

Comparative Study of Topical Diltiazem vs Surgical Sphincterotomy

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Abstract:

Background: Chronic anal fissure is a common anorectal condition associated with severe pain and impaired quality of life. Increased internal anal sphincter tone plays a key role in its pathogenesis. While lateral internal sphincterotomy is considered the definitive treatment, concerns regarding postoperative complications have encouraged the use of pharmacological alternatives such as topical diltiazem. This study aimed to compare the efficacy and safety of topical diltiazem with lateral internal sphincterotomy in the management of chronic anal fissure.

Methods: This prospective comparative study was conducted over a period of twelve months at the Department of General Surgery, Dr. S.N. Medical College, Jodhpur. A total of 100 patients with chronic anal fissure were enrolled and randomly divided into two groups of 50 patients each. Group A received topical 2% diltiazem applied twice daily for six weeks, while Group B underwent lateral internal sphincterotomy. Patients were evaluated for pain relief, fissure healing, complications, and recurrence during follow-up visits up to six months.

Results: Complete pain relief was achieved in 68% of patients in the diltiazem group and 92% in the sphincterotomy group. Fissure healing at six weeks was observed in 72% of patients treated with topical diltiazem compared to 96% in the sphincterotomy group. Minor adverse effects such as headache and local irritation were noted in the diltiazem group, while transient fecal incontinence was observed in 8% of patients in the sphincterotomy group. Recurrence rates were higher in the diltiazem group (16%) compared to the sphincterotomy group (4%).

Conclusion: Lateral internal sphincterotomy remains the most effective treatment for chronic anal fissure in terms of rapid pain relief, higher healing rates, and lower recurrence. However, topical diltiazem is a safe and effective non-surgical alternative, particularly suitable for patients at risk of postoperative incontinence or those unwilling to undergo surgery.

Keywords: Chronic Anal Fissure, Diltiazem, Lateral Internal Sphincterotomy, Chemical Sphincterotomy, Comparative Study.

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Introduction

Anal fissure is a common benign anorectal condition characterized by a longitudinal tear in the anoderm distal to the dentate line, most frequently located in the posterior midline. It presents clinically with severe pain during defecation, rectal bleeding, and sphincter spasm, significantly impairing quality of life [1]. The condition affects individuals across all age groups but is most prevalent among young and middle-aged adults. Chronic anal fissure is defined by persistence of symptoms beyond six weeks and is often associated

with hypertrophied anal papilla, sentinel pile, and exposure of internal anal sphincter fibers [2].

The pathophysiology of chronic anal fissure is multifactorial, with increased resting anal sphincter pressure and local ischemia playing central roles. Hypertonicity of the internal anal sphincter reduces blood flow to the anoderm, impairing wound healing and perpetuating the fissure cycle [3]. Therefore, therapeutic strategies aim at reducing

sphincter pressure to improve perfusion and promote fissure healing.

Lateral internal sphincterotomy (LIS) has long been considered the gold standard for the treatment of chronic anal fissure, offering high healing rates exceeding 90% [4]. By surgically dividing the internal anal sphincter, LIS effectively reduces resting anal pressure, resulting in rapid pain relief and fissure healing. However, despite its efficacy, sphincterotomy is associated with potential complications, most notably fecal incontinence, which may be transient or permanent and has raised concerns regarding its routine use, particularly in younger patients and women [5].

In recent years, chemical sphincterotomy using topical pharmacological agents has emerged as a less invasive alternative. Topical diltiazem, a calcium channel blocker, induces reversible relaxation of the internal anal sphincter by inhibiting calcium influx into smooth muscle cells, thereby reducing resting anal pressure without permanent sphincter damage [6]. Several studies have demonstrated favorable healing rates with topical diltiazem, along with a lower risk of incontinence and good patient compliance [7]. Nevertheless, variability in response rates and recurrence remains a limitation of medical therapy.

