A COMPARATIVE STUDY OF LATERAL SPHINCTEROTOMY AND LOCAL APPLICATION OF 2% DILTIAZEM GEL IN TREATMENT OF CHRONIC ANAL FISSURE

Rajashekar Jade[1], Raghunath B. V.[2], Naveen N[3]

[1]Associate Professor, Department of General Surgery, Rajarajeshwari Medical College & Hospital, Bangalore.
[2]Associate Professor, Department of General Surgery, Rajarajeshwari Medical College & Hospital, Bangalore.
[3]Senior Resident, Department of General Surgery, Rajarajeshwari Medical College & Hospital, Bangalore.

ABSTRACT

BACKGROUND AND OBJECTIVES

Anal fissures are commonly encountered in routine colorectal practice. Chronic fissures have traditionally been treated surgically. Developments in the pharmacological understanding of the internal anal sphincter have resulted in more conservative approaches towards treatment. In this study, we compare topical 2% Diltiazem gel and lateral internal sphincterotomy with respect to symptomatic relief, healing and side effects in the treatment of chronic fissure in ano.

METHODS

60 patients with chronic fissure in ano were randomly divided into Diltiazem gel and internal sphincterotomy groups. Patients were followed up at weekly intervals for minimum of eight weeks. Data was recorded accordingly.

RESULTS

Fissure completely healed in 28(93.33%) out of 30 patients treated with 2% Diltiazem gel between 4-8 weeks. Healing was 100% with internal sphincterotomy. The mean duration required for healing of fissure was 4.86 weeks in Diltiazem gel group and 3.66 weeks in internal sphincterotomy group. 61.5% patients were free from pain after treatment with Diltiazem gel whereas in internal sphicterotomy group 66.66% patients had pain relief at the end of 4 weeks.

INTERPRETATION AND CONCLUSION

Comparison between Diltiazem gel application and internal sphincterotomy did not show any significant difference in fissure healing and pain relief. No side effects were seen in Diltiazem gel therapy. Topical Diltiazem should be the initial treatment in chronic fissure in ano. It is better to reserve internal sphincterotomy for patients with relapse or therapeutic failure to prior pharmacological treatment.

KEYWORDS

Anal fissure, Diltiazem gel, Internal sphincterotomy.

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INTRODUCTION: Anal fissures or anal ulcers are one of the commonest causes of severe anal pain. It refers to a longitudinal tear or ulcerated area in the distal anal canal. They are usually located in the posterior or anterior midline and usually extend from the level of dentate line out to the anal verge. 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 fibres in its base. It is frequently associated with a hypertrophic anal papilla in its proximal aspect and with a sentinel pile at its distal aspect.[1]

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Corresponding Author:
Dr. Rajashekar Jade,
Associate Professor, Department of General Surgery,
Rajarajeshwari Medical College & Hospital, Bangalore.
E-mail: naveen_uno1@yahoo.co.in
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There has been a lot of progress in the understanding of the anatomy of the anal canal and the mechanism of continence of rectum and anal canal. This has enabled the surgeon to deal with the fissure, keeping the spastic anorectal ring intact, without interfering with continence and eradicating the disease.

Surgical techniques like manual anal dilatation or lateral internal sphincterotomy, effectively heal most fissures within a few weeks, but may result in permanently impaired anal continence.[2] This has led to the research for alternative non-surgical treatment, and various pharmacological agents have been shown to lower resting anal pressure and heal fissures without threatening anal continence. The present study comprises the comparative study of 2% Diltiazem gel application and internal sphincterotomy in the treatment of chronic fissure in ano.

AIM OF THE STUDY: To compare the effectiveness of topical 2% Diltiazem gel with lateral sphincterotomy in the treatment of chronic fissure in ano in terms of wound healing, pain relief, complications, duration of hospital stay.

MATERIALS AND METHODS: The study was conducted in the department of General Surgery at Rajarajeswari Medical College and Hospital, Bengaluru, over a span of 18 months from March 2014 to August 2015.

