



A Comparative study of Lateral sphincterotomy and 2% Diltiazem Gel And Local Application in The Treatment of Chronic Fissure in Ano

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ABSTRACT

Anal fissures are commonly encountered in routine colorectal practice. Fissure has 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 symptomatic relief, healing and side effects of topical 2% Diltiazem gel and lateral internal sphincterotomy in the treatment of chronic fissure in ano.

Diltiazem gel and lateral internal sphincterotomy in the treatment of chronic fissure in ano.

Methods: 60 patients with chronic fissure in ano were divided into Diltiazem gel and internal sphincterotomy groups. Patients were followed up at weekly intervals for four weeks minimum for symptomatic relief and healing.

Results: Fissure was completely healed in 23 (88.46%) out of 26 patients treated with 2% Diltiazem gel between 4-8 weeks. Healing was 100% with internal sphincterotomy. Time and duration required for healing of fissure was 5.04 weeks in Diltiazem gel group and 3.6 weeks in internal sphincterotomy group. 78.26% patients were free from pain after treatment with Diltiazem gel whereas 85.18% patients were free from pain after treatment with internal sphincterotomy. No patient had any side effects after Diltiazem therapy.

Conclusion: Comparison between Diltiazem gel and internal sphincterotomy did not show any difference in fissure healing and pain relief. No side effects were reported from Diltiazem gel therapy. Topical Diltiazem should be the initial treatment in chronic fissure in ano. Internal sphincterotomy should be reserved for patients with relapse and therapeutic failure to prior pharmacological treatment.

KEYWORDS : Anal Fissure; Diltiazem Gel; Internal Sphincterotomy

INTRODUCTION

Anal fissures or anal ulcers are considered one of the commonest causes of severe anal pain. An anal fissure is a longitudinal tear or ulcerated area in the distal anal canal. Usually in the posterior or anterior midline and usually extending from the level of dentate line out to the anal verge. An acute anal fissure has the appearance of longitudinal tear in the ano-derm, with little surrounding inflammation. A chronic fissure is usually deeper and generally has exposed internal sphincter fibers in its base. It is frequently associated with a hypertrophic anal papilla at its upper aspect and with an irritated skin or sentinel pile at its distal aspect. Painful fissures are generally associated with spasm of the internal sphincter. The internal sphincter is an involuntary muscle, a continuation of the circular muscle layer of the colon and rectum. Its natural resting tone, along with that of external sphincter complex, maintains continence. Like the involuntary muscle of colon and rectum, the internal sphincter possesses the ability to go into spasm involuntarily. It is this involuntary spasm, in response to trauma of the exposed subcutaneous tissue of the fissure, that creates the severe pain associated with anal fissure disease. 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. 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.

Materials and methods

Clinical study of the treatment of chronic fissure in ano over a period of 2 years, i.e., between September 2012 to September 2014. To highlight the efficacy of 2% Diltiazem Gel in the treatment of chronic fissure in ano. Comparison of Lateral Sphincterotomy and 2% Diltiazem Gel local ap-

plication in a minimum of 60 patients in context with effectiveness, complications, side effects and hospital stay etc.

Inclusion Criteria

Patients between 20 to 60 years of age of both sexes, surgical outpatients and/or admitted patients of chronic fissure in ano.

Exclusion Criteria

Recurrent fissures, Fissures with hemorrhoids and fistula, Fissure associated with malignancies, Fissure secondary to specific diseases like Tuberculosis, Crohn's disease etc.

Method of application of 2% Diltiazem gel

Informed consent from the patient was taken prior to the study. Patients were advised to apply 1.5 to 2 cms length of gel twice daily at least 1.5 cm into the anus.

Internal Sphincterotomy

Internal sphincterotomy was carried out under spinal anaesthesia. Post-operatively on the day of operation patients were kept nil orally till evening. The foot end of the table elevated. I.V. fluids were administered. A dose of sedation was given at night. All patients were given antibiotics for one week. On the same day liquid diet was administered and from first post-operative day onwards solid diet. All patients were given mild laxatives like cremaffin (milk of magnesia 11.25 ml, liquid paraffin 3.75 ml, per 15 ml of emulsion) three tea spoons, at bedtime next day onwards following the operation and sitz bath was started from second post-operative day. Post-operative assessment 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 or for infection. Patients were further followed up at weekly intervals for four weeks minimum.

