

# A Comparative Study of Role of Topical Diltiazem 2% Organo Gel and Lateral Internal Sphincterotomy for the Management of Chronic Fissure in Ano

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## ABSTRACT

**Introduction:** Fissure in ano is a common proctologic disease affecting both men and women of all age groups particularly young. They require surgery like manual anal dilation or lateral internal sphincterotomy which heal the fissure in more than 90% cases but with a significant risk of impaired anal continence. Newer non surgical therapies such as topical 2% diltiazem gel, topical glyceryltrinitrate have shown good efficacy without impairing anal continence. Hence this study was taken up to compare 2% diltiazem organo gel topical application and lateral internal sphincterotomy for the treatment of chronic fissure in ano.

**Material and Methods:** 100 patients diagnosed with chronic fissure in ano were randomly divided into Diltiazem and lateral internal sphincterotomy groups. Patient were followed up at regular interval for symptomatic relief and healing of fissure.

**Result:** In 89.36% of patients in diltiazem group and 100% of patients in lateral internal sphincterotomy group fissure healed completely between 4-8 weeks. In the diltiazem group pain relief was fairly good. 42 patients (89.4%) had pain relief at the end of 14 weeks. 5 patients (10.6%) had no pain relief. But the pain relief in lateral internal sphincterotomy group was excellent with 100% patients having complete pain relief by 8 week's time. Mild headache was experienced with diltiazem by 3(6.4%) patients. 1 patient (2.1%) complained of flatus incontinence with lateral internal sphincterotomy.

**Conclusion:** We conclude that lateral internal sphincterotomy is the gold standard treatment for the chronic fissure in ano but chemical sphincterotomy using 2% topical diltiazem organo gel can be considered a good second line treatment option in those unfit for surgery or for those not willing for surgery.

**Keywords:** fissure in ano, Sphincterotomy, pruritis ani, constipation

## INTRODUCTION

Fissure in ano is a common proctologic disease affecting both men and women of all age groups particularly young. Anal fissure is defined as linear ulceration of the squamous lining of the distal and canal.<sup>1</sup> Anal fissures are associated with bleeding per anum, constipation, pain on defecation and pruritis. The etiopathogenesis of the fissure in ano is not well understood. Fissure is commonly attributed to passage of hard stool, dietary irregularities, spicy food, poor local hygiene, forceful passage of foreign body causing trauma to the distal anal canal lining.<sup>2</sup> In females traumatic delivery have been found to be associated with anterior anal fissure.<sup>3</sup> Anal fissure are of two types, acute and chronic. Acute anal fissure usually resolve spontaneously with stool softeners and high fibre diet whereas chronic anal fissure does not heal spontaneously with lifestyle modification, unlike acute

anal fissure.<sup>4</sup> They require surgery like manual anal dilation or lateral internal sphincterotomy which heal the fissure in more than 90% cases<sup>5</sup> but with a significant risk of impaired anal continence.<sup>6-8</sup>

This has led to research of alternate non surgical therapies such as topical 2% diltiazem gel, topical glyceryltrinitrate which has shown to heal fissure without impairing anal continence.<sup>9</sup>

The present study aims at comparing 2% diltiazemorgano gel topical application and lateral internal sphincterotomy for the treatment of chronic anal fissure.

## MATERIAL AND METHODS

The study was undertaken at Rohilkhand Medical College and Hospital from December 2013 to March 2015. 100 patients diagnosed with chronic fissure in ano on the basis of history of painful defecation with or without bleeding per rectum of more than 6 weeks and per rectal examination findings were enrolled in this study after obtaining an informed written consent from them. The sample size was based on inclusion, exclusion criteria mentioned in the study. Ethical approval was obtained from the ethical committee of the institute. Exclusion criteria included tuberculosis, anal malignancies, haemorrhoids, immunocompromised patients, IBD, anorectal abscess, previous history of fecal incontinence or anal stenosis or anal surgeries, patients with bleeding diathesis and cardiac problems.

Systemic examination and routine investigations were done. Patients were randomly divided into 2 groups. (Group A and Group B), each containing 50 patients. Group A patients were subjected to local application of 1.5 cm length of 2% Diltiazem organo gel into the anus thrice daily for a period of 8 weeks.

