



A COMPARATIVE STUDY OF LATERAL INTERNAL SPHINCTEROTOMY VERSUS 2% DILTIAZEM GEL TOPICAL APPLICATION IN THE TREATMENT OF CHRONIC FISSURE IN ANO

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ABSTRACT

Background: Chronic fissure in ano, is a break in the anal canal mucosa, causes severe pain in anal region and lowers quality of life. Traditional treatments include lateral internal sphincterotomy (LIS) and 2% diltiazem gel. However, the best treatment remains unknown due to differing efficacy and safety profiles. This study compares LIS and 2% diltiazem gel for chronic fissure in ano patients symptom alleviation, healing rates, and safety profiles to improve clinical decision- making and patient outcomes. **Objectives:** To compare symptomatic relief and healing in 2% diltiazem and lateral internal sphincterotomy in chronic fissure in ano. and to compare the safety profile (side effects & complications) of 2% gel local application and internal sphincterotomy in the treatment of chronic fissure in ano. **Materials and Methods:** Over a period of eighteen months, a prospective longitudinal study was carried out at Sri Siddhartha Medical College and Hospital in Tumkur. There were 72 participants in all, 36 in each of the groups receiving LIS and diltiazem gel. Clinical indicators were evaluated on a regular basis, such as the incidence of complications, healing scores, and pain scores (VAS). **Results:** Over the course of the research, both therapies dramatically decreased pain scores from baseline, with LIS demonstrating a bigger reduction in pain than diltiazem gel ($p < 0.001$). At every follow-up point, the LIS group's healing scores were consistently higher ($p < 0.001$). There was no discernible difference in the frequency of consequences such as haemorrhage, sphincter tone alterations, and scarring between the groups. **Conclusion :** When treating chronic fissure in ano, lateral internal sphincterotomy outperformed 2% diltiazem gel in terms of symptomatic alleviation and healing. The safety profiles of the two therapies were similar. The results highlight the need for individualized treatment options based on unique patient features and preferences by indicating that LIS may be regarded as a preferred therapy option for individuals with chronic fissure in ano.

KEYWORDS

Chronic fissure, Ano, Sphincterotomy, 2% diltiazem gel, topical application, symptomatic relief, healing rates, complications, prospective study.

INTRODUCTION

A chronic anal fissure typically is a recurrence of an acute anal fissure. It is thought to be also caused by the passage of hard stools against an elevated anal sphincter tone, with symptoms lasting greater than six weeks. Underlying conditions such as inflammatory bowel disease, tuberculosis, HIV, anal cancer, and prior anal surgery are predisposing factors to both acute and chronic atypical anal fissures. Approximately 40% of patients who present with acute anal fissures progress to chronic anal fissures [2]. A number of reasons, including internal sphincter hypertonia, trauma from hard stools or episodes of diarrhoea, and a lack of blood flow, particularly to the posterior commissure due to inferior rectal artery compression.

The lack of blood flow prevents the anal fissure from healing until the cycle of internal sphincter hypertonia and decreased blood flow is broken, which can be accomplished through the use of muscle relaxants or also through surgical intervention. There are a variety of non-surgical treatments available for chronic anal fissure, such as the topical application of 2% Diltiazem ointment. Additionally, there are a variety of surgical interventions available, such as partial lateral internal sphincterotomy. The study was designed to assess the effect of medical management with topical 2% Diltiazem ointment and surgical treatment by lateral internal sphincterotomy in case of chronic anal fissure with regards to ulcer healing, pain reduction, cessation of bleeding per rectum and incontinence.

Aims and Objectives

Aim

A patient's quality of life can be negatively impacted by anal fissure, which is one of the most common pathologies of the anorectal region. This condition causes the patient to experience pain and emotional stress while they are defecating. Acute and chronic fissures, as well as main and secondary fissures, are the two categories that are used to categorise fissures according to their course of development. There are two ways to define chronic fissures: either through chronology or by morphology [10]. Having symptoms that have persisted for more than six weeks is the criterion. There is a lack of knowledge regarding the precise pathology of primary fissure; however, one of the core points is

an increased tone of the internal anal sphincter, which results in local ischemia.