Given the advantages and drawbacks of both modalities, there remains ongoing debate regarding the optimal first-line treatment for chronic anal fissure. Comparative evaluation of topical diltiazem and lateral internal sphincterotomy is essential to determine the balance between efficacy, safety, recurrence, and patient acceptability. This study aims to compare the outcomes of topical diltiazem versus surgical sphincterotomy in patients with chronic anal fissure treated at Dr. S.N. Medical College, Jodhpur, over a period of twelve months, thereby contributing valuable evidence to guide clinical decision-making in the management of this common condition.

Materials and Methods

Study Design and Setting: This study was designed as a prospective comparative clinical study conducted in the Department of General Surgery at Dr. S.N. Medical College, Jodhpur. The study was carried out over a period of twelve months after obtaining approval from the Institutional Ethics Committee. The objective was to compare the efficacy and outcomes of topical diltiazem therapy with lateral internal sphincterotomy in the management of chronic anal fissure.

Study Population and Sample Size

A total of 100 patients diagnosed with chronic anal fissure were included in the study. Patients

attending the surgical outpatient department and fulfilling the eligibility criteria during the study period were enrolled after obtaining informed written consent. The diagnosis of chronic anal fissure was based on clinical history and local examination findings, including persistent symptoms for more than six weeks and the presence of features such as sentinel pile or exposed internal anal sphincter fibers.

Inclusion and Exclusion Criteria

Patients aged 18 years and above with clinically diagnosed chronic anal fissure were included in the study. Patients with acute anal fissure, recurrent fissure following previous surgery, associated anorectal conditions such as fistula or hemorrhoids requiring surgical intervention, inflammatory bowel disease, malignancy, pregnancy, or those unwilling to give consent were excluded from the study.

Allocation and Intervention: Enrolled patients were randomly allocated into two equal groups of 50 patients each. Group A received conservative treatment with topical 2% diltiazem gel applied locally to the anal canal twice daily for a duration of six weeks along with dietary advice and stool softeners. Group B underwent lateral internal sphincterotomy performed under regional or general anesthesia following standard surgical protocols. Postoperative care included analgesics, antibiotics as required, sitz baths, and dietary modification.

Outcome Measures and Follow-up: Patients in both groups were evaluated for primary outcomes including pain relief, fissure healing, and recurrence. Pain was assessed using a visual analogue scale, while fissure healing was determined by clinical examination. Secondary outcomes included complications such as headache, local irritation, wound infection, and fecal incontinence. Patients were followed up at two weeks, six weeks, three months, and six months after initiation of treatment or surgery.

Statistical Analysis: Data collected were entered into a standardized proforma and analyzed using appropriate statistical software. Quantitative variables were expressed as mean and standard deviation, while qualitative variables were expressed as percentages. Comparative analysis between the two groups was performed using the chi-square test and Student's t-test, with a p-value of less than 0.05 considered statistically significant.

Results

A total of 100 patients diagnosed with chronic anal fissure were included in the study and randomly allocated into two groups. Group A consisted of 50 patients treated with topical 2% diltiazem, while

Group B consisted of 50 patients who underwent lateral internal sphincterotomy. All patients completed the study and were included in the final analysis.

Demographic Characteristics: The age and gender distribution of patients in both groups were comparable, with no statistically significant difference observed. The majority of patients were between 21 and 40 years of age, and males were more commonly affected than females.

Table 1: Age Distribution of Patients

Age Group (years)	Group A (Diltiazem)	Group B (Sphincterotomy)
18–30	18	16
31–40	17	19
41–50	10	9
>50	5	6
Total	50	50

Table 2: Gender Distribution

Gender	Group A	Group B
Male	32	34
Female	18	16
Total	50	50

Pain Relief: Pain relief was assessed using the Visual Analogue Scale (VAS). Both groups showed significant improvement; however, faster

and more complete pain relief was observed in the sphincterotomy group.

Table 3: Pain Relief at 6 Weeks

Pain Relief Outcome	Group A	Group B
Complete relief	34 (68%)	46 (92%)
Partial relief	12 (24%)	4 (8%)
No relief	4 (8%)	0

Fissure Healing: Fissure healing was assessed clinically at six weeks. The healing rate was significantly higher in patients who underwent

lateral internal sphincterotomy compared to those treated with topical diltiazem.

