Original Article ISSN (O):2395-2822; ISSN (P):2395-2814

A Prospective, Randomised Comparative Study of Lateral Sphincterotomy and Local Application of 2% Diltiazem Gel in Treatment of Chronic Anal Fissure.

Sunesh Kumar[1]

[1]Associate Professor, Department of Surgery, Teerthankar Mahaveer Medical College & Research Centre, Bagarpur, Moradabad (U.P.).

Received: September 2016
Accepted: October 2016

ABSTRACT

Background: Surgical management is used for the treatment of most of the fissures including manual anal dilation or performing lateral sphincterotomy. The present study carries a comparative research between the patients posted for lateral internal sphincterotomy and application of 2% Diltiazem gel in chronic anal fissure. **Methods:** The study was conducted in Department of General Surgery, Teerthankar Mahaveer Medical College & Research Centre from May 2015 to April 2016. After informed written consent, 60 patients were enrolled in the study. All patients were allocated in two groups; Group S (30 patients) posted for Lateral Sphincterotomy and Group D (30 patients) consisting of 2 % Diltiazem gel therapy. **Results:** Out of 30 patients, 3 lost during the follow up period in Group D. 19 patients (63.33%) had complete healing at the fissure site upon application of Diltiazem (2%) gel at 4 week follow up. In case of Group S, 26 patients (86.67%) had complete healing of fissure at 4 weeks follow up while 2 patients had complete healing at 8 week follow up visit. 22 (73.33%) of the patients treated with diltiazem (2%) gel were pain free at the end of 4 weeks. 27 (90.00%) out of 30 patients undergoing lateral internal sphincterotomy were free from pain at the end of 4 weeks post operatively. **Conclusion:** Lateral internal Sphincterotomy is the first line of treatment in patients for the chronic fissure in ano.

Keywords: Anal Fissure, Diltiazem, Lateral Sphincterotomy.

INTRODUCTION

Anal fissure is the ulcer or longitudinal tear on the distal end of anal canal.[1] It is a condition associated with severe pain at the anal area. The extent of anal fissure is from the dentate line up to the anal verge. Anal fissures are found at the anterior or posterior midline surface. Anal fissures are of two types; Acute and Chronic. Acute anal fissure is a longitudinal tear at the distal anal canal associated with inflammation surrounding the periphery.[2] Chronic anal fissure consists of exposure of fibres of internal sphincter and is deeper as compared to acute one.[3] In many cases, anal papillary hypertrophy with sentinel pile is observed in chronic anal fissures.

Name & Address of Corresponding Author
Dr. Sunesh Kumar
Associate Professor,
Department of Surgery,
Teerthankar Mahaveer Medical College & Research Centre,
Bagarpur, Moradabad (U.P.)-244 001.

The bottom line of the treatment of anal fissure is to keep the ring around the anorectal area intact. This has been facilitated by the progressive understanding of the anatomy of rectum and anal canal together with the process of continence of bowel. The treatment lies in the fact that during the eradication of the disease the continence of the patient should not suffer.

Traditionally, surgical management is used for the treatment of most of the fissures including manual anal dilation or performing lateral sphincterotomy.[3] These treatments were found to be successful in most of the cases. However, some patients still complaints of bowel incontinence.[4-6] Therefore, researchers focused on some non-operative methods by which the healing of fissures can be fulfilled without compromising anal continence.

Various pharmacological agents such as nitrates (glyceryl trinitrate, isosobide dinitrate), calcium channel blockers (nifedepine, diltiazem) had been tried for the better outcome of the patients with anal fissure.[7] Therefore, the present study carries a comparative research between the patients posted for lateral internal sphincterotomy and application of 2% Diltiazem gel in chronic anal fissure.