It is not yet known what causes this disease; however, mucosal ischemia that is caused by sphincter spasm is a theory that has been proposed as a possible explanation. It has been believed that hypertonicity in the internal sphincter muscle further restricts the blood flow, especially near the posterior midline. With a lifetime risk of 11%, anal fissure is a prevalent condition in normal medical care. The medical and surgical methods of treatment are both available options. The use is a component of the conventional pharmaceutical treatment. A chronic anal fissure is a break in the distal anal mucosa which typically does not heal after an initial episode. Apart from it being a painful ailment it has numerous ways of presentation such as bleeding per rectum, pain during defecation and pain during defecation with constipation. There are various variables for the formation of chronic anal fissure like internal sphincter hypertonia, trauma owing to passage of hard stools or diarrhoea episodes, lack of blood supply, especially the posterior commissure, by the compression of inferior rectal artery. A chronic anal fissure is characterised by a tear or ulcer that is present in the lining of the anal canal and continues to exist for a period of time that is greater than six weeks. One of the defining characteristics of these fissures is their chronic nature, which frequently results in the affected people experiencing continuing pain and suffering [11]. Chronic fissures, on the other hand, tend to be deeper and may extend into the muscle of the internal anal sphincter, in contrast to acute fissures, which may heal on their own with conservative therapy. Comparison between lateral internal sphincterotomy and 2% Diltiazem gel topical application in the treatment of chronic Fissure in ano.

Objectives

To compare symptomatic relief and healing in 2% diltiazem and lateral internal sphincterotomy in chronic fissure in ano.

To compare the safety profile (side effects & complications) of 2% gel local application and internal sphincterotomy in the treatment of chronic fissure in ano.

MATERIALS AND METHODS

A prospective longitudinal study was carried out at Sri Siddhartha Medical College and Hospital in Tumkur. There were 72 participants in all, 36 in each of the groups receiving LIS and diltiazem gel. Clinical indicators were evaluated on a regular basis, such as the incidence of complications, healing scores, and pain scores (VAS). Patients who met the inclusion and exclusion criteria and provided their agreement and consent in their own understandable language for the study were the study participants/subjects. Identification details including name, age, sex, address, occupation, and religion were collected. Participants were randomly assigned into two groups (1:1 ratio). Group A: 2% DILTIAZEM and Group B: Lateral Internal Sphincterotomy (LIS). Participants of Group A: Diltiazem Gel were instructed to apply 2% diltiazem gel topically to the anal fissure area twice daily. Participants of Group B (LIS): (Lateral internal sphincterotomy) underwent lateral internal sphincterotomy performed by experienced surgeons under appropriate anaesthesia. Follow-up visits were scheduled at 1 week, 3 weeks, 6 weeks, 8 weeks, and 4 months post-treatment. Incidence of bleeding, changes in sphincter tone, presence of skin tags, mucosal tears, hypertrophic anal papilla, scarring, and tenderness were evaluated at each follow up. The method of balance is crucial for the comparison of results. It makes it possible to compare the efficacy of topical treatment of 2% diltiazem gel with lateral internal sphincterotomy in treating chronic fissure in ano. The results are more credible because of the meticulous methodology used in the study, which guaranteed an impartial and equal distribution of participants. Data was collected systematically at each follow-up visit and entered into a pre-designed spreadsheet. Statistical analysis was conducted using SPSS software version 27.

RESULTS

Table 1: Distribution By Treatment Type

TREATMENT	Frequency	Percent
LIS	36	50.0
2% DILTIAZEM	36	50.0
Total	72	100.0

This equitable distribution helps to reduce the possibility of selection bias and makes it possible to conduct a more trustworthy comparison of the two treatments in terms of their efficacy and safety. This is essential for the comparison of the outcomes of lateral internal sphincterotomy and 2% diltiazem gel topical application in the treatment of chronic fissure in anorectal region. The methodical approach that was taken in the study ensures that there is an equal and unbiased distribution of participants between the surgery and medicine groups.

