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# Management of chronic fissure in ano-lateral internal sphincterotomy versus 2% diltiazem gel local application

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#### Abstrac

**Background and Aim:** Anal fissures are frequently seen in everyday clinical practice. In the past, surgical intervention was the typical approach for treating anal fissures. Advancements in the field of pharmacology have led to a shift towards more cautious treatment methods for the internal anal sphincter. In this study, we compared the effectiveness of applying 2% diltiazem gel and undergoing internal sphincterotomy in treating chronic fissure-in-ano. We examined how well each method promoted fissure healing and provided pain relief.

Material and Methods: One hundred patients with chronic fissure in ano were identified and included in this prospective comparative study conducted over a period of one year at a tertiary care institute in India. There were two groups of patients, with 50 in each group, labeled as group A and group B. Patients in group A were instructed to use 2% diltiazem gel twice a day for duration of 6 weeks. Patients in group B received left lateral internal sphincterotomy while under spinal anesthesia. The healing of fissures and the relief of pain were documented upon presentation and throughout subsequent visits.

**Results:** The findings indicate that a significant majority of the cases were observed in individuals aged 21-30 years, with a higher prevalence among females (55%) compared to males (45%). At the end of 3 months, a significant number of patients in both group A, who used diltiazem gel, and group B, who used LIS, experienced complete healing of their fissures. Specifically, 78% of patients in group A and 84% of patients in group B achieved this positive outcome. At the end of 3 months, a significant number of patients in both group A, who used Diltiazem gel, and group B, who received LIS, experienced pain relief. Specifically, 82% of patients in group A and 90% of patients in group B were free from pain.

**Conclusion:** It is recommended that chemical sphincterotomy with topical 2% diltiazem gel application be considered as the primary treatment option for chronic anal fissure. It can also be beneficial for individuals who are not suitable candidates for surgery. Patients who have experienced relapse and therapeutic failure of previous pharmacological treatment should be considered for LIS.

Keywords: Anal sphincter, chemical sphincterotomy, diltiazem gel, fissure in ano

#### Introduction

Anal fissures are a frequent source of intense anal discomfort. A longitudinal tear or ulcer in the distal anal canal is known as an anal fissure. Typically found in the middle of the back or front, it stretches from the dentate line to the anal verge. An acute fissure typically occurs within 3-6 weeks of the onset of symptoms. The anoderm displays a clean longitudinal tear with minimal inflammation in its surroundings. An acute fissure typically heals on its own within six weeks. A chronic fissure, typically lasting over 6 weeks, tends to be deeper and often exposes internal sphincter fibers at its base. It is often linked to a hypertrophic anal papilla at its upper part and a sentinel pile at its lower part. It is classified as primary (Idiopathic) or secondary based on its etiology. Secondary fissures are caused by underlying conditions like Crohn's disease, anal tuberculosis, or AIDS. Typically, individuals experience discomfort while passing stool and notice the presence of fresh blood when they go to the bathroom. The precise etiology of anal fissure is unknown. Fissure is most commonly attributed to trauma from the passage of a large hard stool, but it is also seen after acute episodes of diarrhea. Painful fissures are generally associated with involuntary spasm of the internal sphincter with high resting pressure in the anal canal. So it seems that chronic over activity of the internal sphincter may be the cause. Reduction of anal sphincter spasm results in improved blood supply and healing of fissure. Surgical techniques like manual anal dilatation or lateral internal sphincterotomy, effectively

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heal most fissures within a few weeks [1-6].

Various pharmacological agents have been shown to lower resting anal pressure and heal fissures without threatening anal continence <sup>[7]</sup>. In this study, we compared the effectiveness of applying 2% diltiazem gel and undergoing internal sphincterotomy in treating chronic fissure-in-ano. We evaluated the healing of the fissure and the relief of pain.

## **Material and Methods**

One hundred patients with chronic fissure in ano were identified and included in this prospective comparative study conducted over a period of one year at a prestigious healthcare institute in India. The study was conducted following the approval from the hospital ethics committee. All patients were provided with thorough explanations of the study's procedure and purpose, and their informed written consent was obtained.

**Inclusion criteria**: All patients between 20 to 60 years of age of both sexes were included in our study.

**Exclusion criteria:** Children and mentally handicapped patients, recurrent fissures, fissures with hemorrhoids and fistula, fissures associated with malignancies, fissures secondary to specific diseases like tuberculosis, and Crohn's disease, and pregnant women were excluded from the study.

There were two groups of patients, with 50 individuals in each group, labeled as group A and group B. Group A patients were instructed to use 2% diltiazem gel twice a day for a period of 6 weeks. Patients in group B received left lateral internal sphincterotomy while under spinal anesthesia.

Participants in both groups were instructed to incorporate mild laxatives such as cremaffin (Milk of magnesia and liquid paraffin) into their bedtime routine, follow a high fiber diet, and utilize warm sitz baths. The cases were carefully reviewed in the outpatient department (OPD) on a weekly basis for a period of four consecutive weeks, followed by monthly reviews for the next two months. During each visit, the healthcare provider inquired about pain relief, any issues with flatus or fecal leakage, and any other symptoms. The healing process was evaluated through clinical examination, specifically looking for the complete disappearance of the fissure. Pain was evaluated using a pain score chart.

