



PROSPECTIVE COMPARATIVE STUDY BETWEEN TOPICAL 2% DILTIAZEM PLUS 2% LIGNOCAINE GEL WITH LATERAL SPHINCTEROTOMY AND SUBCUTANEOUS FISSURECTOMY TO TREAT CHRONIC FISSURE IN ANO

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Abstract

Introduction: An anal fissure is characterized by an ulcer in the anoderm, typically located along the posterior midline, less commonly in the anterior midline, and rarely in the lateral regions of the anal canal. Treatment options vary and include non-invasive pharmacological therapies, lateral internal sphincterotomy (LIS), which is considered the gold standard, as well as newer approaches such as perineal support devices, Gonyautoxin injection, fissurectomy, fissurotomy, sphincterolysis, and flap procedures. The objective of this study was to compare the treatment outcomes of lateral internal sphincterotomy and subcutaneous fissurectomy with topical 2% Diltiazem plus 2% lignocaine gel in the management of chronic fissure in ano

Objective of the study

- To compare the effectiveness of topical 2% diltiazem plus 2% Lignocaine gel with lateral sphincterotomy and subcutaneous fissurectomy to treat chronic fissure in ano

Materials and methods:

Sixty patients with chronic fissure-in-ano attending the outpatient department of General Surgery at RAICHUR INSTITUTE OF MEDICAL SCIENCES, RAICHUR, during the period 1st June 2024 to 30th December 2024, were randomly selected and assigned into two groups: Group A (n=30), who underwent lateral internal sphincterotomy (control group), and Group B (n=30), who received subcutaneous fissurectomy combined with topical 2% diltiazem plus 2% Lignocaine gel (test group)..

Results:

Group B patients had a significantly shorter mean duration of absenteeism (2.88 weeks) compared to those in Group A. Statistically significant differences between Group B and Group A were also observed in terms of pain relief ($P < 0.0001$), complication rates ($P = 0.03$), average duration of sitz baths ($P < 0.0001$), and absenteeism ($P < 0.0001$)

Interpretation & Conclusion:

Therefore, subcutaneous fissurectomy combined with topical 2% diltiazem plus 2% lignocaine gel presents a superior surgical alternative to conventional lateral internal sphincterotomy for the treatment of chronic anal fissure

Key words: 2%lignocaine, 2%Diltiazem, Chronic fissure in ano, Lateral internal sphincterotomy, Subcutaneous fissurectomy.

An anal fissure is a well-defined clinico-pathological condition affecting the lower anal canal. It is characterized by an ulcer or tear in the anoderm, most commonly located in the posterior midline, less often in the anterior midline, and rarely in a lateral position^{1,2}. When traction is applied to both sides of the anus, the fissure takes on a triangular or navicular shape, with its apex located near the dentate line and its base extending along the lower anal canal^{1,3}.

The fissures can be divided into the primary type and the secondary type. The primary or the idiopathic type is most common but the exact cause of this type of fissure is not known. A fissure typically occurs along the midline, either posteriorly or anteriorly. If a primary fissure is not treated during its acute phase, it can lead to permanent structural changes in the tissue. These may include induration of the ulcer edges, fibrosis at the base of the ulcer, and the development of features such as a sentinel pile and anal papilla, eventually progressing to a chronic stage. Secondary fissures, on the other hand, arise due to underlying pathological conditions of the anal canal, such as Crohn's disease, ulcerative colitis, trauma, prior anorectal surgeries, or infections^{1,3}. They will heal only when that causative pathology is removed or treated. Mostly, such types of fissures are situated eccentrically around the anal margin. There is no trace of surgery of anal fissure in literature before 19th century. At that time, only conservative measures such as high fibre diet and stool softeners used to be prescribed. Recamier recommended stretching of anal sphincter in 1829 and it became popular in 1968 when Lord also used this procedure on a large number of patients.^{1,4} High ratios of complications lead Eisenhammer to describe internal sphincterotomy by dividing the sphincter in the posterior midline. Due to the comparatively long healing time required in this type of operation, Parks described open LAS (lateral anal sphincterotomy) in 1967. This was further simplified to the closed lateral anal sphincterotomy by Notaras in 1969.¹ The standard algorithm for anal fissure treatment is traditionally consisted of a trial of fibre supplementation, sitz baths, and topical analgesics. If the pain is intolerable or conservative care fails then surgery is the option. Since Lord's anal dilatation, numerous treatment options have been evolved including lateral internal sphincterotomy,¹ sclerotherapy (using Sodium tetradecyl sulphate),⁵ chemical sphincterotomy using topical glyceryl trinitrate,^{6,7} calcium channel blockers such as Nifedipine or Diltiazem and Botulinum toxin.⁸ New therapies include perineal support devices, Gonyautoxin injection, fissurectomy, fissurotomy, sphincterolysis and flap procedures.⁹

