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## A Comparative Study of Effectivity Of Glyceryl Trinitrate Ointment Application With Lateral Internal Sphincterotomy In Chronic Fissure In Ano

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#### Abstract

**Introduction:** Anal fissures remains one of the main reasons for anal pain. Topical nitro-glycerine is the most preferred treatment in chronic anal fissure. Surgical procedures such as lateral internal sphincerotomy results in faster healing. This study aimed to compare the effectiveness of nitroglycerine and lateral internal sphincerotomy in the treatment of chronic fissure in ano.

**Materials and Methods**: A hospital based prospective study was done chronic fissure in ano patients admitted to Vinayaka missions' medical college and hospital, Salem. The study period was from February to September 2021. After getting ethical clearance informed consent was obtained from all the participants. A total of 40 patients were included in the study. Out of the 40 patients, 16 patients were administered with nitro-glycerine (NTG) topical application and 24 patients had surgical treatment by Lateral Internal Sphincterotomy (LIS). Follow up was done at 6 weeks and 6 months. The intensity of pain during defecation was assessed by using Visual Analogue Scale (VAS).

**Results:** The mean age group of the participants was 36.68 years. Females constitute 55% of the participants. At 6 weeks and 6 months the mean score of pain was comparatively more in the nitroglycerine group. When the two groups were checked for association with presence of bleeding, persistence of spasm and healing rates at 6 weeks and 6 months the difference between the groups was statistically significant (p value<0.05) which shows that persistence of bleeding, spasm and delayed healing was significantly more among subjects who were treated with nitro-glycerine (NTG).

**Conclusion:** Treatment with Nitro-glycerine has been found to provide less symptomatic relief when compared with Lateral Internal Sphincterotomy (LIS).

**Keywords**: LIS, NTG, Follow up, Chronic fissure in ano **Introduction** 

Anal fissures remains one of the main reason for anal pain. Pain that occurs immediately after defecation is the characteristic feature. Anatomically, an fissure is the longitudinal split that occurs in the anoderm in the anal canal that extends from anal verge at the proximal end but this split does not extend beyond dentate line.<sup>[1]</sup> Anal fissures generally occurs in midline when 90% of anal fissures are located posteriorly and 10% are located anteriorly. Chronic anal fissure is one in which the fissure extends for a period of more than 6 weeks.<sup>[2]</sup> There are two types of anal fissures - Primary which is mostly idiopathic and secondary. Causes of secondary anal fissure may be due to pathology such as Anal Tuberculosis and Crohn's disease.<sup>[3]</sup> It occurs in both sexes in equal incidence.<sup>[4]</sup> The common complaints of patients would be pain during and following defecation and passage of blood per anus which is bright red in colour. The symptoms have been found to be the cause for reduced quality of life.<sup>[5]</sup> Fissure usually occurs due to a trauma which occurs when hard stools are passed per anus. Patients with anal fissure most commonly have complaints of constipation. It is also seen in conditions such as childbirth and acute diarrhoea.<sup>[6]</sup> Anal fissures are mainly due to involuntary spasm of internal sphincter and high resting anal pressure.<sup>[7]</sup> Normally anal pressure is maintained at 80 - 160 mm Hg. When the pressure around the anal sphincter is reduced, it results in healing of sphincter by reduction of blood flow. Healing of anal fissures requires surgical and pharmacological measures.<sup>[8]</sup> Pharmacologically, the anal sphincter tone can be reduced by using calcium channel blockers and nitrates. Medical management of fissure is referred to as "chemical sphincerotomy". Nitric oxide is the most important non-adrenergic non-cholinergic neurotransmitter that relaxes the internal anal sphincter (NO). It can be either exogenous or endogeneous.Isosorbide dinitrate and Nitro-glycerine are both nitric oxide donors. The internal anal sphincter relaxes and the fissure heals as a result of these NO donors.<sup>[2]</sup> Topical nitro-glycerine is the most preferred treatment in chronic anal fissure.<sup>[9]</sup>Non surgical measures have been preferred by many but many studies has not shown it superior to surgical management.<sup>[10]</sup> Surgical procedures such as lateral internal sphincerotomy (LIS) results in faster healing but has the disadvantage of impaired anal continence. So it has been preferred as the first line of treatment.<sup>[11]</sup> Sphincerotomy requires theatre time, day care beds and significant minor side effects whereas nitroglycerine though safe is also found to be associated with side effects like headache. It was also found that LIS is superior to non-surgical measures. Calcium channel blockers though found to be associated with less side effects have not been proved effective. Other surgical methods like manual anal stretch also was not effective when compared to LIS.<sup>[12]</sup> The main aim of the study is to compare the

result of nitroglycerine versus lateral internal sphincterotomy. With this background this study has been done with the objective of comparing the effectiveness of nitro-glycerine and lateral internal sphincerotomy in the treatment of chronic fissure in ano.