MATERIALS AND METHODS

After Institutional Ethical approval, the study was conducted in Department of General Surgery, Teerthankar Mahaveer Medical College & Research Centre from May 2015 to April 2016. The study was conducted between the age group of 20-60 year old

patients. All patients visiting to Out-patient department or admitted to the hospital with diagnosis of Fissure-in-Ano were included in the study. The patients of extremes of age, pregnant women, mentally handicapped patients, patients with recurrent fissures, fissures associated with malignancies, hemorrhoids or fistula, fissures secondary to specific diseases like Tuberculosis, Crohn's disease etc.; and patients not giving consent to be a part of the study were excluded.

After informed written consent, 60 patients were enrolled in the study. All patients were allocated in two groups; Group S (30 patients) posted for Lateral Sphincterotomy and Group D (30 patients) consisting of 2 % Diltiazem gel therapy. Randomisation was performed by chit and box method.

All patients enrolled for Group D were advised for application of 2 % Dilatiazem gel of 1.5 -2 cm length, about 1.5 cm into the anus. Before and after application of gel all patients were instructed to wash their hands. The therapy is advised for application twice a day and all patients were instructed to revisit Out-patient department once a week.

The patients under Group S underwent Lateral Internal Sphincterotomy under spinal anaesthesia. A thorough pre-operative check-up was performed one day prior to surgery. Single dose of Inj. Ofloxacin and Ornidazole was administered prior to surgical intervention. At the bed time, laxative syrup was advised and Sitz bath was given on second post-operative day. Monitoring of complications of surgery like hematoma formation or bleeding was done in the post-operative period. All patients were discharged within 3rd to 7th post-operative day. The relaxation of sphincter was assessed post-operatively by digital examination. All patients were advised to revisit for follow up every week for 8 weeks. After the epithelisation of the mucosa the healing of fissure was confirmed.

RESULTS

All patients were successfully enrolled and participated in the study. Out of 60 patients, 32 patients were from the age group between 20-30 years, while 15 patients from 31-40 years of age. Only 8 and 5 number of patients is between 41-50 & 51-60 years of age respectively [Table 1, Figure 1].

The present study comprises of 37 patients (61.66%) as males and 23 patients (38.33%) as females [Table 2, Figure 2].

In 52 patients, the site of the fissure was posterior while in 8 patients the fissure was anteriorly placed [Table 3, Figure 3].

Sphincter spasm was observed in all the cases while sentinel pile was found in 24 cases. Out of 30 patients, 3 lost during the follow up period in Group D. 19 patients (63.33%) had complete healing at the fissure site upon application of Diltiazem (2%) gel at 4 week follow up. 4 patients had complete healing of the fissure at 8 weeks while the rest 4 patients who failed to heal by Diltiazem (2%) gel underwent lateral sphincterotomy.

In case of Group S, 26 patients (86.67%) had complete healing of fissure at 4 weeks follow up while 2 patients had complete healing at 8 week follow up visit. The rest of 2 patients did not revert back during their follow up visit. On comparing the two groups, insignificant results was observed (p= 0.06). 22 (73.33%) of the patients treated with diltiazem (2%) gel were pain free at the end of 4 weeks. 7 (23.33%) patients were free of pain by 3 months. Remaining 1 patient who did not have symptomatic relief was subjected to lateral sphincterotomy.

27 (90.00%) out of 30 patients undergoing lateral internal sphincterotomy were free from pain at the end of 4 weeks post operatively, while the remaining 3 (10.0%) patients had slight pain on follow-up which gradually resolved over a period of 3 months. Comparison between the groups revealed comparable results (p= 0.23).

During the course of the study, no complications were reported in any of the patients in both the groups.

Table 1: Age of patients.