Fissurectomy involves refreshing the anal fissure to promote healing. This procedure typically includes excising the fissure edges, curettage or removal of the fissure base, and potentially the excision of associated sentinel skin tags and anal polyps.

Diltiazem, a non-dihydropyridine calcium channel blocker, promotes relaxation and dilation of vascular smooth muscle. When applied topically as a 2% gel, it can reduce the maximum resting pressure (MRP) by approximately 28%, with the effect lasting 3–5 hours post-application. Side effects of topical Diltiazem are minimal, the most common being perianal dermatitis.

Unlike nitric oxide donors such as glyceryl trinitrate and isosorbide dinitrate—which are also used for chemical sphincterotomy but often cause headaches leading to poor patient compliance—2% topical Diltiazem is not associated with headaches, thereby improving patient adherence and treatment outcomes

2% Lignocaine gel (also known as lidocaine gel) is commonly used as a topical anesthetic for symptomatic relief in patients with chronic fissure-in-ano. It does not directly heal the fissure but plays a supportive role in managing the condition

Mechanism of Action in Chronic Fissure-in-Ano:

1. Local Anesthetic Effect:

- Lignocaine is a sodium channel blocker.
- It prevents the generation and conduction of nerve impulses by blocking sodium channels in the neuronal membrane.
- This results in temporary numbing of the area, reducing pain, especially during and after defecation.

2. Pain Relief → Reduction in Sphincter Spasm:

- Pain from the fissure leads to reflex spasm of the internal anal sphincter.
- This spasm worsens ischemia (reduced blood flow), delaying healing.
- By relieving pain, lignocaine gel helps break the cycle of pain-spasm-ischemia, allowing for better blood flow and potential healing.

3. Improved Compliance with Defecation:

- Reduced pain can make patients less fearful of passing stools, helping maintain a more regular bowel routine and avoiding constipation—a key factor in fissure formation and persistence..

The aim of this study was to compare the effectiveness of lateral internal sphincterotomy and subcutaneous fissurectomy combined with topical 2% Diltiazem plus 2% Lignocaine gel in treating chronic anal fissures. The study specifically sought to evaluate and compare the two approaches in terms of symptomatic relief, healing rates, and associated complications

Materials and methods:

Setting: This is a cross sectional study done on 60 patients between June 1st 2024 to December 30th 2024.

This study was conducted at the department of General Surgery, RAICHUR INSTITUTE OF MEDICAL SCIENCES, RAICHUR. Patients fulfilling the inclusion and exclusion criteria were approached, explained about the study and were requested for enrolment. They were provided with a patient information sheet either in Kannada or English (depending upon their choice). Only those patients who volunteered for participation after fully satisfying themselves about the nature of the study and who gave written consent for this study were included.

All patients coming to OPD at RIMS, Raichur, with chronic fissure in ano enrolled in the study for 6 months.

Conduct of study

Patients were recruited for the purpose of the study.

In the cases who had given consent for the study, history was collected and thorough physical examination done at the time of admission. Data collection included age, sex, and clinical presentation.

For this study, patients coming to RIMS OPD, department of General Surgery

Inclusion Criteria

Male and female patients aged between 20 and 60 years who have been admitted with chronic fissure-in-ano unresponsive to conservative treatment for over 2 months

Exclusion Criteria

1. Recurrent fissures
2. Fissures with haemorrhoids and fistula
3. Fissure associated with malignancies
4. Fissure secondary to specific diseases like tuberculosis, Crohn's disease etc.
5. Pregnant women
6. Patients who have undergone previous anal surgeries

STUDY DESIGN

Sixty patients were randomly assigned to two groups, with thirty patients in each. The sample size was determined using the following formula:

$$Z^2 \frac{1-\alpha}{2} [P_1 (1-P_1) + P_2 (1-P_2)]$$

Sample size (n) = $d^2 = 30$ in each group [$Z = 1.96$, $d = 13\%$, $P_1 = 88\%$, $P_2 = 100\%$]

Group A (n=30): Patients were treated with lateral internal sphincterotomy (control group).

