



A COMPARATIVE STUDY OF 2% DILTIAZEM OINTMENT AND LATERAL ANAL SPHINCTEROTOMY IN THE TREATMENT OF CHRONIC ANAL FISSURE

General Surgery

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ABSTRACT

Background And Objective: In ordinary clinical practice, acute anal fissures are often seen. Historically, surgery has been used to treat acute anal fissure. The internal anal sphincter has come to be better understood from a pharmacological perspective, leading to more conservative treatment modalities. This study assesses the prognosis, outcome, and management of an acute anal fissure in addition to comparing the efficacy of lateral anal sphincterotomy and 2% diltiazem as treatments for anal fissures. **Methods:** In this prospective research, 104 people with acute anal fissures were randomly selected and assigned to one of two groups: 52 received 2% Diltiazem gel daily dressings and other 52 cases underwent surgery. Patients were followed up on a weekly basis for seven weeks, then biweekly for the next three months. The REALISE score was utilized to alter a significant factor between study groups. Chi square test used to correlate the complications between 2 groups. **Results:** The majority of cases were healed in one of two groups. In group A, 10/52 instances were not healed, while in group B, 5/52 cases were not healed. About 5 cases in Group A and 4 cases in Group B were followed up on. There appears to be no substantial difference between research groups. About 40 cases appear to be without complications. Six patients experienced post-operative pain, two experienced seroma, two experienced hematoma, and two experienced infection. About 38 cases healed after 4 weeks. 7 cases healed after 5 weeks, whereas 2 and cases healed after 6 and 7 weeks of surgery. Significant results were observed in Group B using Realise score. There was statistically significant correlation of complications seen between 2 groups. **Conclusion:** According to the findings of the study, in the case of an acute anal fissure, 2% Diltiazem gel application might be regarded as a first line of treatment. Surgery has few complications and negative effects. Although the pace of fissure healing with Diltiazem gel is quite modest. On the whole, Patients with recurrence and therapeutic failure of past pharmacological therapy should be administered internal sphincterotomy.

KEYWORDS

2% Diltiazem gel, lateral anal sphincterotomy, Realise score, Significant and acute anal fissure.

INTRODUCTION

Anorectal conditions like anal fissure (fissure-in-ano) are quite prevalent. A linear or oval-shaped tear in the anal canal that begins just below the dentate line and extends to the anal margin is known as an anal fissure. Lockhart-Mummery initially characterized it in 1934. [1] Fissures in the anorectum can be acute or chronic. A small rip in the anoderm characterises acute fissures. A longitudinal tear or defect in the anal canal's skin distal to the dentate line is known as an anal fissure. Anal fissures are categorised based on what causes them. Primary fissures are frequently benign and are probably the result of local trauma, such as penetration, protracted diarrhoea, vaginal birth, hard faeces, or extended diarrhoea. [2,3] Patients with prior anal surgeries, inflammatory bowel illness (such as Crohn's disease), granulomatous disorders (such as TB, sarcoidosis), infections (such as HIV/AIDS, syphilis), or cancer are more likely to develop secondary fissures.

The typical recovery time for an acute anal fissure is 4 to 8 weeks of conservative treatment. Surgery is typically needed if this treatment fails and the fissure develops into a chronic condition. [4] Both males and females experience fissures on an equal basis. The majority of patients with fissures are middle-aged or younger, with a mean age of onset of 39.9 years. Even young toddlers and the elderly can develop fissures. The posterior midline, where more than 75% of cases occur, is the most frequent spot for both males and females. A quarter of fissures occur in the anterior region, and women are more likely to have them. Atypical fissures, which make up less than 1% of all fissures, are those that are not in the midline position. [5,6] The diagnosis of anal fissures is typically simple and may frequently be determined based only on the patient's medical history. The suspicion of an anal fissure is confirmed by a physical examination, which also excludes any other disease. The digital exam and anoscopic exam may be postponed owing to discomfort if a fissure has been identified. A digital exam is necessary to confirm that there is no underlying infection, though, if the diagnosis is murky or there is fear for an abscess. [7,8]

