

Original Research Article

A COMPARATIVE STUDY BETWEEN TOPICAL GLYCERYL TRINITRATE (0.2%) AND LATERAL ANAL SPHINCTEROTOMY IN MANAGEMENT OF FISSURE IN ANO

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ABSTRACT

Background: Chronic fissure-in-ano is a common anorectal disorder characterized by severe pain, bleeding per rectum, and internal anal sphincter hypertonia. Although lateral internal sphincterotomy (LIS) is considered the gold standard treatment, topical glyceryl trinitrate (GTN) offers a non-invasive alternative. This study compared the efficacy and safety of 0.2% topical GTN with LIS in the management of chronic fissure-in-ano.

Materials and Methods: A prospective comparative study was conducted at the Department of General Surgery, Government Medical College and Hospital, Ongole, over 18 months. A total of 180 patients with chronic fissure-in-ano were allocated into two equal groups. Group A (n=90) received 0.2% topical GTN three times daily for six weeks, while Group B (n=90) underwent lateral internal sphincterotomy. Patients were followed at 2, 4, 6, 8, and 10 weeks. Primary outcome was fissure healing. Secondary outcomes included pain relief, bleeding per rectum, recovery time, return to work, complications, fecal incontinence, and recurrence.

Results: Complete fissure healing was achieved in 84.4% of patients in the GTN group and 97.85% in the LIS group ($p=0.002$). Mean recovery time was 5.18 and 4.84 weeks, respectively ($p=0.041$). Pain relief and resolution of bleeding occurred significantly earlier in the surgical group. Temporary fecal incontinence occurred in 2.22% of the GTN group and 29.03% of the LIS group, while permanent incontinence was observed only after surgery (3.22%). Recurrence occurred in 6.67% of GTN-treated patients and in none of the surgically treated patients.

Conclusions: Lateral internal sphincterotomy provides superior healing, faster symptom relief, and lower recurrence compared with topical GTN. However, 0.2% topical glyceryl trinitrate is an effective, safe, inexpensive, and non-invasive first-line treatment for selected patients with chronic fissure-in-ano, reserving surgery for those who fail conservative management.

Keywords: Chronic fissure-in-ano; Glyceryl trinitrate; Chemical sphincterotomy; Lateral internal sphincterotomy; Anal fissure; Conservative management.

INTRODUCTION

Chronic fissure-in-ano is one of the most common benign anorectal disorders encountered in surgical practice. It is characterized by a longitudinal tear in the anoderm distal to the dentate line, most

commonly located in the posterior midline. The condition is associated with severe pain during and after defecation, bleeding per rectum, and sphincter spasm, which significantly impair patients' quality of life and daily activities. Although acute anal fissures often heal with conservative measures, chronic

fissures persist because of sustained hypertonia of the internal anal sphincter, resulting in reduced anodermal blood flow and delayed wound healing. The resulting cycle of pain, sphincter spasm, ischemia, and impaired healing perpetuates the disease process. Therefore, treatment strategies aim to reduce internal anal sphincter pressure, improve local blood perfusion, relieve symptoms, and promote fissure healing.^[1,2]

Lateral internal sphincterotomy (LIS) remains the gold standard surgical treatment for chronic fissure-in-ano because of its consistently high healing rates, which exceed 95% in most published studies. However, despite its excellent efficacy, the procedure requires hospitalization and anesthesia and carries a risk of postoperative complications, particularly transient or permanent fecal incontinence. These concerns have encouraged the development of effective non-surgical alternatives that preserve anal sphincter function.

