

# Comparative Study of Lateral Internal Sphincterotomy versus Local 0.4% Glyceryl Trinitrate Ointment for the Treatment of Chronic Anal Fissure

Utban Ali Shah, Tabish Iqbal, Khurram Sarafaraz, Muhammad Idress, Momina Javed, Jawad Hamed

## ABSTRACT

**Objectives:** To compare the outcomes of “Lateral Internal Sphincterotomy (LIS)” versus local “0.4% Glyceryl Trinitrate (GTN)” ointment for the treatment of chronic anal fissure.

**Study Design and Setting:** Randomized controlled trial, Combined Military Hospital (CMH) / Pak Emirates Military Hospital (PEMH), Rawalpindi from October 2022 to March 2023.

**Methodology:** A total of 100 patients [50 in GTN group and 50 in LIS group] who underwent treatment for chronic anal fissure were included in study. Patients in both groups were followed up at eight weeks after the surgery to assess for the outcomes including anal pain healing and recurrence of fissure. Data was analyzed by SPSS 22.00.

**Results:** In our study, mean age was  $30.48 \pm 5.82$  years. 61 (61.00%) were male while 39 (39.00%) were female. Mean duration of having anal fissure was  $10.69 \pm 2.59$  weeks. Mean post-therapy pain VAS at week 8 follow up in “GTN” group was  $0.64 \pm 1.06$  while in “LIS” group it was  $0.16 \pm 0.37$ , ( $p = 0.003$ ). Complete healing of chronic anal fissure was achieved in 35 (70.00%) in “GTN” group while in “LIS” group healing was achieved in 42 (84.00%), ( $p = 0.096$ ). Recurrence occurred in 2 (4.00%) of patients in “GTN” group and none in “LIS” group, ( $p = 0.153$ ).

**Conclusion:** “Lateral Internal Sphincterotomy (LIS)” is a better treatment option for management of chronic anal fissure.

**Keywords:** Chronic anal fissure, Glyceryl trinitrate, Healing, Lateral internal sphincterotomy.

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## INTRODUCTION:

An “anal fissure” is a superficial split in the skin that is located distally towards the “dentate line” and is a common reason for patients to seek treatment in the urgent care<sup>1</sup>. In the majority of instances, anal fissures are the result of trauma due to passage of very hard feces and constipation<sup>2</sup>. Other potential conditions that can lead to development of anal fissure include use of diet low in fiber, tuberculosis (TB), inflammatory bowel disease (IBD), history of having surgery of anal region, anal malignancy, to name a few. These are quite common in both youngsters and adults and individuals who have a background of persistent constipation are more likely to experience this problem on a more regular basis. It can either present acutely or can become chronic<sup>3</sup>.

Anal fissures can appear in people of all age groups; yet, these are most commonly seen in children and people in the middle years of their lives with no major difference in prevalence between the sexes<sup>4</sup>. Anal fissures have the potential to reoccur, get infected and even progress into formation of abscesses if they are not treated adequately. Since patients withhold defecation because of the pain caused by the spasm of the anal canal that is caused by the elevated sphincteric tone, this can also lead to impaction of stool<sup>5</sup>. In addition to this, these factors can also contribute to a general decline in one's quality of life<sup>6</sup>.

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The majority of fissures can be healed with conservative therapy, but in cases where they become chronic, the goal of treatment is often predicated on lowering the anal pressures which is achieved by utilization of various surgical and non-surgical interventions<sup>6</sup>. Among non-surgical interventions used for managing chronic anal fissures most common agents are calcium channel blockers, nitrates and botulinum toxin or “botox”<sup>7</sup>. These help by reducing the sphincteric tone and improving the anal canal spasm. Amongst surgical intervention, most useful technique is “lateral internal sphincterotomy (LIS)”<sup>8</sup>. When it comes to choice of therapy between nitrates particularly “glyceryl trinitrate (GTN)” and “lateral internal sphincterotomy (LIS)”, literature shows high degree of variability. A study in this regard reported that when post-operative pain and healing rate was compared between “glyceryl trinitrate (GTN)” and “lateral internal sphincterotomy (LIS)” it was found that mean pain score and healing rate in GTN group was  $1.64 \pm 2.43$  and 72%, respectively while in LIS group mean pain score was less ( $0.24 \pm 1.20$ ) and healing rate was high (100%), making LIS a better treatment option for chronic anal fissure<sup>9</sup>. On the other hand, another study reported in favor of GTN being better than LIS with higher percentage of pain relief (95% vs 86.7%) and healing (88.3% vs 83.3%) in GTN group as compared to LIS group<sup>10</sup>.