The majority of acute anal fissures heal on their own without needing surgery. Healing becomes more challenging if cracks become persistent. The three components that make up nonoperative therapy's objectives are simple and basic. The initial step is to treat the underlying condition that led to the fissure's formation. This frequently entails easing straining and constipation as well as avoiding further anal trauma triggers. To enhance blood flow and promote healing, the second element is relaxing the internal anal sphincter. This can be

accomplished using a variety of the therapies indicated below. Reducing the symptoms of the fissure, which are often discomfort and bleeding, makes up the third part. [9]

High-fibre diets, sitz baths, topical CCB, or topical nitrates are examples of medical therapy. The use of BT injection, which has few side effects and reasonable cure rates, may be considered when conservative therapy fails. The restricted lateral internal sphincterotomy, with no distinction between open or closed procedures, is the gold standard of surgical intervention. There is extremely little and typically no faecal incontinence associated with restricted lateral internal sphincterotomy. Prior to receiving any surgical intervention, individuals with low-pressure fissures should have ultrasonography and manometry. [10] This present study compares the effectiveness of 2% diltiazem and lateral anal sphincterotomy as a therapy for acute anal fissures and evaluates the prognosis, outcome, and care of an acute anal fissure.

MATERIALS AND METHODS:

Study design: Prospective interventional study,

Sample size: 104

Subject selection: All patients diagnosed with Anal fissures at Sri Lakshmi Narayana Institute of Medical Sciences.

Sampling technique: Purposive sampling,

Study area: Sri Lakshmi Narayana Institute of Medical Sciences.

Source of data:

Patients from Sri Lakshmi Narayana Institute of Medical Sciences were selected during the study period from September 2020 to December 2022.

Inclusion criteria

1. Every patient presenting to OPD with complaints of difficulty in passing stool along with bleeding on passing stool for a period of more than 6 weeks
2. Patients who fall under the age group of 18 to 68.

Exclusion criteria

1. Anal malignancies.

2. Haemorrhoids
3. Anal abscess
4. Bleeding diathesis
5. Patients with a history of previous anal surgery
6. Inflammatory bowel disease.

METHODOLOGY:

Demographic data, the nature of the complaints, a detailed history and clinical examination, and appropriate investigations to identify etiological factors and management were recorded in a predesigned Form including the surgical intervention undertaken. Patients in Group 1 were advised to apply 1.5 to 2 cms length of gel twice daily at least 1.5 cm into the anus for 6 consecutive weeks. Patients were instructed to wash hands before and after use of gel. Cases in Group 2 underwent left lateral internal sphincterotomy under spinal anaesthesia. Cases from both Groups were asked to take mild laxatives like cremaffin (milk of magnesia 11.25 ml, liquid paraffin 3.75 ml, per 15 ml of emulsion) three teaspoons at bedtime, high fiber diet and to use warm sitz baths. Cases were reviewed in Outpatient Department weekly for 6 consecutive weeks and biweekly for subsequent 3 months. At each visit questions were asked regarding pain relief, leakage of flatus/feces, and any side effects. Healing was assessed visually and defined as complete disappearance of fissure.

Statistical analysis:

The data was then tabulated and subjected to statistical analysis. A value of $P < 0.05$ was regarded as statistically significant after statistical analysis utilizing the student T-test and chi-square test. Quantitative variables with Gaussian distribution were given as mean \pm standard deviation for categorical variables and numbers with percentages for the latter.

RESULTS AND OBSERVATION

This is prospective research with 104 individuals who were diagnosed with acute anal fissure. All 104 patients with acute anal fissures were randomly selected and allocated into two groups, out of which 52 were with the application of 2% Diltiazem gel daily dressing, and 52 cases underwent surgery. The study was done after receiving clearance from the Sri Lakshmi Narayana Institute of Medical Sciences ethics council in Chennai. Those who satisfied the inclusion criteria were asked to participate in the study.

Demographic Profile

The current study included patients ranging in the age above 20 years old, with an average age of 44.65 ± 11.1 in group A and 42.96 ± 11.1 in group B. 29% of patients in group A were between the age range of 31-40 and maximum patients in group B were between the ages of 41 and 50. (Table 1). Of the 102 patients in each of the two trial groups. In both group A (52% men, 48% women) and group B (62% men, 38% women), there were more men than women. Table: 2 demonstrates that there were no significant sex differences in this example and that the sex distribution was uniform.

