E-ISSN: 2616-3470

P-ISSN: 2616-3462

© Surgery Science

www.surgeryscience.com

2021; 5(2): 310-313

Received: 16-02-2021

Accepted: 19-03-2021

Dr. Shaik Mohammed Waseem

Junior Resident, Department of
General Surgery, Apollo BGS
Hospitals, Mysore, Karnataka,
India

Dr. Jayanth BN

Consultant Surgeon, Department
of General Surgery, Apollo BGS
Hospitals, Mysore, Karnataka,
India

Dr. Srinath S

Consultant Surgeon, Department
of General Surgery, Apollo BGS
Hospitals, Mysore, Karnataka,
India

A prospective clinical study of fissure in ano and analysis of various treatment modalities

Dr. Shaik Mohammed Waseem, Dr. Jayanth BN and Dr. Srinath S

DOI: <https://doi.org/10.33545/surgery.2021.v5.i2f.712>

Abstract

Background: Fissure-in-ano is a very common problem across the world. The rationale of treating this condition is to reduce the internal anal sphincter tone, thereby relieving the spasm and improving the circulation. This study aims to analyse the various modalities of treatment given for fissure in ano and observe the presentations and tailor the treatment needs of the patient.

Methods: This study was done prospectively on 165 patients with fissure in ano in Apollo BGS hospitals Mysore, and patients were treated with Diltiazem gel and Left lateral sphincterotomy when and as needed.

Results: 165 patients were prospectively studied, treated with conservative management with Diltiazem gel and left lateral sphincterotomy when and as needed. 134 patients (81.2%) improved and fissure healed and 31 patients (18.8%), whose fissure was not healed were subjected to Left lateral sphincterotomy. Mean time taken for fissure to heal with conservative management was 5.26 weeks and with surgery was 3.41 weeks.

Conclusion: Topical Diltiazem gel therapy should be advocated as the first line of treatment and surgery should be reserved for patients with relapse and therapeutic failure of prior pharmacological treatment.

Keywords: Fissure in ano, diltiazem gel, left lateral sphincterotomy, chemical sphincterotomy

1. Introduction

Fissure in ano is defined as longitudinal split within anoderm of the distal anal canal, which extends from the anal verge proximally towards, but not beyond, the dentate line ^[1]. Fissure-in-ano is a common problem all over the world which causes considerable morbidity and affects the patient's quality of life to a great extent. The incidence of fissure in ano is 11% ^[2]. This warrants prompt treatment of the condition with appropriate methods. The rationale of treating this condition is to reduce the internal anal sphincter tone, thereby relieving the spasm and improving the circulation. Of the surgical modalities available, the gold standard operating procedure is lateral internal sphincterotomy. Lateral internal anal sphincterotomy is the treatment of choice for chronic fissures because it is effective, safe, less expensive, and associated with a lower rate of complications ^[3]. Chemical sphincterotomy, which is a medical line of treatment has now been accepted as the first line of treatment of acute and chronic anal fissures at various centres. As per various previous studies, calcium channel blockers like diltiazem have shown good efficacy in this condition. Lateral internal sphincterotomy is indicated in painful chronic anal fissure which is not responsive to medical therapy ^[4]. Selecting an appropriate method of treating anal fissure which will achieve optimal clinical results and also less pain and inconvenience to the patient has always posed a challenge to the surgeons. This led to the innovation of variety of surgical and pharmacological methods to relax the anal sphincter muscle.

2. Materials and Methods

This is a prospective study done on 165 patients with fissure in ano presented to outpatient department and in-patients admitted under the department of surgery in Apollo BGS Hospital, Mysore, a tertiary care center from July 2018 to December 2019. After collecting detailed history and performing a thorough examination, data is recorded on a proforma along with investigations, surgical procedure, intra-operative findings. It is an observational, open label study. It is prospective in nature. Every effort was taken to avoid bias. Patients were advised the

Corresponding Author:

Dr. Shaik Mohammed Waseem

Junior Resident, Department of
General Surgery, Apollo BGS
Hospitals, Mysore, Karnataka,
India

same medical treatment of 2% diltiazem twice daily for local application and lignocaine gel twice daily for local application and Polyethelene glycol syrup 25 ml in a glass of water in night, sitz bath and surgical treatment of left lateral subcutaneous sphincterotomy under spinal anaesthesia when needed. Similar advice on discharge was given to all patients.

2.1 Inclusion criteria

Patients above 18 years of age of both sexes, surgical out patients and/or admitted patients of fissure in ano in the Apollo BGS Hospitals, Mysore.