Group B (n=30): patients were treated with subcutaneous fissurectomy with topical 2% Diltiazem plus 2% Lignocaine gel (test group).

All patients in Group B were prescribed topical 2% Diltiazem plus 2% lignocaine gel starting from the second post-operative day and continuing for three months. Both groups received the standard treatment for fissure management, which included laxatives like Syrup Cremaffin (containing 11.25 ml of milk of magnesia and 3.75 ml of liquid paraffin per 15 ml of emulsion), taken as three teaspoons once daily at bedtime], a high-fibre diet, and sitz baths three times daily, beginning on the second post-operative day.

All operated patients in both groups received a broad-spectrum antibiotic for five days starting from the day of surgery. Injection Diclofenac (50 mg) was administered twice daily for the first three days, followed by use on an as-needed basis, provided renal function parameters remained within the acceptable range. If renal parameters were not within the safe limits, injection Paracetamol (500 mg) was used instead, following the same protocol. All patients were discharged on the sixth postoperative day.

Postoperatively, patients were monitored for signs of bleeding and hematoma formation. They were followed up weekly for a duration of three months to assess symptom relief. Pain levels during the postoperative period were measured using the Numeric Rating Scale (NRS, 0–10), which is sensitive in evaluating acute postoperative pain. A score of '0' represented 'no pain,' while a score of '10' indicated the 'worst pain imaginable'. Observations were documented at the end of the three-month follow-up period.

Assessment parameters included pain relief, presence of incontinence (fecal, flatus, or both), and the number of workdays lost. Digital rectal examination was performed to evaluate sphincter relaxation. Healing of the fissure was defined as complete re-epithelialization of the mucosal surface. Monitored complications included incontinence, wound infection, and recurrence in both groups.

Patients assigned to Group B were instructed to apply a 2 cm length of 2% Diltiazem plus 2% lignocaine gel twice daily, inserting it at least 1.5 cm into the anus. They were also advised to wash their hands before and after gel application. The collected data were analyzed using SPSS software version 20.0. Comparisons between Group A and Group B were made using the Student's t-test and chi-square test. Descriptive results are presented as means and standard deviations for various parameters. Statistical significance was determined using the p-value, with $p < 0.05$ considered significant and $p < 0.01$ considered highly significant

RESULTS

1. In the current study, most participants were aged between 30 and 50 years (Table 1). Additionally, the study revealed that the majority of patients were male, accounting for 70% (Table

Table 1: Age distribution.

Age in years	No. of patients	percentage(%)
21-30	14	24
31-40	22	36
41-50	18	30
51-60	6	10

Table 2: Sex distribution.

Sex incidence	No. of patients	Percentage(%)
Males	42	70
Females	18	30

2. Posterior fissure in ano was more common (70%) in this study (Table 3).

Table 3: Site distribution

Site	No. of patients	Percentage
Anterior	12	20
Lateral	6	10
Posterior	42	70

3. According to the study, a preoperative sentinel pile was observed in 24 patients (40%), while sphincter spasm was present in all cases (100%). All patients were followed up, and after 3 weeks, the mean NRS pain score in Group A was significantly higher than in Group B ($p = 0.0004$; see Table 4).

Table 4: Comparison of pain score in patients after 3 weeks follow up.

NRS score for pain	Group A		Group B	
	Mean	SD	Mean	
Pain	6.84	1.46	6.48	
t-value	3.8			

After a 3-month follow-up, the mean pain score was 1.84 in Group A and 0.6 in Group B. This difference in mean pain scores was statistically significant ($p < 0.0001$) (Table 5).

Table 5: Comparison of pain score in patients after 3 months follow up

NRS score for pain	Group A		Group B	
	Mean	SD	Mean	SD
Pain	1.84	1.18	0.6	0.7
t-value	4.51		P	<0.0001

In this study, a comparison of complications observed after a 3-month follow-up revealed no complications in any patients from Group B. In contrast, 16% of patients in Group A experienced complications, including one case of wound infection, two cases of flatus incontinence, and one case of symptom recurrence. The incidence of complications was significantly higher in Group A ($p = 0.03$) (Table 6).

