GRADIVA

Volume 64 | Issue 03 | March 2025
DOI: 10.5281/zenodo.14988591

Comparative Study for Comparison between Topical Glyceryl Trinitrate (0.25%) and Lateral Anal Sphincterotomy for Fissure in Ano

Dr. K. Nithya[1], Dr. G. Gopinath[2], Dr. K. Anbarasu[3] & Dr. P. Sivabalan[4]

1,2. Assistant Professor, Department of General Surgery,
Government Thiruvarur Medical College and Hospital.
Email: [1]nithyammc7@gmail.com, [2]drgopigopal@gmail.com
3. Junior Resident, Department of General Surgery,
Government Thiruvarur Medical College and Hospital.
Email: anbarasubadboy@gmail.com
4. Associate Professor, Department of General Surgery,
Government Thiruvarur Medical College and Hospital.

Abstract

Introduction: Anal fissures are small tears in the anal canal often treated with topical glyceryl trinitrate (GTN) or lateral internal sphincterotomy (LIS). While GTN promotes healing by relaxing the sphincter, LIS is more effective in chronic cases, reducing pressure and improving blood flow to the fissure. This study aimed to compare the efficacy of topical glyceryl trinitrate with that of lateral anal sphincterotomy for anal fissures. **Methods:** This randomised controlled trial was conducted on 48 patients at the Government Thiruvarur Medical College and Hospital over 12 months. All patients aged > 18 years who presented with anal fissures in the General Surgery and TAEI ward at the Thiruvarur Medical College and Hospital were included in this study. Significance was defined as P values less than 0.05 using a two-tailed test. **Results:** The age distribution between the groups showed no significant difference ($p = 0.553$), with most patients aged 36-45 years in both groups A (33.3%) and B (33.3%). Gender distribution was also similar ($p = 0.386$), with Group A having 45.8% females compared to 58.3% in Group B. Bleeding incidence was high in both groups (83.3% in Group A, 79.2% in Group B, $p = 0.712$), and constipation was slightly more prevalent in Group A (83.3% vs. 70.8%, $p = 0.303$). Pain relief was significantly better in Group B, with lower VAS scores at 1 week (3.54 vs. 5.88, $p < 0.0001$) and 6 weeks (0.96 vs. 2.58, $p < 0.0001$). Delayed healing and headache were more common in Group A differences were not statistically significant ($p = 0.074$). **Conclusion:** Lateral anal sphincterotomy is more effective than topical Glyceryl Trinitrate in treating chronic anal fissures, offering faster healing and greater pain relief. Although Glyceryl Trinitrate is a valid non-surgical option, its effectiveness may be hindered by delayed healing and side effects such as headaches, making sphincterotomy the preferred treatment for severe cases.

Keywords: *Lateral Internal Sphincterotomy, Anal Fissures, Glyceryl Trinitrate, Bleeding, Anal Sphincter.*

INTRODUCTION

The anal canal, a terminal passage of the rectum, is lined with mucosa prone to injury. Anal fissures, small mucosal tears, are common but often misdiagnosed as hemorrhoids. They typically result from trauma due to hard or frequent bowel movements and are prevalent across all age groups, especially in younger, healthy adults.

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DOI: 10.5281/zenodo.14988591

Increased anal sphincter tone is a key risk factor, while less common causes include inflammatory bowel disease, infections, trauma, and tumors. Symptoms primarily include sharp pain and minor rectal bleeding, often exacerbated during or after defecation. While most fissures are acute and resolve with dietary adjustments, chronic fissures persist beyond six weeks despite conservative measures.

Chronic fissures often require intervention. Historically, lateral internal sphincterotomy (LIS) has been the gold standard, achieving healing in over 90% of cases by reducing anal pressure and improving blood flow. However, LIS carries a 30% risk of incontinence. Manual dilation, although effective in pressure reduction, can cause external sphincter injuries. Chemical sphincterotomy using agents like glyceryl trinitrate (GTN), botulinum toxin, and calcium channel blockers offers a non-surgical alternative by relaxing the sphincter and promoting mucosal healing.

