MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.36478/makrjms.2024.11.297.300

Management of Chronic Fissure in Ano with 2% Diltiazem Local Application (or) Lateral Internal Sphincterotomy: A Comparative Study

[1]Maheboob Pasha, [2]P.T. Sushanth, [3]Gajula Vinod Reddy and [4]T.U. Subashini

[1-4]Department of General Surgery Basaveshwara Medical College and Hospital, Chitradurga, Karnataka, India

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Key Words
Fissure, ano-rectal disorders, lateral internal sphincterotomy, diltiazem, ointments

Corresponding Author
P.T. Sushanth,
Department of General Surgery Basaveshwara Medical College and Hospital, Chitradurga, Karnataka, India

Author Designation
[1,3,4]PG Student
[2]Associate Professor

Received: 12 August 2024
Accepted: 20 October 2024
Published: 26 October 2024

Citation: Maheboob Pasha, P.T. Sushanth, Gajula Vinod Reddy and T.U. Subashini, 2024. Management of Chronic Fissure in Ano with 2% Diltiazem Local Application (or) Lateral Internal Sphincterotomy: A Comparative Study. Res. J. Med. Sci., 18: 297-300, doi: 10.36478/makrjms.2024.11.297.300

ABSTRACT

Fissure in ano is one among the most common ano-rectal disorders encountered in surgical practice and management ranges from topical ointments to surgical sphincterotomies. Chronic anal fissure has traditionally been treated by lateral internal sphincterotomy, an effective and standard procedure but as with any surgical procedure, it is not devoid of surgical stress and complications. Topical Diltiazem 2% gel is the most commonly used pharmacological agent for treating chronic fissure in ano with variable success rates. Our study aims to compare the efficacy of Diltiazem 2% gel with lateral internal sphincterotomy. This prospective comparative study was conducted by selecting 60 cases presenting with symptoms and signs suggestive of chronic fissure in ano with specific inclusion and exclusion criteria. The study population was divided into two groups of 30 patients each. Group A was treated with topical application of Diltiazem 2% gel and Group B was taken up for lateral internal sphincterotomy. The outcome regarding the fissure healing, pain relief, any adverse effect and the recurrence was collected by the use of a pretested proforma and data concerning the 2 groups were then compared. In our series, the maximum incidence was in the age group of 21-30yrs (54%). The sex incidence ratio was 1.14:1 in favor of males. All cases presented with painful defecation and most common location of fissure was posterior midline. The final cure rates for both the groups were 83.33% in Chemical sphincterotomy and 100 % in lateral internal sphincterotomy. The conversion rate and recurrence rate were 16.33 % and 13.33% respectively in Group A while nil recurrence in Group B. The drawbacks were unique to their respective groups. Group A had headache (16.7%) and itching (23.33%) as its unique side effects. Group B patients had Post-Operative Pain (36.66%), surgical site bleeding (26.66%), surgical site infections (13.33%) and temporary fecal incontinence (23.33%). Topical application of Diltiazem 2% gel could be used as first line treatment for chronic anal fissures thereby avoiding trauma of surgery.

INTRODUCTION

Anal fissure represents one of the most common painful anorectal problems encountered in practice which affects people of various age groups and deteriorates their quality of life. Anal fissure is a painful tear in the lining of the anal canal, often accompanied by bleeding on defecation. It is a linear tear or crack that extends into the anoderm from the mucocutaneous junction to the dentate line. Acute fissures, defined as symptoms present for fewer than six weeks followed by spontaneous resolution thereafter, will appear as a longitudinal tear. Fissures of a longer duration will manifest one or more stigmata of chronicity, including a hypertrophied anal papilla at the proximal aspect of the fissure, a sentinel tag at the external apex and exposed internal anal sphincter smooth-muscle fibers. The etiology of anal fissure is not so clear. It was thought that the internal sphincter contraction was the primary objective in causing fissure secondary to mechanic trauma. Fissures are ischemic ulcers with the combination of raised resting tone of internal anal sphincter and reduced anodermal blood supply[1]. The cycle of spasm, pain and ischemia contributes to the development of a chronic ulcer[2]. Hence most modalities of management focus on relaxing the internal anal sphincter spasm. This can be achieved by surgical techniques such as anal dilatation, posterior midline sphincterotomy, lateral internal sphincterotomy or by pharmacol. therapy. Chronic anal fissure has traditionally been treated by surgery, an effective and standard procedure[3]. Lateral internal sphincterotomy heals chronic anal fissure in over 90% of cases but it is associated with potential long term complications[4]. Incontinence to flatus and faecal soiling are distressing complications of sphincterotomy, some of them had delayed wound healing and recurrence of disease. A number of pharmacological agents reducing the tone of internal sphincter through their pharmacodynamics and pharmacokinetic have been introduced and claimed to show good results but surgical treatment is frequently needed. Among the medical management, Chemical sphincterotomy using topical 2% Diltiazem has been considered to be the safest, simple, cost effective, efficacious method. It decreases the tone of the internal anal sphincter and increases the blood supply of the region, there by augmenting the fissure healing. The greatest advantage of chemical sphincterotomy over surgical techniques is avoiding the risk of permanent impairment of continence. The objective of our study was to compare efficacy of 2% Diltiazem gel with lateral internal sphincterotomy in terms of fissure healing, relief of pain, persistent symptoms and complications associated with it.

