

Comparative study of outcome of topical anal application of Diltiazem 2 % and lateral internal sphincterotomy in treatment of chronic anal fissure.

Dr Pranav Wadhokar¹, Dr Hardik Patel², Dr Rajendra Shinde³.

¹Postgraduate Surgery Resident, Dept of Gen Surgery, MGM Medical College and Hospital, Aurangabad, Maharashtra, India.

²Senior Registrar, Dept of Gen Surgery, MGM Medical College and Hospital, Aurangabad, Maharashtra, India.

³Associate Professor, Dept of Gen Surgery, MGM Medical College and Hospital, Aurangabad, Maharashtra, India.

** Dr Pranav Wadhokar, Dept of Gen Surgery, MGM Medical College and Hospital, N-6 CIDCO, Aurangabad, Maharashtra, India. 431003.

Abstract:

Introduction: Anal fissures are very common clinical entity encountered in surgical practice. Traditionally Lateral Internal Sphincterotomy is considered as the gold standard for treatment of chronic fissures. But recent developments in understanding the pathophysiology of anal fissures has helped to develop better conservative treatment options. In this study we compare the healing, symptomatic relief, and side effects of topical 2% Diltiazem gel and lateral internal sphincterotomy in treatment of chronic anal fissures.

Material and methods: In this prospective, randomised comparative study, 60 patients with chronic anal fissure were randomly divided into Group 1 (Diltiazem gel) and Group 2 (lateral internal sphincterotomy) with total 30 patients in each group. Patients were followed up at 1st, 2nd, 3rd weeks and 1st, 2nd, 3rd months and symptomatic relief, healing, and side effects were noted for each group.

Results: At the end of 3 months pain relief was seen in 90% patients in group 1 and 96.7% in group 2. Both the groups had 100% control of bleeding at 3 months. Healing was seen in 70% patients in group 1 and 96.7% in group 2 at the end of 3 months. In group 1 no significant side effects were seen, in Group 2 flatus incontinence was seen in 6.66% patients.

Conclusion: Study concludes that lateral internal sphincterotomy remains the gold standard treatment for chronic anal fissure. Diltiazem therapy is a good alternative for patients who refused surgery or prefer medical line of treatment and can be used as a first choice in management of chronic fissures.

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I. Introduction

An Anal fissure or fissure-in-ano is a common painful anal condition. It is defined as a linear or oval shaped tear in the anal canal starting just below the dentate line and extending to the anal verge [1]. Anal fissures can be acute or chronic. Acute fissures are shallow tears in the anoderm with duration of symptoms less than 6 weeks. It involves only the superficial mucosal layer and at its base the internal sphincter fibres are not visible. Patients present with severe acute pain and bright streak of blood during defecation along with constipation or straining during defecation.

Chronic anal fissures represent an acute fissure which fails to heal. Clinically it presents with above symptoms for more than 6 weeks, with exposed sphincter fibres at its base, inflammation at its margin, a sentinel pile distally and hypertrophied anal papilla proximally.

The exact cause of anal fissure is not known but is thought to be a result of trauma to the anoderm in the form of passage of hard stools, irritation from diarrhoea, anorectal surgery and anoreceptive intercourse. As a response to this trauma the internal anal sphincter tone is raised. This persistently raised tone impairs the healing by reduced anodermal perfusion and is responsible for the pain and spasm felt by the patient during defecation. Crohn's disease, Ulcerative Colitis, anal cancer, Tuberculosis, HIV, syphilis, herpes, leukemia are the causes of atypical anal fissures.

90% of the anal fissures are located in the posterior midline. Elliptical arrangement of the external anal sphincter posteriorly leading to less support to anal canal, relatively less blood supply to the posterior commissure of anal canal during sphincter spasm are theories to explain this finding.[2]

The main goal of treatment is to reduce the sphincter spasm and thereby increase the anoderm perfusion to promote healing of fissure along with prevention of straining and passage of hard stools and

maintain local hygiene. Surgical approach of lateral internal sphincterotomy reduces the sphincter spasm and heals chronic fissures. But this procedure is associated with complications like gas incontinence, stool incontinence which can cause significant morbidity to patients. This created a need to explore for other alternative conservative treatment options without the above-mentioned surgical complications. Various drugs like nitrates, Calcium channel blockers have shown to reduce the sphincter tone and improve fissure healing without any incontinence. In this study we compare the outcome of topical application of 2% Diltiazem gel and lateral Internal sphincterotomy for management of chronic anal fissures by assessing the healing, symptomatic relief and side effects of both the treatment modality.