It was a randomised controlled trial wherein the subjects were randomly allocated into two groups; either medical (Diltiazem therepy) or Surgical (lateral sphincterotomy), based on random numbers allocated by a computer. Informed written consent was taken from all patients prior to enrolling into the study.

A total of 60 patients were involved in the study, with 30 patients allocated to each group of Diltiazem therapy and Lateral sphincterotomy. Patients in the study aged between 20 to 60 years and included both sexes. Both surgical out-patients and admitted patients with chronic fissure in ano were included in the study. Mentally handicapped patients, children with fissures, patients with recurrent fissures, fissures associated with hemorrhoids and fistula, fissures associated with malignancies, fissures secondary to specific diseases like Tuberculosis, Crohn's disease etc.; pregnant women and patients refusing to be a part of the study were excluded.

Ethical committee clearance was taken from the Institute prior to the study.

Method of application of 2% Diltiazem gel: Patients who were allocated in the Diltiazem group were advised to apply 1.5 to 2 cm length of gel twice daily at least 1.5 cm into the anus. Patients were instructed to wash hands before and after use of gel. All patients preferred to undergo domiciliary treatment and hence were reviewed once a week on outpatient basis.

Internal Sphincterotomy: All patients allocated in the surgical group underwent lateral Internal sphincterotomy after necessary pre-operative investigations. Surgery was carried out under spinal anaesthesia. All patients were given one dose of Inj. Ornidazole and Ofloxacin (single dose), pre-operatively. Analgesics were given as per standard protocol. All patients were advised laxative, Cremaffin (milk of magnesia 11.25 ml, liquid paraffin 3.75 ml per 15 ml of emulsion) three teaspoons, at bedtime. Sitz bath was started from second post-operative day. Post operatively patients were watched for bleeding and hematoma formation was done. Patients were discharged between 3rd and 7th post operative days. They were followed up on 7th post operative day. Digital examination was done to assess the relaxation of sphincter. Patients were further followed up at weekly intervals for a minimum of eight weeks.

The fissure was said to be healed when mucosa re-epithelise over the surface.

RESULTS: The following were the results inferred from the study. Majority of the subjects were in the age group of 30-50 years.

Age in years	No. of Patients	Percentage
20-30	16	27%
31-40	24	40%
41-50%	18	30%
51-60%	2	3%

Table 1: Age distribution

Bulk of the patients were males (70%).

Sex Incidence	No. of Patients	Percentage
Females	18	30%
Males	42	70%

Table 2: Sex distribution

Posterior fissure in ano was more common (70%).

Site	No. of Patients	Percentage
Anterior	18	30%
Posterior	42	70%

Table 3: Fissure location

Sentinel pile was present in 20 (33.33%) patients and sphincter spasm was present in all cases (100%). Out of 30 patients undergoing treatment with Diltiazem gel, 4 patients were lost during follow-up. Out of the remaining 26 patients, 23(88.4%) fissures healed completely between 4-8 weeks. All the fissures treated with internal sphincterotomy healed completely at the end of 4 weeks. The mean duration required for healing of fissure was 4.86 weeks in Diltiazem gel group and 3.66 weeks in internal sphincterotomy group.

16(61.5%) of the patients treated with diltiazem were pain free at the end of 4 weeks. 8(30.7%) patients were free of pain by 3 months. Remaining 2 patients(7.6%) who did not have symptomatic relief were subjected to lateral sphincterotomy.

20 (66.66%) out of 30 patients undergoing internal sphincterotomy were free from pain at the end of 4 weeks post operatively, while the remaining 10 (33.3%) patients had slight pain on follow-up which gradually resolved over a period of 3 months.

No complications were reported in any of the patients in both the groups.

DISCUSSION: Anal fissure is a very common problem across the world. It causes considerable morbidity and adversely affects the quality of life. Therefore appropriate treatment is mandatory. 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.[1,2,3] 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.[4,5] In the present study, a comparative evaluation of topical 2% Diltiazem gel

and internal sphincterotomy has been done to examine the effectiveness, complications, side-effects and hospital stay in the treatment of chronic anal fissure.