Based on such highly opposing results regarding the outcomes of GTN vs LIS for the management of chronic anal fissure, in terms of pain relief and healing rate, it is still unclear that which of these treatment options can provide best outcome making conductance of further research in this regard highly imperative. Therefore, this study was conducted with the purpose of finding out the best possible treatment option for the patients presenting at our health care facility with chronic anal fissure by comparing non-surgical option of “glyceryl trinitrate (GTN)” with the surgical one i.e., “lateral internal sphincterotomy (LIS)”. This will not only help gaining evidence regarding the best possible treatment modality but also will help improving patient care and their outcome.

#### **METHODOLOGY:**

This “randomized controlled trial” was conducted at “Combined Military Hospital (CMH)/Pak-Emirates Military Hospital (PEMH), Rawalpindi” which after obtaining the approval from the Ethical Review Board (ERB) of the aforementioned institution (ERB No.376) was started from October 2022 and continued till March 2023. To calculate the appropriate sample size for this study WHO sample size calculator using formula for “sample size estimation for two population proportions” was used by assuming 5% level of significance, 80% power of the test, anticipated frequency of healing of chronic anal fissure achieved in GTN group of 51.11% and anticipated frequency of healing of chronic anal fissure achieved in LIS group of 77.78%<sup>11</sup>. Based on these, calculated sample size was 100 [50 in each group].

**Inclusion criteria:** All adult patients (having age of eighteen years or more), either of male or female gender, presenting with chronic anal fissure (for more than six weeks)<sup>12</sup> were included in the study.

**Exclusion criteria:** Patients who had a history of tuberculosis (TB), inflammatory bowel disease (IBD), history of having surgery of anal region, anal malignancy and pre-existing fecal incontinence were excluded from the study. Patients were selected through “non-probability consecutive sampling technique”. Once the study pool was selected patients were interviewed to document their baseline demographic features including their age (in years), gender, duration of having anal fissure (in weeks) and pain at the anal region (based on visual analogue scale scored from 1 to 10; 1 being least while 10 being severe pain). Patients were then randomly divided into two equal groups. In group A, patients underwent management with “topical 0.4% glycerl trinitrate (GTN) ointment” applied thrice daily for a period of eight weeks while in group B, patients were scheduled to undergo “lateral internal sphincterotomy (LIS)”. LIS was performed by consultant surgeon, with a minimum experience of five years, under spinal anesthesia keeping patient at “lithotomy” position<sup>13</sup>. First step was making an incision in circumferential fashion at the anal verge, of about 1-2 cm at 5’o’clock position. With the help of diathermy, surgeon divided the lower part of the anal sphincter below the “dentate line” of size that was equal to the fissure length. After that surgical wound was left open and patients was advised to regularly take “sitz bath” for eight weeks. Additionally, patients were advised to consume diet rich in fibrous content. Patients in both the groups were given oral analgesics (tab. Tramadol 50mg) to be used regularly for 7 days. In case of any pain during the eight weeks post-surgery period, patients were advised to visit surgical outdoor department where additional simple analgesic (tab Paracetamol 1000mg) was given on as per need basis. To assess outcomes in study participants, patients were advised to re-visit our outdoor department for follow up consultation at week 8 after surgery and of GTN therapy to assess for anal pain, healing and recurrence of fissure. Fissure was labeled to “heal” if there was “complete absence of pain (VAS 0) and no visual lesion at the anoderm”. In addition, occurrence of treatment related complications including headache, anal incontinence and anal bleeding were also assessed. “To analyze the data we used Statistical Package for Social Sciences (SPSS) software version 22:00. To represent quantitative data (age, duration of anal fissure, pre- and post-intervention pain at anal site) we used mean +/- standard deviation (SD) and median (IQR). For representation of qualitative data (gender and healing of anal fissure) we used percentages and frequencies. Normality of data was checked using Shapiro-Wilk test. To analyze quantitative data we used sample t-test and for qualitative data Chi-square test was utilized. A p-value of = 0.05 was considered to be statistically significant”.

