

## A Prospective Study To Evaluate Medical Management Vs Surgical Intervention In Pain Relief And Healing Of Anal Fissure

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### Abstract

**Introduction:** Anal fissure is a commonly encountered problem for surgeons. It is a longitudinal tear in distal anal canal with or without an ulcer. It causes significant changes in quality of life. This study was done to compare the efficacy of medical management and surgical intervention in cases of anal fissures.

**Methods:** 50 patients were divided into two groups of 25 each. Group A patients were treated with topical application of 2% diltiazem gel and Group B patients were treated with Lateral sphincterotomy. Both groups were examined weekly for 4 weeks for pain using VAS score and at 12 weeks for healing.

**Results:** 21(84%) patients were pain free after 4 weeks under Group A, 24 (96%) patients were pain free after 4 weeks under Group B. 22(88%) patients were completely healed at 12 weeks under Group A, 25(100%) patients were completely healed at 12 weeks under Group B.

**Conclusion:** Lateral sphincterotomy can be advocated as treatment of choice for anal fissures. It has better pain relief and healing rates compared to topical application of 2% diltiazem gel. Medical Management can be used in patients refusing surgery or unfit for surgery.

**Keywords:** Constipation; Diltiazem; Fissure; Laxatives; Sphincterotomy.

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## Introduction

Amongst the various causes of pain in the anorectal region, anal fissure is the commonest encountered condition in routine clinical practice.<sup>1,2</sup> Anal fissures have drastic effects on quality of life because of the pain associated with it on defecation.<sup>3</sup> A longitudinal tear in the distal anal canal with or without an ulcer is known as an anal fissure.<sup>1,2</sup>

Anal fissures are classified into acute and chronic based on the duration of onset of symptoms. An acute anal fissure presents within 3-6 weeks of onset of symptoms first encountered by the patient and generally heals by 6 weeks either spontaneously or by medical management. A chronic fissure usually persists more than 6 weeks after onset of symptoms and is usually associated with a sentinel pile distally.<sup>1,2</sup>

Fissures are also classified into primary and secondary based on etiology. The exact etiology of primary anal fissure is still debatable but it is generally accompanied with local trauma to the distal anal canal due to hard stools, prolonged diarrhoea, vaginal delivery, repetitive injury or penetration.<sup>4</sup> This is followed by a triad of pain on defecation, internal anal sphincter spasm and ischaemia.<sup>1,5</sup> Secondary fissures are most often related to underlying pathology like Tuberculosis, AIDS etc. Thus chronic hypertonicity may generally be the underlying cause and patient generally presents with pain on defecation and blood in stools.<sup>1,2</sup> Anal fissure carries a lifetime risk of 11% and is thus a common problem for a surgeon.<sup>6</sup>

There are various treatment options, both medical and surgical, available for anal fissure both of which aim at reducing the spasm of anal sphincter and facilitating blood supply and tissue healing.<sup>1,2</sup> The mainstay of treatment includes correction of constipation by conservative methods like increasing fibre intake in diet by addition of raw fruits, vegetables and wholegrain.<sup>4</sup> Along with dietary changes, increased fibre intake can be achieved by use of psyllium fibre and bulking agents, all of this accompanied by warm sitz bath which involves warm bathing of the perineum. This has been proven to be effective in almost 50% of patients with acute anal fissures.<sup>7,8</sup> Medical management includes muscle relaxants, calcium channel blockers (diltiazem, nifedepine), nitrates (isosorbide dinitrate, glyceryl trinitrate) which help in reducing sphincter tonicity in resting state and improve healing.<sup>9</sup> Diltiazem and Glyceryl trinitrate have similar healing rates, but side effects related to diltiazem are less frequent compared to those of glyceryl trinitrate. The incidence of headaches and perianal itching are low with use of diltiazem compared to that of glyceryl trinitrate.<sup>10</sup> In a study on 39 patients with anal fissures by Jonas et al, it was concluded that use of 2% diltiazem topically had similar healing rates to that of 0.2% glyceryl nitrate ointment with relatively less side effects. It was also concluded in the same study that topical 2% diltiazem had healed fissures that were otherwise resistant to treatment with 0.2% glyceryl trinitrate.<sup>11</sup>

Surgical management includes the most commonly performed lateral sphincterotomy and less commonly performed manual anal dilatation both of which are highly effective but are sometimes associated with anal incontinence as a complication.<sup>1,2</sup>

Thus, the purpose of this study is to compare the effectiveness of lateral sphincterotomy and application of 2% diltiazem gel locally along with their side effects in the management of anal fissure.

## Methods

This present study was performed at the Department of General Surgery, FH Medical College and Hospital, Agra, Uttar Pradesh, India during the period of March 2022 to August 2022 after approval from the ethical committee (FHMC/IEC/R.Cell/2022/21). 50 patients between the age of 20 and 65 years of both sexes were included in the study. 25 patients were treated on OPD basis and 25 patients were admitted in the surgery ward planned for lateral sphincterotomy.

