

# A Quazi-Experimental Study to Compare Outcome between Lateral Sphincterotomy, Topical 2% Diltiazem and Topical 0.2% Nitro-Glycerine in the Management of Chronic Anal Fissure

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**Abstract:** *Though fissures had traditionally been treated surgically, developments in the pharmacological understanding of the internal anal sphincter have resulted in more conservative approaches towards treatment. The objective was to compare the efficacy of topical 2% Diltiazem gel, 0.2% Nitroglycerine ointment and lateral internal sphincterotomy in the treatment of chronic fissure in ano. 60 patients with chronic fissure in ano were divided into Diltiazem gel, Nitroglycerine ointment and internal sphincterotomy groups with each group containing 20 patients each. Fissure was completely healed in 16 (80%) out of 20 patients treated with 2% Diltiazem gel and 0.2% Nitroglycerine ointment between 4-8 weeks. Healing was 100% with internal sphincterotomy. 95% patients were free from pain after treatment with Diltiazem gel, 90% patients were free from pain after treatment with Nitroglycerine ointment whereas 100% patients were free from pain after treatment with lateral sphincterotomy. Topical Diltiazem can be established as the initial treatment in chronic fissure in ano. Lateral sphincterotomy should be reserved for patients with relapse and therapeutic failure to prior pharmacological treatment.*

**Keywords:** Anal Fissure, Diltiazem, Nitroglycerine, Internal sphincterotomy

## 1. Introduction

Painful ulcer in the squamous epithelium of anus is called as anal fissure(1)(2)(3). These ulcers are usually located in the posterior midline of the skin just outside the entry of rectum(2). They are associated with pain and bleeding(4). The pain usually occurs during defecation and sometimes remains for two hours after that(1).

Anal fissure is known as Acute type; mostly relieving in one week and chronic; usually lasting for more than 6 weeks, having a hypertrophic papilla of the fissure and a sentinel tubercle and exposure of sphincter muscle fibers on the floor of the wound(5). Anal fissures could be typical and atypical(4). Atypical fissures could be multiple, away from the midline, large and irregular. Many diseases were found to cause these atypical anal fissures like inflammatory bowel disease, local or systemic malignancy, venereal infection, trauma, tuberculosis, or chemotherapy(1).

The cause of typical or benign fissure is still not clear(2). Schouten WR et al in his study to find out the relationship between anal pressure and anodermal blood flow reported that anal fissure ulcers were ischemic ulcers. He reported that the blood supply is significantly lower at the posterior midline than at the other sides of the anal canal. He also reported that the anodermal blood pressure at the posterior midline were related to anal pressure and both are inversely proportional(6). The most common

associated pathology in case of anal fissures was documented to be the spasm of the internal anal sphincter (2).

The ultimate aim of management of anal fissures was the relief of the spasm. Relieving the spasm was followed by relief of pain and healing of the ulcers without recurrence(2). Most commonly the relief of spasm is achieved by means of surgery. Operative techniques commonly used for fissure in ano include: anal stretch, open lateral sphincterotomy, closed lateral sphincterotomy, posterior midline sphincterotomy and to a lesser extent dermal flap coverage of the fissure(7).

The last decade had seen a number of changes in the management of chronic anal fissure. As a non invasive procedure and not damaging the anal sphincter, medical management is now presumed to be the first option. Mostly used medications are diltiazem, nitric oxide derivatives, and botulinum toxin injections. Still surgical treatment is the gold standard method of choice(5). Nitroglycerin is converted into nitric oxide (NO) within the body. The NO causes relaxation of the internal anal sphincter muscle(4). The objective of the study was to compare the efficacy of diltiazem and nitroglycerin topical ointments with surgical lateral sphincterotomy. Similar studies have never been conducted in the study area before.

## 2. Material and Methods

The present study was a quazi experimental study where three

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interventions against chronic anal fissure namely, Topical 2% Diltiazem gel, topical 0.2% nitroglycerine ointment and lateral sphincterotomy were compared. The study was conducted in the department of general surgery, Government Mohan Kumaramangalam medical College, a tertiary care centre located in the district of salem, Tamilnadu, India.

All the patients admitted to the department with the diagnosis of chronic anal fissure were the study population for the present study. The study was conducted between June 2017 to April 2019. All the cases of chronic anal fissure for more than 6 weeks and anal fissure associated with sentinel pile were included into the study, while the patients with secondary fissures, fissures complicated with fistula and anal stenosis, patient with history of previous anorectal surgeries, patients with co-morbid conditions like diabetes mellitus, malignancies, history of long steroid therapies were excluded from the study.

Sixty patients were included as study participants for the present study. The study participants were then randomly divided into three arms each consisted of 20 study participants, respectively. The arm A,B,C were intervened with 2% Diltiazem gel, 0.2% nitroglycerine ointment and lateral sphincterotomy, respectively. Informed consent was obtained from all the study participants included in the study.