**RESULTS:**

Study sample was 100 patients [50 in GTN group and 50 in LIS group]. In this study, it was found out that value of mean age of study pool was  $30.48 \pm 5.82$  years. There were 61 (61.00%) male participants while remaining 39 (39.00%) participants were female. Mean duration of having anal fissure was  $10.69 \pm 2.59$  weeks. The baseline characteristics between study groups were then compared. It was found that mean age of the study participants who were in "GTN" group was  $31.02 \pm 6.09$  years while in "LIS" group mean age was  $29.94 \pm 5.54$  years, ( $p = 0.356$ ). In "GTN" group ( $n = 50$ ), 32 (64.00%) were male and 18 (36.00%) were female while in "LIS" group ( $n = 50$ ), 29 (58.00%) were male and 21 (42.00%) were female, ( $p = 0.539$ ). Mean duration of having anal fissure in our study participants who were in "GTN" group was  $10.68 \pm 2.64$  weeks while in "LIS" group mean duration of having anal fissure was  $10.70 \pm 2.56$  weeks, ( $p = 0.969$ ). Mean baseline pain VAS score in "GTN" group was  $5.16 \pm 0.79$  while in "LIS" group  $4.92 \pm 1.05$ , ( $p = 0.199$ ). This data is represented below in table I. In this study, it was found that mean post-therapy pain VAS at week 8 follow up in "GTN" group was  $0.64 \pm 1.06$  while in "LIS" group it was  $0.16 \pm 0.37$ , ( $p = 0.003$ ). Additionally, complete healing of chronic anal fissure was achieved in 35 (70.00%) in "GTN" group while in "LIS" group healing was achieved in 42 (84.00%), ( $p = 0.096$ ). Recurrence occurred in 2 (4.00%) of patients in "GTN" group and none in "LIS" group, ( $p = 0.153$ ). This is tabulated below in table II. In addition to these outcomes, patients were also assessed for treatment related complications. Main complication that was encountered by patients in "GTN" group was "headache" which occurred in 4 (8.00%) of the patients and none of the patients had "anal incontinence" or "bleeding" after 8 weeks of therapy. On the other hand, in "LIS" group, "anal incontinence" occurred only in 1 (2.00%) patients and none reported any "headache" or "bleeding".

**DISCUSSION:**

Some authors argue that a fissure needs to be present for 6-8 weeks before being considered chronic, however there is a proportion of patients in which spontaneous healing may also occur<sup>14</sup>. Anal fissure patients have an anal sphincter pressure that is elevated to approximately 121 mm Hg (much higher than the normal tone at which pressure is 69mmHg), which produces a diminished supply of blood that reaches the diseased area, which in turn results in ischemia and poor healing. Fiber rich nutrition, botulinum toxin injection, "sitz baths", topical diltiazem ointment and topical glyceryl-trinitrate are all non-surgical options for treating chronic anal fissure while "lateral internal sphincterotomy" is a surgical procedure used to treat "chronic anal fissure"<sup>15</sup>. In this study, latter two management options were primarily compared.

In this study, it found that majority of patients who presented with this chronic condition were young male patients with a frequency of 61%. This was congruent with the finding of Lee *et al.*<sup>16</sup>, Butt *et al.*<sup>17</sup> and Qureshi *et al.*<sup>10</sup> who reported a high frequency of "chronic anal fissure" among younger male population at 57.7%, 53.33% and 53.3%, respectively. In this study, upon performing comparison of baseline characteristics of study groups including age, gender distribution, duration of disease and baseline pain scores, it was found that there was absence of any significant difference between "GTN" and "LIS" group. However, post-treatment follow up after 8 weeks status yielded somewhat different results. Upon comparing post-treatment parameters we found that both the relief of pain as well as healing rate was much higher in "LIS" group while recurrence only occurred in "GTN" group. In terms of pain relief, we found that pain score was significantly lower in association with "lateral internal sphincterotomy (LIS)" indicating that better pain relief was achieved with LIS. Similar results were observed in a study conducted by Jan *et al.*<sup>18</sup> who reported that higher percentage of patients in "LIS" group had pain relief (90%) as compared to those in "GTN" group (80%).