Group B patients underwent lateral internal sphincterotomy under spinal anesthesia.

Cases from both groups were advised high fibre diet, sitz bath and laxatives like Cremaffin (milk of magnesia 11.25 ml, liquid paraffin 3.75 ml, per 15 ml of emulsion) three tea-

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spoon at bed time.

Patients were reviewed in the OPD at 2,4,6,8,14 weeks and 6 months. During each visit details on fissure healing and anal tone on per rectal examination and pain relief was assessed from a visual analogue score and noted.

Also, specific questions were asked, regarding the leakage of flatus and faecus particular for group B and headache, vertigo and local irritation for group A.

**STATISTICAL ANALYSIS**

The results were tabulated and analyzed using SPSS software. Descriptive statistics was used to infer results.

**RESULTS**

In our study most of the cases belonged to age group 21 – 30 years (figure 1) with slight male preponderance (figure 2).

It was noted that 100% patients, both males and females had painful defecation which was followed by constipation, bleeding per anum, local pruritis and discharge per anus (figure 3). Majority of the fissures were posterior in location with sentinel pile present in 78% of the patients.

Cases were followed up at 2,4,6,8,14 weeks and 6 months for fissures healing, pain alleviation, side effects and recurrences. Three patients from group A and 2 patients from group B were lost to follow up and hence not included in statistical analysis. In 89.36% of patients in Group A and 100% of patients in group B fissure healed completely between 4-8 weeks.

In the group A, who underwent treatment with 2% Diltiazemorgano gel pain relief was fairly good. 42 patients (89.4%) had pain relief at the end of 14 weeks. 5 patients

(10.6%) had no pain relief. But the pain relief in group B patients, who underwent lateral internal sphincterotomy, pain relief was excellent with 100% patients having complete pain relief by 8 week’s time (figure 4). Mild headache was experienced by 3(6.4%) patients in group A (Diltiazem group). In group B, 1 patient (2.1%) complained of flatus incontinence and none in group A.

1 patient (2.1%) in the diltiazem group had recurrence which was subsequently managed by lateral internal sphincterotomy and fissure healed in 4 weeks after surgery. There was no recurrence in lateral internal sphincterotomy group.

**DISCUSSION**

Anal fissure is linear ulceration of the squamous lining of the distal anal canal causing pain on defecation, bleeding per anum and pruritis.<sup>1</sup>

It most commonly effects middle aged adults with no sex preponderance.<sup>10</sup> In our study most effected age group was 21-30 and there was slight male preponderance.

Anal fissures can occur in posterior midline, anterior midline or both with commonest being posterior midline because of lack of muscular support of the anal canal epithelium posteriorly and also poor blood supply posteriorly.<sup>11</sup> In our study also posterior midline was the most common position affecting 92% of the patients.

The exact pathogenesis of fissure in ano is unknown. It has been generally accepted that hypertonicity of the internal anal sphincter is responsible for anal fissure. Hence therapies like anal dilatation and lateral internal sphincterotomy which aims at reducing resting anal pressure have been effective in treating anal fissures.<sup>3</sup>

