.0%)	3 (9.1%)	3 (4.5%)	**0.076**
	Absent	33 (100.0%)	30 (90.9%)	63 (95.5%)	
Week 2	**Present**	0 (0.0%)	1 (3.0%)	1 (1.5%)	**0.314**
	Absent	33 (100.0%)	32 (97.0%)	65 (98.5%)	
Week 3	**Present**	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Absent	33 (100.0%)	33 (100.0%)	66 (100.0%)	-
Week 4	**Present**	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Absent	33 (100.0%)	33 (100.0%)	66 (100.0%)	-

#Fisher exact test (- represent p value can't be estimated)

Complete fissure healing at four weeks was achieved in 20 of 33 patients (60.6%) treated with topical 2% Diltiazem gel and 29 of 33 patients (87.9%) who underwent lateral internal sphincterotomy. Conversely, non-healing was observed in 13 patients (39.4%) in Group A and 4 patients (12.1%) in Group B. The difference in healing rates was statistically significant (p=0.010), indicating superior healing outcomes in the lateral internal sphincterotomy group (Table 7).

Table 7. Comparison of Complete Fissure Healing at Week 4

Healing Status	Group A (Diltiazem) n=33	Group B (LIS) n=33	p-value
Complete healing	20 (60.6%)	29 (87.9%)	0.01
Not healed	13 (39.4%)	4 (12.1%)	
Relative risk	1.45 (1.08–1.95)		

Note: Fisher exact test.

The relative risk of complete healing with lateral internal sphincterotomy compared with topical Diltiazem therapy was 1.45 (95% CI: 1.08–1.95), with an absolute risk

difference of 27.3%. Overall, both treatment modalities resulted in significant clinical improvement over the four-week follow-up period. However, lateral internal sphincterotomy achieved significantly higher fissure healing rates and significantly lower week-4 pain scores compared with topical 2% Diltiazem gel.

DISCUSSION

In the present study, pain was the predominant presenting symptom of chronic fissure-in-ano, frequently associated with constipation and bleeding per rectum. Pain was commonly described as sharp or throbbing in nature. Similar findings were reported by Giridhar et al., who observed painful defecation in all patients and noted gradual symptom improvement with topical diltiazem and more rapid relief following lateral internal sphincterotomy (LIS).[6] Popat et al. also identified pain as the most common presenting complaint, with bleeding occurring in approximately 40–50% of patients.[7] The low prevalence of associated symptoms such as pruritus and discharge in our study is consistent with previous reports.

Bleeding per rectum was reported by approximately one-third of patients at baseline. Comparable findings have been reported in earlier studies, where bleeding was present in 50–60% of cases.[6] These observations support the fact that bleeding is a common manifestation of chronic fissure-in-ano irrespective of treatment modality.

The prevalence of systemic comorbidities, particularly diabetes mellitus and hypertension, was relatively high in our cohort. Previous studies have generally reported lower frequencies of systemic illness among patients with anal fissure.[8–10] This difference may reflect the inclusion of common metabolic disorders in the present study population.

Dietary factors may contribute to the development of fissure-in-ano. Mixed dietary habits were common among our participants, and previous investigators have highlighted the association of low-fiber diets, inadequate fluid intake, and irregular bowel habits with fissure formation.[11,12] Rectal wall tenderness was the most frequent local examination finding in both groups, consistent with the characteristic clinical presentation of chronic anal fissure.

Both treatment modalities resulted in progressive normalization of anal sphincter tone during follow-up. Patients undergoing LIS showed a more rapid early reduction in sphincter hypertonia, whereas those treated with topical diltiazem demonstrated a gradual improvement. By week 4, nearly all patients in both groups had achieved normal anal tone. Repeated-measures analysis demonstrated significant improvement over time within both groups; however, no significant differences were observed between the treatment modalities. These findings suggest that both treatments are effective in reducing sphincter hypertonia, although LIS may provide faster initial relaxation.