Chemical sphincterotomy using topical glyceryl trinitrate (GTN) has become one of the most widely accepted conservative treatment options. Glyceryl trinitrate acts as a nitric oxide donor, producing relaxation of the internal anal sphincter, reducing resting anal pressure, and increasing anodermal blood flow, thereby promoting fissure healing. The treatment is inexpensive, non-invasive, and can be administered on an outpatient basis. However, its effectiveness may be limited by adverse effects such as headache, poor patient compliance, recurrence, and comparatively lower healing rates than surgical sphincterotomy. Although several studies have compared medical and surgical treatment of chronic fissure-in-ano, the choice of initial therapy remains controversial, particularly in resource-limited settings where cost, patient preference, compliance, and treatment-related morbidity play important roles. Furthermore, limited prospective data are available from Indian tertiary care centers directly comparing the outcomes of topical glyceryl trinitrate with lateral internal sphincterotomy.^[3,4]

The present prospective comparative study was therefore undertaken in the Department of General Surgery, Government Medical College and Hospital, Ongole, to compare 0.2% topical glyceryl trinitrate with lateral internal sphincterotomy in the management of chronic fissure-in-ano. A total of 180 patients were enrolled over an 18-month period and allocated equally to the two treatment groups. The primary outcome was complete fissure healing, while secondary outcomes included pain relief, resolution of bleeding per rectum, recovery time, return to normal activities, treatment-related complications, fecal incontinence, recurrence, and conversion to surgery. The findings of this study aim to provide evidence regarding the relative effectiveness and safety of these two treatment modalities and to determine whether topical glyceryl trinitrate can be recommended as an effective first-line treatment before surgical intervention.

MATERIALS AND METHODS

Study Design and Setting

This prospective comparative interventional study was conducted in the Department of General Surgery, Government Medical College and Hospital, Ongole, Andhra Pradesh, India. The study compared the efficacy and safety of 0.2% topical glyceryl trinitrate (GTN) ointment (chemical sphincterotomy) with lateral internal sphincterotomy (LIS) in the management of chronic fissure-in-ano.

Study Population

The study included patients diagnosed with chronic fissure-in-ano who attended the Surgical Outpatient Department during the study period. Diagnosis was established based on a detailed clinical history, physical examination, and anoscopy whenever tolerated. Patients typically presented with severe anal pain during defecation, bleeding per rectum, and symptoms persisting for more than six weeks. Clinical examination included gentle separation of the buttocks to identify a linear ulcer in the anoderm with or without a sentinel pile.

Eligibility Criteria

Inclusion Criteria

- Patients aged 20–60 years.
- Patients with symptomatic chronic fissure-in-ano.
- Patients willing to participate and provide written informed consent.

Exclusion Criteria

Patients with any of the following were excluded:

- Pregnant or lactating women.
- Inflammatory bowel disease, tuberculosis, anorectal malignancy, or sexually transmitted diseases.
- Previous anal surgery.
- Previous failure of treatment with 0.2% topical glyceryl trinitrate.
- Associated anorectal disorders such as haemorrhoids or fistula-in-ano.
- Significant cardiovascular disease.
- Patients requesting a specific treatment modality before enrolment.

Sample Size

The sample size was calculated for a prospective comparative study using the formula:

$$N = Z^2 \{P_1 \times (1 - P_1) + P_2 \times (1 - P_2)\} / (P_1 - P_2)^2 \text{ Where:}$$

- Z corresponds to the standard normal deviate based on the desired power and level of significance
- P₁ = Expected success rate in Group A
- P₂ = Expected success rate in Group B
- (P₁ – P₂) = Expected difference between groups

Based on previous reports demonstrating healing rates of approximately 80% with topical GTN and 95% with lateral internal sphincterotomy, a minimum sample size of 90 patients per group was calculated using a 95% confidence level and 80–90% statistical

power. Accordingly, 180 patients were enrolled, with 90 patients in each treatment group.

Sampling and Allocation

Eligible patients were enrolled consecutively after satisfying the inclusion and exclusion criteria. Patients were allocated by an alternate assignment method into two equal groups:

Group A (n = 90): 0.2% topical glyceryl trinitrate (chemical sphincterotomy).