#### **Materials and Methods:**

This is a hospital based prospective analytical study done among chronic fissure in ano patients admitted to Vinayaka missions' medical college and hospital, Salem. The study period was from February to September 2021. Ethical clearance was obtained from the Institutional Ethics committee. Informed consent to participate in the study was obtained from all the participants. A total of 40 patients were included in the study. Sociodemographic information such as age, sex and socioeconomic status, details about the presenting complaints and per rectal examination was done. Later theraphy was initiated. Out of the 40 patients, 16 patients were administered with nitroglycerine (NTG) topical application and 24 patients had surgical treatment by Lateral Internal Sphincterotomy (LIS). Follow up was done at 6 weeks and 6 months. The intensity of pain during defecation was assessed by using Visual Analogue Scale (VAS). In the scale of 0 to 10, in which 10 indicates most severe pain and 0 indicates no pain. Categorical variables were expressed in frequency and percentages. Continuous variables are expressed in mean and standard deviation. When association is computed for a categorical variable with categorical variable, chi square test is used for checking significance. Fischer's exact test is used when more than 20% of the cell values have expected values less than 5. p value < 0.05 were considered statistically significant. Data was entered in MS Excel sheet and analysed using IBM SPSS software version 16.

#### **Results:**

The age and sex distribution of the participants has been given in table 1. The duration of the presenting complaint was enquired. The duration of complaint for the two groups has been given in table 2. The patients were asked for complaints like constipation, bleeding, pain and spasm. All the patients in both the groups have the four complaints. Then per rectal examination was done to find out the position of fissure and presence of skin tag. Skin tag was present in all the patients. Of the total subjects, 18.8% and

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81.3% had fissure in the anterior and posterior position respectively whereas 8.3% and 91.7% of the participants in the nitroglycerine group had fissure in the anterior and posterior position respectively. This has been depicted in figure 1. The patients were followed up for both 6 weeks and 6 months. At six weeks the mean score of pain was comparatively more in the nitroglycerine group. The patients in the LIS group had no persistence of spasm and bleeding. All the participants in the LIS group had complete healing. This has been depicted in table 3. When the two groups were checked for association with presence of bleeding, persistence of spasm and healing rates at 6 weeks, the difference between the groups was statistically significant (p value<0.05). This has been given in table 4. At six months the mean score of pain was comparatively more in the nitroglycerine group whereas none of the participants in the LIS group had complaints of pain. Some of the participants (62.5%) had persistence of spasm. Persistence of bleeding and problems with healing was present in 37.5% and 75% of the participants respectively. This has been depicted in table 5. When the two groups were checked for association with presence of bleeding, persistence of spasm and healing rates at 6 months the difference between the groups was statistically significant (p value<0.05) which shows that persistence of bleeding, spasm and delayed healing was significantly more among subjects who were treated with nitro-glycerine (NTG). This has been given in table 6. There were no side effects experienced by the subjects in group which underwent lateral internal sphincerotomy.

#### **Discussion:**

The mean age group of the participants was 36.68 years with standard deviation of 8.12. Females constitute 55% of the participants. The persistence of bleeding, spasm and delayed healing after theraphy was significantly more among subjects who were treated with nitro-glycerine (NTG). In a study done by Buddha et al<sup>[3]</sup>done among 60 individuals, divided into 30 in two groups, group 1 being treated with 0.2% glyceryl trinitrate and group 2 being treated with lateral sphincterotomy.Mean age of occurrence is 34.92 years. Painful defecation was the most common symptom.90% of patients treated with 0.2% glyceryl trinitrate healed completely between 4 to 8 weeks and 10% experienced mild headache and local irritation whereas all the patients treated with lateral

of the patients in group 2. In our study there were no post operative side effects experienced by the subjects. In a study among 60 patients by Garikaparti et al<sup>[4]</sup> divided into two groups of 30, 60% of the patients in group treated with medical management (topical glyceryl trinate) had relief of symptoms whereas 90% of the patients treated with surgical management had healing of fissure. Among the 60 participants, the major predisposing factor was constipation. The findings is similar to our study where all the participants had constipation and the healing rates was comparatively higher in the group which underwent LIS. In a study by Bansal et  $al^{[2]}$ done among 50 patients divided into two groups equally. Group A had 0.2 percent glyceryl trinitrate treatment, whereas Group B received lateral internal sphincterotomy. The discomfort level during defecation was measured using the Visual Analogue Scale (VAS). On a scale of 0 to 10, 10 represents the most intense pain. Before therapy, the mean pain score in both groups was 8.64 0.95 in group A and 8.44 1.19 in group B. After 6 weeks of treatment, the mean pain score in group A was 1.64 2.43, while in group B it was 0.24 1.20. It was also discovered that patients treated surgically experienced total pain alleviation, with a statistically significant difference between the two groups. Only 4% of patients in group B developed a mild haematoma in the perianal area, whereas 36% of patients in group A had a headache. Incontinence was not a problem for any of the patients in either group. In our study, the mean pain score of the participants in the NTG group was comparatively higher at 6 weeks. In a study by Evans et al<sup>[13]</sup>done among 60 individuals, only 60.6% of patients treated with glyceryl trinitrate had healed fissures in eight weeks compared to 97 percent in the lateral sphincerotomy group. The difference between the two groups was statistically significant (P value < 0.01). The reason for delay in healing with glyceryl trinitrate treatment has been attributed to poor compliance and adherence. Our findings was also similar to the study done by Subramaniam et al<sup>[14]</sup>in which recovery was faster in the surgical group when compared with the medical management group. In a multicentre randomized controlled trial by Richard et

