

Original Research Article


# Comparative study of glyceryl trinitrate ointment versus surgical management of chronic anal fissure

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## Abstract

**Background:** Fissures are common, but are often confused with other anal conditions, such as haemorrhoids. Fissures are usually caused by trauma to the inner lining of the anus from a bowel movement or other stretching of the anal canal.

**Aim:** This study evaluated the efficacy of 0.2% glyceryl trinitrate versus lateral internal sphincterectomy in treatment of chronic anal fissure.

**Materials and Methods:** This was a study which included 80 patients between November 2014 to September 2017. In this study, based on computer generated randomization, the patients were divided into two groups. Group A consisted of 40 patients with chronic anal fissure who were treated with 0.2% glyceryl trinitrate ointment, which was applied twice daily for 5 weeks. Group B included 40 patients who were treated by lateral internal sphincterotomy.

**Results:** The mean duration of symptoms was 15.35±10.87 weeks in group A, it was 15.02±11.7 weeks in group B. Mean pain score during defecation was 7.89±1.58 in group A, it was 7.52±2.41 in group B. Bleeding during defecation was observed in 82% of patients in group A, 75% of patients in group B. Constipation was present in 27 patients i.e. 67% in group A and it was present in 31 patients i.e. 77% in group B. In Group A, 36 (90%) patients had posterior midline fissure, 4 (10%) had anterior midline fissure, In group B, 40 (100%) had posterior midline fissure. In group A, 24 (60%) had anal tag, in group B, 22 (56%) had anal tag. The VAS score in both the groups decreased gradually but the decrease was more in group B compared to group A at the end of 7<sup>th</sup> week which was statistically significant (p<0.05). Hence, the number of patients who had pain relief after surgical treatment was statistically significant as compared to patients who were treated with 0.2% glyceryl trinitrate ointment

application. At the end of the 1<sup>st</sup> week, none of the patients were healed completely. But at the end of the 4<sup>th</sup>, in group A, only 14 patients were completely healed, 38 patients were completely healed in group B. At the end of the 7<sup>th</sup> week, all patients in group B were healed i.e. 100% were healed and in group A, 32 patients were healed completely.

**Conclusion:** Chemical treatment by applying glyceryl trinitrate is also advantageous in that it doesn't cause any complications. Surgical treatment by lateral sphincterotomy is most effective when patients fail to respond to chemical treatment.

## Key words

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Glyceryl trinitrate ointment, Surgical management, Chronic anal fissure.

## Introduction

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The anal canal is a short tube surrounded by muscle at the end of your rectum. The rectum is the bottom section of your colon (large intestine). An anal fissure (also called fissure-in-ano) is a small rip or tear in the lining of the anal canal. Fissures are common, but are often confused with other anal conditions, such as haemorrhoids [1]. Fissures are usually caused by trauma to the inner lining of the anus from a bowel movement or other stretching of the anal canal. This can be due to a hard, dry bowel movement or loose, frequent bowel movements [2]. Patients with a tight anal sphincter muscle are more likely to develop anal fissures. Less common causes of fissures include inflammatory bowel disease, anal infections, or tumors. Anal fissures typically cause a sharp pain that starts with the passage of stool. This pain may last several minutes to a few hours. As a result, many patients may try not to have bowel movements to prevent pain [3]. Other symptoms include Bright red blood on the stool or toilet paper after a bowel movement. A small lump or skin tag on the skin near the anal fissure (more common when chronic). Treatment includes a high-fibre diet and over-the-counter fibre supplements (25-35 grams of fibre/day) to make stools soft, formed, and bulky Over-the-counter stool softeners to make stools easier to pass. Drinking more water to help prevent hard stools and aid in healing. Warm tub baths (sitz baths) for 10 to 20 minutes, a few times per day (especially after bowel movements to soothe the area and help relax anal sphincter muscles). This is thought to help the healing process. Medications, such as lidocaine, that can be

applied to the skin around the anus for pain relief. Medications such as diltiazam, nifedipine, or nitroglycerin ointment to relax the anal sphincter muscles which helps the healing process. Narcotic pain medications are avoided because they can cause constipation which could make the situation worse. Although most anal fissures do not require surgery, chronic fissures are harder to treat and surgery may be the best option. The goal of surgery is to help the anal sphincter muscle relax which reduces pain and spasms, allowing the fissure to heal. Surgical options include Botulinum toxin (Botox®) injection into the anal sphincter or surgical division of an inner part of the anal sphincter (lateral internal sphincterotomy) [4]. Your colon and rectal surgeon will find the best treatment for you and discuss the risks of surgery. Both types of surgery are typically done as same-day outpatient procedures. Glyceryl trinitrate lowers the sphincter pressure and heals the anal fissure [5]. For treatment of anal fissure, glyceryl trinitrate has been more effective, cost effective and decreases anal tone. Hence, this study evaluates the efficacy of 0.2% Glyceryl trinitrate versus lateral internal sphincterotomy in treatment of chronic anal fissure.

