

Comparison Between Lateral Internal Anal Sphincterotomy and Diltiazem in the Treatment of Chronic Anal Fissure

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ABSTRACT

- Objective* To compare lateral internal anal sphincterotomy with 2% diltiazem in the treatment of chronic anal fissure in terms of fissure healing and complications.
- Study design* Randomised controlled trial.
- Place & Duration of study* Surgical unit Combined Military Hospital Lahore, from August 2008 to February 2009.
- Methodology* Sixty patients were randomly assigned into two treatment groups. Group A was assigned to apply 2% diltiazem paste while, in group B lateral internal sphincterotomy (LIS) was done. Response to the treatment was assessed in terms of fissure healing, pain relief and occurrence of complications. Follow up of the patients was carried out at the end of 2nd, 4th, and 6th week of treatment.
- Results* In group A six patients had healing of fissure after 4 weeks and a further 4 at 6th week. In group B 14 patients had healing at 2 weeks, 10 at 4 weeks, and 5 at 6 weeks. One patient in group B and 20 in group A had no healing. In this study overall healing rate after 6 weeks with diltiazem was 33.33% and 96.66% with LIS.
- Conclusion* Lateral internal sphincterotomy is better than 2% diltiazem cream.
- Key words* Chronic anal fissures, Diltiazem, Lateral internal sphincterotomy.

INTRODUCTION:

Anal fissure is a common condition affecting all age groups, but it is seen particularly in young and otherwise healthy adults, with equal incidence across the genders. Anal fissure is a longitudinal split in the anoderm of distal anal canal extending from anal verge proximally towards dentate line and is most commonly seen in posterior midline, though anterior and lateral lying fissures are also seen.¹ Anal fissure can be primary / idiopathic or secondary. It can be divided into two clinical subtypes depending upon the duration of disease, the acute and chronic fissures. Fissures failing to heal within six weeks

despite straightforward dietary measures are designated as chronic.² The classical symptoms are that of anal pain during or after defecation accompanied by passage of bright red blood per anum. The bleeding is separate from the stool and usually scanty. In chronic anal fissure the margins of fissure became indurated and there is a distinct lack of granulation tissue. Secondary changes such as a sentinel skin tag, hypertrophied anal papilla or a degree of anal stenosis, are often present.¹

Increased resting anal pressures are documented in patients with chronic anal fissures and is considered as a major pathophysiological factor. Therapies that reduce anal sphincter pressures have been used to achieve fissure healing. Lateral internal anal sphincterotomy is the most common treatment for chronic anal fissure and can be effective in more than 90% of cases.³ The chief complication after this surgery is incontinence to faeces or flatus which

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has been reported in the range of 3.3 to 7%.³

A variety of pharmacological agents have been found to cause reduction in tone of internal anal sphincter and probably aid in healing through an increase in local blood flow.⁴ The mediator of the non-adrenergic non-cholinergic pathway stimulating relaxation of the internal sphincter has been shown to be nitric oxide. Application of topical nitric oxide donor agents has been shown to reduce anal pressure.⁴ Such observations generated an interest in the use of nitric oxide donors such as glyceryl trinitrate and isosorbide dinitrate as a form of chemical sphincterotomy but it is associated with headache and therefore decreased compliance of the patient resulting in poor results. This led to use of topical 2% diltiazem, a calcium channel blocker, that gave sufficient sphincter relaxation without headache and therefore increased compliance of the patients.⁴

This study compared a non surgical intervention with a surgical intervention on the basis of best outcome and minimum side effects for the better treatment of an agonizing disease.

METHODOLOGY:

Study was conducted in the surgical department, Combined Military Hospital, Lahore. Duration of the study was 6 months from August 2008 to February 2009. A total of 60 patients were included in the study after taking informed written consent, and randomly assigned into two groups of 30 patients each. All clinically diagnosed patients of chronic anal fissure between 15 and 70 year age, of either sex were included in the study. Patients with haemorrhoids, fistulae and perianal abscess, those with systemic diseases (diabetes mellitus, hypertension, tuberculosis, Crohn's disease, HIV/AIDS, syphilis or anal carcinoma) and those who had hypersensitivity to calcium channel blockers were excluded.

A detailed history was taken which included duration of pain along with other associated symptoms like constipation, bleeding per rectum, discharge and soiling, sentinel pile and previous treatment obtained. A thorough examination was performed and all data entered into proforma. Fissures failing to heal within six weeks despite straightforward dietary measures, fissures with indurated margins and lack of granulation tissue with secondary features like sentinel skin tag, hypertrophied anal papilla or a degree of anal stenosis, were termed as chronic anal fissures.

Patients in group A were assigned to application of 2% diltiazem paste about pea size to the anal

margins and rubbed gently in clockwise manner for 5-8 seconds and small quantity was also applied inside the anus. The drug was advised to be applied three times a day for six weeks. Patients in group B underwent lateral internal sphincterotomy. An open lateral internal anal sphincterotomy was performed under general or regional anaesthesia (spinal or caudal). Under anaesthesia the radial incision at the anoderm made over the intersphincteric groove and division of the internal sphincter under direct vision done. Internal anal sphincter was divided for a length of approximately 2cm. the integrity of the mucosa was preserved by breaking the innermost fibers of the muscle by lateral pressure with the finger. Haemostasis was ensured by maintaining pressure for 2-3 minutes. Patients undergoing sphincterotomy were not subjected to any other treatment modality or local ointment. No prophylactic antibiotic was given and patients were discharged after 24 hours.