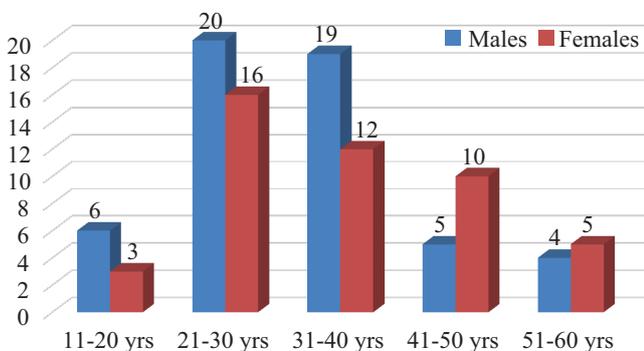


Figure-1: Age and sex distribution of the patients

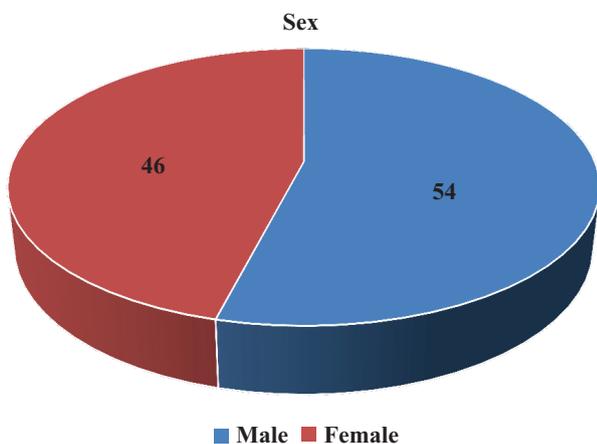


Figure-2: Sex distribution

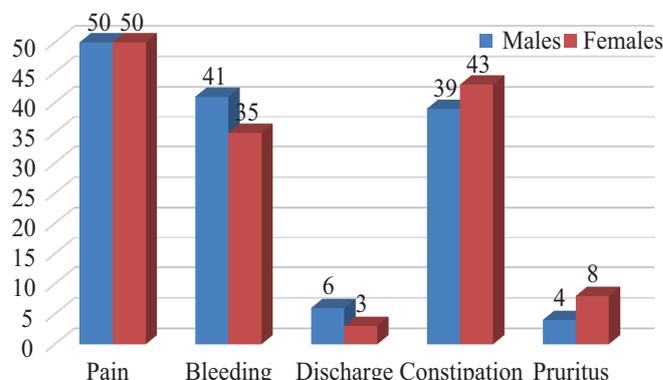


Figure-3: Various symptoms according to sex and age

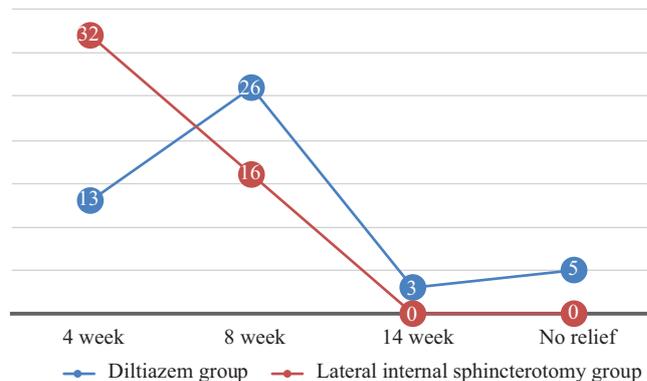


Figure-4: Pain relief in diltiazem and lateral internal sphincterotomy group

Anal fissure are divided into two types acute and chronic. Chronic anal fissures unlike acute anal fissures do not heal spontaneously with dietary modifications and stool softeners and persist beyond six weeks.<sup>9</sup> They are characterised by indurated edges, visible internal sphincters at floor, sentinel pile and hypertrophied anal papilla. Surgeries like anal dilatation and lateral internal sphincterotomy have been the gold standard for the treatment of chronic and fissures.<sup>5</sup> Newer non surgical therapies such as calcium channel blocker like diltiazem, nifedepine and nitrates like glyceryl trinitrates, have taken their place as first line of treatment for chronic anal fissures in many centers because of decreased fecal or flatus incontinence rate and OPD based treatment.<sup>12-14</sup>

Rithin Suvarna et al reported a healing rate of 69.23% with 2% topical diltiazem gel and healing rate of 95.87% with lateral internal sphincterotomy.<sup>15</sup>

Giridhar C.M. et al reported a healing rate of 88.46% in 5 weeks with 2% diltiazem gel and 100% healing rate by 4 weeks with lateral internal sphincterotomy.<sup>16</sup>

In our study, fissure healed completely in 89.36% of patients treated with 2% topical diltiazem organo gel with 89.4% of patients having pain relief at the end of 14 weeks. 10.6% of patients had no pain relief and 2.1% of patients in the group had recurrence.

In LIS group fissure healed in 100% of patients by 4 weeks and 100% of patients had pain relief by 8 weeks. 1 patient (2.1%) in this group had fecal incontinence.

## CONCLUSION

We conclude that lateral internal Sphincterotomy is the gold standard treatment for the chronic fissure in ano but chemical sphincterotomy using 2% topical diltiazem organogel can be considered a good second line treatment option in those unfit for surgery or for those not willing for surgery.

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