# Statistical analysis

The data was compiled and entered into a spreadsheet computer program (Microsoft Excel 2007) and then exported to the data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). Quantitative variables were reported using measures such as means and standard deviations or median and interquartile range, depending on their distribution. The data for qualitative variables were displayed as counts and percentages. Confidence level and level of significance were set at 95% and 5% respectively for all tests.

#### **Results**

Our study found that a majority of the cases were in the young age group of 21-30 years, with a higher incidence among females (55%) compared to males (45%). Here is Table 1. The majority of the fissures were located posteriorly, accounting for 82% of the cases, and in 50% of the cases, a sentinel pile was present. We conducted weekly follow-ups for four weeks and then switched to monthly follow-ups for the next two months. In the study, it was found that 78% of patients in group A, who used diltiazem gel and 84% of patients in group B who used LIS

had fully healed fissures after 3 months (Table 2). At the end of 3 months, the results showed that 82% of patients in group A, who used Diltiazem gel and 90% of patients in group B who used LIS were pain-free (Table 3). Group A had a longer healing duration compared to group B. There were no complications reported in either group. There was no significant difference in pain relief or fissure healing between group A and group B. (p>0.05)

Table 1: Gender wise Distribution of study Population

Gender	Number	Percentage (%)
Male	45	45
Female	55	55
Total	100	100

**Table 2:** Healing at 3 months

Healing	Number	Percentage (%)
Group A (Diltiazem 2%)	39	78
Group B (Surgery (LIS))	42	84

Table 3: Pain relief at 3 months

Pain relief	Number	Percentage (%)
Group A (diltiazem 2%)	41	82
Group B (surgery (LIS))	45	90

# Discussion

Anal fissure is a prevalent issue that affects people worldwide. It leads to significant illness and has a negative impact on one's well-being. Anal fissure is a condition that is commonly seen in young or middle-aged adults, affecting both men and women equally. It is often observed in the back position, although the front fissure is more common in females [10]. Surgery is the simplest and most effective method for reducing internal anal sphincter tone. The gold standard for treating chronic anal fissures is lateral internal sphincterotomy [11, 12]. This procedure includes a partial separation of the internal anal sphincter from the fissure. Postoperative management in LIS surgery is straightforward and the healing process is accelerated. On the other hand, there are potential complications, such as permanent anal incontinence, that can be associated with the surgery.5 Studies have demonstrated that calcium channel blockers can effectively reduce resting anal pressure and facilitate the healing of fissures [7, 8].

Diltiazem, a calcium channel blocker of the non-dihydropyridine type, promotes relaxation and dilation of vascular smooth muscle. According to a study conducted by Medhi *et al*, diltiazem has been found to be effective in treating chronic fissure-in-ano. A recent study revealed that the use of diltiazem, whether taken orally or applied topically, resulted in a significant reduction in anal pressure and improved healing rates [8]

According to Gupta's study, medical manipulation of the internal sphincter is recommended as the initial treatment option. Only if this approach is unsuccessful or if the fissure reoccurs, should subcutaneous lateral internal sphincterotomy be considered <sup>[6]</sup>. Chemical sphincterotomy with diltiazem is a reversible procedure that is not expected to negatively impact continence. Patients with hypertension, diabetes, and medical conditions that make them unsuitable for surgery may be advised to consider treatment with diltiazem. While the healing rate may be slower with diltiazem, using this medication can help avoid the trauma of surgery <sup>[13, 14]</sup>. In a study conducted by Rithin Suvarna *et al.*, it was found that the healing rate achieved with 2% topical

diltiazem gel was 69.23%. On the other hand, the healing rate observed with lateral internal sphincterotomy was much higher at 95.87%. A study conducted by Giridhar C.M. *et al.* found that a 2% diltiazem gel resulted in a healing rate of 88.46% within 5 weeks. Additionally, a lateral internal sphincterotomy achieved a 100% healing rate within 4 weeks [15].

In our study, we followed up with patients for a 3-month period to assess the recurrence of fissures. It is important to note that recurrence is a common occurrence and often requires lifestyle modifications and dietary changes. However, it is worth mentioning that the limited duration of our study may not fully capture the long-term effectiveness of these interventions in curing the disease. One limitation of our study is the challenge of measuring pain relief, which can be subjective and vary among individuals.

Unlike surgery, chemical sphincterotomy with Diltiazem is a reversible procedure that is unlikely to have any negative impact on continence. Patients with hypertension, diabetes, and medical conditions that make them unfit for surgery may be prescribed treatment with Diltiazem. While the healing rate may be slower with Diltiazem, it offers the advantage of avoiding surgery and the need for hospitalization. Treatment proves to be highly cost-effective.

## Conclusion

Chemical sphincterotomy with topical 2% diltiazem gel application is a recommended first-line treatment for chronic anal fissure. It can be beneficial for individuals who are not suitable for surgery. Patients who have experienced relapse and therapeutic failure of previous pharmacological treatment should be considered for LIS.

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