II. Materials And Methods

This is a prospective, comparative study undertaken at MGM Medical College and Hospital, Aurangabad, India from October 2017 to Oct 2019. After approval from the local ethics committee, a total of 60 patients were enrolled in the study presenting to MGM hospital OPD with symptoms of chronic anal fissure as per the inclusion and exclusion criteria after informed consent from the patient. Inclusion criteria included patients of age 18 to 70 years of both genders with more than 6 weeks of duration of symptoms of anal fissure. Exclusion criteria included fissures with fistula/haemorrhoids, fissures with malignancy, fissures associated with pregnancy, fissures secondary to TB/IBD etc, immunocompromised status of patient, patients on nitrates for other medical conditions like IHD. 60 patients were randomised in 2 groups. 30 patients in Group 1 were treated with application of 1.5 to 2 cm of 2% Diltiazem Gel of single brand, 1.5 cm into the anal canal with the device provided by manufacturer twice daily. 30 patients in Group 2 underwent lateral internal sphincterotomy under spinal anaesthesia. Patients in both the groups were started on laxatives, high fibre diet and warm sitz bath. Patients in both the group were followed up at the OPD at the 1st, 2nd, 3rd weeks and then at 1st, 2nd and 3rd month. At each follow up setting the healing, pain relief, bleeding and side effects of the treatment modality were assessed. Healing was assessed by visual examination of fissure and defined as complete disappearance of the fissure. Pain relief was assessed by visual analogue scale to map the pain score. Complications like headache, dizziness and faecal incontinence, flatus incontinence were noted if any. Data was collected and analysed.

III. Results

In this study, out of the 60 patients, 53 (88.33%) were male and 7 (12.67%) were female (table 1). Majority of patients were from 30 to 60 years of age with mean age as 42 years (table 2). All patients presented with complaints of pain during defecation, bright streak of blood and constipation with increased sphincter tone. Situation of fissure was posterior midline in 52 (86.67%) patients, anterior midline in 5 (8.33%) patients and both in 3 (5%) patients (table 3). Sentinel pile was noted in 43 (71.66 %) patients.

In group 1, 21 patients (70%) at the end of 3 weeks and 27 patients (90%) at the end of 3 months had complete pain relief while in group 2, 26 patients (86.67%) at the end of 3 weeks and 29 patients (96.67%) at the end of 3 months had complete pain relief (table 4-5). Bleeding was controlled in 28 patients (93.33%), 30 patients (100%) at end of 3weeks and 3months respectively in group 1 and all 30 patients (100%) at end of 3weeks group 2. Healing was seen in 8 patients (26.67%), 21 patients (70.00%) at end of 3weeks and 3months respectively in group 1 and 18 patients (60%) ,29 patients (96.67%) at end of 3weeks and 3months respectively in group 2 (table 6-7). No complications were noted in group 1 while 2 patients (3.33%) had flatus incontinence in group 2. Comparison in both groups shows significant difference in healing of fissure with no difference in pain relief and bleeding control.