A pretested semi-structured questionnaire was used for collecting the data. For the two groups receiving 2% Diltiazem gel and 0.2% nitroglycerine ointment respectively, the following instructions were provided. The participants were instructed to apply the gel at least 1.5 cms into the anus. They were asked to continue the application twice daily for four weeks. They were also advised to wash hands before and after the application of the medication. They were also advised to take sitz bath thrice daily. They were also provided with oral antibiotics (Tab. Amoxicillin 500 mg twice daily, Tab. Metronidazole 400 mg thrice daily) for the first week along with high fibre diet and adequate hydration. Since the above treatments were provided as domiciliary treatment and

were followed in OPD every 2nd, 4th, 6th and 8th week.

Group C was admitted to ward and routine blood investigations with ECG and Chest X ray done. Open lateral Sphincterotomy was carried out under spinal anaesthesia. The participants were kept nil oral post operatively till the evening on the day of surgery. Liquid diet was started later followed by soft solid diet the 2nd post operative day. All the patients were given antibiotics, analgesics and laxatives like liquid paraffin 10 ml HS for one week and started on sitz bath thrice daily. Post operative assessment of pain relief, bleeding, seroma formation was done. Digital examination was done to assess the tone of anal spinchter. Patients were discharged between the 3rd and 7th post operative day. Followed up on 2nd, 4th,6th and 8th weeks in OPD.

### 3. Results

All the three arms were similar with respect to age, sex and symptoms like pre-operative pain, bleeding and constipation. All the study participants reported to have pre-operative pain. In NTG group 100% reported to have bleeding while in the diltiazem and lateral sphincterotomy group, 80% reported to have bleeding respectively. Similar pattern to bleeding was found with the presence of constipation. (Table 1). Most of the fissures were found to be posterior in nature. 19 (95%) of the fissures in each group was found to be in the posterior wall (fig 1).

None reported post procedure pain in the lateral sphincterotomy group. One person (5%) reported pain in the 2% Diltiazem group and 2 (10%) reported post procedure pain in the 0.2% nitroglycerine group. 4 (20%) reported to have headache in the post procedure period in the nitroglycerine group while none reported to have headache in the other two groups. Healing was present in all the study participants belonged to the lateral sphincterotomy group and 80% in the rest of the groups, respectively (table 3).

**Table 1:** Baseline characteristics of the study participants

Variable		2% Diltiazem group		0.2% Nitroglycerin ointment		Lateral Sphincterotomy		P-value
		N	%	N	%	N	%	
Age ( in years)	≤25	3	15	1	5	3	15	>0.05
	26-35	4	20	7	35	8	40	
	36-45	6	30	8	40	6	30	
	46-55	3	15	3	15	3	15	
	>55	4	20	1	5	0	0	
Sex	Female	5	25	6	30	3	15	>0.05
	Male	15	75	14	70	17	85	
Pain	Present	20	100	20	100	20	100	>0.05
Bleeding	Present	16	80	20	100	16	80	>0.05
Constipation	Present	16	80	20	100	17	85	>0.05

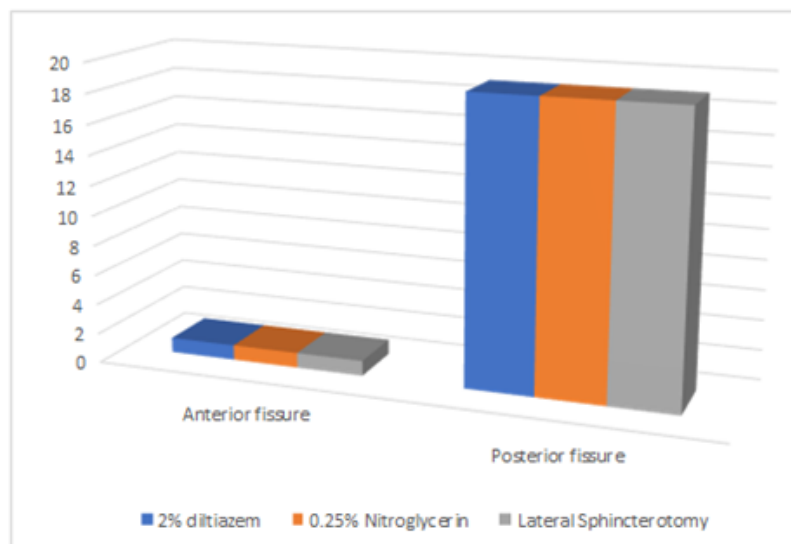


Figure 1: Distribution of study participants according to position of fissure

Table 3: Comparison of Outcome variables of the study

Variable		2% Diltiazem group		0.2% Nitroglycerin ointment		Lateral Sphincterotomy		P-value
		N	%	N	%	N	%	
Post procedure Pain	Present	1	5	2	10	0	0	>0.05
Headache	Present	0	0	4	20%	0	0	
Healing	Present	16	80	16	80	20	100	>0.05

## 4. Discussion

The present study was quazi experimental study done to compare three treatment modalities of chronic anal fissure namely 2% diltiazem gel, 0.2% nitro-glycerine ointment and lateral sphincterotomy. The three outcome variables namely post procedure pain, headache and healing were compared between the groups.