Age (years)	20-30	31-40	41-50	51-60
Number of patients	32	15	8	5

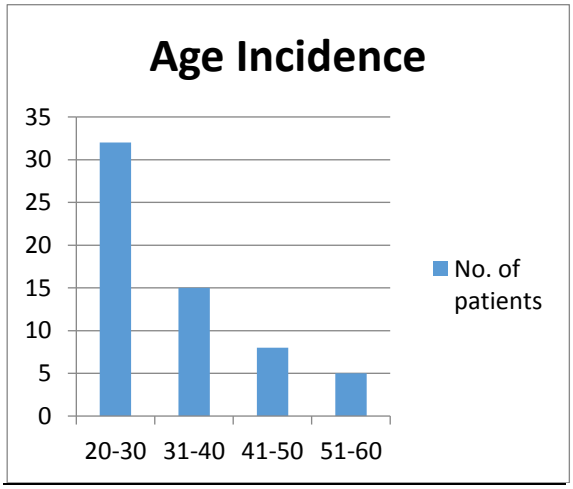

Figure 1: Age of patients.

Table 2: Sex Incidence.

Male (%)	Female (%)
37 (61.66%)	23 (38.33%)

Table 3: Site of Fissure.

Anterior (%)	Posterior (%)
8 (13.33)	52 (86.67)

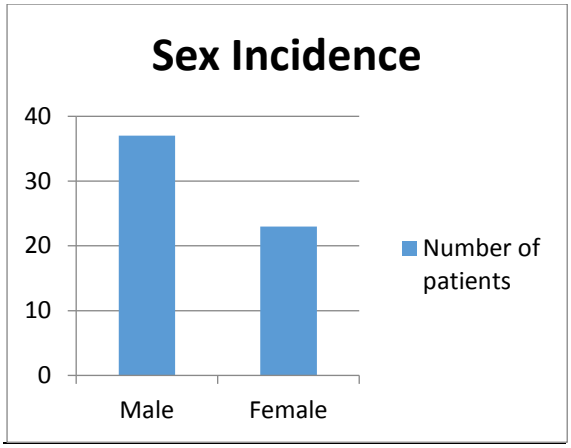

Figure 2: Sex Incidence.

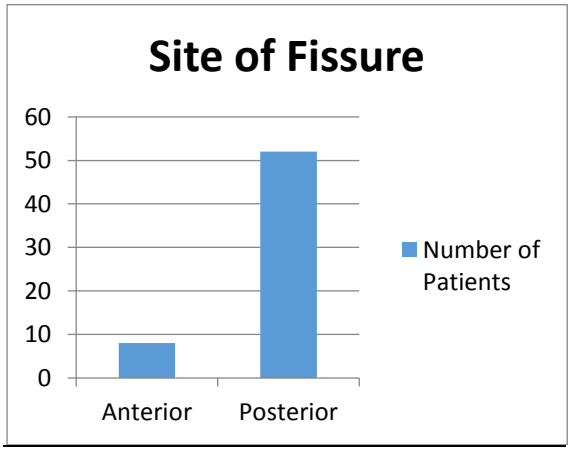

Figure 3: Site of Fissure.

Table 4: Healing after 4 weeks.

Diltiazem	Lateral Sphincterotomy
19 (63.33%)	26 (86.67%)

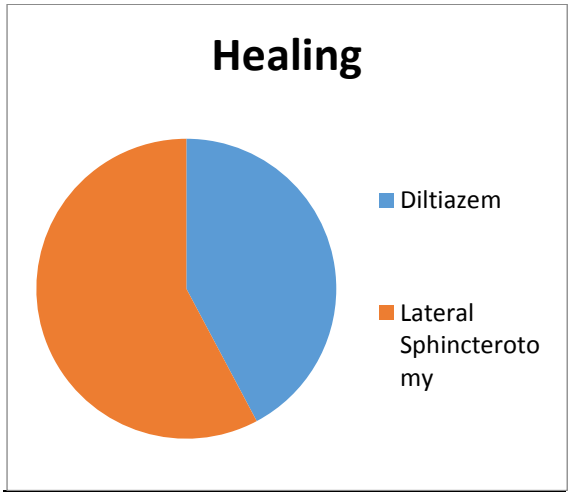

Figure 4: Healing after 4 weeks.

Table 5: Pain Relief after 4 weeks.

