# **Original Research Article**

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# Prospective comparative study between lateral sphincterotomy and subcutaneous fissurectomy with topical 2% diltiazem gel in the treatment of chronic fissure in ano

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#### **ABSTRACT**

**Background:** Anal fissure is defined as an ulcer in the anoderm usually in the posterior midline, less frequently in the anterior midline and rarely in the lateral position of the anal canal. Different treatment modalities include non-invasive pharmacological therapies, lateral internal sphincterotomy (LIS) which is the gold standard for treatment and new therapies that include perineal support devices, Gonyautoxin injection, fissurectomy, sphincterolysis, and flap procedures. Thus, aim of the study was to compare the efficacy of outcome of lateral internal sphincterotomy and subcutaneous fissurectomy with topical 2% Diltiazem gel in the treatment of chronic fissure in ano.

**Methods:** 50 patients with chronic fissure in ano attending OPD of Department of General Surgery, KVGMCH, Sullia were randomly selected and divided into Group A (n=25): Lateral internal sphincterotomy (control group) and Group B (n=25): Subcutaneous fissurectomy + topical 2% Diltiazem Gel (test group).

**Results:** Patients of Group B showed much less mean duration of absenteeism (2.88 weeks) compared to Group A. Comparison between Group B and Group A showed statistically significant differences in pain relief (P<0.0001), complications (p=0.03), mean duration of sitz baths (p<0.0001), absenteeism (p<0.0001) respectively.

**Conclusion:** Hence Subcutaneous fissurectomy with topical 2% Diltiazem gel is a better surgical option for chronic fissure in ano than conventional Lateral internal sphincterotomy.

Keywords: Chronic fissure in ano, Diltiazem, Lateral internal sphincterotomy, Subcutaneous fissurectomy

## INTRODUCTION

Anal fissure is a distinct clinico-pathological condition of the lower anal canal. It can be defined as an ulcer in the anoderm usually in the posterior midline, less frequently in the anterior midline and rarely in the lateral position of the anal canal. <sup>1,2</sup> When traction is applied on each side of the anus, the fissure appears to be triangular in shape, with the apex near the dentate line and the base over the lower anal canal. <sup>1,3</sup> 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. Fissure is present in the midline, posteriorly or anteriorly. If the primary fissure is not treated in its acute stage then permanent organic changes take place in tissues like indurations of the ulcer margins, fibrosis in the ulcer base, development of sentinel pile and anal papilla leading to chronic stage. The secondary types of fissures are caused by some pathological conditions of the anal canal such as Crohn's disease, ulcerative colitis, trauma, previous anorectal operations or infection. 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.<sup>1,4</sup> 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. 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, sclerotherapy (using Sodium tetradecyl sulphate), chemical sphincterotomy using topical glyceryl trinitrate, <sup>6,7</sup> calcium channel blockers such as Nifedipine or Diltiazem and Botulinum toxin.3 New therapies include perineal support devices, Gonyautoxin injection, fissurectomy, fissurotomy, sphincterolysis and flap procedures.9

Fissurectomy involves freshening of the anal fissure to allow healing, and this includes excision of the fissure edges, curetting or excision of the fissure base and possibly excision of sentinel skin tags and anal polyps.<sup>9</sup> Diltiazem, a non-dihydropyridine calcium-channel blocker, induces vascular smooth muscle relaxation and dilatation. Topical 2% Diltiazem reduces maximum resting pressure (MRP) by approximately 28% and this effect lasts 3-5 hrs after application. Side effects are minimal with Diltiazem and include perianal dermatitis. 10 Also, use of topical 2% Diltiazem is not associated with headache and therefore increased compliance of the patients unlike the use of nitric oxide donors such as Glyceryl trinitrate and Isosorbide dinitrate as a form of chemical sphincterotomy as it is associated with headache and therefore decreased compliance of the patient resulting in poor results. 11 The aim of the study was thus to compare the efficacy of outcome of lateral internal sphincterotomy and subcutaneous fissurectomy with topical 2% Diltiazem gel in the treatment of chronic fissure in ano. The objectives of the study were to compare symptomatic relief, healing and complications in case of these two treatment modalities.

#### **METHODS**

## Patients selection

The study was a prospective, parallel group, randomised, comparative study. 50 patients were randomly selected from the admitted patients with chronic fissure in ano in

the department of General Surgery of KVG Medical College Hospital. The study was approved by the Institutional Ethics Committee. Informed written consent was taken from all patients prior to enrolling into the study. Study was done from August 2017 to August 2018.