Group B (n = 90): Lateral internal sphincterotomy. Patients allocated to the surgical group were admitted for operative management.

Intervention

Group A: Chemical Sphincterotomy

Patients received 0.2% topical glyceryl trinitrate ointment. Approximately 1.5 cm of ointment was applied to the anoderm three times daily for six weeks. Patients were instructed regarding proper application techniques and advised to maintain good perianal hygiene. Based on the quantity required, each patient required approximately two 30-g tubes of ointment for completion of therapy.

Group B: Lateral Internal Sphincterotomy

Patients underwent lateral internal sphincterotomy under appropriate anaesthesia using standard surgical techniques. Postoperative care was provided according to institutional protocol.

Supportive Treatment

Patients in both groups received standard conservative measures including:

- High-fibre diet
- Warm sitz bath
- Mild analgesics
- Stool softeners/laxatives

Follow-up

Patients were evaluated at 2, 4, 6, 8, and 10 weeks following initiation of treatment. During each follow-up visit, the following parameters were assessed:

- Fissure healing
- Pain severity
- Bleeding per rectum
- Adverse events
- Return to normal activities
- Fecal incontinence
- Recurrence

Outcome Measures

Primary Outcome

The primary outcome was complete fissure healing, defined as complete epithelialization of the fissure with absence of visible ulcer on clinical examination.

Secondary Outcomes

Secondary outcome measures included:

- Time to complete healing.
- Reduction in pain intensity.
- Resolution of bleeding per rectum.
- Time to return to routine work.
- Treatment-related complications.
- Fecal incontinence.
- Recurrence.

- Requirement for conversion to alternative treatment.

Assessment Tools

Pain Assessment

Pain severity was assessed using the Visual Analogue Scale (VAS) ranging from 0 (no pain) to 10 (worst imaginable pain). Pain scores were categorized as mild (1–3), moderate (4–7), and severe (8–10).

Fecal Incontinence

Continence was evaluated using the Wexner Incontinence Score, which assesses solid stool leakage, liquid stool leakage, gas incontinence, pad usage, and lifestyle alteration. Scores were categorized as:

- 0: Perfect continence
- 1–7: Good continence
- 8–14: Moderate incontinence
- 15–20: Severe incontinence

Bleeding Per Rectum

Bleeding was graded as:

- Grade 0: No bleeding
- Grade 1: Occasional spotting
- Grade 2: Blood-streaked stool
- Grade 3: Visible bleeding with stool
- Grade 4: Passage of blood clots

Return to Work

Return to work was defined as the time required for adequate symptom relief permitting resumption of normal daily activities and was recorded in weeks.

Recovery Time

Recovery time was defined as the duration required for complete fissure healing and was recorded in weeks.

Recurrence

Recurrence was defined as reappearance of a fissure at the same site 2 months after surgery or 6 weeks after completion of topical GTN therapy.

Dropouts and Treatment Failure

Patients who failed to complete the 10-week follow-up or opted for alternative treatment before study completion were considered dropouts.

Patients in the GTN group who failed to respond after completing treatment were offered lateral internal sphincterotomy and were classified as treatment failures. Patients requiring crossover from surgical to medical treatment were analysed separately as conversion cases and were excluded from the primary comparative analysis.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using SPSS version 16.0. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were presented as frequency and percentage. Comparisons between the two treatment groups were performed using the independent samples t-test. A p-value <0.05 was considered statistically significant.

RESULTS

Baseline Characteristics

A total of 180 patients diagnosed with chronic fissure-in-ano were included in this prospective comparative study. Patients were equally allocated into Group A (chemical sphincterotomy; n = 90) and Group B (lateral internal sphincterotomy; n = 90).

The age of the participants ranged from 20 to 60 years, with a mean age of approximately 37 years. Females constituted 55.6% (100/180) of the study population, while males accounted for 44.4% (80/180). Posterior fissures were the predominant anatomical type (91.25%), followed by anterior fissures (7.0%) and combined anterior and posterior fissures (1.64%).