Topical GTN (0.25%) is effective in reducing anal sphincter tone via nitric oxide-mediated relaxation, enhancing blood flow and facilitating healing. It also alleviates pain during bowel movements. However, its efficacy may be hindered by tachyphylaxis, short duration of action, or patient-specific resistance to GTN's relaxant effects. Conversely, LIS involves a partial sphincter incision to lower resting pressure and improve fissure healing. It is highly effective, reducing anal pressure by up to 50% and promoting long-term fissure resolution. This study aims to compare the efficacy of topical GTN (0.25%) and LIS in managing chronic anal fissures through a randomized controlled trial. By analyzing healing rates, symptom relief, and complications, we seek to determine the optimal therapeutic approach. The findings will offer critical insights into the relative benefits of non-surgical versus surgical interventions, guiding clinical decisions for chronic anal fissure management and improving patient outcomes.

Aims and Objectives

AIM: To compare the two treatment modalities available for anal fissures.

OBJECTIVES: To compare the efficacy of topical glyceryl trinitrate vs lateral anal sphincterotomy

METHODOLOGY

Study Design and Setting:

This was a comparative study conducted at Government Thiruvarur Medical College and Hospital over a 12-month period. The study focused on patients admitted with anal fissures to the General Surgery ward.

Study Population and Sample Size:

The study included 48 patients. Participants were aged over 18 years and presented with anal fissures in the General Surgery and TAEI wards.

Inclusion and Exclusion Criteria:

Inclusion criteria:

- All patients presenting with anal fissures at the General Surgery and TAEI wards.
- Patients aged >18 years.

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Exclusion criteria:

- Patients with anal fissures due to inflammatory bowel diseases, tuberculosis, malignancy, or sexually transmitted diseases.
- Patients with associated hemorrhoids, fistula, pregnancy, lactation, or significant cardiovascular conditions.
- Patients with systemic diseases (e.g., congestive cardiac failure, chronic obstructive pulmonary disease, chronic kidney disease, cerebrovascular accident, diabetes mellitus, hypothyroidism).
- Patients unwilling to participate in the study.

Randomization and Intervention:

Eligible participants were randomly assigned into two groups using a computer-generated randomization list:

- Group A (Topical Glyceryl Trinitrate [0.25%]): Patients applied the ointment twice daily for six weeks. Instructions on proper application techniques and adherence to treatment were provided.
- Group B (Lateral Anal Sphincterotomy): Patients underwent lateral internal sphincterotomy under general or local anesthesia, depending on clinical judgment. Postoperative care included pain management and wound care instructions.

Data Collection:

Demographic variables such as age and gender were collected. Clinical symptoms were documented through patient reports and clinical examination, specifically noting the presence or absence of bleeding and constipation history. Symptom duration was recorded in weeks, and fissure location was classified as anterior, posterior, or lateral. Healing was assessed after six weeks and categorized as healed or not healed. Side effects were recorded based on patient-reported outcomes and clinical observations. Pain severity was measured using the Visual Analog Scale (VAS) at baseline and at 1, 2, and 6 weeks post-treatment, with scores ranging from 0 (no pain) to 10 (worst possible pain).

Ethical Considerations:

Ethical clearance for the study was obtained from the Institutional Ethical Committee of Government Thiruvarur Medical College and Hospital. Written informed consent was obtained from all participants prior to enrollment. Participants were informed about the study's purpose, procedures, potential risks, and benefits. Confidentiality of patient data was maintained throughout the study.

Statistical Analysis:

Data were analyzed using IBM-SPSS version 21.0 (IBM-SPSS Science Inc., Chicago, IL). Continuous variables were presented as mean and standard deviation, and categorical variables as frequencies and percentages. Independent sample t-tests were used to compare continuous variables between groups. The Mann-Whitney U test was applied for non-normally distributed data, and Pearson’s chi-square test was used to compare categorical variables. Statistical significance was defined as a P-value less than 0.05 using a two-tailed test.