Lord's anal dilatation was the earliest method of treatment of fissure-in-ano, first described in 1838. Since then, numerous treatment options have been used including sclerotherapy[6] (using sodium tetradecyl sulphate), lateral internal sphincterotomy,[1] chemical sphincterotomy using calcium channel blockers like Glyceryl trinitrate,[7,8] Isosorbide dinitrate, use of Botulinum Toxin.[9]

Diltiazem, another calcium channel blocker was also gradually introduced. A study by Medhi, et al[10] 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. Another review by Bharadwaj, et al[11] showed that diltiazem was a valid alternative to glyceryl trinitrate with improved healing rates and lower rates of recurrence.

A study on the different methods by Gupta PJ,[12] 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.

Diltiazem, a nondihydropyridine 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. Diltiazem is given 60 mg BD in oral form or applied as 2% cream BD for 4 to 6 weeks.[10]

The commonest age group affected in this study was 31-40 years (40%) age group, which concurs with the data by Goligher, et al.[13] in whom, the commonest age group affected was 31-40 years. Though the incidence of chronic fissure is equal in both sexes,[13] in our study we found a higher incidence in males compared to females (2.33:1).

Approximately, 90% of anal fissures in both men and women are located posteriorly in the midline. Anterior fissures occur in 10% of patients, more commonly women.[14] In this study, we found the incidence of anterior fissure to be around 30% and posterior fissure 70%.

In our study, 16 (61.5%) of the patients treated with Diltiazem were pain free at the end of 4 weeks. 8 (30.7%) patients were free of pain by 3 months. Remaining 2 patients (7.6%) who did not have symptomatic relief were subjected to lateral sphincterotomy.

Akira Tsunoda, et al[15] reported an initial healing rate of 70% in patients treated with topical Diltiazem. J. S. Knight, et al[16] reported a healing rate of 75% after 8-12 weeks treatment with Diltiazem gel. In our study, we found a healing rate of 88.4%. The mean duration of healing was 4.86 weeks.

Minor side-effects like perianal dermatitis, headache were reported in other series.[15] In a study conducted by G. F. Nash, et al,[17] 112 patients were treated with 2% Diltiazem gel for 6 weeks and were followed up over 2 years. The success rate and satisfaction of topical Diltiazem were each over two-thirds. Nearly 80% of patients reported no adverse effects, and it seems that those complaints attributed to Diltiazem rarely led to reduced compliance. However in our study, none of our patients reported any of these complications.

In our study 20 (66.66%) patients out of 30 undergoing internal sphincterotomy were free from pain, while the remaining 10 patients had slight pain on follow up which gradually resolved over a period of 3 months. Scouten WR, et al,[18] reported pain relief in 98% of cases after undergoing internal sphincterotomy.

Adriano Tocchhi, et al,[19] reported a healing rate of 100% with internal sphincterotomy at the end of 6 weeks with a patient satisfaction rate of 96%. Our results were very similar with a healing rate of 100%.

In our study, no complications were reported in patients undergoing internal sphincterotomy after follow up of patients for 1 month. Comparison between Diltiazem gel therapy and internal sphincterotomy did not show much difference in pain relief ($p = 0.2148$) or fissure healing ($p = 0.2458$). Noncompliance with Diltiazem gel therapy was not observed.

The follow up available after successful treatment with Diltiazem gel is short and therefore no long term conclusions can be drawn. Long term follow up is needed to assess the risk of recurrent fissure after initial healing with Diltiazem gel therapy.

CONCLUSION: Internal sphincterotomy is the current standard treatment for chronic fissure. However, it is not without complications. Topical Diltiazem is a relatively new weapon in the armamentarium of the colorectal surgeon in the treatment of chronic fissure. Complications or side effects related to Diltiazem gel are minimal. In contrast with surgery, 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 with Diltiazem. Though fissure healing rate is comparatively slow with Diltiazem, patients can be avoided from the trauma caused by surgery. Hospital stay is not required. Treatment works out to be very cost effective. Topical 2% Diltiazem should be advocated as the first option of treatment for chronic anal fissure. Internal sphincterotomy should be offered to patients with relapse and therapeutic failure of prior pharmacological treatment.

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