Table 1: Baseline characteristics of study participants

Variable	Value
Total patients	180
Group A (Chemical sphincterotomy)	90
Group B (Lateral internal sphincterotomy)	90
Mean age (years)	37
Age range (years)	20–60
Female	100 (55.6%)
Male	80 (44.4%)
Posterior fissure	91.25%
Anterior fissure	7.0%
Combined anterior & posterior	1.64%

Clinical Outcomes

Healing was significantly better in the surgical group throughout follow-up. At the end of 10 weeks, complete healing was achieved in **84.4%** of patients

in Group A compared with **97.85%** in Group B (p=0.002). Significant differences were observed from the fourth week onward.

Table 2: Comparison of fissure healing rates

Follow-up	Group A n (%)	Group B n (%)	p value
2 weeks	0	0	-
4 weeks	38 (42.2)	54 (58.1)	0.032
6 weeks	70 (77.8)	88 (94.6)	0.001
8 weeks	76 (84.4)	91 (97.9)	0.001
10 weeks	76 (84.4)	91 (97.9)	0.002

Pain Relief

The mean pain score decreased progressively in both groups. However, pain relief was significantly faster following lateral internal sphincterotomy. By the

tenth week, the mean pain score had decreased to 0.55 in Group B compared with 2.24 in Group A (p<0.001).

Table 3: Comparison of mean pain scores

Follow-up	Group A	Group B	p value
Baseline	7.66	7.92	0.151
2 weeks	3.93	3.40	0.016
4 weeks	3.41	2.17	<0.001
6 weeks	2.81	1.41	<0.001
8 weeks	2.36	0.83	<0.001
10 weeks	2.24	0.55	<0.001

Bleeding per Rectum

Both treatment groups demonstrated progressive improvement in bleeding per rectum. Although initial improvement at two weeks was comparable, Group

B demonstrated significantly better recovery from the fourth week onwards. Complete resolution of bleeding occurred in 98.92% of patients in Group B compared with 87.78% in Group A (p=0.003).

Table 4: Recovery of bleeding per rectum

Follow-up	Group A (%)	Group B (%)	p value
2 weeks	74.4	67.7	0.320
4 weeks	87.8	95.7	0.051
6 weeks	87.8	98.9	0.003
8 weeks	87.8	98.9	0.003
10 weeks	87.8	98.9	0.003

Recovery Time, Complications and Recurrence

The mean recovery time was significantly shorter in Group B (4.84 weeks) than in Group A (5.18 weeks; p=0.041). Patients in Group B resumed normal

activities slightly earlier (3.19 vs. 3.37 weeks), although this difference was not statistically significant (p=0.455). Temporary fecal incontinence occurred significantly more frequently following

lateral internal sphincterotomy (29.03%) than chemical sphincterotomy (2.22%; $p < 0.001$). Conversely, recurrence was observed only in Group A (6.67%), while no recurrence occurred in Group B.

Conversion to surgery was also significantly higher in Group A (16.67%) compared with Group B (2.15%; $p < 0.001$).

Table 5: Comparison of secondary outcomes

Variable	Group A	Group B	p value
Mean recovery time (weeks)	5.18	4.84	0.041
Return to work (weeks)	3.37	3.19	0.455
Fecal incontinence	2.22%	29.03%	<0.001
Recurrence	6.67%	0%	0.049
Conversion to surgery	16.67%	2.15%	<0.001

DISCUSSION

The present prospective comparative study evaluated the efficacy and safety of 0.2% topical glyceryl trinitrate (GTN) and lateral internal sphincterotomy (LIS) in the treatment of chronic fissure-in-ano. The outcomes were assessed in terms of fissure healing, recovery time, pain relief, bleeding per rectum, complications, fecal incontinence, and recurrence. The findings were compared with those reported in previous studies.