MATERIALS AND METHODS

The study consists of clinical observation and analysis of consecutive sixty cases of chronic anal fissure, diagnosed and treated at single institution. Patients were randomly divided into group A and group B with 30 patients in each group. Group A patients were treated with Diltiazem 2% local application gel and group B were treated with internal lateral sphincterotomy.

Inclusion Criteria:

- Patients above 18 years of age with chronic anal fissure.
- Patients willing to undergo study.

Exclusion Criteria:

- Acute anal fissure and recurrent fissures.
- Pregnant women with chronic anal fissure.
- Fissures associated with haemorrhoids or fistula.
- Fissures secondary to diseases like Tuberculosis, Crohn's disease etc. or associated with malignancy.
- Patient with history of fecal incontinence or anal stenosis.
- Patients with coagulative disorders.

The diagnosis of the chronic anal fissure was made on the basis of history, clinical findings and proctoscopic examination. Study cases were divided into group A and group B randomly after obtaining consent. The Group A Patients were treated with topical application of 2% Diltiazem gel. The patients were taught to maintain hygiene and were advised to apply 1.5 to 2 cms length of gel to the anoderm twice daily for 6 consecutive weeks. All patients preferred to undergo domiciliary treatment and hence were reviewed once a week on outpatient basis. For the group B cases that underwent internal lateral sphincterotomy, written informed consent was taken and prophylactic antibiotic was given 1hr prior to surgery. Postoperatively, the patients were followed from the date of operation till the day of discharge. They were reviewed once a week on outpatient basis during which patients were assessed. Both the group of patients were asked to consume high fibre diet, analgesics and to undergo Sitz Bath and take laxatives at bed time. At every visit, details regarding the fissure healing, pain relief, complications and the recurrence were noted. Results of follow up were tabulated and analyzed. Healing of the fissure was assessed visually which was defined as the complete resolution of the fissure on examination. The pain perception was measured using visual analog score (VAS). Score ranges from 0 to 10. A score of >7 is considered as severe

pain, a score between 4-6 considered moderate and 1-3 as mild pain. Anal Fissure was considered as recurrent if the fissure reappeared or causes symptomatic pain at the same site after 2 months of surgery or after application of 2% topical Diltiazem gel.

RESULTS AND DISCUSSIONS

This study included 60 patients with various symptoms of chronic fissure in ano attending surgery department. The incidence of the disease was more in the age group of 21-30 years (32 patients).17 patients were in the age group 31-40 yrs. 8 patients were in 5th decade and only 3 patients were in 6th decade of life. There were 32 males and 28 females with male to female ratio 1.14:1. Posterior fissure was seen in 54 patients (90%) and anterior fissure in 6 (10%) patients. Sentinel pile was present in 31(51.66%) cases. All 60 cases (100%) were presented with painful defecation for more than 6 weeks. 25 patients in group A and 27 patients in group B presented with associated bleeding.

Fissure Healing: In group A healing of fissure in ano was complete in 12 patients by the 4th week and in 25 patients by 6th week. The final cure rate was 83.33 %(25/30). In five patients, fissures did not heal after 6 weeks of Diltiazem application and remained symptomatic. 4 patients developed fissures at the same site after complete healing of the Fissure within 2 months past the treatment. These patients subsequently underwent internal sphincterotomy and fissures healed in 4 weeks. In group B who underwent lateral internal sphincterotomy, Fissure was completely healed in all patients between 3-5 weeks.

Table 1: Comparison of Fissure Healing in Group A and Group B

Fissure healing	Group A	Group B
Healed fissure 4th week	12(40%)	30(100%)
Healed fissure 6th week	25(83.33%)	30(100%)
Fissure cure rate	83.33%	100%
Conversion rate	5(16.66%)	0
Recurrence rate	4(13.33%)	0

Pain Relief: Visual analog score (VAS) of 3 and lesser than 3 (Mild) was taken as target pain score. In Group A the response in the form of immediate pain relief was achieved early in the treatment and by 2nd week 20 patients and by 4th week 27 patients were relieved of pain. Even though severity of pain decreased, 3 patients didn't achieve the target pain score. In group B pain relief was more pronounced starting from the 2nd week and the score less than 3 was achieved by 4th week itself in all patients (Table 1).