#### Inclusion criteria

- Patients between 20 to 60 years of age of both sexes
- Admitted patients of chronic fissure in ano not responding to conservative management for more than 2 months

#### Exclusion criteria

- Children and mentally challenged patients
- Recurrent fissures
- Fissures with haemorrhoids and fistula
- Fissure associated with malignancies
- Fissure secondary to specific diseases like tuberculosis, Crohn's disease etc.
- Pregnant women
- Patients who have undergone previous anal surgeries

## Study design

50 patients were randomly divided into 2 groups with 25 patients in each group. Sample size was estimated applying the following formula: <sup>12</sup>

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

Sample size (n) = -

 $d^2$ 

= 25 in each group [Z = 1.96, d = 13%, P1 = 88%, P2 = 100%]

Group A (n=25): Patients were treated with lateral internal sphincterotomy (control group).

Group B (n=25): patients were treated with subcutaneous fissurectomy with topical 2% Diltiazem gel (test group).

Topical 2% Diltiazem gel was prescribed to all the patients of Group B from 2nd post-operative day to 3 months. Patients in both the groups were prescribed standard treatment for fissure in the form of laxatives [Syrup Cremaffin (milk of magnesia 11.25 ml, liquid paraffin 3.75 ml per 15 ml of emulsion) three teaspoons, once at bedtime], high fibre diet, sitz bath (thrice daily) started from second post-operative day.

Also, the operated patients of both groups were treated with a broad spectrum antibiotic for 5 days from the day of surgery and injection Diclofenac (50mg) given twice daily for all patients for first 3 days and then as per

required basis if renal parameters were within acceptable range else injection Paracetamol (500 mg) was administered as per same protocol. All patients were discharged on 6th postoperative day.

Post operatively patients were watched for bleeding and hematoma formation. The patients were followed up once in a week for a period of 3 months and were evaluated for relief of symptoms. Numeric rating scale (NRS) score (0-10) was used to evaluate pain in the post-operative period as it is sensitive in assessing acute pain after surgery. Score '0' indicates 'no pain' and score '10' indicates 'worst pain imaginable'. 13

Observations were recorded at the end of 3 months following the treatment. Evaluation was done on the basis of pain relief, incontinence (faecal/flatus or both), and no. of work days lost. Digital examination was done to assess the relaxation of sphincter. The fissure was said to be healed when mucosa re-epithelise over the surface. The complications looked out were incontinence, wound infection and recurrence in both groups.

## Application of diltiazem gel

Patients who were allocated in the Group B were advised to apply 2 cm length of 2% Diltiazem gel twice daily at least 1.5 cm into the anus. Patients were instructed to wash hands before and after use of gel. <sup>13</sup>

The data obtained was analysed using SPSS software version 20.0. Student's t test and chi square test were used to compare Group A & Group B. Descriptive results are expressed as mean and SD of various parameters. Probability value (p value) was used to determine the level of significance, p value <0.05 was considered as significant, p value <0.01 was considered as highly significant.

#### **RESULTS**

In the present study we found majority of the subjects were in the age group of 30-50 years (Table 1). This study showed bulk of the patients were males (70%) (Table 2).

Table 1: Age distribution.

Age in years	No. of patients	Percentage (%)
21-30	13	26
31-40	20	40
41-50	15	30
51-60	2	4

Table 2: Sex distribution.

Sex incidence	No. of patients	Percentage (%)
Females	15	30
Males	35	70

Posterior fissure in ano was more common (80%) in this study (Table 3).

Table 3: Fissure location.

Site	No. of patients	Percentage (%)
Anterior	10	20
Posterior	40	80

According to this study preoperative sentinel pile was present in 17 (34%) patients and sphincter spasm was present in all cases (100%). All the patients were followed up and the mean NRS score for pain in Group A was significantly higher than Group B with p=0.0004 (Table 4) after 3 weeks.

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

NRS score for	NRS Group A		Group 1	Group B	
pain	Mean	SD		Mean	
Pain	6.84	1.46	Pain	6.84	
t- value	3.8112				

It was also observed that mean pain score was 1.84 in Group A compared to 0.6 in Group B after 3 months follow up of all the patients. This decrease in mean pain score 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	Group A		В
	Mean	SD	Mean	SD
Pain	1.84	1.1789	0.6	0.707
t- value	4.5102		P	< 0.0001

In this study comparison of complications in patients after 3 months follow up showed that there were no complications in any patient of Group B but in Group A, 16% presented with complications- one case wound infection, two cases presented with flatus incontinence and one case presented with recurrence of symptoms. Occurrence of complication was significantly higher (p=0.03) in Group A (Table 6).