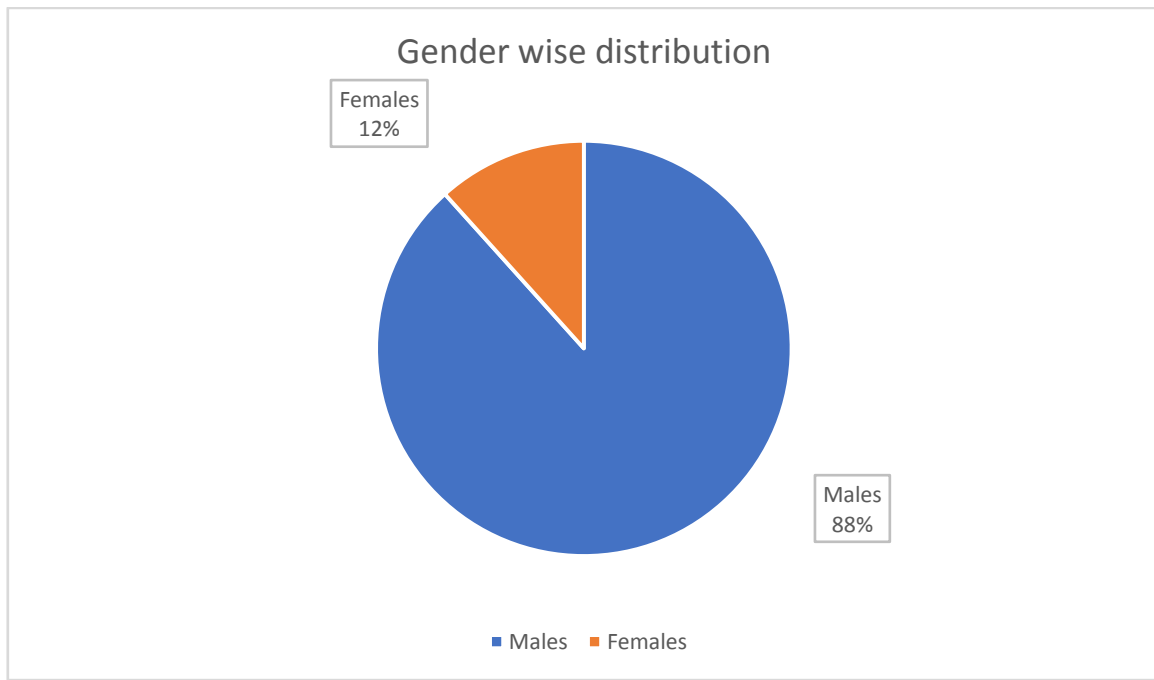


Table 1: Gender wise distribution of cases.