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sphincerotomy had complete resolution at the end of

4 weeks and 33.33% of the patients experienced post

operative pain and transient incontinence. Recurrence

was seen in 10% of the patients in group 1 and none

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al<sup>[15]</sup>, done among 82 patients, follow up was done at 6 weeks and 6 months. At 6 weeks, 89.5% in the internal sphincerotomy group had complete healing when compared to 29.5% in the nitro-glycerine group. At 6 months, 92.1% in the internal sphincerotomy group had complete healing when compared to 27.2% in the nitro-glycerine group. It was also found that 28.9% in the internal sphincerotomy group had side effects when compared with 84% in the nitro-glycerine group and the difference between the two groups was statistically significant. Side effects like headache or a syncopal attack was seen in 20.5% of the patients in the nitro glycerine group. In our study, 33.4% of the patients had complaints of headache.

#### **Conclusion:**

Treatment with Nitro-glycerine has been found to provide less symptomatic relief when compared with Lateral Internal Sphincerotomy (LIS). However, the use of nitroglycerine in acute conditions will be useful to prevent chronicity. Even though nitroglycerine medications has been found to have side effects, often they are minor and can be treated with simple medications.

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Glyceryl trinitrate group				
	Males	Females		
< 25 years	1	0		
26 – 29 years	3	0		
30 – 34 years	2	1		
35 – 39 years	2	3		
40 – 44 years	1	1		
> 44 years	1	1		
Lateral Internal S	Sphincterotomy			
< 25 years	3	0		
26 – 29 years	2	0		
30 – 34 years	3	2		
35 – 39 years	2	1		
40 – 44 years	0	5		
> 44 years	2	4		

 Table 1: Age and sex distribution of patients in both treatment arms

Table 2: Duration of the complaints among the patients in both treatment arms

	Nitro-glycerine	Lateral internal sphincterotomy
Duration		
3 months	8	6
3.5 months	7	6
4 months	8	3
4.5 months	1	1

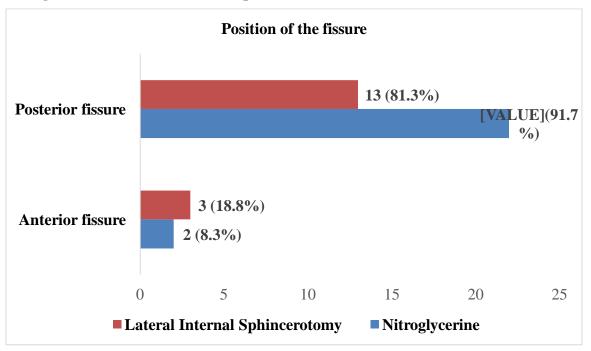


Fig 1: Position of the fissure on per rectal examination in both treatment arms

Table 3: Six week follow up visit in both treatment arms

Treatment arm	Pain score (1-10)	Persistence of spasm	Bleeding	No healing
Nitro-glycerine (n=24)	5.83 ± 2.3	19 (79.2%)	9 (37.5%)	10 (41.7%)
Lateral Internal Sphincterotomy (n=16)	1.19 ± 2.5	0	0	0

Table 4: Association of bleeding, persistence of spasm and healing rates at 6 weeks between both
treatment arms

Characteristics	NTG Group	LIS Group	Table value	P value
Persistence of bleeding				
Yes	9 (100%)	0	7.742	0.005**
No	15 (48.4%)	16 (51.6%)	-	
Persistence of spasm			I	
Absent	5 (23.8%)	16 (76.2%)	24.127	<0.001*

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Decreased	19 (100%)	0		
Healing rates				
Yes	14 (46.7%)	16 (53.3%)	8.889	0.003**
No	10 (100%)	0	-	

#### \*-Chi square test

\*\*-Fischer exact test

#### Table 5: Six month follow up visit in both treatment arms

Treatment arm	Pain score (1-10)	Persistence of spasm	Bleeding	No healing
Nitro-glycerine (n=24)	3.25 ± 2.1	15 (62.5%)	9 (37.5%)	18 (75%)
Lateral Internal Sphincterotomy (n=16)	0	0	0	0

# Table 6: Association of bleeding, persistence of spasm and healing rates at 6 months between both treatment arms

Characteristics	NTG Group	LIS Group	Table value	P value
Persistence of spasm				
Absent	9 (36%)	16 (64%)	16.000	<0.001*
Decreased	15 (100%)	0		
Healing rates				
Yes	6 (27.3%)	16 (72.7%)	21.818	0.001*
No	18 (100%)	0		

\*-Chi square test

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Side effects **6** (66.6%) **6** Headache **•** No side effects