Fissure Healing

The overall healing rate in the present study was 84.4% in the GTN group and 97.85% in the LIS group. The healing rate achieved with GTN compares favorably with the 89.36% reported by Madhusudhan M. et al,^[5] the 88.4% reported by Giridhar C.M. et al,^[6] and the 80% reported by Nelson et al,^[7] It was higher than the rates observed by Rithin Suvarna et al,^[8] (69.23%), Ansar Latif et al,^[9] (74%) and Sanei et al,^[10] (67%).

The superior healing rate observed after lateral internal sphincterotomy (97.85%) is consistent with numerous published studies reporting healing rates above 95%, reaffirming LIS as the gold standard treatment for chronic fissure-in-ano. Earlier healing observed from the fourth week onward in the surgical group further supports the advantages of operative management.

Recovery Time

The mean recovery time in the present study was 5.18 weeks with topical GTN and 4.84 weeks following lateral internal sphincterotomy. These findings closely resemble those of Giridhar C.M. et al,^[6] who reported an average recovery time of 5.04 weeks, and Abd Elhady et al,^[11] who observed healing in 5.1 ± 1.13 weeks. In contrast, Sanei et al,^[10] reported longer recovery periods of 7.58 ± 2.01 weeks respectively. The shorter recovery observed in the present study may be attributed to strict follow-up, better patient compliance, and standardized treatment protocols.

Pain Relief

Pain reduction was significantly faster in the surgical group. Patients undergoing LIS achieved a Visual Analogue Scale (VAS) score below 3 by the fourth week, whereas patients treated with GTN reached similar pain levels by the sixth week. The final mean pain score in the present study was 2.24 in the GTN group and 0.55 in the surgical group. Similarly,

Giridhar C.M. et al,^[6] reported 78.26% pain recovery, whereas the present study demonstrated an 84% reduction, indicating good symptomatic improvement with topical GTN despite slower recovery compared with surgery.

Resolution of Bleeding per Rectum

Resolution of bleeding per rectum was observed in 87.78% of patients treated with GTN and 98.92% of patients treated with LIS by the tenth week. Approximately three-fourths of patients in both groups experienced improvement within the first two weeks.

These findings indicate earlier symptom control than that reported by Watson et al,^[12] who documented bleeding resolution at approximately three weeks. Although published literature on bleeding recovery is limited, the present study suggests that both treatment modalities provide rapid relief, with surgical treatment producing superior long-term resolution.

Fecal Incontinence

Fecal incontinence remains the principal concern following lateral internal sphincterotomy. In the present study, temporary fecal incontinence occurred in 2.22% of patients treated with GTN and 29.03% of patients treated surgically. Permanent incontinence occurred only in the surgical group (3.22%).

The absence of permanent incontinence following GTN therapy is consistent with reports by Madhusudhan M. et al,^[5] Ansar Latif et al,^[9] Rithin Suvarna et al,^[13] and Majid Aziz et al,^[14] all of whom reported no incontinence with topical treatment. The permanent incontinence rate observed after surgery in the present study is comparable with the 3.33% reported by Majid Aziz et al,^[14] although higher temporary incontinence may reflect more rigorous postoperative assessment using the Wexner continence scoring system.

Headache

Headache was the most common adverse effect of GTN therapy, occurring in 22.22% of patients. This incidence is higher than the 5.71% reported by 5.49% reported by Rithin Suvarna et al.^[8] Nevertheless, all headaches were transient and managed conservatively without discontinuation of treatment, suggesting acceptable tolerability.

Local Itching

Local itching occurred in 15.6% of patients receiving topical GTN, which is higher than the 4.3% incidence reported by Madhusudhan M. et al.^[5] However, the

itching was mild, self-limiting, and did not necessitate withdrawal of therapy.