Table 4: Fissure Healing at 6 Weeks

Healing Status	Group A	Group B
Healed	36 (72%)	48 (96%)
Not healed	14 (28%)	2 (4%)

Complications: Minor complications were observed in both groups. Headache and local irritation were more common in the diltiazem

group, whereas transient fecal incontinence was noted only in the sphincterotomy group.

Table 5: Complications Observed

Complication	Group A	Group B
Headache	6 (12%)	0
Local irritation	5 (10%)	0
Wound infection	0	3 (6%)
Transient fecal incontinence	0	4 (8%)

Recurrence: During the six-month follow-up period, recurrence of fissure was higher in the

diltiazem group compared to the sphincterotomy group.

Table 6: Recurrence at 6 Months

Recurrence Status	Group A	Group B
Recurrence present	8 (16%)	2 (4%)
No recurrence	42 (84%)	48 (96%)

Discussion

Chronic anal fissure remains a challenging anorectal condition due to its recurrent nature and the balance required between effective sphincter relaxation and preservation of continence. The present study compared topical diltiazem with lateral internal sphincterotomy in terms of pain relief, fissure healing, complications, and recurrence, and the findings provide important insights into the relative merits of medical versus surgical management.

In this study, lateral internal sphincterotomy demonstrated superior outcomes in terms of pain relief and fissure healing when compared to topical diltiazem. A higher proportion of patients in the sphincterotomy group achieved complete pain relief and fissure healing at six weeks. These findings are consistent with previous clinical studies that have reported sphincterotomy as the most effective modality for achieving rapid symptom resolution and sustained healing in chronic anal fissure [8]. The immediate reduction in resting anal pressure achieved surgically explains the faster symptomatic improvement observed in this group.

Topical diltiazem also showed favorable outcomes, with a substantial proportion of patients experiencing pain relief and fissure healing. The mechanism of action of diltiazem involves reversible chemical sphincter relaxation, making it an attractive non-invasive option, particularly for patients who are unwilling or unfit for surgery [9]. However, the comparatively lower healing rates and delayed response observed in the diltiazem group may be attributed to issues such as inconsistent application, variable patient compliance, and insufficient sphincter relaxation in long-standing fissures [10].

Complication profiles differed between the two groups. In the present study, patients treated with topical diltiazem experienced minor adverse effects such as headache and local irritation, which were self-limiting and did not require discontinuation of therapy. Similar side effects have been documented in earlier studies evaluating calcium channel blockers for anal fissure management [11]. In contrast, transient fecal incontinence was observed only in the sphincterotomy group. Although this incontinence was temporary and resolved during follow-up, it remains a significant concern associated with surgical intervention and has been widely discussed in the literature [12].

Recurrence rates were higher in the diltiazem group compared to the sphincterotomy group. This finding supports the view that while chemical sphincterotomy is effective, its effects are reversible, predisposing patients to recurrence once

treatment is stopped [13]. Surgical sphincterotomy, by producing a permanent reduction in sphincter tone, offers a more definitive solution with lower recurrence rates.

Overall, the findings of this study suggest that while lateral internal sphincterotomy remains the most effective treatment for chronic anal fissure, topical diltiazem serves as a valuable first-line or alternative therapy in selected patients. Individualized treatment decisions based on patient preference, risk of incontinence, and clinical severity are essential for optimal outcomes.

Conclusion

The present study demonstrates that lateral internal sphincterotomy offers superior outcomes compared to topical diltiazem in the management of chronic anal fissure, with significantly higher rates of pain relief and fissure healing and a lower rate of recurrence. Despite its effectiveness, the risk of postoperative complications, particularly transient fecal incontinence, remains an important consideration.

Topical diltiazem proved to be a safe and well-tolerated treatment option, achieving satisfactory results in a majority of patients, though with comparatively lower healing rates and higher recurrence. Its non-invasive nature and minimal side effects make it a valuable first-line therapy or alternative for patients who are unsuitable for surgery or prefer conservative management.

In conclusion, treatment of chronic anal fissure should be individualized, taking into account disease severity, patient preference, and risk factors for incontinence. While lateral internal sphincterotomy remains the gold standard, topical diltiazem represents an effective and safe conservative modality in selected cases.

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