Table:1 Distribution of Age in Years

Age	2% Diltiazem				Surgery			
	Frequency (%)	Mean	SD	Range	Frequency (%)	Mean	SD	Range
21-30	4 (7.6%)	44.65	11.1	24-65	9 (17.3%)	42.96	11.1	22-65
31-40	15 (28.8%)				12 (23.1%)			
41-50	12 (23.1%)				16 (30.7%)			
51-60	10 (19.2%)				10 (19.2%)			
61-70	9 (17.3%)				3 (5.8%)			
Chi square / P value	5.827 / 0.2123							

Table 2: Gender distribution

Gender	2% Diltiazem	Surgery
Male	27 (51.92%)	32 (61.53%)
Female	25 (48.07%)	20 (38.46%)
Chi-square/P value	0.979/0.3223	

Chief Complaints Among Study Groups

The majority of patients present with primary complaints of Pain and bleeding per rectum.

Table: 3 demonstrates that there were no significant differences among chief complaints.

Table: 3 Distribution of Chief complaints among study groups

Chief complaints	2% Diltiazem	Surgery
Pain	13 (25%)	13 (25%)
Pain while passing stools	6 (11.53%)	3 (5.7%)
Bleeding per rectum	18 (34.61%)	19 (36.53%)
Pain and passing mucous per rectum	8 (15.38%)	9 (17.3%)
Pain and passing blood per rectum	7 (13.46%)	8 (15.38%)
Chi-square/P value	1.152/0.885	

Bowel Habits

Table: 4 demonstrates that there were no significant differences in bowel habits among study groups

Table: 4 Percentage and Frequency distribution of bowel habits

Bowel habits	2% Diltiazem	Surgery
Normal	15 (28.84%)	13 (25%)
Constipation	27 (51.92%)	28 (53.84%)
Altered bowel habits	6 (11.53%)	5 (9.61%)
Diarrhea	4 (7.6%)	6 (11.53%)
Chi-square/P value	0.651/0.884	

Site Of Fissure

There was no statistically significant difference between the two groups.

Table: 5 Different site of fissure among study groups

Site of fissure	2 % Diltiazam		Surgical group	
	Frequency	%	Frequency	%
Anterior	12	23.07%	10	19.23%
Posterior	40	76.92%	42	80.76%
Chi-square/P value	0.2306/0.63108			

Ulcer Discharge

In group A, 15 of the 52 cases had mucopurulent discharge, 13 had purulent discharge, and 24 had blood stained from ulcers. In group B, 20 of the 52 cases had mucopurulent discharge, 9 had purulent discharge, and 23 had blood stained from ulcers.

Table: 6 Ulcer discharge and it's distribution

Discharge from ulcer	2 % Diltiazam		Surgical group	
	Frequency	%	Frequency	%
Mucopurulent	15	28.84%	20	38.46%
Purulent	13	25%	9	17.3%
Blood stained	24	46.15%	23	44.23%
Chi-square/P value	1.4628/0.48122			

Complications

42 cases in group A appear to have no complications. Four individuals appear to have headaches, while only six cases appear to have perianal itching.

Table: 7 Distribution of complications in group A

Complications of 2% diltiazem	Frequency (%)
Perianal itching	6 (11.53%)
Headache	4 (7.6%)
nil	42 (80.76%)

Length Of Stay After Surgery

After treatment, 40/52 cases remained for 2 days. Only 4 out of 52 instances (or 8/52 cases) lasted for more than 3 days.

Table: 8 Length of hospital stay and it's distribution

Duration of hospital stay	Frequency (%)
2 Days	40 (76.92%)
3 days	8 (15.38%)
4 days	4 (7.6%)

Recovery Status

The majority of cases were healed in one of two groups. In group A, 10/52 instances were not healed, while in group B, 5/52 cases were not healed. About 5 cases in Group A and 4 cases in Group B were followed up on. There appears to be no substantial difference between research groups.