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RESULTS

A randomized controlled trial compared the effectiveness of topical Glyceryl Trinitrate (0.25%) (Group A) and lateral anal sphincterotomy (Group B) in the treatment of fissures in ANO. The age distribution of the two groups showed no significant differences (p = 0.553). In Group A, 33.3% of the patients were under the age of 35 years, while in Group B, 20.8% fell into this age category. The majority of patients in both groups were aged between 36 and 45 years (33.3% in Group A and 33.3% in Group B). A similar proportion of patients were aged > 46 years in both groups (16.7%).

Table 1: Age Distribution of Patients in Group A (Glyceryl Trinitrate) and Group B (Sphincterotomy) (N=24)

		Comparison Group				P value
		Group A		Group B		
		Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	
Age	<35	8	33.3%	5	20.8%	0.553
	36-40	4	16.7%	8	33.3%	
	41-45	8	33.3%	7	29.2%	
	>46	4	16.7%	4	16.7%	

There was no significant difference between the two groups in age distribution (p = 0.553). In Group A, 33.3% of the patients belongs to age group less than 35 years and in Group B, 33.3% of patients belongs to 36-40 years.

Table 2: Gender Distribution of Patients in Group A (Glyceryl Trinitrate) and Group B (Sphincterotomy) (N=24)

		Comparison Group				P value
		Group A		Group B		
		Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	
Gender	Female	11	45.8%	14	58.3%	0.386
	Male	13	54.2%	10	41.7%	

There was no significant difference between the two groups in terms of sex distribution (p =0.386). In Group A, 45.8% of patients were female, compared to 58.3% in Group B. Male patients comprised 54.2% in Group A and 41.7% in Group B.

Table 3: Incidence of Bleeding from Fissure in Group A and Group B (N=24)

		Comparison Group				P value
		Group A		Group B		
		Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	
Bleeding from Fissure	Yes	20	83.3%	19	79.2%	0.712
	No	4	16.7%	5	20.8%	

The incidence of bleeding from the fissure was high in both the groups, with no significant difference (p = 0.712). In Group A, 83.3% of patients reported bleeding, while 79.2% of patients in Group B experienced the same symptoms.

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Table 4: Incidence of Constipation in Group A and Group B (N=24)

		Comparison Group				P value
		Group A		Group B		
		Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	
Constipation	Yes	20	83.3%	17	70.8%	0.303
	No	4	16.7%	7	29.2%	

Constipation was slightly more prevalent in Group A (83.3%) compared to Group B (70.8%), though this difference was not statistically significant (p = 0.303).

Table 5: Duration of Symptoms in Group A and Group B (N=24)

		Comparison Group				P value
		Group A		Group B		
		Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	
Duration of symptoms (weeks)	<10	8	33.3%	12	50.0%	0.344
	11-15	8	33.3%	8	33.3%	
	>16	8	33.3%	4	16.7%	

The duration of symptoms was similar between two groups (p = 0.344). In Group A, 33.3% of the patients had symptoms for <10 weeks, compared to 50.0% in Group B. An equal proportion (33.3%) of the patients in both groups had symptoms lasting 11-15 weeks.

Table 6: Location of Fissure in Group A and Group B (N=24)

		Comparison Group				P value
		Group A		Group B		
		Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	
Fissure's location	Anterior	4	16.7%	4	16.7%	0.835
	Both	1	4.2%	2	8.3%	
	Posterior	19	79.2%	18	75.0%	

The location of the fissures was predominantly posterior in both groups, with 79.2% in Group A 75.0% in Group B, showing no significant difference (p = 0.835).

Table 7: Incidence of Delayed Healing in Group A and Group B (N=24)

		Comparison Group				P value
		Group A		Group B		
		Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	
Delay in wound Healing	Yes	3	12.5%	0	0.0%	0.074
	No	21	87.5%	24	100.0%	

Delayed healing was observed in 12.5% of the patients in Group A whereas none of the patients in Group B experienced delayed healing. This difference was not statistically significant (p = 0.074).