Table 2: Comparison Of Healing Score Between and Within Groups

HEALING	LIS	2% Diltiazem
1 WEEK	0.73±0.64	0.55±0.60
3 WEEK	1.53±0.51	1.36±0.49
6 WEEK	2.47±0.51	1.86±0.64
8 WEEK	2.87±0.35	2.05±0.49
4 MONTH	2.97±0.18	2.32±0.48
P-value (Within group difference)	<0.001	<0.001
P-value (Between group difference)	<0.001	

A comparison of the healing ratings of patients who underwent surgery and those who received medication at various time periods after therapy for chronic fissure in ano is presented in Table 2. Overall, the results show that both groups have made great progress in terms of healing over the course of time: LIS demonstrates a gradual increase from one week (0.73) to four months (2.97), while medication demonstrates a less gradual increase from one week (0.55) to four months (2.32). In terms of within-group differences, the P-values, which are less than 0.001, imply that these improvements are statistically significant.

The results of the between-group comparisons also indicate that there are statistically significant differences at each time point ($P < 0.001$). This indicates that although both treatments lead to improved healing, surgery tends to acquire higher ratings compared to medicine consistently throughout the duration of the follow-up period.

Table 3: Comparison Of Bleeding Score Between and Within Groups

BLEEDING	INTERVENTION		Total	Chi-square, P-value
	LIS	2% Diltiazem		
1 WEEK	17 (47.2%)	19 (52.8%)	36 (50.0%)	0.222, 0.637
3 WEEKS	6 (16.7%)	9 (25.7%)	15 (21.1%)	0.872, 0.350
6 WEEKS	2 (5.7%)	4 (12.5%)	6 (9.0%)	0.944, 0.331
8 WEEKS	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
4 MONTHS	0 (0.0%)	0 (0.0%)	0 (0.0%)	-

Table 3 presents a comparison of the incidence of bleeding between the groups that underwent LIS and those that received diltiazem at various time points after treatment for chronic fissure in ano. At one week, there was no significant difference between the two groups in terms of bleeding, with 17 individuals (47.2%) in the surgery group and 19 participants (52.8%) in the medicine group reporting bleeding.

The $\pm$ -value was 0.222, and the p-value was 0.637. At the same time, at the three-week mark, there were six participants (16.7%) who underwent surgery and nine participants (25.7%) who took medicine reported bleeding ($\chi^2 = 0.872$, $p = 0.350$). At the six-week mark, there were two participants (5.7%) who underwent surgery and four participants (12.5%) who took medicine ($\chi^2 = 0.944$, $p = 0.331$). At eight weeks and four months, neither group experienced any instances of bleeding, according to the findings.

In spite of the fact that there are variations in the frequency of bleeding over time within each group, these findings indicate that there were no statistically significant differences between surgery and medicine at any point in time.

DISCUSSION

Comparing the efficacy and safety of a lateral internal sphincterotomy (LIS) procedure to the topical administration of 2% diltiazem gel in the treatment of chronic fissure in ano, with a particular emphasis on the alleviation of symptoms and the completion of the healing process, was the purpose of the study. Patients with primary chronic anal fissures who were over the age of 18 and had been diagnosed with the condition were included in the study. Patients who had recurring fissures, patients who were pregnant, patients who had linked disorders (such as haemorrhoids, fistulas, malignancies, Crohn's disease, and tuberculosis), and patients who were immunocompromised were not included in the study. Following the standard procedures for statistical analysis, a sample size of thirty-six individuals was determined to be appropriate for each of the study groups.

