

Original Research Article

A comparison of lateral internal sphincterotomy versus subcutaneous fissurectomy under local anaesthesia with 2% diltiazem gel in the management of chronic fissure in ano: prospective study

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ABSTRACT

Background: Anal fissure is one of the most common benign anorectal condition that is caused by an ulcer or breach in the anoderm of the anal canal. It causes very severe pain and discomfort and directly affects the quality of life. From the past, various surgical treatment modalities have been practised to bring complete cure and relief but have always been associated with secondary complications. The aim of the study was to compare efficacy of outcome of lateral internal sphincterotomy and subcutaneous fissurectomy with topical 2% diltiazem gel in the treatment of chronic fissure in ano.

Methods: 60 patients who were diagnosed with chronic anal fissure between 2019-2021 at MGM Medical College were undertaken in this study. Patients were selected randomly on alternate basis. Group A patients were subjected to subcutaneous fissurectomy under local anaesthesia with post-operative application of 2% diltiazem gel. Group B patients were subjected to LIS. Surgical wound infection, absenteeism from work, symptomatic relief were assessed and compared between the groups.

Results: There was no significant difference among both the study population in terms of age and gender. There was a statistically significant association between post-operative wound infection ($p=0.011$), number of work days lost ($p=0.008$) and satisfaction level ($p=0.020$).

Conclusions: LIS is still a better surgical choice for treating chronic anal fissures than subcutaneous fissurectomy with 2% diltiazem gel, due to less complications, faster pain alleviation, and fewer missed work days.

Keywords: Lateral internal sphincterotomy, Sub-cutaneous fissurectomy, 2% Diltiazem gel

INTRODUCTION

Anal fissures are benign anorectal disorder that causes pain and bleeding during defecating.

An anal fissure is a superficial rupture or ulcer within the distal anoderm that extends from the anal margin to the dentate line and is most typically observed within the posterior midline, less frequently in the anterior midline, and infrequently within the lateral side of the anal canal. Primary (idiopathic) and secondary (underlying pathological condition) fissures can be distinguished.¹

Chronic anal fissures are defined as anal fissures that last longer than 6 weeks. Various treatment modalities like anal dilatation, sphincterolysis, flap procedures, fissurectomy, fissurotomy, non-invasive pharmacological therapies like chemical sphincterotomy, sclerotherapy, and sclerotherapy had been developed and emphasised in fissure patients in the past, resulting in secondary complications.

Chronic anal fissures are more persistent and relapsing than acute fissures, which heal spontaneously.^{2,3} Persistent hypertonia of the sphincter muscle is reported to be the

well-established etiology of fissures in terms of etiopathogenesis.^{3,4} As a result, common treatment options include medicinal and surgical procedures for alleviating the spasm of the internal sphincter ani. Lateral internal sphincterotomy is the preferred treatment for persistent anal fissures, with healing rates exceeding 95%. However, the need for an alternative to alleviate postoperative stress and the possibility of incontinence has long existed. Diltiazem, a calcium channel blocker with a unique profile of outstanding healing rates and moderate side effects, is one such chemical approach that has been utilized in its locally relevant form.^{4,5}

This study was designed with all of the aforementioned in mind, and it looks at the recovery rates of persistent fissures using subcutaneous fissurectomy with 2 percent diltiazem as chemical sphincterotomy, with the surgical lateral internal sphincterotomy (surgical sphincterotomy) as the main goal. It also looks at ancillary goals such pain relief, rectal bleeding, the chance of incontinence, and the recurrence rate in the two treatment modalities.

METHODS

Source of data

All cases of chronic anal fissure admitted/operated in department of surgery, MGM Medical College and MY Hospital, Indore. The study will include prospective cases for 1 year from date of approval

Method of collection of data

Study design

The study design was prospective and comparative study.

Study period

The study period was January 2020 to January 2021.

Place of study

The study was carried at department of surgery, MGM Medical College and MY Hospital, Indore.