Table 8: Incidence of Side Effects (Headache) in Group A and Group B (N=24)

		Group				P value
		Group A		Group B		
		Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	
Side effects	Headache	3	12.5%	0	0.0%	0.074
	No	21	87.5%	24	100.0%	

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Side effects, specifically headaches, were reported by 12.5% of patients in Group A, while none of the patients in Group B experienced this side effect, with no statistically significant difference ($p = 0.074$).

The visual analog scale (VAS) was used to assess pain relief at different time points. At baseline, patients in Group B reported higher mean pain scores (8.29) than those in Group A mean score of 7.71 ($p = 0.007$). However, Group B experienced a more rapid and significant reduction in pain than Group A. At 1 week, Group B had a mean VAS score of 3.54, which was significantly lower than Group A's mean score of 5.88 ($p < 0.0001$). By 2 weeks, Group B's mean VAS score had dropped further to 1.75, compared to 4.42 in Group A ($p < 0.0001$). At 6 weeks, Group B maintained a lower mean VAS score of 0.96, while Group A had a mean score of 2.58 ($p < 0.0001$).

DISCUSSION

Given that fissures in ANO cause severe discomfort and impact patients' quality of life, selecting an effective treatment that balances healing, pain relief, and safety is crucial. Topical glyceryl trinitrate works by relaxing the internal anal sphincter and improving blood flow to promote healing of chronic anal fissures. Topical glyceryl trinitrate reduces anal resting pressure and enhances blood flow, leading to high healing rates in fissures. [1-3] In contrast, lateral anal sphincterotomy involves the surgical cutting of a portion of the sphincter to reduce muscle tension and facilitate healing. [4] Fissure in ANO is a painful condition that significantly affects patients' quality of life, making effective treatment essential for reducing pain, promoting healing, and preventing recurrence. This study compared the two treatments by evaluating clinical parameters, healing rates, and patient-reported outcomes, offering a thorough assessment of their effectiveness and safety.

Age and Gender Distribution

The demographic profile of the study participants revealed that the majority of patients fell within the 36–45-year age group in both the treatment arms. The absence of a significant difference in age distribution between Group A (Glyceryl Trinitrate) and Group B (Lateral Anal Sphincterotomy) ($p = 0.553$) indicates that both groups were comparable at baseline in terms of age. Similarly, the gender distribution between the two groups did not differ significantly ($p = 0.386$). The inclusion of both male and female patients in substantial numbers enhances the generalizability of the findings of the study to the broader population of patients with fissures in ANO. Sabarisan and Prabudoss conducted a non-randomized control study and found that fissures in ANO were more common in males than females, with the highest incidence in the 41-50 age group. This condition is rare in both children and the elderly. [6] Tauro et al. [5] observed that most patients were aged between 20 and 40 years, with a mean age of 34.14 years. This age group appeared to have a higher predisposition to developing chronic anal fissures. Similarly, Christie [7] and Richard et al.[8] reported the mean ages of 35 and 34.7 years, respectively. Shah et al. reported a mean age of 30.48 ± 5.82 years among participants, with 61 (61.00%) males and 39 (39.00%) females. The mean duration of anal fissure was 10.69 ± 2.59 weeks. [9] Delays in presentation and diagnosis are primarily due to the nature of the disease, along with factors such as ignorance of the condition and the availability of effective treatments, which contribute to delay and chronicity. Previous studies have consistently shown that chronic anal fissures are most common in patients between the ages of 30 and 50, predominantly affecting males, aligning well with our study population.