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

Complications	Group A		Group	В
	No	%	No	%
Present	4	16	0	0
Absent	21	84	25	100
Chi square	4.34		p	0.03

We found in the present study that sitz bath after surgery was required for patients of Group A for a mean duration

of 6.12 weeks compared to a mean duration of 3.44 weeks for patients of Group B. The duration of sitz bath was significantly higher (p<0.0001) in Group A (Table 7).

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

Sitz bath	Group	Group A		В
(weeks)	Mean	SD	Mean	SD
Sitz bath	6.12	1.4525	3.44	1.5567
t value	6.2937		р	< 0.0001

Mean duration of absenteeism in patients after surgery was compared and patients of Group A showed a higher mean duration of absenteeism i.e. 4.56 weeks, whereas patients of Group B showed 2.88 weeks of absenteeis. The duration of absenteeism was significantly higher (p <0.0001) in Group A (Table 8).

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

Absenteeism	Group A		Group	В
(weeks)	Mean	SD	Mean	SD
Absenteeism	4.56	0.961	2.88	1.364
t value	5.0343		p	< 0.0001

#### **DISCUSSION**

Anal fissure causes considerable morbidity and adversely affects the quality of life. The simplest and most effective way of reducing internal anal sphincter tone is surgery. Lateral internal sphincterotomy is the golden standard in the treatment of chronic anal fissures. 14-16 It involves partial division of the internal anal sphincter away from the fissure. Calcium channel blockers have been shown to lower resting anal pressure and promote fissure healing.<sup>17,18</sup> A study by Medhi et al described Diltiazem to be efficacious in the treatment of chronic fissure in ano.10 Study showed that oral intake and topical applications of Diltiazem reduced the anal pressure significantly with better healing rates. Another review by Bharadwaj et al showed that Diltiazem was a valid alternative to glyceryl trinitrate with improved healing rates and lower rates of recurrence.11

The commonest age group affected in this study was 31-40 years (40%), which concurs with the data by Goligher et al in which, the commonest age group affected was 31-40 years. <sup>18</sup> In the same study though the incidence of chronic fissure was equal in both sexes, in our study we found a higher incidence in males compared to females (2.33:1). <sup>18</sup> According to Pelta et al approximately 90% of anal fissures in both men and women are located posteriorly in the midline and anterior fissures occur in 10% of patients, more commonly women. <sup>19</sup> In this present study, we found the incidence of anterior fissure

to be around 20% and posterior fissure 80%. In Group B mean pain score was 5.36 by the end of 3rd week and 0.6 by the end of 3 months. Fissure was completely healed in 22 (88%) out of 25 patients by 3 weeks and 25 (100%) at the end of 3 months. Subcutaneous fissurectomy is novel procedure; there are fewer studies available in this aspect. According to Pelta et al, with subcutaneous fissurectomy, out of 118 patients, 100% patients achieved undisturbed wound healing rates, only 2% patients experienced flatus incontinence. 19 In this study there was no incontinence in Group B Tocchhi et al reported no long-term complication after internal sphincterotomy and patient satisfaction was 96%. 20 According to Aziz et al with LIS, 140 out of 146 patients had completed healing of fissure by 3 months out of which 124 patients healed by 6 weeks, 12 patients healed by 7 weeks and 4 patients by 3 months.<sup>21</sup> The overall healing rate was 97.5%. But 4.1% patients experienced transitory flatus incontinence. In this study there was no long term complications and patient satisfaction was 100% but transient incontinence for flatus was present in 2 (4%) patients of the Group A. In the present study there was no recurrence in Group B but 1 (2%) recurrence occurred in the Group A. patients of Group B required sitz bath for a mean duration of 3.44 weeks when compared 6.12 weeks in case of patients of group A. Patients of group B showed much less duration of absenteeism 2.88 weeks; as compared to 4.56 weeks for patients of group A. Comparison between Group B and group A showed a difference in pain relief (P<0.0001), complications (P=0.03), mean duration of baths (P<0.0001), absenteeism (P<0.0001) respectively; which is statistically significant.

#### **CONCLUSION**

Hence, subcutaneous fissurectomy with topical 2% Diltiazem gel local is a better surgical option for chronic fissure in ano than conventional lateral internal sphincterotomy. However, much remains to be done regarding its long term results through more extensive and larger clinical trials.

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