The improvement in anal tone observed in our study is consistent with the known mechanisms of action of the two therapies. Diltiazem acts through pharmacological relaxation of the internal anal sphincter, whereas LIS produces an immediate mechanical reduction in resting sphincter pressure. Giridhar et al. similarly reported gradual reductions in anal tone with diltiazem and more rapid reductions following surgery.[6]

Pain scores improved significantly in both treatment groups throughout the follow-up period. However, patients undergoing LIS achieved significantly lower pain scores by week 4 compared with those receiving topical diltiazem ($p=0.002$). Repeated-measures analysis further demonstrated a significant treatment–time interaction, indicating greater pain reduction in the surgical group. These findings suggest that although both interventions are effective for pain relief, LIS provides superior symptomatic improvement. Similar observations have been reported by Giridhar et al., who noted faster pain relief after sphincterotomy.[6] Narayan et al. also

demonstrated substantial pain relief with both diltiazem and sphincterotomy, although surgical treatment tended to achieve earlier symptom resolution.[13]

Bleeding improved progressively in both treatment groups, with complete resolution achieved in all patients by week 4. Although earlier studies have suggested more rapid bleeding control following sphincterotomy, the present study found no statistically significant differences between treatment modalities at any follow-up assessment. Therefore, both treatments appear highly effective in controlling bleeding associated with chronic fissure-in-ano.

The most important finding of the present study was the difference in fissure healing rates. Complete healing at four weeks was achieved in 87.9% of patients undergoing LIS compared with 60.6% of patients treated with topical diltiazem (p=0.010). These findings indicate that LIS provides superior healing outcomes within a shorter period. Similar results have been reported by Giridhar et al., who observed healing rates of 100% following LIS and 88.4% following diltiazem therapy.[6] Tsunoda et al. reported a healing rate of approximately 70% with diltiazem therapy,[15] while Knight et al. documented healing in 75% of patients after 8–12 weeks of treatment.[16] Excellent healing outcomes following LIS have also been reported by Tocchi et al., with healing rates approaching 100%.[17]

Both treatment modalities were generally well tolerated. Minor adverse effects such as headache and perianal dermatitis decreased progressively during follow-up and were infrequent by week 4. Transient incontinence was observed only in the LIS group during the early postoperative period and resolved completely during follow-up. Previous studies have similarly reported low complication rates with both treatment strategies.[13,14,18]

Overall, the findings of the present study demonstrate that both topical 2% diltiazem gel and lateral internal sphincterotomy are effective treatments for chronic fissure-in-ano. However, LIS achieved significantly higher healing rates and superior pain reduction by week 4, supporting its role as the more effective treatment modality. Nevertheless, topical diltiazem remains a valuable first-line conservative option for patients who prefer to avoid surgery or are unsuitable surgical candidates.

Limitations:

The sample size was relatively small and the study was conducted at a single center, which may limit the generalizability of the findings. In addition, the follow-up period was limited to four weeks, preventing assessment of long-term healing, recurrence, and late complications. Furthermore, blinding of patients and surgeons was not feasible because of the nature of the interventions. Larger multicenter studies with longer follow-up are needed to confirm these findings.

CONCLUSION

Both topical 2% Diltiazem gel and lateral internal sphincterotomy were effective in reducing symptoms and promoting healing in patients with chronic fissure-in-ano. However, lateral internal sphincterotomy achieved significantly higher fissure healing rates (87.9% vs. 60.6%) and superior pain reduction at four weeks compared with topical Diltiazem therapy. These findings indicate that lateral internal sphincterotomy remains the more effective treatment modality for achieving rapid symptom relief and definitive healing. Nevertheless, topical 2% Diltiazem gel was well tolerated and produced substantial clinical improvement, supporting its role as a safe and effective first-line conservative treatment option, particularly for patients who prefer to avoid surgery or are unsuitable surgical candidates. A stepwise treatment approach may therefore be recommended, with initial medical management using topical Diltiazem followed by lateral internal sphincterotomy in patients with persistent symptoms, delayed healing, or inadequate response to conservative therapy.

Further multicenter studies with larger sample sizes and longer follow-up periods are warranted to evaluate long-term healing, recurrence rates, and treatment-related complications.