## Materials and methods

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This was a study which included 80 patients between November 2014 to October 2016. In this study, based on computer generated randomization, the patients were divided into two groups. Group A consisted of 40 patients with chronic anal fissure who were treated with 0.2% glyceryl trinitrate ointment, which was applied

twice daily for 5 weeks. Group B included 40 patients who were treated by lateral internal sphincterotomy. All the patients were treated with the same technique of sphincterotomy. Inclusion Criteria were patients who were willing to give written informed consent, anal fissure suffering patients from more than duration of 6 weeks, anal fissure associated with chronicity like piles or hypertrophied papillae or horizontal fibres exposure of internal sphincter. Exclusion criteria was patients who were under medication of nitrate compound for medical conditions such as ischemic heart disease, women who were pregnant, with inflammatory bowel diseases like ulcerative colitis, crohn's disease, human immuno-deficiency, tuberculosis. All the patients were advised for high fibre diet and stool softener. The patients were followed twice a week initially, and then at the end of 4 weeks and 7 weeks. Visual Analogue scale is a 10 cm line on which 0 represents no pain and 10 represents most severe pain. VAS score was examined at each visit, healing of fissure, any side effect or complication of treatment was evaluated. The patients were advised to stop treatment i.e. ointment application and were asked to continue high fibre content. At 4 months, the healed fissures were followed up subsequently for recurrence. The time needed for complete healing and relief of fissure was recorded in each case. Patients were allowed to undergo lateral sphincterotomy, if they did not recover due to glyceryl trinitrate application at 7 weeks. The data was collected and analysed statistically by chi square test for determining the significance for qualitative data in terms of pain reduction and healing time. Student t-test was used as a test of significance for quantitative data. P value of <0.05 was considered significant.

## Results

The patients of both the groups were followed twice a week initially, and then at the end of 4 weeks and 7 weeks. VAS score was examined at each visit, healing of fissure, any side effect or complication of treatment was evaluated. At 4

months, the healed fissures were followed up subsequently for reoccurrence.

The mean age in group A was  $35.9 \pm 11.0$  years and in group B, it was  $31.87 \pm 10.49$ . The range in group A was 17-66 and in group B, it was 20-65. Males were 28 and females were 12 in group A, males were 30 and females were 10 in group B (**Table – 1**).

**Table - 1:** Demographics.

Age distribution (years)	Group A	Group B
Mean Age	$35.9 \pm 11.0$	$31.87 \pm 10.49$
Range	17-66	20-65
Sex distribution	Group A	Group B
Males	28	30
Females	12	10

The mean duration of symptoms was  $15.35 \pm 10.87$  weeks in group A, it was  $15.02 \pm 11.7$  weeks in group B. Mean pain score during defecation was  $7.89 \pm 1.58$  in group A, it was  $7.52 \pm 2.41$  in group B. Bleeding during defecation was observed in 82% of patients in group A, 75% of patients in group B. Constipation was present in 27 patients i.e. 67% in group A and it was present in 31 patients i.e. 77% in group B (**Table – 2**).

**Table - 2:** Symptoms before treatment.

Symptoms	Group A	Group B
Mean duration of symptoms (weeks)	$15.35 \pm 10.87$	$15.02 \pm 11.7$
Mean pain score during defecation	$7.89 \pm 1.58$	$7.52 \pm 2.41$
Bleeding during defecation	82%	75%
Constipation	27 (67%)	31 (77%)

In Group A, 36 (90%) patients had posterior midline fissure, 4 (10%) had anterior midline fissure, In group B, 40 (100%) had posterior midline fissure. In group A, 24 (60%) had anal tag, in group B, 22 (56%) had anal tag (**Table – 3**).

The VAS score in both the groups decreased gradually but the decrease was more in group B compared to group A at the end of 7<sup>th</sup> week which was statistically significant ( $p < 0.05$ ). Hence, the number of patients who had pain relief after surgical treatment was statistically significant as compared to patients who were treated with 0.2% glyceryl trinitrate ointment application (**Table – 4**).