Diltiazem	Lateral Sphincterotomy
22 (73.33%)	27 (90.00%)

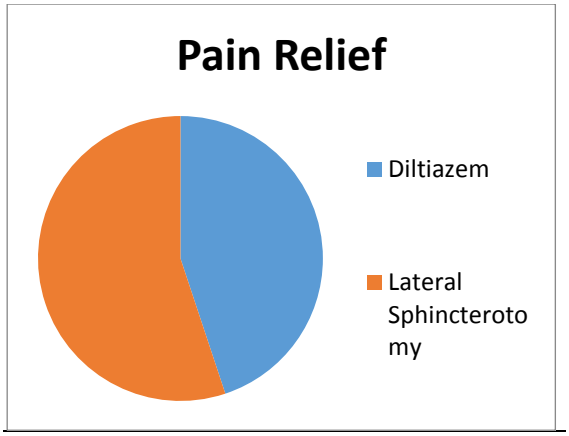

Figure 5: Pain-Relief after 4 weeks.

DISCUSSION

Anal fissure is a common problem worldwide that refers to a linear ulcer at the distal lining of anal canal.[1] The patient presents with the symptoms of difficulty/pain during defecation, bleeding per rectum and a compromised quality of life. The disease commonly affects young-middle aged peoples. The disease carries no sex preponderance.[8] Although, the fissure is most often observed at the posterior part of the anal canal but in case of females, anteriorly placed fissure is more common.

The treatment targets to curtail down the cycles of pain, bleeding and spasm. Traditionally, surgical management in the form of lateral sphincterotomy was performed in the cases of chronic fissure in ano. However, in some cases bowel incontinence was observed in post-surgery patients.

Now a days, various medications are used for the treatment of Chronic fissure in ano. The use of Calcium channel blockers like Nifedipine/Diltiazem has shown lowering of anal pressure thereby leading to relaxing the distal anal canal spasm and promoting healing.[9-11] The use of such agents has shown the occurrence of headache and dermatitis at the perianal region. Rithin Suvarna et al reported a healing rate of 69.23% with 2% topical diltiazem gel and healing rate of 95.87% with lateral internal sphincterotomy. Giridhar C.M. et al reported a healing rate of 88.46% in 5 weeks with 2% diltiazem gel and 100% healing rate by 4 weeks with lateral internal sphincterotomy.[12] Healing rates of chronic anal fissure in various studies ranged from 47%-80%.[13,14] In our study we reported the 63.33% healing rate in the patients treated with Diltiazem 2% while 86.67% in patients underwent lateral sphincterotomy at 4 weeks follow up.

In our study, 22 (73.33%) of the patients treated with diltiazem (2%) gel were pain free at the end of 4 weeks. 7 (23.33%) patients were free of pain by 3 months. Remaining 1 patient who did not have symptomatic relief was subjected to lateral sphincterotomy. 27 (90.00%) out of 30 patients undergoing lateral internal sphincterotomy were free

from pain at the end of 4 weeks post operatively, while the remaining 3 (10.0%) patients had slight pain on follow-up which gradually resolved over a period of 3 months. Popat et al[15] observed that fissure healed completely in 89.36% of patients treated with 2% topical diltiazem organo gel with 89.4% of patients having pain relief at the end of 14 weeks. 10.6% of patients had no pain relief and 2.1% of patients in the group had recurrence.

We did not observed any side effects in any of our patient during the course of the study. However, in some studies the incidence of side effects was found to be 0%- 10%.[3,10,13] Popat et al observed 1 patient (2.1%) having fecal incontinence.[15]

CONCLUSION

From the present study we conclude that lateral internal Sphincterotomy is the first line of treatment in patients for the chronic fissure in ano. However, treatment with Diltiazem 2% gel can be reserved in patients who are unwilling/unfit for the surgery.

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How to cite this article: Kumar S. A Prospective, Randomised Comparative Study of Lateral Sphincterotomy and Local Application of 2% Diltiazem Gel in Treatment of Chronic Anal Fissure. Ann. Int. Med. Den. Res. 2016; 2(6):SG50-SG53.

Source of Support: Nil, **Conflict of Interest:** None declared