Table: 9 Healing status and it's distribution

	Diltiazem group	Surgical group
Healing status	Frequency (%)	Frequency (%)
Healing	37 (71.15%)	43 (82.69%)
Not healed	10 (19.235)	5 (9.6%)
Loss to follow up	5 (9.6%)	4 (7.69%)
Chi square value	2.2278	
P value	0.328	

Complications Of Surgery

About 40 cases appear to be without complications. Six patients experienced post-operative pain, two experienced seroma, two experienced hematoma, and two experienced infection.

Table: 10 Surgery complications and it's distribution

Complications of surgery	Frequency (%)
Hematoma	2 (3.8%)
Infection	2 (3.8%)
Post operative pain	6 (11.53%)
Seroma	2 (3.8%)
Nil	40 (76.92%)

Healing Duration

About 38 cases healed after 4 weeks. 7 cases healed after 5 weeks, whereas 2 and cases healed after 6 and 7 weeks of surgery.

Table: 11 Duration of Healing and it's distribution in weeks

Duration of Healing	Frequency (%)
4 weeks	38 (73.07%)
5 weeks	7 (13.46%)
6 weeks	2 (3.8%)
7 weeks	1 (1.92%)

REALISE score

The REALISE score was utilised to alter a significant factor between study groups. The mean score of groups A and B before and after therapy is presented in the table below. Significant results were observed in Group B.

Table: 12 Score evaluation of study groups before and after treatment

REALISE score	2% diltiazem group	Surgical group
	Mean	Mean
Before treatment	20.788	20.38
After treatment	9.04	6.604
T value	24.14	28.065
P value	0.0023	0.0001

Correlation Of Complications Among Study Groups

There was statistically significant correlation seem between 2 groups.

Table: 13 Correlation Of Complications Between 2 Groups

Complications	Diltiazem group	Surgical group
Frequency	10	12
Odds ratio	0.7936	
Chi square test value	0.2305	
P value	>0.05	

DISCUSSION

Anal fissure is a common cause of severe anal discomfort and causes significant morbidity. The posterior midline is the most commonly used location, followed by the anterior midline, especially in females. A variety of non-surgical and operational therapy have been documented, including the injection of botulin toxin into the fissure, oral nifedipine, topical Glyceryl Trinitrate (GTN), and topical diltiazem ointment. Diltiazem is a calcium channel blocker that causes relaxation by blocking the slow L-type calcium channels in smooth muscle. Recamier described anal dilation in 1838, and it was one of the most popular and acknowledged methods of treating anal fissures in surgical procedures such as stretching of the anal sphincter [Lord's anal dilatation]. [11] This is prospective research with 104 individuals who were diagnosed with acute anal fissure. All 104 patients with acute anal fissures were randomly selected and allocated into two groups, out of which 52 were with the application of 2% Diltiazem gel daily dressing, and 52 cases underwent surgery. Comparable demographic information existed for both groups.

Giridhar CM et al, 2014 conducted a prospective study in which 60 surgical outpatients and/or hospitalized patients with chronic fissure in ano were randomly assigned to Group 1 (Diltiazem gel) and Group 2 (internal sphincterotomy), each with 30 patients. Patients were checked in on a weekly basis for six weeks, then bimonthly for the next three months. [12] Luai Farhan Zghair (2016) investigated the effect of topical 2% diltiazem gel treatment on acute fissure healing in ANO. This is an interventional research on 70 patients with acute anal fissure who were investigated at Al-Yarmouk Teaching Hospital from January to September 2016. All patients were given 2% diltiazem gel for a maximum of 8 weeks. [11]

The current study included patients ranging in age above 20 years old, with an average age of 44.65 ± 11.1 in group A and 42.96 ± 11.1 in group B. 29% of patients in group A were between the age range of 31-40 and maximum patients in group B were between the ages of 41 and 50. Of the 102 patients in each of the two trial groups. In both group A (52% men, 48% women) and group B (62% men, 38% women), there were more men than women. There were no significant sex differences in this example and the sex distribution was uniform.