**Table - 3:** Midline fissure.

Midline fissure	Group A	Group B
Posterior	36(90%)	40(100%)
Anterior	4(10%)	---
Anal Tag	24(60%)	22(56%)

**Table - 4:** VAS score (Pain relief).

VAS score	Group A	Group B
1 <sup>st</sup> follow up (72 hrs)	8.68±9.65	3.52±2.55
1 <sup>st</sup> week	7.01±5.54	1.20±0.45
4 <sup>th</sup> week	3.25±2.11	0.62±1.52
7 <sup>th</sup> week	1.50±1.05	0.26±1.11

At the end of the 1<sup>st</sup> week, none of the patients were healed completely. But at the end of the 4<sup>th</sup>, in group A, only 14 patients were completely healed, 38 patients were completely healed in group B. At the end of the 7<sup>th</sup> week, all patients in group B were healed i.e. 100% were healed and in group A, 32 patients were healed completely. 15 out of 40 had complained of headache in group A and no other side effect was seen in this group. None of the patients in group A stopped medication due to side effects. 2 patients had minor hemotoma in the perianal area in group B which was conservatively relieved by treatment within 6 days. No temporary or permanent incontinence was observed in patients who were operated.

## Discussion

In present study, the mean age in group A was 35.9±11.0 years and in group B, it was 31.87±10.49. The range in group A was 17-66 and in group B, it was 20-65. Males were 28 and females were 12 in group A, males were 30 and females were 10 in group B. The mean duration

of symptoms was 15.35±10.87 weeks in group A, it was 15.02±11.7 weeks in group B. Mean pain score during defecation was 7.89±1.58 in group A, it was 7.52±2.41 in group B. Bleeding during defecation was observed in 82% of patients in group A, 75% of patients in group B. Constipation was present in 27 patients i.e. 67% in group A and it was present in 31 patients i.e. 77% in group B. In Group A, 36 (90%) patients had posterior midline fissure, 4 (10%) had anterior midline fissure, In group B, 40 (100%) had posterior midline fissure. In group A, 24 (60%) had anal tag, in group B, 22 (56%) had anal tag. The VAS score in both the groups decreased gradually but the decrease was more in group B compared to group A at the end of 7<sup>th</sup> week which was statistically significant ( $p < 0.05$ ). Hence, the number of patients who had pain relief after surgical treatment was statistically significant as compared to patients who were treated with 0.2% glyceryl trinitrate ointment application. At the end of the 1<sup>st</sup> week, none of the patients were healed completely. But at the end of the 4<sup>th</sup>, in group A, only 14 patients were completely healed, 38 patients were completely healed in group B. At the end of the 7<sup>th</sup> week, all patients in group B were healed i.e. 100% were healed and in group A, 32 patients were healed completely. 15 out of 40 had complained of headache in group A and no other side effect was seen in this group. None of the patients in group A stopped medication due to side effects. 2 patients had minor haematoma in the perianal area in group B which was conservatively relieved by treatment within 6 days. No temporary or permanent incontinence was observed in patients who were operated.

One study [6] reported the mean age of patients in group A was 34.6±12.8 years and in Group B was 32.12±11.57 years ( $p > .05$ ). In group A, out of 25 patients, 19 were male and 6 females, whereas in group B, there were 20 males and 5 females. The mean pain score of patients before treatment in group A was 8.64±0.95 where as in group B was 8.44±1.19. At the end of six weeks of treatment the mean pain score was 1.64±2.43 in group A and 0.24±1.20 in group B respectively.