Bleeding Per Ano: In group A 20 patients were freed of bleeding per ano in first 2 weeks and by 4th week 25 patients and 28 patients by 6th week were cured of this symptom. In group B bleeding per ano was relieved in 17 patients by 2nd week, 27 patients by 4th week and in 30 patients by 6th week (Table 2).

Table 2: Pain Relief in Group A and Group B

Pain score of 3 or less	Group A (N=30)	Group B (N=30)
2nd week	20 (66.66%)	23 (76.66%)
4th week	27 (90%)	30 (100%)
6th week	27 (90%)	30 (100%)

Table 3: Relief from Bleeding Per Ano in Group A and Group B

Relief from bleeding per ano	Group A (N=30)	Group B (N=30)
2nd week	20 (66.66%)	17 (56.66%)
4th week	25 (83.33%)	27 (90%)
6th week	28 (93.33%)	30 (100%)

Morbidity: In group A adverse effects like headache and itching were noted in 5(16.66%) and 7(23.33%) patients respectively. Post operative complications in group B were tabulated in table 4 .The observed fecal incontinence of various grades was temporary and all patients were recovered satisfactorily (Table 3).

Table 4: Morbidity of Surgical Sphincterotomy

Morbidity	Patients(N=30)	Percentage
Post-OP pain	11	36.66%
Post-OP bleeding	8	26.66%
Surgical Site Infection	4	13.33%
Faecal Incontinence	7	23.33%

Patient of post-op Pain were 36.66% and post-op bleeding were 26.66% (Table 4). Anal fissure is a common disorder, with equal gender distribution[5]. Fissures can occur at any age, but are usually seen in younger and middle-aged adults and are rare in the aged due to muscular atony. In our study majority of cases were in the age group between 21-30 years and male to female ratio was 1.14:1. The principal clinical feature is intense anal pain during defecation, often associated with a small amount of bright red bleeding. Fissures occur most commonly seen in the midline posteriorly, the least protected part of the anal canal, although anterior fissure is compararatively common in females[6]. Blood supply to the anoderm at the posterior midline is significantly lower and it is further reduced by high anal resting tone in patients with fissure in ano. The cause of anal fissure has been long debated. The persistence of a fissure after any initiating event of trauma to the anal canal secondary to the passage of a hard stool is associated with increased resting anal pressure. Hence most modalities of management focus on relaxing the internal anal sphincter spasm which remains the centre in vicious cycle of fissure propagation and perpetuation. Various pharmacological and surgical options are available to manage increased internal anal sphincter tone with associated local ischaemia. Topical calcium channel blockers (typically diltiazem or nifedipine) have been associated with healing rates of anal fissures of 65% to

95% but recurrence is a problem[7]. Lateral internal sphincterotomy remains the surgical treatment of choice for chronic anal fissures with healing rates of 88-100%[8]. In our study the final cure rate was 83.33 % and recurrence rate was 13.33% in Diltiazem group whereas the cure rate was 100% and there was no incidence of recurrence in lateral sphincterotomy group. Group B patients who underwent surgical sphincterotomy had a better cure rate than the Group A patients with Chemical sphincterotomy. On comparison the Pain relief was much better and quicker in Group B (100%) compared to Group A (90%). Most people find that the pain from the surgery was less than the fissure pain. Madhusudhan[9] reported pain recovery in 89.4% with 2 % Diltiazem and Scouten[10] reported pain relief in 98% of cases after undergoing internal sphincterotomy. Recovery from bleeding per ano was actually similar in both groups but appeared to be little faster in Group A during the early course of treatment. However the final cure rate was correlated with fissure healing rate. Each group had its own specific morbid aspects such as Headache and Itching in Group A and Post-operative pain, Surgical site bleeding and Infection in Group B. The most common unwanted effect headache observed in Diltiazem 2% gel was not severe or long lasting and can be treated with simple painkillers. Localized itching (23.33%), which was higher than that reported by Madhusudhan[9] (4.3%) was temporary which lasted few minutes after application of the gel. Fundamental drawback of lateral internal sphincterotomy is anorectal seepage and incontinence, which are reported in 8-30% of patients[11]. In our study 23.33% patients had experienced incontinence which was of mild grade and temporary.

CONCLUSION

The chief objective of fissure treatment is to reduce the sphincter spasm and with a quiet and reasonably relaxed sphincter. Lateral internal sphincterotomy is the most effective surgical procedure for anal fissure with healing rates above 95%. But the need for the alternative is always been there to overcome the surgical stress and risk of incontinence. Chemical Sphincterotomy using 2% Diltiazem gel has good comparable healing rates in the treatment of symptomatic fissures with acceptable morbidity rate. The drawbacks that warrant patient interest are the slower response, longer duration of treatment, more chances of recurrence and conversion rate with Diltiazem. With view of all these parameters, it could be recommended that 2% Topical Diltiazem is the best available alternative for surgical method in treatment of chronic fissure in ano and surgery can be reserved for non-responders and recurrences.

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