Similarly, According to Boulos PB et al. (2018), Anal fissure is more frequent in young or middle-aged individuals and is equally common in both sexes. Although anterior fissures are more prevalent in females, posterior fissures are more common in males. [13] Of the 52 cases in group A, maximum number of cases were employer, homemaker and business (27%, 26.9% and 17%). Of the 52 surgery cases, maximum number of cases were IT Workers, employers, homemaker and business (12%, 21%, 25% and 19%). According to Leong APK et al., 2003, when it comes to surgical therapy in anal fissures, the majority of patients work in IT. [14]

The majority of patients present with primary complaints of Pain and bleeding per rectum. There were no significant differences among chief complaints. There were no significant differences in bowel habits among study groups. The majority of cases in the study groups appear to have no prior history. Six cases in Group A had postpartum haemorrhage, six experienced haemorrhage, and only one had previous anal surgery. In group B, five of the 52 individuals had postpartum haemorrhage, three had haemorrhage, and only one had previous anal surgery. There was no statistically significant difference between research groups.

According to Beaty JS et al., 2016, the majority of patients come with pain and bleeding per rectum. There was no difference in bowel habits between research groups. Many suffered postpartum hemorrhage, and six had hemorrhage. [15] Among group A cases, about 12 had a fissure on the anterior side and approximately 40 had a fissure on the posterior side. In group B, approximately 10 cases had anterior fissures and 42 instances had posterior fissures. There was no statistically significant difference between the two groups.

In group A, 15 of the 52 cases had mucopurulent discharge, 13 had purulent discharge, and 24 had blood-stained from ulcers. In group B, 20 of the 52 cases had mucopurulent discharge, 9 had purulent discharge, and 23 had blood-stained from ulcers. Among study groups, the sentinel pile appears to have the fewest cases. A sentinel pile was absent in about 36/52 cases (group A) and 35/52 cases (group B). There was no significant difference between the two groups. About 71% in group A and 75% in group B cases seem to have tenderness. In patients belonging to groups A and B, roughly 94% appear to exhibit tenderness. Similar to our study results, Abcarian, H et al., 2019, few instances had a fissure on the anterior side and many had a fissure on the posterior side. Few individuals had mucopurulent discharge during pharmacological treatment, while several had blood stained from ulcers. The majority of the patients in this study's surgical treatment had blood stains from ulcers. The sentinel pile appeared to have the fewest instances across the research groups. Tenderness appears to be present in around 75% of their instances. [16]

Medication took 4 weeks in 9 cases, 5 weeks in 23 cases, 6 weeks in 15 cases, and 7 weeks in one case. 42 cases in group A appear to have no complications. Four individuals appear to have headaches, while only six cases appear to have perinatal itching. After treatment, 40/52 cases remained for 2 days. Only 4 out of 52 instances (or 8/52 cases) lasted for more than 3 days. The majority of cases were healed in one of two groups. In group A, 10/52 instances were not healed, while in group B, 5/52 cases were not healed. About 5 cases in Group A and 4 cases in

Group B were followed up on. There appears to be no substantial difference between research groups.

About 40 cases appear to be without complications. Six patients experienced post-operative pain, two experienced seroma, two experienced hematoma, and two experienced infection. About 38 cases healed after 4 weeks. 7 cases healed after 5 weeks, whereas 2 and cases healed after 6 and 7 weeks of surgery. The REALISE score was utilised to alter a significant factor between study groups. The mean score of groups A and B before and after therapy is presented in the table below. Significant results were observed in Group B. There was statistically significant correlation seen between 2 groups.

CONCLUSION

This prospective study was carried out at Sri Lakshmi Narayanan Medical College's Department of General Surgery. According to the findings of the study, most acute fissures in ano heal with conservative treatment. Patients with persistent fissures and symptoms should be evaluated for lateral anal partial internal sphincterotomy. As a result, in the case of an acute anal fissure, 2% Diltiazem gel application might be regarded as a first line of treatment. Surgery has few complications and negative effects. Although the pace of fissure healing with Diltiazem gel is quite modest. On the whole, Patients with recurrence and therapeutic failure of past pharmacological therapy should be administered internal sphincterotomy.

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