Table 6: Comparison of complications in patients after 3 months follow up

Complications	Group A		Group B	
	No	%	No	%
Present	5	16		
Absent	25	84	30	100
Chi-Square	4.3		p	0.03

In the present study, patients in Group A required sitz baths for an average of 6.12 weeks following surgery, whereas those in Group B needed them for an average of 3.44 weeks. This difference was statistically significant, with a longer duration observed in Group A ($p < 0.0001$) (Table 7)

Table 7: Comparison of mean duration of Sitz bath in patients after surgery

Sitz bath(weeks)	Group A		Group B	
	Mean	SD	Mean	SD
Sitz bath	6.12	1.45	3.4	1.5
t-value	6.29		p	<0.0001

The mean duration of absenteeism following surgery was compared between the two groups. Patients in Group A had a significantly longer mean absenteeism period of 4.56 weeks, compared to 2.88 weeks in Group B ($p < 0.0001$), as shown in Table 8."

Table 8: Comparison of mean duration of absenteeism in patients after surgery

Absenteeism(weeks)	Group A		Group B	
	Mean	SD	Mean	SD
Absenteeism	4.56	0.96	2.88	1.36
t-value	5.03		p<0.0001	

Discussion:

1. Anal fissures can cause significant discomfort and negatively impact quality of life. Surgery remains the most straightforward and effective method for reducing internal anal sphincter tone. Lateral internal sphincterotomy, which involves a partial division of the internal anal sphincter away from the fissure site, is considered the gold standard for treating chronic anal fissure^{14-16s}.
2. Calcium channel blockers have been found to decrease resting anal pressure and support fissure healing^{17,18}. A study by Medhi et al demonstrated the effectiveness of Diltiazem plus lignocaine gel in managing chronic anal fissures, with both oral and topical formulations significantly lowering anal pressure and improving healing outcomes. Additionally, a review by Bharadwaj et al concluded that Diltiazem is a viable alternative to glyceryl trinitrate, offering better healing rates and lower recurrence.
3. In this study, the most commonly affected age group was 31–40 years (40%), aligning with findings by Goligher et al., who also reported the highest incidence in the 31–40-year age group.¹⁸ While Goligher et al. observed an equal incidence of chronic anal fissure in both sexes, our study showed a higher prevalence in males compared to females, with a ratio of 2.33:1.¹⁸ According to Pelta et al., approximately 90% of anal fissures in both men and women occur posteriorly in the midline, while anterior fissures—which are more common in women—account for about 10% of cases.
4. In the present study, anterior fissures were observed in approximately 20% of cases, while posterior fissures accounted for 80%. In Group B, the mean pain score decreased to 5.36 by the end of the third week and further reduced to 0.6 by the end of three months. Complete healing of the fissure was achieved in 22 out of 25 patients (88%) within three weeks, and in all 25 patients (100%) by three months.
5. Subcutaneous fissurectomy is a relatively novel procedure, with limited studies available. According to Pelta et al., among 118 patients treated with subcutaneous fissurectomy, 100% achieved uninterrupted wound healing, with only 2% experiencing flatus incontinence. In our study, no incontinence was reported in Group B.
6. Tocchi et al. reported no long-term complications following internal sphincterotomy, with a patient satisfaction rate of 96%. Similarly, Aziz et al. found that 140 out of 146 patients (97.5%)

achieved complete healing following lateral internal sphincterotomy (LIS) by three months—124 patients by six weeks, 12 by seven weeks, and 4 by three months. However, 4.1% experienced transient flatus incontinence. In contrast, our study found no long-term complications and a 100% satisfaction rate in Group A, though 2 patients (4%) experienced transient flatus incontinence. Additionally, recurrence was noted in 1 patient (2%) in Group A, while no recurrence occurred in Group B.

7. Patients in Group B required sitz baths for a mean duration of 3.44 weeks, significantly less than the 6.12 weeks required by Group A. Furthermore, Group B showed a shorter duration of work absenteeism (mean 2.88 weeks) compared to Group A (4.56 weeks).
8. Statistical analysis revealed significant differences between Group B and Group A in terms of pain relief ($P < 0.0001$), complications ($P = 0.03$), mean duration of sitz bath use ($P < 0.0001$), and absenteeism ($P < 0.0001$)

Conclusions

Therefore, subcutaneous fissurectomy combined with topical 2% Diltiazem plus 2% Lignocaine gel appears to be a superior surgical option for treating chronic anal fissures compared to conventional lateral internal sphincterotomy.

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