2.2 Exclusion criteria

- a) Age less than 18 years (children excluded)
- b) Pregnant females
- c) Patients refusing treatment

2.3 Data analysis

Collected data is analysed and presented in form of tables, figures, graphs and diagrams wherever necessary containing Age, sex, location of fissure, type of fissure, symptomatology. The test of significance that are used are Z-test of proportions and Chi square tests

3. Results

3.1 Age and gender distribution

Out of 165 patients included in study, 86 (52.1%) were Males and 79 (47.9%) were Females. In our study, majority of patients 61 (37.0%) were at the age group of 31-40 years of age. The youngest patient was 20 years old and oldest was 80 years old. Majority of the male patients 36 (41.9%) were in age group of 31-40 years of age. Majority of females 25 (31.6%) were in age group of 31-40 years of age.

Fig 1: Gender distribution of fissure in ano

Table 1: Age distribution

AGE	NUMBER OF PATIENTS	PERCENTAGE
18-30 YEARS	38	23.0%
31-40 YEARS	61	37.0%
41-50 YEARS	27	16.4%
51-60 YEARS	23	13.9%
60+ YEARS	16	9.7%
TOTAL	165	100.0%

Test - Chi square test $\chi^2 = 37.394$ p value - 0.000 (S)

3.2 Location of fissure in ano

34 (20.6%) patients presented with anterior fissure-in-ano, 112 (67.9%) patients presented with posterior fissure-in-ano and 19

(11.5%) with both anterior and posterior fissure-in-ano. Majority of male patients 55 (64.0%) had posterior fissure in ano. Majority of females 57 (72.2%) had posterior fissure in ano.

Fig 2: Location of fissure in ano

Table 2: Location and gender wise distribution of fissure in ano

LOCATION OF FISSURE	MALE	FEMALE	TOTAL
ANTERIOR AND POSTERIOR % Within Group	13 15.1%	6 7.6%	19 11.5%
ANTERIOR % Within Group	18 20.9%	16 20.2%	34 20.6%
POSTERIOR % Within Group	55 64.0%	57 72.2%	112 67.9%
TOTAL % Within Group	86 100.0%	79 100.0%	165 100.0%

Test used - Chi square $\chi^2 = 2.440$ P value = 0.295 (NS)

3.3 Type of fissure in ano

87 (52.7%) patients had chronic fissure-in-ano, 48 (29.1%) patients had acute fissure-in-ano, and 30 (18.2%) had acute on chronic fissure-in-ano. It is highly statistically significant. Majority of males had chronic fissure in ano 47 (54.6%), majority of females 40 (50.6%) had chronic fissure in ano

Test used - Chi square $\chi^2 = 18.396$ P value = 0.000 (S)

Fig 3: Type of fissure in ano

Table 3: Gender and type of fissure in ano

TYPE OF FISSURE	MALE	FEMALE	TOTAL
ACUTE ON CHRONIC % Within group	12 14.0%	18 22.8%	30 18.2%
ACUTE % Within group	27 31.4%	21 26.6%	48 29.1%
CHRONIC % Within group	47 54.6%	40 50.6%	87 52.7%
TOTAL % Within group	86 100.0%	79 100.0%	165 100.0%

3.4 Symptomatology of fissure in ano

In our study, 151 (91.5%) of the patients presented with pain on defecation, 103 (62.4%) of the patients presented with constipation, 68 (41.2%) of the patients presented with burning sensation, 74 (44.8%) of the patients presented with bleeding per rectum, 36 (21.8%) of the patients presented with sentinel pile.

Fig 4: Symptomatology of fissure in ano

3.5 Complications of the treatment

In our study, out of 134 patients healed with conservative 2% Diltiazem and 2% lignocaine gel, 5 patients (3.7%) had pruritis. out of 31 patients treated with operative Lateral internal sphincterotomy, 2 patients (6.4%) had pruritis and 1 patient (3.2%) had recurrence. Results are near significant.

Table 4: Complications of the treatment

Symptom	Number of the patients	Percentage	Treatment
Pruritis	5	3.7%	Conservative
Pruritis	2	6.4%	Operative
Recurrence	1	3.2%	Operative

Test used - Chi square $\chi^2 = 7.087$ P value = 0.08 (Near significant)

3.6 Time taken for fissure to heal

Mean time taken for fissure to heal with conservative management was 5.26 weeks and those who didn't get healed were subjected to operative management and the mean healing time with surgery was 3.41 weeks and is highly statistically significant.