Complete healing was observed in 18 out of 25 (72%) patients in group A whereas all 25 (100%) patients in group B had completely healed fissures at the end of six weeks. Except headache which was reported in 9 out of 25 (36%) patients in group A no other side effect was seen in this group whereas only 1 out of 25 (4%) patients in group B developed hematoma in the perianal area, which was relieved conservatively within 1 week. Leo Francis Tauro, et al. [7] reported that chronic anal fissure was more in male 59 patients (66%) than the female 31 patients (34%), the ratio being 1: 0.52. The maximum number of patients was encountered in the age group of 20 to 40 years with mean duration of age 34.14 years. In all three groups symptoms like pain, bleeding, constipation and sphincter spasm were present. Sentinel pile was present in 56% of the patients. Common site of fissure was found to be posterior in 94% of patients. Observations with respect to relief of pain, no bleeding and healing were recorded at 2, 6 and 12 weeks of duration. Lateral sphincterotomy remains effective but should be reserved for the patients who fail to respond to initial chemical sphincterotomy or GTN therapy. GTN is good alternative mode of therapy for patients who refuse surgery and prefer medical line of treatment. Mohamed M. Al Sayed, et al. [8] conducted a prospective study which included forty patients with CAF divided into two equal groups: The first group underwent surgical treatment in the form of Subcutaneous Lateral Internal Sphincterotomy (SLIS), and the second group used the topical treatment in the form of 0.2% glyceryl trinitrate applied twice daily for six weeks. All the patients came to general surgery outpatient clinics at the 6<sup>th</sup> of October Health Insurance Hospital at Cairo, in the period from May to December 2016. Follow-up was done at regular pre-specified intervals and two main outcomes were outlined: "Fissure healing" and "pain relief" to compare between both groups. In the first group with surgical treatment, fissure healing rates were as the following; (20%) by 4 weeks, (80%) by 6 weeks and (100%) by 8 weeks. Pain relief rates were (90%) by 2 weeks postoperatively and (100%) by the end of 4<sup>th</sup> week. With regard to post-operative complications, (65%) of cases had post-operative discharge, (35%) had incontinence to gases but not to stool (0%). And (20%) had pruritis during the first 2 weeks. For the second group subjected to topical treatment, fissure healing rates were (20%) by 4 weeks, (70%) by 6 weeks and (85%) by 8 weeks. Pain relief rates were (65%) by 2 weeks and (100%) by 4 weeks. Regarding treatment related side effects, headache (45%) was the commonest problem, anal itching (35%), three patients (15%) failed to heal and two patients (10%) had recurrence within 6 months. This study has a non-significant *p*-value for the outcome difference between both groups regarding fissure healing and pain relief. One study [9] showed 50 patients were treated with 2 % Diltiazem ointment and rest 50 underwent lateral internal sphincterotomy for chronic anal fissure. Patients were followed for 8 weeks and thereafter evaluated for symptoms relief in both the groups. Observations were recorded at 2<sup>nd</sup>, 4<sup>th</sup>, 6<sup>th</sup> and 8<sup>th</sup> week regarding relief of symptoms like pain, bleeding per rectum, healing of ulcer and side effects of fecal incontinence in surgical group. All data were collected and analyzed accordingly. It revealed that 56% were male and 44% were female and maximum numbers of patients were in the age group 30-39 years. The chief complaints of patients at presentation - 29% had pain during defecation with constipation, 22% bleeding per rectum and 49% had only pain during defecation. Most of them (90 %) had posterior anal fissure. Most of the patients (63%) had ulcer only. But in 37% of cases there were ulcer with sentinel piles. Lateral internal sphincterotomy is the treatment of choice while treating chronic anal fissure, because of its simplicity, better healing rates, better patient satisfaction, minimal morbidity and low complication rates. Taking this option also helps the patient to resume his/her normal works earlier than that of topical 2% Diltiazem ointment. Our study compared topical application of GTN on liposomal base with the surgical procedure i.e.

internal lateral sphincterotomy and according to the method of treatment the patients were divided into two groups; group 1 which included 40 patients with anal fissure and agreed to have the medical treatment with topical GTN 0.2% applied to the anoderm twice daily. Group 2 also included 40 patients and treated with lateral internal sphincterotomy. In group1, healing of fissures occurred in 85% of patients after 8 weeks therapy. Headache as a side effect developed in 65% of patients but no patient ceased to apply the ointment due to headache. In group 2, healing occurred in 97.5% of patients after 8 weeks. Incontinence to flatus occurred in 3 patients (7.5%) and mild soiling occurred in 2 patients (5%), but all were temporary and there was no gross incontinence and one patient with wound infection. The improvement in group 2 faster than group 1 but at the end of 8 weeks both groups become equal in pain score. The main anal resting pressure (MARF) assessment changes in the two groups were nearly equal. This study done by Ellaban, et al. [10] concluded that topical application of nitroglycerin represents a new easily handled and effective alternative in the treatment of anal fissure.

## Conclusion

Glyceryl trinitrate is a good alternative form of treatment for those patients who refuse to undergo surgery and it is the best medical line of treatment. Chemical treatment by applying glyceryl trinitrate is also advantageous in that it doesn't cause any complications. Surgical treatment by lateral sphincterotomy is most effective when patients fail to respond to chemical treatment.

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