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Original Research Article

Management of chronic fissure in ano-lateral internal sphincterotomy versus 2% diltiazem gel local application: a prospective comparative study

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ABSTRACT

Background: Fissure-in-ano is one of the most common benign anorectal disorders often encountered in surgical outpatient department. Various pharmacological agents and surgical interventions have been tried in the management of fissure in ano. In this study we have compared medical management by topical diltiazem gel with established surgical procedure of lateral internal sphincterotomy (LIS) in the management of chronic anal fissure.
Methods: A total of 50 patients with chronic fissure in ano involved in this prospective comparative study, between December 2020 to May 2022, at Rajarajeswari Medical College and Hospital, Bengaluru. Selected patients were put under two groups of 25 participants each, A (2% diltiazem group) and B (lateral internal sphincterotomy - LIS group) using simple randomization technique and were to receive treatment accordingly. Fissure healing and pain relief were recorded on presentation and during follow up visits.
Results: The results were compared weekly for 4 weeks and monthly for 2 consecutive months. Fissure healing and pain relief were recorded.
Conclusions: Both 2% diltiazem group and LIS group are equally effective and did not show any difference in pain relief or fissure healing with p value not significant (>0.05).

Keywords: Chronic anal fissure, Topical 2% diltiazem, Lateral internal sphincterotomy

INTRODUCTION

Anal fissures are one of the most common causes of severe anal pain. It refers to a longitudinal tear in the distal anal canal.[1] An acute anal fissure has the appearance of a clean longitudinal tear in the anoderm, with little surrounding inflammation. A chronic fissure is usually deeper and generally has exposed internal sphincter fibers in its base. Surgical techniques, such as manual anal dilatation or lateral internal sphincterotomy, effectively heal most fissures within a few weeks but may result in permanently impaired anal continence.[2] Various pharmacological agents have been shown to lower resting anal pressure and heal fissures without threatening anal continence.[3] The present study comprises the comparative study of 2% diltiazem gel application and internal sphincterotomy in the treatment of chronic fissure-in-ano, fissure healing and pain relief were compared.

METHODS

A total of 50 patients with chronic fissure in ano were identified and involved in this prospective comparative study, between December 2020 to May 2022, at Rajarajeswari Medical College and Hospital, Bengaluru. Study was undertaken after the approval from the hospital ethics committee. Informed written consent was taken from all the patients after explaining to them, the procedure and purpose of this study.

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.

Patients were divided into two groups of 25 each as group A and group B. Patients in group A were advised to apply 2% diltiazem gel twice daily for 6 consecutive weeks. Patients in group B underwent left lateral internal sphincterotomy under spinal anaesthesia. Cases from both groups were asked to take mild laxatives like cremaffin (milk of magnesia, and liquid paraffin) 15 ml at bedtime, high fiber diet and to use warm sitz baths.

Cases were reviewed in outpatient department (OPD) weekly for 4 consecutive weeks and monthly for subsequent 2 months. At each visit questions were asked regarding pain relief, leakage of flatus/faeces or any other symptoms. Healing was assessed clinically on inspection and defined as complete disappearance of fissure. Pain was assessed using a pain score chart. The data was collected and analyzed; p values were calculated using Chi square test.

RESULTS

In our study, most of the cases belonged to young age group between 20-30 years (64%), with incidence more common in females (72%) as compared to males (28%). Majority of the fissures were posterior (80%) in location with sentinel pile present in 50% of cases (Table 1). Cases were followed up weekly for 4 consecutive weeks and monthly for subsequent 2 months. 76% of patients in group A of diltiazem gel application and 84% of patients in group B with LIS had completely healed fissures at the end of 3 months (Table 2).

80% of patients in group A of Diltiazem gel application and 88% of patients in group B with LIS were free from pain at the end of 3 months (Table 3). The mean duration of healing was comparatively longer in group A than group B. No complications were reported in either group. Comparison between group A and group B did not show any difference in pain relief or fissure healing with p value not significant (>0.05).

Table 1: Demographic data.

Gender	No. of patients	Percentage
Female	36	72
Male	14	28

Table 2: Healing at 3 months.

Healing	No. of patients	Percentage
Group A (diltiazem 2%)	19	76
Group B (surgery (LIS))	21	84

Table 3: Pain relief at 3 months.

Pain relief	No. of patients	Percentage
Group A (diltiazem 2%)	20	80
Group B (surgery (LIS))	22	88

DISCUSSION

Anal fissure is a very common anorectal problem worldwide. It causes considerable morbidity and adversely affects the quality of life. Therapy focuses on breaking the cycle of pain, spasm, and ischemia thought to be responsible for the development of fissure in ano. The simplest and most effective way of reducing internal anal sphincter tone is surgery. Lateral internal sphincterotomy is the gold standard in the treatment of chronic anal fissures.[1,2] It involves partial division of the internal anal sphincter away from the fissure. Postoperative management in LIS surgery is simple and rate of healing is faster. However, complication such as permanent anal incontinence is associated with the surgery.[3] Calcium channel blockers have been shown to lower resting anal pressure and promote fissure healing.[4,5]

Diltiazem, a non-dihydropyridine calcium channel blocker, induces vascular smooth muscle relaxation and dilatation. A study by Medhi et al described diltiazem to be efficacious in the treatment of chronic fissure-in-ano. Study showed that oral intake and topical applications of diltiazem reduced the anal pressure significantly with better healing rates.[6] Another review by Bhardwaj and Parker showed that diltiazem was a valid alternative to GTN with improved healing rates and lower rates of recurrence.[7] A study on the different methods by Gupta showed that medical manipulation of the internal sphincter should be the first line of treatment and that only if this fails or if the fissure recurs then subcutaneous lateral internal sphincterotomy should be done.[8] Chemical sphincterotomy with diltiazem is reversible and therefore unlikely to have adverse effects on continence. Patients who are hypertensive, diabetic and medically unfit for surgery can be recommended treatment with diltiazem. Though fissure healing rate is comparatively slower with diltiazem, the trauma caused by surgery can be avoided.[9-12]

Recurrence of fissure is a known entity, it also expects life style modifications and dietary changes, in our study we have followed up patients for 3-months period, which is limitation of our study to consider cure from disease. Pain relief is an another limitation of our study as is subjective and varies in individuals.

CONCLUSION

Chemical sphincterotomy with topical 2% diltiazem gel application should be advocated as the first option of treatment for chronic anal fissure. It is also useful in individuals who are not fit for surgery. LIS should be offered to patients with relapse and therapeutic failure of prior pharmacological treatment.

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