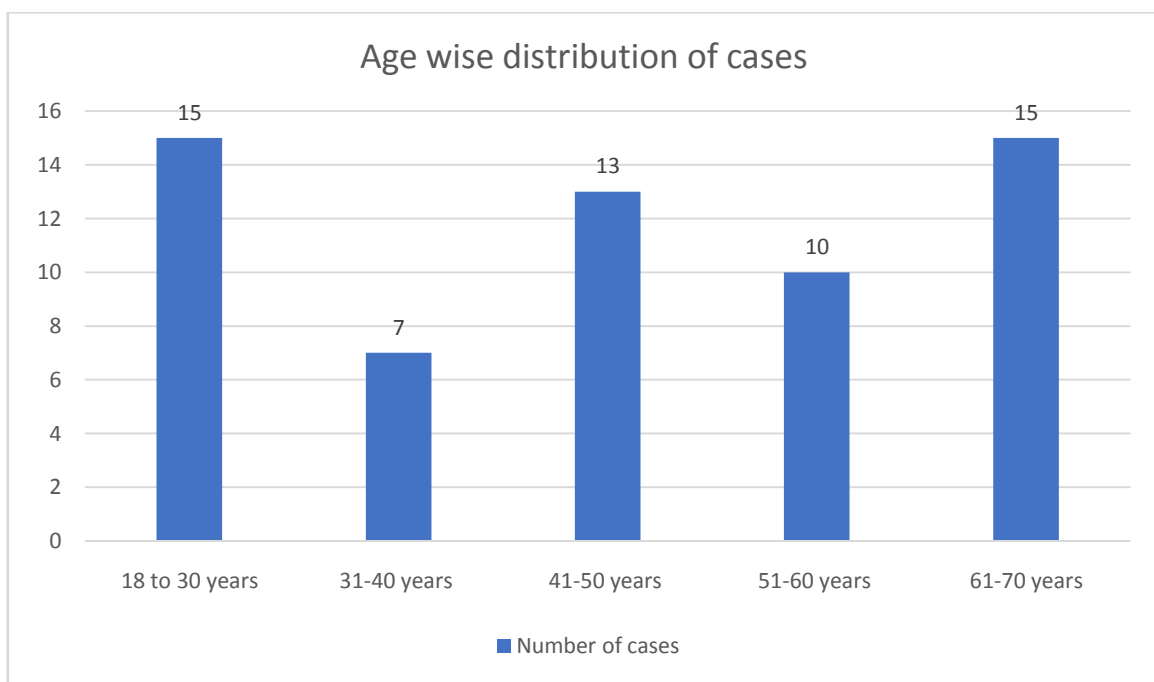


Table 2: Age wise distribution of cases

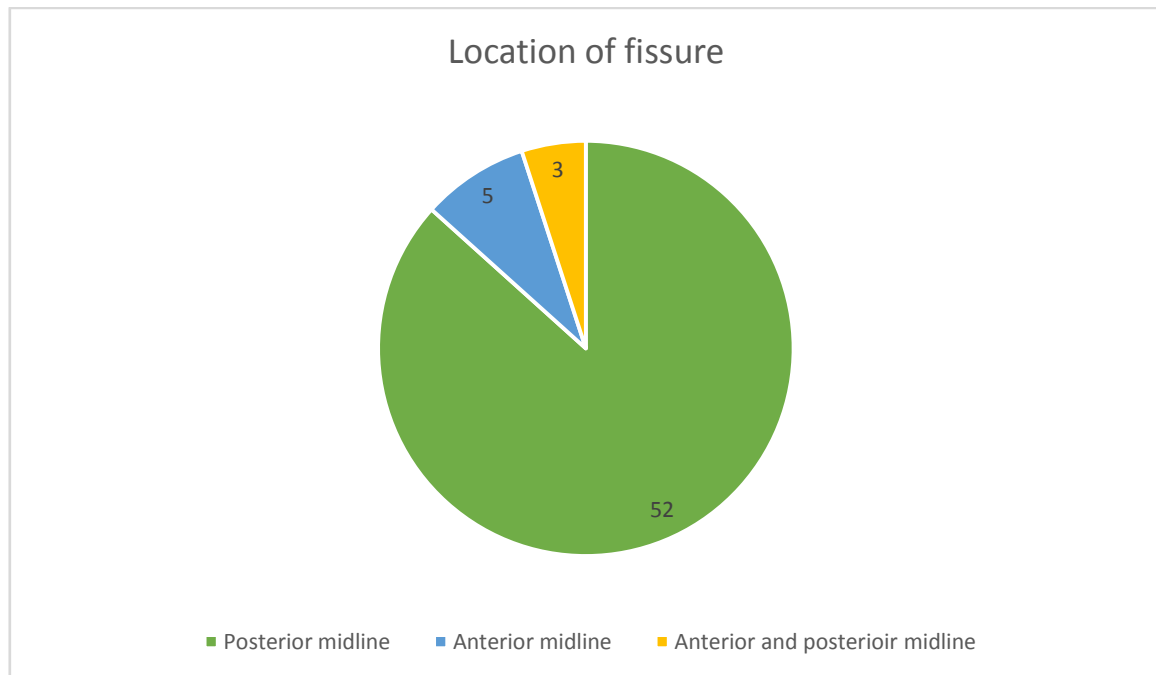


Table 3: Location of fissure.

Pain relief at 3 weeks		
	Number of patients	Percentage
Group 1 (Diltiazem therapy)	21	70%
Group 2 (Lateral internal sphincterotomy)	26	86.67%

Table 4: Pain relief at 3 weeks.

Pain relief at 3 months		
	Number of patients	Percentage
Group 1 (Diltiazem therapy)	26	86.67 %
Group 2 (Lateral internal sphincterotomy)	29	96.67 %

Table 5: Pain relief at 3 months.

Healing achieved at 3 weeks		
	Number of patients	Percentage
Group 1 (Diltiazem therapy)	8	26.67 %
Group 2 (Lateral internal sphincterotomy)	18	60 %

Table 6: healing at 3 weeks

Healing achieved at 3 months		
	Number of patients	Percentage
Group 1 (Diltiazem therapy)	21	70%
Group 2 (Lateral internal sphincterotomy)	29	96.67%

Table 7: healing at 3 months

IV. Discussion

Anal fissure is a very common clinical problem which can severely reduce the quality of life of an individual. Most common age of presentation is between 30 to 40 years of age [3,4,5,6] with equal distribution in the genders. In our study the male : female ratio was 7.5:1 due to social factors and embarrassing location of the disease. 90 % of primary fissures are found in the posterior midline. The treatment modalities aim at breaking the vicious cycle of increased sphincter spasm, pain and ischemia to promote the healing of the chronic anal fissure. Lateral internal sphincterotomy is considered the gold standard surgical treatment for anal fissures [7]. As the name suggests, the internal anal sphincter is divided upto the proximal extent of fissure or the dentate line. LIS has excellent healing rate of up to 95% [7], but at the same time is associated with complications like recurrence in up to 6 % and flatus or stool incontinence in 17 % patients [8].