Sample size

Simple random sampling was done. Minimum 60 cases (30 in each group).

$$N = \frac{Z^2 \left(1 - \frac{\alpha}{2}\right) [P_1(1 - P_1) + P_2(1 - P_2)]}{d^2}$$

Inclusion criteria

Patients with following criteria were included (a) between 18 to 60 years of age of both sexes; and (b) those admitted

patients of chronic fissure in ano not responding to conservative management for more than 2 months.

Exclusion criteria

Patients with following criteria were excluded (a) children and mentally challenged patients; (b) recurrent fissures/acute anal fissure; (c) fissures with hemorrhoids and fistula; (d) fissure related to malignancies; (e) fissure secondary to specific diseases like tuberculosis, Crohn's disease etc; and (f) pregnant women.

Informed/written consent will be taken from all the patients included in the study. All patients in study will undergo a detailed history taking including general examination and investigations. Patients will be categorized into two groups A and B.

Group A

Subcutaneous fissurectomy with 2% diltiazem gel under local anaesthesia.

Patients were advised to apply 1.5 to 2 cm length of gel twice daily at least 1.5 cm into the anus for 6 consecutive weeks. Patients were instructed to wash hands before and after use of gel.

Group B

Patients with lateral internal sphincterotomy under spinal anaesthesia.

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. Patients from the both the group were followed up for a period of 3 months on 1st week, 1st month and 3rd month respectively.

Assessment tools

Assessment tools were (a) NRS score/visual analogue pain scale; (b) incontinence (fecal/flatus) number of work days lost; (c) wound infection; (d) recurrence; and (e) per rectal digital examination.

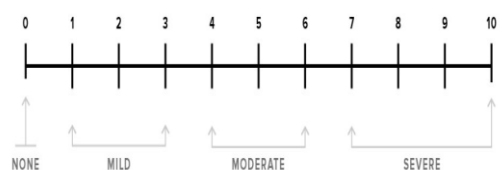


Figure 1: 0-10 numeric pain rating scale.

Statistical analysis

Statistical software SPSS was used to calculate the p value. Pearson chi-square and unpaired t test was applied for comparing the data of both the groups and a p value of <0.05 was considered statistically significant.

RESULTS

Group A

30 patients subjected to subcutaneous fissurectomy with 2% diltiazem gel under local anaesthesia.

Table 1: Distribution of patients according to age (n=60).

Age (years)	N	%
20-30	17	28.3
31-40	14	23.3
41-50	14	23.3
51-60	15	25.0
Total	60	100.0

Table 2: Distribution of patients according to sex (n=60).

Sex	N	%
Female	21	35.0
Male	39	65.0
Total	60	100.0

Table 3: Distribution of patients according to site of anal fissure.

Site of anal fissure	N	%
6 o'clock	60	100.0
Total	60	100.0

Group B

30 patients subjected to lateral internal sphincterotomy under spinal anaesthesia. Majority of the patients were in the age group 20-30 years and 51-60 years. The mean age of the patients was 39.48±11.29 years (range: 20 to 60 years) (Table 1).

21 (35%) patients were females and 39 (65%) patients were males. Males were more compared to the females (Table 2). All the patients 60 (100%) patients were having anal fissure at 6 O'clock position (Table 3).

In subcutaneous fissurectomy with 2% diltiazem gel, 8 (26.7%) patients had post-operative wound infection and 1

(3.3%) patient of lateral internal sphincterotomy had postoperative wound infection. There was a statistically significant association between post-operative wound infection and the groups ($p=0.011$), showing that the groups are dependent on post-operative wound infection (Table 4). Post-operative wound infection was significantly higher in subcutaneous fissurectomy with 2% diltiazem gel. In subcutaneous fissurectomy with 2% diltiazem gel, 3 (10%) patients had postoperative incontinence and 1 (3.3%) patients of lateral internal sphincterotomy had postoperative incontinence. There was no statistically significant association between post-operative incontinence and the groups ($p=0.300$), showing that the groups are independent of postoperative incontinence (Table 5). The mean work days lost in subcutaneous fissurectomy with 2% diltiazem gel was 6.97±1.38 days and in lateral internal sphincterotomy group was 6.10±1.06 days. The difference was found to be statistically significant ($p=0.008$), showing a higher work-days lost in subcutaneous fissurectomy with 2% diltiazem gel (Table 6).