RESULTS

- Sixty patients with various symptoms of chronic fissure in ano attending surgery OPD and/or admitted to MGM hospital / Kakatiya Medical College were taken for study. Thirty patients in each group were studied on randomized basis.
- The commonest age group affected was 20-30 years age group

- (29 cases) and least affected were 51-60 years age group (3 cases).
- The incidence in males was slightly greater than females. Male female ratio was 1.4:1.
 - Posterior midline fissure (56 cases) was more common than anterior midline fissure (4 cases).
 - Sentinel pile was present in 28 cases and sphincter spasm was present in all cases.
 - The mean duration required for healing of fissure was 5.04 weeks in Diltiazem gel group and 3.6 weeks in Internal Sphincterotomy group.
 - Three patients in Diltiazem gel group underwent internal sphincterotomy because fissures did not heal even after eight weeks of therapy.
 - Patients in Diltiazem gel group did not complain of any side effects.
 - Patients undergoing internal sphincterotomy had no complications.
 - In Diltiazem gel group, 18 out of 23 patients were free from pain and 5 had slight pain on follow up after 3 months.
 - In internal sphincterotomy group, 23 out of 27 patients were free from pain and 4 had slight pain on follow up after 1 month.
 - Four patients in Diltiazem gel group were lost to follow up and three patients in internal sphincterotomy group were lost to follow up.
 - Comparison between Diltiazem gel and internal sphincterotomy did not show any difference in fissure healing at $P = 0.0679$.

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. 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 and chemical sphincterotomy is now the first line of treatment in many centers. In the present study, a comparative evaluation of topical 2% Diltiazem gel and internal sphincterotomy groups on randomized basis. Patients with symptoms of fissure in ano for more than 6 weeks were labeled as having chronic fissure in ano and clinical examination was done to confirm chronic fissure in ano. All the data were analyzed as per the proforma sheet. In this study the commonest age group affected was 20-30 years age group (48.3%) and least affected were 51-60 years age group (5%). According to J.C. Goligher (1984) the disease is usually encountered in young or middle aged adults. In Udwardia T.E. series maximum incidence was seen in 31-40 years age group. The incidence of fissure in males was slightly greater than females.

Male female ratio being 1.4: 1. It is confirmed with study from Bennett and Goligher (1962) which says anal fissure is equally common in the two sexes.

In this study posterior midline fissure (93.3%) was more common than anterior midline fissure. It has been observed that posterior fissure is more common in both sexes, although anterior fissure is common in females comparatively. Both anterior and posterior fissures are common in female sex. This was confirmed by study from Boulous P.B. and Araujo J.G.C. (1984) which says posterior fissure (85.7%) is more common than anterior fissure (14.2%). Patients receiving Diltiazem gel therapy underwent domiciliary treatment and were reviewed once a week on outpatient basis. Out of 30 patients undergoing treatment with Diltiazem gel 23 healed completely. Four patients were lost to follow up. The mean duration of healing was 5.04 weeks. Duration for healing was comparatively longer than internal sphincterotomy group. In our study 18 (78.26%) out of 23 patients were free from pain and 5 had slight pain on follow up after 3 months. Four patients were lost to follow up. In our study 23 (88.46%) out of 26 patients treated with Diltiazem gel healed completely. Study conducted by J. S. Knight et al. (2001) reported a healing rate of 75% after 8-12 weeks treatment with Diltiazem gel. U. K. Shrivastava (2007) reported

a healing rate of 80% with Diltiazem gel in 12 weeks. In our study no side effects were reported after 8 weeks of therapy with Diltiazem gel. In a study conducted by J. Knight et al. 71 consecutive patients were treated with 2% Diltiazem gel for a median period of 9 weeks. Four patients experienced perianal dermatitis and one patient experienced headache. Study conducted by U. K. Shrivastava reports no side effects in patients treated with Diltiazem gel. In a study conducted by G. F. Nash et al. 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. Three patients in Diltiazem gel group whose fissures did not heal after 8 weeks of therapy underwent internal sphincterotomy and fissure healed in 4 weeks. Patients in internal sphincterotomy group underwent surgery under spinal anaesthesia. Post operative hospital stay was between 2-4 days. In internal sphincterotomy group, fissure healed in 27 out of 27 patients. Mean duration required for healing was 3.6 weeks. Three patients were lost to follow up. In our study 23 (85.18%) patients out of 27 undergoing internal sphincterotomy were free from pain and 4 patients had slight pain on follow up after 3 months. Three patients were lost to follow up. Scouten W.R. et al. reported pain relief in 98% of cases after undergoing internal sphincterotomy. Our study shows a healing rate of 100% after internal sphincterotomy. Adriano Tocchhi et al. (2004) reported a healing rate of 100% with internal sphincterotomy at the end of 6 weeks post-sphincterotomy review. In our study no complications were reported in patients undergoing internal sphincterotomy after follow up of patients for 1 month. Adriano Tocchhi et al. report no long-term complication after internal sphincterotomy. Patient satisfaction was 96%. Comparison between Diltiazem gel therapy and internal sphincterotomy did not show any difference in pain relief ($P = 0.5261$) or fissure healing ($P = 0.0679$). Non-compliance was uncommon with Diltiazem gel therapy. Only four patients discontinued treatment. 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. In conclusion, though fissure healing is comparatively slow with Diltiazem gel therapy, patients can be avoided from the trauma of surgery and they can take treatment at home. Therefore topical Diltiazem gel therapy should be advocated as the first line of treatment and surgery should be reserved for patients with relapse and therapeutic failure of prior pharmacological treatment.

CONCLUSION

The conclusion from this study is though internal sphincterotomy is the current standard treatment; many chronic fissures heal with topical 2% Diltiazem therapy. Complications or side effects of 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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