Surgical Complications

Postoperative pain (43.01%), bleeding (22.58%), and surgical site infection (3.23%) were the principal complications observed following lateral internal sphincterotomy. Valiyeva S et al showed postoperative complications included 3 cases of early postoperative bleeding, 3 abscesses at surgical wound and persisting postoperative bleeding in 28 cases (median 4 days).

Recurrence

Recurrence occurred in 6.67% of patients receiving GTN, whereas no recurrence was observed after lateral internal sphincterotomy. The recurrence rate in the present study is lower than those reported by Nelson et al,^[2] (12.5%), Ansar Latif et al,^[9] (25%), Rithin Suvarna et al,^[13] (10.43%). The relatively low

recurrence observed in the present study may be attributed to better compliance with treatment, regular follow-up, and adherence to dietary advice and sitz bath therapy.

The findings of the present study are consistent with published literature demonstrating that lateral internal sphincterotomy provides superior healing rates, faster symptom relief, and lower recurrence than topical glyceryl trinitrate. However, surgery is associated with a higher incidence of transient fecal incontinence. Conversely, 0.2% topical GTN achieved satisfactory healing in more than 84% of patients with minimal continence disturbances, supporting its role as an effective first-line treatment in selected patients. Patients who fail conservative therapy can subsequently undergo lateral internal sphincterotomy with excellent clinical outcomes.

Table 6: Comparison of our study with other studies

Studies	Result
Healing rate with 0.2% Glyceryl Trinitrate	
Rithin Suvarna et al, ^[13]	69.23%
Giridhar C. M et al, ^[6]	88.4%
Ansar Latif et al, ^[9]	74%
Madhusudhan M. et al, ^[5]	89.36%
Nelson et al, ^[7]	80%
Sanei et al, ^[10]	67%
Present study	84.4%
Average recovery time with topical 0.2% Glyceryl Trinitrate	
Sanei et al, ^[10]	7.58±2.01
Abd Elhady et al, ^[11]	5.1±1.13 weeks
Giridhar C. M et al, ^[6]	5.04 weeks
Present Study	5.18 Weeks
% Of Recovery With Glyceryl Trinitrate	
Madhusudhan M. et al, ^[5]	89.4%
Giridhar C. M et al, ^[6]	78.26%
Present Study	84%
Surgical Sphincterotomy	
Madhusudhan M. et al, ^[5]	2.1%
Ansar Latif et al, ^[9]	6%
Rithin Suvarna et al, ^[13]	9.27%
Majid Aziz et al, ^[14]	3.33%
Present Study	Temporary-29.03% Permanent- 3.22%
Incidence of Headache	
Rithin Suvarna et al, ^[13]	5.49%
Present Study	22.22% .
Incidence of Itching	
Madhusudhan M et al, ^[5]	4.3%
Present Study	15.6%
Recurrence rate	
Nelson et al, ^[7]	12.5% .
Abd Elhady et al, ^[11]	65%
Suvarna et al, ^[13]	10.43%
Madhusudhan M et al, ^[5]	2.1%
Ansar Latif et al, ^[9]	25%
Present Study	6.67%

CONCLUSION

The present study demonstrates that chemical sphincterotomy using 0.2% topical glyceryl trinitrate is an effective initial treatment modality for chronic fissure in ano when compared to surgical sphincterotomy. It provides a satisfactory rate of fissure healing along with faster relief from

symptoms such as pain and bleeding per rectum, resulting in shorter recovery duration. Additionally, this conservative approach is associated with a lower incidence of complications, particularly minimizing the risk of fecal incontinence. However, a notable proportion of patients may experience recurrence or inadequate response, necessitating subsequent surgical intervention. Successful outcomes with

topical therapy largely depend on appropriate patient education, adherence to treatment, and motivation. Based on these findings, it can be concluded that chemical sphincterotomy with 0.2% glyceryl trinitrate should be considered the first-line treatment for chronic fissure in ano, while surgical sphincterotomy should be reserved for patients who fail to respond to conservative management.

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