After 1 week

The mean pain relief in subcutaneous fissurectomy with 2% diltiazem gel was 82.33±5.53% and in lateral internal sphincterotomy pain relief was 86.83±5.17%. The mean pain relief was significantly higher in lateral internal sphincterotomy.

After 1 month

The mean pain relief in subcutaneous fissurectomy with 2% diltiazem gel was 88.00±3.62% and in lateral internal sphincterotomy pain relief was 93.83±5.97%. The mean pain relief was significantly higher in lateral internal sphincterotomy.

After 3 months

The mean pain relief in subcutaneous fissurectomy with 2% diltiazem gel was 96.67±5.92% and in lateral internal sphincterotomy pain relief was 98.50±4.76%. The mean pain relief was higher in lateral internal sphincterotomy, but the difference was statistically not significant ($p=0.191$). The mean satisfaction level in subcutaneous fissurectomy with 2% diltiazem gel was 8.97±1.19 and in lateral internal sphincterotomy was 9.57±0.68. The mean satisfaction level was significantly higher in lateral internal sphincterotomy patients compared to subcutaneous fissurectomy with 2% diltiazem gel ($p=0.020$).

Table 4: Distribution of patients according to post-operative wound infection in relation to type of surgery.

Post-operative wound infection	Subcutaneous fissurectomy with 2% diltiazem gel		Lateral internal sphincterotomy	
	N	%	N	%
No	22	73.3	29	96.7
Yes	8	26.7	1	3.3

Continued.

Post-operative wound infection	Subcutaneous fissurectomy with 2% diltiazem gel		Lateral internal sphincterotomy	
	N	%	N	%
Total	30	100.0	30	100.0

Note: Pearson Chi-square test applied. Chi-square value=6.405, df=1, p value=0.011, significant.

Table 5: Distribution of patients according to post-operative incontinence in relation to type of surgery.

Post-operative incontinence	Subcutaneous fissurectomy with 2% diltiazem gel		Lateral internal sphincterotomy	
	N	%	N	%
No	22	73.3	29	96.7
Yes	8	26.7	1	3.3
Total	30	100.0	30	100.0

Note: Significant: Pearson Chi-square test applied. Chi-square value=1.071, df=1, p value=0.300, not significant.

Table 6: Comparison of number of work days lost in relation to type of surgery (n=60).

Type of surgery	N	Mean±SD	t value	P value
Subcutaneous fissurectomy with 2% diltiazem gel	30	6.97±1.38	2.730, df=58	0.008*
Lateral internal sphincterotomy	30	6.10±1.06		
Total	60			

Note: Unpaired t test applied, p value=0.008, *-significant.

Table 7: Comparison of relief at different time intervals in relation to type of surgery (n=60).

Duration	Type of surgery	N	Mean±SD	t value	P value
After 1 week	Subcutaneous fissurectomy with 2% diltiazem gel	30	82.33±5.53	-3.257, df=58	0.002*
	Lateral internal sphincterotomy	30	86.83±5.17		
After 1 month	Subcutaneous fissurectomy with 2% diltiazem gel	30	88.00±3.62	-4.575, df=58	0.001*
	Lateral internal sphincterotomy	30	93.83±5.97		
After 3 months	Subcutaneous fissurectomy with 2% diltiazem gel	30	96.67±5.92	-1.322, df=58	0.191, NS
	Lateral internal sphincterotomy	30	98.50±4.76		

Note: Unpaired t test applied, p value<0.05 was taken as statistically significant.