### Inclusion Criteria:

Patients with both acute and chronic fissures.

### Exclusion Criteria

- Children and mentally impaired patients.
- Recurrent fissures
- Fissures with haemorrhoids and fistula
- Fissures associated with malignancies
- Fissures associated with crohns diseases, tuberculosis etc.
- Pregnant women
- Patients with cardiac problems
- Patients with bleeding disorders
- Patients in immunocompromised state

Patients with history of anal fissure which was confirmed on clinical examination were included in this comparative study.

50 patients were divided into two groups of 25 each. Convenience sampling was used and each successive patient was enrolled alternatively in group 1 and group 2 in a non-randomized manner. Group 1 consisted of patients treated with 2% diltiazem application and Group 2 consisted of patients treated with lateral sphincterotomy. Informed consent from each patient was taken. Each patient was examined weekly for 4 weeks for sphincter tone, bleeding and relief from pain, and at 12 weeks to check for efficacy of treatment in terms of healing of fissure.

Group 1 patients were advised to apply 1.5-2 cm length of 2% diltiazem gel upto 1.5cm within the anus twice a day for four consecutive weeks. Patients were instructed to wash hands before and after application of gel.

The dose of diltiazem used in this study is chosen 2% as several dose-response studies have reported that diltiazem

does not have any enhanced effect on anal pressure even with higher concentrations of diltiazem.<sup>17</sup>

Group 2 patients underwent lateral sphincterotomy under spinal anaesthesia after proper anaesthetic clearance. Patient was kept nil by mouth preoperatively and upto the evening on the day of operation.

All 50 patients were advised to take mild laxative like cremaffin (milk of magnesia 11.25 ml, liquid paraffin 3.75 ml, per 15 ml of emulsion) three teaspoons at bedtime from the night of application of gel and surgery. Sitz bath was advised from the 2nd post-operative day. Group 2 patients were discharged on the 3rd post-operative day and examined on the 7th post-operative day for any bleeding or hematoma.

Patients of both Groups were examined 1st, 2nd, 3rd and 4th week after starting the treatment and the effectiveness was analysed. Patients were assessed for pain using visual analogue scale (VAS)<sup>12</sup> which is a scale ranging from 0-10 determining minimal and maximal pain as described by the patient. VAS 0 was considered as patient being pain-free. Patients were examined at 12th week for analysing the efficacy of the treatment.

**Results**

In this study, there was a higher male predominance (Figure 1) and most cases belonged to Age group 25-30 years (Figure 2) followed by age group 30-35 years. Out of 50 patients, 46 patients had fissures which were posterior (6’o clock) in location while only 4 patients had anterior (12’o clock) fissures (Figure 3)

**Group 1: Diltiazem Ointment Group**

Out of 25 patients taken for the study 21(84%) patients were pain free while 4(16%) patients were not completely pain free after 4th week of treatment as shown by Table 1. After 12 weeks, 22 out of 25 patients (88%) showed complete healing.

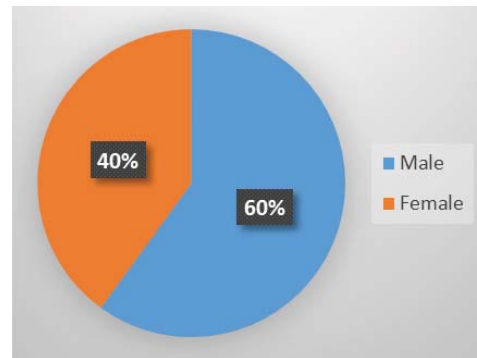


Figure 1. Sex Incidence

**Group 2: Lateral Sphincterotomy Group**

Out of 25 patient taken for the study, 24(96%) patients were pain free while 1(4%) patient was not completely pain free after 4th week of treatment. All 25 patients (100%) showed complete healing after 12th week as shown in Table 2.

Table 1. Pain Relief after 4 weeks

Group no.	Total patients	Pain-free patients	Percentage
Group 1 (Diltiazem)	25	21	84%
Group 2 (Lateral Sphincterotomy)	25	24	96%

Table 2. Healing at 12th weeks

Group no.	Total Patients	Patients with complete healing	Percentage
Group 1 (Diltiazem)	25	22	88%
Group 2 (Lateral Sphincterotomy)	25	25	100%