Table 1: Baseline characteristics (n = 100)

Sr. No	Characteristics	Value	
1	Mean age	$30.48 \pm 5.82$ years	
2	Gender		
	Male	61 (61.00%)	
	Female	39 (39.00%)	
3	Mean duration of having anal fissure	$10.69 \pm 2.59$ weeks	
<b>Comparison of baseline characteristics</b>			
	<b>"GTN" group (n = 50)</b>	<b>"LIS" group (n = 50)</b>	<b>p-value</b>
Mean age	$31.02 \pm 6.09$ years	$29.94 \pm 5.54$ years	0.356
Gender	Male	Male	0.539
	32 (64.00%)	29 (58.00%)	
	Female	Female	
	18 (36.00%)	21 (42.00%)	
Mean duration of anal fissure	$10.68 \pm 2.64$ weeks	$10.70 \pm 2.56$ weeks	0.969
Mean baseline VAS	$5.16 \pm 0.79$	$4.92 \pm 1.05$	0.199



Table 2: Comparison of outcomes between groups (n = 100)

Parameter	“GTN” group (n = 50)	“LIS” group (n = 50)	p-value
Post-therapy VAS at week 8 follow up	0.64 ± 1.06	0.16 ± 0.37	0.003
Healing of chronic anal fissure	35 (70.00%)	42 (84.00%)	0.096
Recurrence of chronic anal fissure	2 (4.00%)	0 (0.00%)	0.153

Contrarily, Qureshi *et al.*<sup>10</sup> found that higher percentage of patients in “GTN” group had relief from pain (95%) as compared to those in “LIS” group (86.7%).

In terms of healing, it was observed that frequency of healing was also higher in patients who had “lateral internal sphincterotomy (LIS)” but its difference from GTN users was not statistically significant. This finding was linear with what was reported by Qureshi *et al.*<sup>10</sup> who reported similar results as of this study and found no significant difference between the two treatment groups (p = 0.321). However, incongruent with the findings, Hassan *et al.*<sup>11</sup> reported that “LIS” group had significantly higher healing rate than “GTN” group [77.78% vs 51.11%; (p = 0.013)]. Similarly, Butt *et al.*<sup>17</sup> reported 100% healing rate with “LIS” as compared to 73.33% healing rate with “GTN” (p < 0.05). Additionally, Jan *et al.*<sup>18</sup> also reported that not only higher healing rates of chronic anal fissure were achieved by treatment through “lateral internal sphincterotomy (LIS)”, the difference in the healing rates from the use of “topical GTN ointment” was also statistically significant [85% vs 74%; (p = 0.0001)]. Also, Paul *et al.*<sup>19</sup> also found that “LIS” provided much higher healing rates as compared to “GTN” (86.8% and 66.6%, respectively). In terms of recurrence, two patients in the “GTN” group had recurrence while none in “LIS” group had recurrence during study period. This was not congruent with the findings of Qureshi *et al.*<sup>10</sup> who reported that no patient in either “LIS” or “GTN” group had recurrence of anal fissure.

Based on these findings, although “lateral internal sphincterotomy (LIS)” is a better treatment option yet “0.2% GTN” can still be used as a safer alternative to surgical treatment with comparable rates of pain relief as well as healing of “chronic anal fissure”. Additionally, it is recommend that further studies should be carried out in this regard to achieve and formulate a standardized plan of managing “chronic anal fissures”.

**CONCLUSION**

In conclusion, “Lateral Internal Sphincterotomy (LIS)” is a better treatment option for management of chronic anal fissure as compared to topical “0.4% Glyceryl Trinitrate (GTN) ointment” as not only it provides significantly better relief from the pain associated with the chronic anal fissure

but also higher rates of healing as well as lesser rates of recurrence. Therefore, for treatment of chronic anal fissure, “Lateral Internal Sphincterotomy (LIS)” should be preferred over medical management.

**Authors Contribution:**

- Utban Ali Shah:** Sampling, manuscript writing, data review
- Tabish Iqbal:** Data collection, data analysis
- Khurram Sarafaraz:** Conception of idea, data review
- Muhammad Idress:** Result analysis
- Momina Javed:** Statistical review
- Jawad Hamed:** Data analysis, statistical review

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