### Baseline characteristics

The baseline characteristics of all the study groups with respect to distribution of sociodemographic characters like age and sex were found to be similar. The distribution of symptoms like pain, bleeding and constipation were also indifferent between the groups. In all the groups, 19 persons had fissure in the posterior wall and one person in the anterior wall respectively. With respect to the above characteristics all the three groups were found to be similar before the start of the intervention. The above feature adds up as strength to the present interventional study.

### Post procedure pain

With respect to the post procedure pain, none in the surgical treatment group reported any pain. In the medical treatment group, one person (5%) from the diltiazem treated group and 2 (10%) from the nitroglycerine treated group reported post procedure pain. Similar results were obtained by Motie MR and Hashemi P in their study. They reported that there was significant difference in pain response between the surgical treatment group, when compared to the medical treatment group(5).

### Headache

In the present study, 4 (20%) from the group treated with nitroglycerin reported headache, while no one from the other groups reported so. Kocher et al reported that more side effects were found in the GTN group when compared to the diltiazem group. Headache was found to occur twice in the GTN treatment group when compared to the diltiazem treatment group(8). Similar results were also reported by Tauro et al who reported 20% among the GTN intervention group to have headache(9).

### Healing

In the present study 100% healing was obtained in the surgical treatment group while in the medical treatment group the healing was found to be 80%. With the medical treatment groups, the healing rate was found to be similar. Tauro et al in his study reported that the healing of the ulcer was similar between the Nitoglycerine and the Diltiazem group(9).

## 5. Conclusion

The conclusion from this study is though lateral sphincterotomy is the current standard treatment, many chronic anal fissures heal with topical 2 % Diltiazem gel therapy and topical 0.2% Nitroglycerine ointment therapy. In contrast with surgery, chemical sphincterotomy is reversible and therefore unlikely to have adverse effects on continence. Patients who are hypertensive, diabetic and medically unfit for surgery can be recommended for chemical sphincterotomy. Hospital stay is not required. Treatment works out to be cost effective. Though topical Diltiazem and

topical Nitroglycerine have the same healing rates in this study, Diltiazem has a better patient compliance with headache an important side effect of Nitroglycerine. Topical 2% Diltiazem can be established as the first option of treatment for chronic anal fissure. Lateral sphincterotomy should be offered to patients with relapse and therapeutic failure of prior pharmacological treatment.

## Reference

- [1]. Nelson R. A Systematic Review of Medical Therapy for Anal Fissure. *Dis Colon Rectum*. 2004;47(4):422–31.
- [2] Nelson RL, Thomas K, Morgan J, Jones A. Non surgical therapy for anal fissure. *Cochrane Database Syst Rev*. 2012;(4).
- [3] Utzig MJ, Kroesen AJ, Buhr HJ. Concepts in pathogenesis and treatment of chronic anal fissure - A review of the literature. *Am J Gastroenterol*. 2003;98(5):968–74.
- [4] Bailey HR, Beck DE, Billingham RP, Binderow SR, Gottesman L, Hull TL, et al. A study to determine the nitroglycerin ointment dose and dosing interval that best promote the healing of chronic anal fissures. *Dis Colon Rectum*. 2002;45(9):1192–9.
- [5] Motie MR, Hashemi P. Chronic anal fissure: Medical treatment versus surgical sphincterotomy; a comparison study. *Acta Med Iran*. 2016;54(7):437–40.
- [6] Schouten WR, Briel JW, Auwerda JJA. Relationship between anal pressure and anodermal blood flow - The vascular pathogenesis of anal fissures. *Dis Colon Rectum*. 1994;37(7):664–9.
- [7] Nelson RL, Chattopadhyay A, Brooks W, Platt I, Paavana T, Earl S. Operative procedures for fissure in ano. *Cochrane Database Syst Rev*. 2011;2017(12).
- [8] Kocher HM, Steward M, Leather AJM, Cullen PT. Kocher HM, Steward M, Leather AJM, Cullen PT. Randomized clinical trial assessing the side effects of glyceryl trinitrate and diltiazem hydrochloride in the treatment of chronic anal fissure. *Br J Surg*. 2002; 89:413–417. 2002;413–7. Available from: [www.bjs.co.uk](http://www.bjs.co.uk)
- [9] Tauro LF, Shindhe V V., Aithala PS, Martis JJS, Shenoy HD. Comparative Study of Glyceryl Trinitrate Ointment Versus Surgical Management of Chronic Anal Fissure. *Indian J Surg*. 2011;73(4):268–77.

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