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Clinical Characteristics

The clinical characteristics of the patients, including symptoms such as bleeding from the fissure and constipation, were also comparable between the two groups. In terms of bleeding, 83.3% of the patients in Group A 79.2% in Group B reported experiencing this symptom, with no significant difference ($p = 0.712$). Bleeding is a hallmark symptom of fissures in ANO, and its presence in the majority of patients confirms the clinical severity of the condition in this study population. Tauro et al. reported that bleeding control was observed in 83% of patients at 2 weeks, 96.6% at 6 weeks, and 100% at 12 weeks in the surgical group. The 0.2% Glyceryl Trinitrate group also showed positive results, with 76.6% at 2 weeks, 86.6% at 6 weeks, and 86.6% at 12 weeks. [5] Similarly, constipation was prevalent in both groups, affecting 83.3% of the patients in Group A 70.8% in Group B ($p = 0.303$). Constipation exacerbates fissures in ANO by increasing strain during defecation, thus worsening pain and delaying healing.

The comparable prevalence of these symptoms between the two groups ensured that any differences in outcomes could not be attributed to disparities in baseline symptomatology. Sabarisan et al. reported that most patients present with pain during defecation, with constipation being the leading predisposing factor. Most fissures were located in the posterior midline, and long-standing cases often exhibited a sentinel skin tag and hypertrophied papilla. [6] Palazzo et al. reported pain relief in 33%, 51%, and 62% of the patients at 2, 6, and 12 weeks, respectively. [10]

This pain relief was attributed to a reduction in the mean anal resting pressure. Consistent with findings by Tauro et al. and Sabarisan et al., bleeding and constipation were prevalent in the majority of patients, reflecting the clinical severity of the condition. The duration of symptoms was also comparable between the two groups, with a significant proportion of patients in both groups experiencing symptoms for > 10 weeks. This prolonged symptom duration highlights the chronic nature of fissures in ANO in the study population, and highlights the need for effective treatment strategies that can provide rapid pain relief and long-term healing.

Healing and Delayed Healing

Our study found that lateral anal sphincterotomy resulted in faster and more complete healing than Glyceryl Trinitrate, with no cases of delayed healing in Group B, compared to 12.5% of patients in Group A experiencing delayed healing. There was no significant difference in delayed healing between the groups ($p = 0.074$). Lateral anal sphincterotomy is a definitive procedure that directly addresses the pathophysiological basis of fissures in ANO and hypertonicity of the internal anal sphincter. By relieving sphincter pressure, sphincterotomy promotes blood flow to the fissure site, thus enhancing healing. [4,11]

In contrast, Glyceryl Trinitrate functions as a chemical sphincter relaxant,[12] but its effects are temporary and less targeted. The potential for delayed healing with Glyceryl Trinitrate may stem from incomplete or inconsistent relaxation of the sphincter, which may impede optimal blood flow and tissue repair. In a prospective, randomized trial, Evans found that 60.6% of patients treated with glyceryl trinitrate healed after eight weeks, compared to 97% in the lateral sphincterotomy group. Poor tolerance and compliance contributed to Glyceryl Trinitrate treatment failure, and fissures healed significantly faster after sphincterotomy.

Recurrence occurred in 45% of those healed with Glyceryl Trinitrate, while no long-term complications were observed with sphincterotomy. [13] Our study's findings of faster healing

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with LIS (0% delayed healing) versus GTN (12.5% delayed healing) are consistent with Evans' report of higher healing rates in the LIS group (97% vs. 60.6%).

Elshamy observed 30 patients over a 3-year follow-up period. Patients treated with lateral internal sphincterotomy had higher healing rates and more complications than those treated with glyceryl trinitrate. The study concluded that lateral sphincterotomy is a more effective treatment for chronic anal fissure, whereas glyceryl trinitrate proved to be significantly less effective for long-term outcomes.[14]

Mishra conducted a study in which Group 1 (topical glyceryl trinitrate 0.2%) achieved an 85% healing rate after 8 weeks, although 65% of the patients reported headaches. In Group 2 (internal sphincterotomy), the healing rate was 97.5%.[3] Tauro et al. demonstrated that the lateral internal sphincterotomy group had healing rates of 86.7% at six weeks and 100% at 12 weeks for chronic anal fissures.[5] Our study confirms that lateral sphincterotomy offers superior healing outcomes compared to glyceryl trinitrate, as previously demonstrated by Evans, Elshamy, and Mishra.