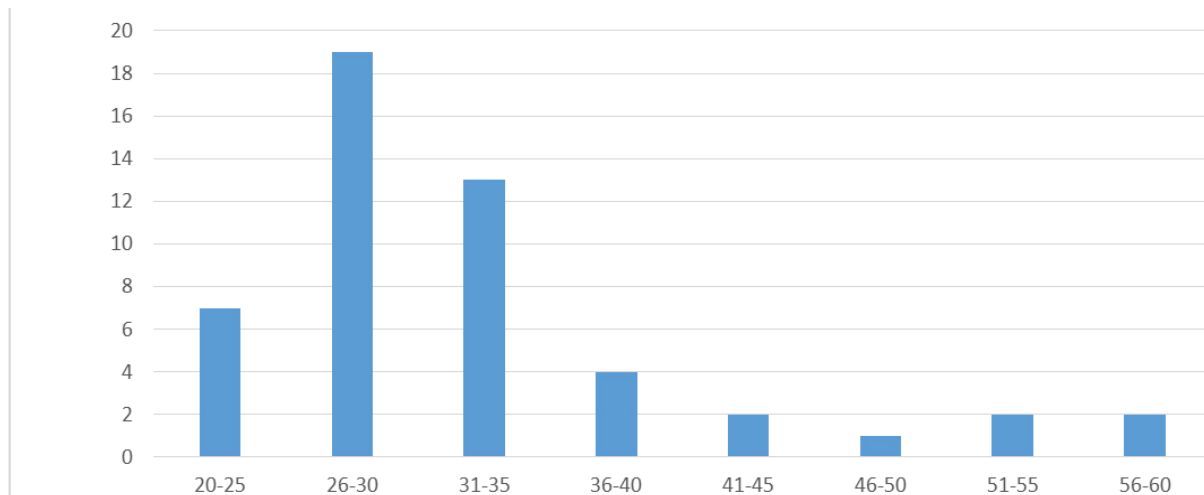


Figure 2. Age Incidence

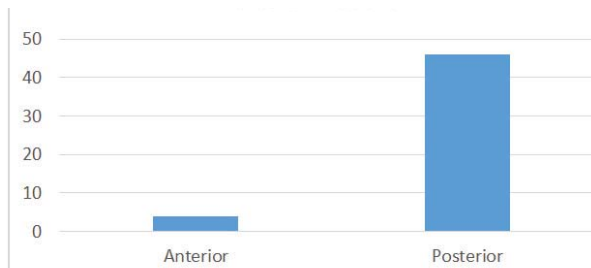


Figure 3. Site of Fissure

## Discussion

One of the most common problems faced by patients all around the world is anal fissure. It causes significant changes to quality of life and is discomforting to the patient. There is a slight male predominance and it is most commonly found in young adult, this has also been observed in our present study.<sup>13,14</sup>

Anal fissures can be managed either by medical management or surgical intervention which helps in reducing pain and anal spasm which is responsible for the development of anal fissure. Along with dietary changes, use of warm bathing of perineum (warm sitz baths) has been hypothesized to provide relaxation to internal anal sphincter by a somatoanal reflex.<sup>15</sup>

For the medical management of anal fissure, calcium channel blockers like Diltiazem and Nifedipine have been used which help in lowering the resting anal pressure<sup>16</sup>, which aids in healing of anal fissure. They are associated with minor complications like headache<sup>7</sup> and perianal dermatitis. Laxatives are also used as first line management of anal fissures as they are mostly accompanied by constipation.

The surgical interventions include procedures like anal dilatation and lateral internal sphincterotomy. Lateral sphincterotomy is the surgical procedure of choice to be performed in patients with chronic anal fissures. Lateral internal sphincterotomy reduces the anal pressure and improves the blood flow at posterior midline which promotes fissure healing.<sup>1</sup> In this, healing is faster than patients treated by medical management<sup>17</sup> and postoperative management is simple but there is a risk of developing complications like permanent anal incontinence.

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Patients who received treatment with 2% Diltiazem Gel were reviewed on 1st, 2nd, 3rd, 4th and 12th week on an outpatient basis. In our study, 88% of patients had completely healed fissures by 12th week while healing rates in several studies varied from 47-80%.<sup>9,16,18,19</sup> After 4 weeks, 84% patients were relieved of pain while 16% were not pain free. In a study done by Carmine Antropoli, M.D. et. Al, 65% of the patients were pain free and 35% of patients still had pain after 3 weeks.<sup>20</sup>

Under Spinal anaesthesia, patients underwent lateral internal sphincterotomy. In our study, 96% of patients who underwent surgery did not complain of pain while 4% still had complains after 4 weeks. In a study conducted by Motie et al, 98% of cases who underwent surgical intervention were relieved of pain.<sup>21</sup> In a study conducted by Sileri et al, the healing rates were found to be 94% among the patients who underwent lateral internal sphincterotomy.<sup>22</sup> In contrast to this our study showed 100% healing rates after surgical intervention.

In our study anal incontinence was not encountered in any of our patients while in a research conducted by Melange et al, flatus or liquid stool incontinence had an incidence of 27% while there was a 2% incidence for passive soiling after surgery.<sup>23</sup>

### Limitations of the study:

- Small sample size whose results cannot be generalized
- No known power of the study to make definitive claims
- Non-randomized sampling method has potential to introduce selection bias
- We do not know the proportion of acute and chronic fissures in each group. They may have different success with the two treatment strategies.
- Other variables like safety, cost, patient acceptance have not been studied in our study.

## Conclusion

It is evident from the study that Lateral Sphincterotomy has better healing rates compared to therapy with local application of 2% Diltiazem gel. Lateral sphincterotomy has an advantage over 2% Diltiazem that it has a better pain relief and faster healing rates.

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