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Research Article

A Comparative Study of Lateral Sphincterotomy and Local Application of 2% Dilitiazem Gel in Treatment of Chronic Anal Fissure

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ABSTRACT

Background: *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: *80 patients with chronic fissure in ano were randomly divided into Dilitiazem 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 37 (92.5%) out of 40 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. 61.1% patients were free from pain after treatment with Diltiazem gel whereas in internal sphicterotomy group 67.5% patients had pain relief at the end of 4 weeks.*

Conclusions: *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.*

INTRODUCTION

Anal fissures 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 tag at its distal aspect.[1]

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 anorectic 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.

METHODS

The study was conducted in the Department of General Surgery at A.N. Magadh Medical College & Hospital, Gaya, over a span of 18 months.

It was a randomized controlled trial wherein the subjects were randomly allocated into two groups; either medical (Diltiazem therapy) or Surgical (lateral sphincterotomy), based on random numbers.

A total of 80 patients were involved in the study, with 40 patients allocated to each group of Diltiazem therapy and the 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.

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 1.5cm 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. Analgesics and antibiotics were given as per standard protocol. All patients were advised laxative three teaspoons, at bedtime. Seitz bath was started from second post-operative day. Post operatively patients were watched for bleeding and hematoma formation. 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.

Table1: Age Distribution

Age in years	No. of Patients	Percentage
20-30	22	27%
31-40	32	40%
41-50%	24	30%
51-60%	2	3%

Bulk of the patients were males (70%)

Table 2: Sex distribution

Sex Incidents	No. of Patients	Percentage
Females	24	30%
Males	56	70%

Posterior fissure in ano was more common (70%)

Table 3: Fissure location

Site	No. Of Patients	Percentage
Anterior	24	30%
Posterior	56	70%

Sentinel tag was present in 26 (32.5%) patients and sphincter spasm was present in all cases (100%). Out of 40 patients undergoing treatment with Diltiazem gel, 4 patients were lost during follow-up. Out of the remaining 36 patients, 32 (88.8%) 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.

22(61.1%) of the patients treated with diltiazem were pain free at the end of 4 weeks. 11 (30.5%) patients were free of pain by 3 months. Remaining 3 patients (8.3%) who did not have symptomatic relief were subjected to lateral sphincterotomy.

27 (67.5%) out of 40 patients undergoing internal sphincterotomy were free from pain at the end of 4 weeks post operatively, while the remaining 13 (32.5%) 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 trinitr-ate,[7,8] Isosorbid dinitrate, use of Botulinim Toxin.[9] Dilitiazem, 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 the diltiazem was a valid alternative to glyceryl trinitrate with improved healing rated and lower rater 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 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 60mg twice daily in oral form or applied as 2 % cream twice daily 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, 22 (61.1%) of the patients treated with Diltiazem were pain free at the end of 4 weeks. 11 (30.5%) patients were free of pain by 3 months. Remaining 3 patients (8.3%) 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 88.8%. The mean duration of healing was 4.86 weeks. In our study 27 (67.5%) patients out of 40 undergoing internal sphincterotomy were free from pain, while the remaining 13 (32.5%) patients had slight pain on follow up which gradually resolved over a period of 3 months. Scouten WR et al[17] reported pain relief in 98 % of cases after undergoing internal sphincterotomy.

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 ($p>0.05$) or fissure healing ($p>0.05$). 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 for 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.

DECLARATIONS

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