The non-surgical modalities of treatment include pharmacological agents aimed at reducing the internal anal sphincter spasm. These involve topical Nitrates and Calcium Channel blockers like Diltiazem and Nifedipine. Topical 2% Diltiazem gel is typically applied locally twice daily for 6 to 8 weeks [9]. It blocks slow L type calcium channels, preventing the influx of calcium into the smooth muscles and relaxes the internal anal sphincter. This promotes healing of the fissure and is not associated with complications of surgery as chemical sphincterotomy is reversible. The healing rates in different studies ranges between 47- 80% [10,11,12,13] with 70% in our study. Side effects such as headache, perianal dermatitis ranged up to 10% in different studies with none seen in our study and no complication of incontinence. Due to these advantages, medical treatment has become the first line of treatment even though the healing rates are lower when compared to lateral internal sphincterotomy.

V. Conclusion:

Result of our study shows that lateral internal sphincterotomy remains the gold standard treatment for chronic anal fissure. Topical 2% Diltiazem therapy should be considered as a first line therapy in treatment of chronic fissures to avoid the surgical trauma and complications of incontinence. Lateral internal sphincterotomy should be reserved for individuals who show poor response to medical therapy or have a recurrence

References:

- [1]. Jennifer Sam Beaty, M. Shashidharan Clin Colon Rectal Surg. 2016 Mar; 29(1): 30–37. doi: 10.1055/s-0035-1570390
- [2]. Gordon P H, Nivatvongs S. St. Louis, MO: Quality Medical Publishing, Inc.; 1999. Principles and Practice of Surgery for the Colon, Rectum and Anus, 2nd ed; p. 218
- [3]. Schouten ER ,Briel JW , Boerma MO ,Auwerda JJA, Wilms EB, Gratsma BH (1996) Pathophysiological aspects and clinical outcome of intra anal application of isosorbide dinitrate in patients with chronic anal fissure. Gut 39(3):465-469.
- [4]. oh C, DivinoCM ,Steinhaqen RM (1995) Anal fissure 20 years experience. Dis Colon Rectum 38:378-382.
- [5]. Christie A , Guest JFF (2002) Modeling of Economic impact of managing chronic anal fissure , with proprietary formulation of nitroglycerin (rectogesic) compared to lateral internal sphincterotomy in UK. Int J colorectal Dis 17(4):259-267.
- [6]. Richard CS, Gregoire R, Plewes EA, Silverman R, Burul C, buie D, Reznick R , Ross T,Burnstein M, O'Connor BI,Mukraj D, Mc LEOD RS(2000) Internal sphincterotomy is superior to topical nitroglycerine in the treatment of chronic anal fissure :result of a randomized controlled trail by the Canadian Colorectal Surgical Trails Group,Dis Colon Rectum 43(8):1048-1057
- [7]. Steven Schlichtemeier, Alexander EngelAustPrescr. 2016 Feb; 39(1): 14–17. Published online 2016 Feb 1. doi: 10.18773/austprescr.2016.007
- [8]. Nelson RL, Thomas K, Morgan J, Jones A. Non-surgical therapy for anal fissure. Cochrane Database Syst Rev 2012;2:CD003431
- [9]. Wald A, Bharucha AE, Cosman BC, Whitehead WE. ACG clinical guideline: management of benign anorectal disorders. Am J Gastroenterol 2014;109:1141-57. 10.1038/ajg.2014.190
- [10]. Jonas Marion, Scholefield JH, Anal fissure and chemical sphincterotomy. Taylor I, Johnson CD. Recent advances in Surgery. Churchill Livingstone, 24th Edition, 2001, 115.
- [11]. E Carapeti, M Kamm, B Evans, R Phillips, Topical Diltiazem and Bethanechol decrease anal sphincter pressure and heal anal fissures without side effects. Diseases of the Colon and Rectum. 1999; 43 (10): 1359-62
- [12]. UK Srivastava, BK Jain, Praveen Kumar, Yusuf Saifee. A comparison of the effects of Diltiazem and Glyceryl trinitrate ointment in the treatment of chronic anal fissure: a randomized clinical trial. Surgery Today. 2007;37(6): 482-85.
- [13]. R Dasgupta, I Franklin, J Pitt, PM Dawson, Successful treatment of chronic anal fissure with Diltiazem gel. Colorectal Disease. 4: 20-22.

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