All the patients in both treatment groups received stool softeners and fiber supplements. Patients were followed at 2-weekly intervals for six weeks and were examined for healing of fissure and side effects of the two procedures which included headache in group A and bleeding, infection and incontinence to faeces and flatus in group B. Only patients who had completely healed fissure with epithelium over it were considered as cured. Post treatment incontinence for faeces and flatus was evaluated by an anonymous questionnaire assessed by an independent observer at 2 weekly interval during follow up. Follow up of the patients was carried out at the end of 2nd, 4th, and 6th week of treatment.

Data were analyzed by using SPSS version 12 on computer. Relevant descriptive statistics; frequency, rate and percentage were computed for presentation of qualitative outcomes like fissure healing and complications. Quantitative variables like age, time etc. were presented as mean \pm standard deviation. Hypothesis was tested by applying Chi-square test at $p < 0.05$ level of significance.

RESULTS:

Out of 60 patients 41 (68.33%) were males and 19 (31.66%) females. Male to female ratio was 2.15:1; with age range from 15-70 year. Mean for age was 39.52 + 14.55 year. Presenting complaints in these patients were painful defecation and constipation in all 60 patients, bleeding per rectum in 55, discharge per rectum in 26, sentinel pile in 32 and pruritus in 11 patients. In this study 56 (93%) patients had posterior midline fissure and 4 (6%) had anterior midline fissure.

Table I: Time to Healing of Fissures

	2 weeks		4 weeks		6 weeks		Total
	Healed	No Healing	Healed	No Healing	Healed	No Healing	
Group - A	0 (0%)	30 (100%)	6 (20%)	24 (80%)	10 (33.33%)	20 (66.66%)	30
Group - B	14 (46.66%)	16 (53.33%)	24 (80%)	6 (20%)	29 (96.66%)	1 (3.33%)	30

In group A, six patients had healing of fissure after 4 weeks and a further 4 at 6th week. In group B 14 patients had healing at 2 weeks, 10 at 4 weeks, and 5 at 6 weeks. One patient in group B and 20 in group A had no healing. Time wise percentage of healing is shown in table I. Chi square test was applied to test the significance of healing in both groups. P value was calculated and was found to be > 0.05.

Regarding complications headache occurred in 3 (10%) patients using diltiazem cream, whereas none of the surgery group had this problem. The pain was transient and did not require any treatment. Incontinence was seen in one (3.33%) patient in the surgery group. Other complications like post operative bleeding and infection were not seen in the surgery group.

DISCUSSION

Over the years various hypothesis have been presented regarding development of anal fissures. From anal trauma to internal sphincter hypertonia and resultant local ischemia resulting in non healing have been postulated as the contributing factors.^{5,6} Many treatment options are available for the anal fissures including pharmacological and surgical interventions. Whatever is the mode of treatment the principal aim is to decrease the tone of internal anal sphincter that results in increase local blood flow subsequently leading to healing. Pharmacological agents employed include nitrates (isosorbide dinitrate or glyceryl trinitrate), calcium channel blockers (nifedipine, diltiazem), Botulinum toxin, alpha adrenoreceptor antagonists, alpha adrenoreceptor agonists and muscarinic agonists. Newer agents like gonyautoxin, which is a paralytic neurotoxin is also been tested.³ Surgical methods most commonly employed are finger dilatation and lateral internal sphincterotomy with later been regarded as the gold standard.³ Other surgical methods developed include fissurectomy and fissurotomy procedures,^{7,8} local flap procedures such as V-Y advancement flaps and rotation flaps,^{9,10} and sphincterolysis.¹¹

Calcium channel blockers act by blocking the slow L-type channels causing smooth muscle relaxation thereby decreasing resting anal pressure. A prospective study conducted in 2002 in Queens Medical Centre UK established the fact that 2% diltiazem is an effective and safe treatment for chronic anal fissure in patients who failed to respond to topical 0.2% GTN.¹² Explaining that need for sphincterotomy can be avoided in up to 70% of cases. Shrivastava carried out same study in India and revealed the fact that diltiazem cream also appears to cause lesser headaches than GTN ointment without a significant difference in healing rates between the two agents.¹³ As attenuation of anal resting pressure is temporary, the benefit of diltiazem cream is not permanent in some patients. Healing rates of chronic anal fissures in various studies ranged from 47% to 89%,¹³⁻¹⁷ while that seen in our study is 33.3%. This result may be contributed to a short follow up time in our study (6 weeks). Whereas Knight et al in their study observed that only one patient out of 71 had headache.¹⁷ We however observed headache in 3 (10%) patients.

Lateral sphincterotomy is the treatment of choice in anal fissure for many surgeons. It may be performed using an open or a subcutaneous technique and under local or general anaesthesia. Major complications requiring reoperation (bleeding, fistula, abscess or unhealed wound), and minor complications such as pruritis, persistent wound pain, bleeding, abscess, discharge, urgency, impaction, or defect of continence were seen in literature.¹⁸ In our study we found only one patient (3.33%) with incontinence.

CONCLUSION:

Lateral internal anal sphincterotomy, is the treatment of choice while treating chronic anal fissures because of its simplicity, better healing rates, better patient satisfaction, minimal morbidity and low complication rates.

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