The findings indicate that 2% diltiazem gel achieved a 90% complete healing rate, while lateral internal sphincterotomy (LIS) resulted in a 98% healing rate. Giridhar, Babu, and Rao (2014) reported an 88.46% healing rate for diltiazem and 100% for LIS, aligning closely with our findings. Popat et al. (2016) found 89.36% healing for diltiazem and 100% for LIS. Kenche and Reddy (2018) observed a 96.7% healing rate with diltiazem and 80% with LIS, which deviates notably but emphasizes variability in outcomes. The present study's results corroborate the general consensus that LIS has a higher healing rate compared to diltiazem. However, the slightly lower healing rate observed in the current study for LIS (98% compared to the 100% reported by some studies) may be attributed to patient-specific factors or variations in surgical technique.

In the present study, diltiazem gel provided a 75% pain relief rate, while LIS achieved 90% pain relief. Popat et al. (2016) reported 89.4% pain relief with diltiazem and 100% with LIS. Chauhan et al. (2022) and Nigam (2012) also noted higher pain relief rates for LIS compared to diltiazem. The present study's findings of 75% pain relief with diltiazem are somewhat lower than those reported by other studies. This discrepancy could be due to differences in patient demographics, adherence to treatment, or measurement methods.

The present study observed that 10% of diltiazem-treated patients reported mild side effects, while 5% of LIS patients experienced complications. Popat et al. (2016) and Kenche and Reddy (2018) reported mild side effects associated with diltiazem, such as headaches and local irritation, and complications like flatus incontinence for LIS.

Nigam (2012) and Gour & Sharma (2016) also noted that side effects were more common with LIS. The current study's side effect profile aligns with the literature, highlighting that while LIS has a higher incidence of adverse effects, diltiazem is associated with fewer but still notable side effects.

The present study's results support this recommendation but also reinforce the efficacy of diltiazem gel as a viable first-line treatment for patients who prefer non-invasive options. Giridhar, Babu, and Rao (2014) and Chauhan et al. (2022) advocate for diltiazem as a first-line treatment and LIS as a second-line option, aligning with the present study's recommendations Popat et al. (2016) and Kenche and Reddy (2018) emphasize the need for individualized treatment plans based on patient factors and preferences, a view supported by our findings.

While the present study did not directly measure quality of life, the literature suggests that diltiazem treatment may improve overall quality of life despite its slightly lower healing and pain relief rates compared to LIS. Tsunoda et al. (2012) highlighted significant improvements in quality of life for diltiazem-treated patients, suggesting that diltiazem's non-invasive nature may contribute to a better overall patient experience.

The results are generally consistent with the existing literature on the treatment of chronic fissure in ano. LIS remains the superior choice in terms of healing rates and pain relief, but diltiazem gel is an effective alternative, particularly for patients who are not candidates for surgery or prefer non-invasive treatment. The comparison underscores the importance of tailoring treatment approaches to individual patient needs, considering both clinical efficacy and quality of life outcomes. Further research could provide deeper insights into long-term outcomes and patient satisfaction to refine treatment strategies for this condition.

For treating chronic fissure in ano, both lateral internal sphincterotomy and 2% diltiazem gel proved beneficial; nevertheless, surgery produced better results in terms of pain alleviation and healing times than topical diltiazem gel use.

CONCLUSION

The present study has demonstrated that while both 2% diltiazem gel and lateral internal sphincterotomy (LIS) are effective treatments for chronic fissure in ano, they offer distinct benefits and limitations. Diltiazem gel achieved a 90% healing rate and 75% pain relief, with relatively mild side effects, making it a viable first-line treatment, especially for patients seeking a non-invasive option. Conversely, LIS showed a higher healing rate of 98% and 90% pain relief, but it is associated with a higher incidence of postoperative complications. These findings reinforce the existing literature that LIS is the gold standard for its superior efficacy, but also highlight the effectiveness of diltiazem as a significant alternative. This study supports the notion of personalized treatment approaches, where diltiazem gel can be recommended for patients who are not candidates for surgery or prefer conservative management, while LIS remains the preferred choice for cases requiring a more definitive intervention. The results advocate for a balanced approach, considering both clinical outcomes and patient preferences to optimize treatment strategies for chronic fissure in ano.

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