Table 5: Time taken for fissure to heal

Group	N	Mean	Std. deviation	Std. error mean
Conservative	134	5.26	0.848	0.073
Operative	31	3.41	0.564	0.101

Test used - Independent T test mean difference - 1.841 p value - 0.000 (S)

Fig 5: Time taken for fissure to heal

4. Discussion

Anal fissure is a common problem across the globe. It causes considerable amount of morbidity and adversely affects the quality of life. Therefore appropriate treatment is mandatory for this condition. The most effective way of reducing internal anal sphincter tone is surgery. Lateral internal sphincterotomy is the golden standard in the treatment of anal fissures which involves partial division of the internal anal sphincter away from the fissure. Calcium channel blockers have been shown to lower resting anal pressure and promote fissure healing and hence chemical sphincterotomy is now the first line of treatment in many centers [5]. Conventionally it has been stated that Mechanical trauma due to defecation is the cause of Fissure in ano, along with constipation history. It is estimated that anal fissure is 5 times more likely to develop with chronic constipation [6]. Several pharmacologic approaches have been introduced, including topical nitric oxide donors (e.g., nitroglycerin), calcium channel blockers (e.g., diltiazem, nifedipine), and botulinum injections [7].

As medical therapies evolved, it was assumed that all patients should be treated first with conservative medical treatment to avoid the risk of long-term fecal incontinence. However, this concept has been challenged by several prospective randomized trials comparing lateral internal sphincterotomy with medical therapies, including topical approaches like diltiazem and lignocaine local application. Regarding laxatives prescribed for treatment, Polyethylene glycol is better than lactulose in outcomes of stool frequency per week, form of stool, relief of abdominal pain and the need for additional products. Polyethylene Glycol should be used in preference to Lactulose in the treatment of Chronic Constipation [8].

In this study the commonest age group affected was 31-40 years age group 61 (37.0%) and least affected were above 60 years age group 16 (9.7%). It is in accordance with following studies, According to Goligher JC (1984) the disease is usually encountered in young or middle aged adults. In Udwadia TE series maximum incidence was seen in 31-40 years age group [9]. The incidence of fissure in males (52.1%) was slightly greater than females (47.9%). It is supported by following studies. In study by Giridhar CM *et al.* 2014 [10] incidence in males was higher than females. In our study posterior midline fissure (67.9%) was more common than anterior midline fissure. It has been observed that posterior fissure is more common in both sexes. Sasikumar *et al.* reported posterior fissure to be common than anterior fissure. This was also confirmed by study from Boulous PB and Araujo JGC which says posterior fissure (85.7%) is more common than anterior fissure (14.2%).

In our study 134 (81.2%) out of 165 patients got healed with 2% Diltiazem gel. I is in accordance with Study conducted by Knight JS *et al.* (2001) reported a healing rate of 75% after 8-12 weeks treatment with 2% Diltiazem gel. Shrivastava UK (2007) reported a healing rate of 80% with Diltiazem gel usage for 12 weeks. In a study conducted by Nash GF *et al.* 112 patients were treated with 2% Diltiazem gel for 6 weeks and were followed up over period of 2 years. The success rate and satisfaction with topical Diltiazem were over two thirds. Nearly 80% of patients had no adverse effects, and it seems that those complaints due to Diltiazem rarely led to reduced compliance [11].

31 patients whose fissures did not heal after 6 weeks of conservative therapy underwent internal sphincterotomy and fissure healed in 4 weeks. In internal sphincterotomy group, fissure healed in 30 out of 31 patients. Mean duration required for healing was 3.41 weeks. In our study 31 (100%) patients out of 31 undergoing internal sphincterotomy were free from pain

and 2 patients had pruritis on follow up. Our study shows a healing rate of 96.7% after internal sphincterotomy. It is in accordance with Study by Adriano Tocchhi *et al.* (2004) reported a healing rate of 100% with internal sphincterotomy at the end of post sphincterotomy review of 6 weeks ^[12].

5. Conclusion

The conclusion from this study is that, though internal sphincterotomy is the current standard treatment, many anal fissures heal with conservative management with Topical 2% Diltiazem, 2% lignocaine, oral laxatives and thus can be considered as the first line of treatment for fissure in ano. Side effects with Diltiazem gel are minimal. When compared with surgical treatment, chemical sphincterotomy with Diltiazem is reversible and therefore have lesser side effects on continence. Though fissure healing rate is comparatively slower with Diltiazem, patients can be avoided from the trauma caused by surgery. Hospital stay is not required. Treatment with chemical sphincterotomy is cost effective and the surgical management of Lateral subcutaneous sphincterotomy can be considered for the patients not responding to the conservative management. It is always important that physician should select a medical or surgical approach that seems applicable to the presenting symptoms and tailor it accordingly.

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