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REFERENCES

1. Gerbasi L, Ashurst JV. Anal Fissures. [Updated 2025 Sep 15]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK526063/
2. Beaty JS, Shashidharan M. Anal Fissure. Clin Colon Rectal Surg. 2016 Mar;29(1):30-7. doi: 10.1055/s-0035-1570390.
3. Gupta PJ. Treatment of fissure in ano—revisited. Afr Health Sci. 2004;4(1):58-62.
4. Poh A, Tan KY, Seow-Choen F. Innovations in chronic anal fissure treatment: a systematic review. World J Gastrointest Surg. 2010;2(7):231-241. doi:10.4240/wjgs. v2.i7.231.
5. Vaithianathan R, Panneerselvam S. Randomised prospective controlled trial of topical 2% diltiazem versus lateral internal sphincterotomy for the treatment of chronic fissure in ano. Indian J Surg. 2015;77(Suppl 3):1484-1487. doi:10.1007/s12262-014-1080-z.
6. Giridhar CM, Babu P, Rao KS. A comparative study of lateral sphincterotomy and 2% diltiazem gel local application in the treatment of chronic fissure in ano. J Clin Diagn Res. 2014;8(10):NC01-NC02. doi: 10.7860/JCDR/2014/10480.4925.
7. Popat A, Pandey CP, Agarwal K, Srivastava VP, Sharma SM, Dixit A. A comparative study of role of topical diltiazem 2% organogel and lateral internal sphincterotomy for the management of chronic fissure in ano. Int J Contemp Med Res. 2016;3(5):1363-1366.
8. Stewart DB Sr, Gaertner W, Glasgow S, Migaly J, Feingold D, Steele SR. Clinical practice guideline for the management of anal fissures. Dis Colon Rectum. 2017;60(1):7-14. doi:10.1097/DCR.0000000000000735.
9. Felt-Bersma RJF, Han-Geurts IJM. 6-Anal Fissure. Anorectal Disorders: Diagnosis and Non-Surgical Treatments. 2019:65–80. https://doi.org/10.1016/B978-0-12-815346-8.00006-0.
10. Varadarajan MS, Sony PS, Anandan H. Prevalence and Clinical Presentation of Fissure-in-ANO in A Tertiary Care Centre. Int J Sci Stud 2018;5(12):70-72. DOI: 10.17354/ijss/2018/86
11. Choudhary A, Katti P, Prasad KK. Comparative study of topical diltiazem sphincterotomy and lateral internal sphincterotomy in the treatment of chronic fissure-in-ano: a prospective analytical study. Sch J App Med Sci. 2016;4(4D):1402-1405.
12. Shaffaf MP, Mohammed KPK, Matad S. A study on the dietary habits and their association with the symptoms in patients with hemorrhoids and fissure-in-ano: a case-control study from a South Indian tertiary care hospital. Ann Int Med Dent Res. 2018;4(2):SG11-SG14.
13. Narayan R, Raghunandan. Comparison of lateral sphincterotomy with glyceryl nitrate 0.2% and diltiazem 2% local application in chronic fissure in ano. J Med Sci Clin Res. 2015; 3:7532-7537. DOI: http://dx.doi.org/10.18535/jmscr/v3i9.38
14. Schouten WR, Briel JW, Auwerda JJ, de Graaf EJ. Ischaemic nature of anal fissure. Br J Surg. 1996;83(1):63-65. doi:10.1002/bjs.1800830120.
15. Tsunoda A, Kashiwagura Y, Hirose K, Sasaki T, Kano N. Quality of life in patients with chronic anal fissure after topical treatment with diltiazem. World J Gastrointest Surg. 2012 Nov 27;4(11):251-5. doi: 10.4240/wjgs. v4.i11.251.
16. Knight JS, Birks M, Farouk R. Topical diltiazem ointment in the treatment of chronic anal fissure. Br J Surg 2001; 88:553–6. https://doi.org/10.1046/J.1365-2168.2001.01736.X.
17. Tocchi A, Mazzoni G, Miccini M, et al. Total lateral sphincterotomy for anal fissure. Int J Colorectal Dis. 2004;19(3):245-249. doi:10.1007/s00384-003-0525-9.
18. Nash GF, Kapoor K, Saeb-Parsy K, Kunanadam T, Dawson PM. The long-term results of diltiazem treatment for anal fissure. Int J Clin Pract 2006; 60:1411–3. https://doi.org/10.1111/J.1742-1241.2006.00895.X.

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