DISCUSSION

Chronic anal fissure, among the several benign anorectal diseases, has been regarded as one of the most disabling conditions due to its chronicity and intense discomfort. It has an impact on patient's bodily well-being as well as their psychological well-being, implying a negative impact on their quality of life. As a result, treating this illness first and foremost is critical.⁶ Anal fissures are most commonly found on the posterior aspect of the anal canal, however they can also occur in other locations due to underlying secondary diseases. Raised anal sphincter pressure combined with hypoperfusion is thought to be the key underlying pathogenesis. Various therapeutic approaches, both pharmaceutical and surgical, have been used to reduce sphincter pressure. The gold standard treatment for the management of anal fissures is lateral internal sphincterotomy, in which the internal sphincter is separated in its distal third away from the fissure itself - either in the right or left lateral position, although with the risk of incontinence. We compared LIS to subcutaneous

fissurectomy with 2 percent diltiazem gel application in order to determine the efficacy of both treatments so that a less complication-prone alternative might be developed.⁷⁻⁹

In this study, 60 individuals with chronic anal fissures who had failed to react to medical therapy were chosen at random, with 21 (35%) females and 39 (65%) males, with the most prevalent location of fissure being posterior midline 60 (100 percent). This evidence supports the findings of Varadarajan et al, Saiyad et al, and Khan et al.¹⁰⁻¹²

The majority of the patients affected were in the age groups of 20-30 years and 51-60 years, with a mean age of 39.48, 11.29 years (range: 20 to 60 years). This was discovered to be similar to the findings of Narayan et al, Chaudhary et al, who indicated that chronic anal fissure is primarily a condition of adults.^{13,14}

We looked at post-operative pain alleviation, post-operative wound infection/complications, lost work days,

and satisfaction rates for all of the patients who participated in the study. Post-operative wound infection occurred in 8 (26.7%) of group A patients and 1 (3.3%) of group B patients. The Chi square test revealed a statistically significant connection between both groups' post-operative wound infection ($p=0.011$). The findings of Mousavi et al, Narayan et al, and Dey et al were found to be in conflict with this data. This could be because the 2 percent diltiazem gel was applied in an unsanitary manner.¹³⁻¹⁶ Further examination revealed that 3 (10%) of patients in group A had postoperative incontinence, while 1 (3.3%) of patients in group B had postoperative incontinence. Even though there was no significant difference between the two groups, it was determined to be consistent with earlier research by Charua et al, Goliger et al, and Bara et al who found that patients who underwent LIS had a lower incontinence rate.^{7,8}

Patients in both groups were evaluated for pain reduction at regular intervals using the NRS pain score (1 week, 1st month and 3rd month). The data was compared between the two groups using an unpaired t test. Patients in group B experienced significant pain alleviation for the first two assessments, but by the third month, patients in both groups had experienced significant pain relief. The outcomes of early pain relief in LIS patients were similar to those of previous investigations by Aziz et al, Schouten et al, and Daniel et al.^{6,9,17} When the number of work days lost was compared between the two groups, there was a significant connection ($p=0.008$). Patients in group B missed 6.10 1.06% of their work days, while patients in group A missed 6.97 1.38% of their days. This can be linked to group B's fast pain alleviation. Mousavi et al did a similar study, which found that LIS patients experienced immediate pain reduction. However, one study by Dey et al found opposite outcomes, with the fissurectomy group having fewer mean days of absenteeism from work (2.88 weeks) than the control group.^{15,16,18}

Patients in both groups received complete pain alleviation at the end of the third month, however when the satisfaction rates were compared, lateral internal sphincterotomy patients had a greater mean satisfaction level than patients who had a subcutaneous fissurectomy with 2% diltiazem gel ($p=0.020$). Patients in the LIS group were 95.7 percent satisfied with their treatment and had fewer problems. This was discovered to be similar to prior LIS studies by Aziz et al, Bara et al, and Goligher et al.^{7,9,17,18}

The dreaded complication of fissurectomy is key hole distortion, which fortunately did not occur in any of the patients in our study.

Limitations

This study had a several limitations, including a single-center study, a small sample size and difficulty in follow up due to COVID epidemic.

CONCLUSION

Finally, we believe that LIS is still a better surgical choice for treating chronic anal fissures than subcutaneous fissurectomy with 2% diltiazem gel, due to less postoperative complications, faster pain alleviation, and fewer missed work days. However, to evaluate the long-term results of subcutaneous fissurectomy with 2% diltiazem problem, longer and larger clinical trials are needed.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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