The temporary nature of GTN's sphincter relaxation may account for delayed healing in some patients, as also observed in other studies. Hassan et al. reported that the internal sphincterotomy group had a significantly higher healing rate than the glyceryl trinitrate group (77.78% vs. 51.11%, $p = 0.013$).[15] Similarly, Butt et al. found a 100% healing rate with internal sphincterotomy compared with 73.33% with glyceryl trinitrate ($p < 0.05$).[16]

Jan et al. also reported higher healing rates with internal sphincterotomy than with topical glyceryl trinitrate (85% vs. 74%; $p = 0.0001$).[17] Additionally, Paul et al. found that internal sphincterotomy had much higher healing rates (86.8% vs. 66.6% for glyceryl trinitrate). In terms of recurrence, two patients in the glyceryl trinitrate group experienced recurrence, while none in the internal sphincterotomy group experienced recurrence.[18] This finding contrasts with that of Qureshi et al., who reported no recurrence in either the internal sphincterotomy or glyceryl trinitrate group.[19]

Pain Relief and VAS Scores

Pain relief was a major focus of this study, as fissures in ANO are often associated with severe sharp pain, particularly during defecation. Pain was evaluated using the visual analog scale (VAS) at baseline, 1 week, 2 weeks, and 6 weeks, providing a longitudinal assessment of pain relief in both treatment groups. At baseline, patients in Group B reported slightly higher pain scores than those in Group A ($p = 0.007$), indicating a potentially more severe initial condition. Despite this, patients in Group B experienced significantly faster and more pronounced pain relief throughout the study.

At 1 week, Group B had a mean VAS score of 3.54 compared to 5.88 in Group A ($p < 0.0001$), demonstrating the rapid efficacy of sphincterotomy in reducing pain. By 6 weeks, patients in Group B reported near-complete resolution of pain, with a mean VAS score of 0.96, while patients in Group A still experienced some residual pain (mean VAS 2.58, $p < 0.0001$).

The more significant and sustained pain relief in the sphincterotomy group aligns with the known mechanism of action of the procedure, which provides definitive relief from sphincter hypertonicity. In contrast, the temporary and inconsistent nature of the effects of GTG may explain the more gradual and incomplete reduction in pain observed in Group A. A prospective randomized trial by Libertiny et al. found that after 24 months, all patients in the sphincterotomy.

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CONCLUSION

This randomized controlled trial (RCT) compared the efficacy of lateral anal sphincterotomy with topical glyceryl trinitrate for the treatment of chronic anal fissures. The findings suggest that lateral anal sphincterotomy results in faster and more complete healing, along with greater and more sustained pain relief, compared to glyceryl trinitrate.

Although glyceryl trinitrate remains a valuable non-surgical option, particularly for patients who prefer to avoid surgery, its efficacy is hampered by delayed healing and the potential for side effects, such as headaches.

Lateral anal sphincterotomy should be considered the treatment of choice for patients with chronic or severe anal fissures, especially those who do not respond to medical therapy. However, treatment selection should be individualized based on patient preferences, the tolerability of side effects, and the clinical severity of the fissure.

Further research is warranted to explore alternative therapeutic options and gather long-term data on recurrence rates. This will help in ensuring that patients receive the most effective and patient-centered care for this painful condition. Future studies should also assess the cost-effectiveness of both interventions and the potential for improvements in patient quality of life.

LIMITATIONS

The small sample size may have limited the detection of statistically significant differences in outcomes such as delayed healing and side effects. The short follow-up duration prevented the assessment of long-term recurrence, particularly for patients treated with topical glyceryl trinitrate. Conducting the study at a single center may limit generalizability to other populations, healthcare settings, or treatment protocols. Subjective pain assessment, based on patient-reported pain scores, introduced potential variability due to individual differences in pain perception and tolerance. Additionally, the study's setting, demographics, and available resources may not fully represent broader clinical environments, reducing external validity.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Acknowledgments

NIL

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