A Randomised Study Comparing Topical Glyceryl Trinitrare, Anal Dilatation and Lateral Sphincterotomy for the Treatment of Chronic Anal Fissure

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Abstract:

Background: Anal fissure is a common and minor disorder that needs careful attention because it is a painful condition but the treatment is simple and effective. This has led to the investigation of nonsurgical treatment options that avoid permanent damage to the internal anal sphincter.

Methods: The study was conducted in Geetanjali Medical College and Hospital from year 2015 to 2017, with chronic anal fissure. A comparative study of 101 cases was done between different modalities in the treatment of anal fissure. Study cases were divided into 3 groups.

Treated with topical application of 0.2% glyceral trinitrate GTN, Treated with anal dilation under G.A. or spinal anaesthesia, Treated with lateral sphincterotomy under total intravenous anesthesia (T.I.V.A.) or spinal anaesthesia (S.A.).

Results: A follow up of 101 patients was done for 6 weeks. 30 to 50 years of age with male and female ratio of 2.48:1. Complains of pain in anal region during defecation with blood streak on stool. History of constipation was presented in 71% patients. Out of 101 patients 81 patients could be followed up to 6 weeks. 20 lost were belonging to GTN group. 100%

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and 93.3% patients were relieved of pain in anal dilatation and lateral sphincterotomy as compared to 75% patients with GTN application (significant; p<0.001).

Conclusion: This study concludes that pain relief is early with lateral sphincterotomy anal dilatation. Healing of fissures was early and 100% by lateral sphincterotomy only. Postoperative stay in hospital was short. Incidence of anal incontinence were present with anal dilatation and lateral sphincterotomy which was absent with GTN. Also, healing of fissure was seen in 70% patients at 6 weeks after GTN application. Lateral sphincterotomy is the best choice in terms of surgical treatment but GTN application is a good medical treatment in majority of patients and surgery can be offered to those failures with medical treatment.

Keywords: Fissure in ano; Sphincterotomy; Anal dilatation; Anal incontinence.

Introduction

Anal fissure is a common and minor disorder that needs careful attention because it is a painful condition but the treatment is simple and effective. It is usually common in young adults with almost equal incidences in both sexes.

Diagnosis is based on classic symptoms; i.e. pain during or after defecation often with red streak of blood on faecal matter and a split in the epithelium at or within the anal verge. Secondary features like sentinel skin tag, hypertrophied anal papillae may represent. Causes of anal fissure are uncertain but may be traumatic or result of posterior anal canal ischemia. It is probably due to a chronic increase in resting anal pressure with resultant decreased anodermal perfusion that causes fissure and recurrences. Chronic fissure would not heal spontaneously and nonoperative treatments like injection of botulinum toxin, nitroglycerine ointment, anal dilation; etc. or surgical procedure like anal stretching, fissurectomy and sphincterotomy.

Treatment has shifted from surgical to medical in recent years with aim to reduce the anal spasm or abnormally raised resting anal pressure and pain relief. Anal dilation is a simple procedure and needs no instrument. Fecal incontinence is commonly encountered. Fissures healed in 70%-80% and temporary incontinence is reported in 15%–20% cases. Chemical sphincterotomy using topical 0.2% nitro-glycerine is one of the best medical treatment available but headache and light headedness are common side effects. In lateral sphincterotomy, sphincter is cut in right or left lateral side. It can be divided in closed fashion by tunnelling under the anoderm or in an open method by cutting through anoderm. Following surgery, 93%-97% fissures heal.

Weaver *et al.* (1988) established that manual dilation of anus had no significant differences in outcome than the internal sphincterotomy.

In the proposed study, comparison of various medical and surgical treatment modalities was done and their outcome was studied especially in chronic anal fissure.

Materials and Methods

The present study was conducted on both surgical outdoor and indoor patients attending Geetanjali Medical College and Hospital from year 2015 to 2017, with chronic anal fissure.

A comparative study of 101 cases was done between different modalities in the treatment of anal fissure. In this study cases were divided into 3 groups.

Group 1: Treated with topical application of 0.2% GTN. (60 cases)

Group 2: Treated with anal dilation under G.A. or spinal anesthesia. (26 cases)

Group 3: Treated with lateral sphincterotomy under G.A. or spinal anesthesia. (15 cases)

Routine history was recorded in all cases which included presenting complaints with duration

under following headings anorectal pain, severity (mild, moderate, severe), relation with defecation, blood in stool, sentinel pile, prolapse, history of pruritis, discharge, constipation, diarrhoea, child birth, food habit, past history, drug history.

Local Examination: site of fissure, anal tag, digital rectal examination, proctoscopy, other findings in the form of proctitis, haemorrhoids. Patients were treated randomly by 3 modalities.

Exclusion criteria

Patients with crohn's disease, pregnant woman, patients taking nitrates for other conditions or having ischemic cardiac disease were excluded (especially in GTN group).

Informed consent was taken from the patients undergoing surgical treatment.

GTN Group: patients were started on a course of 0.2% GTN. Applied digitally over perianal and intra-anally three times daily, for 6 weeks. The amount applied was minimal i.e. pea size.

ANAL Dilatation Group: the procedure was performed with the patient under spinal anaesthesia/total intravenous anesthesia.

Digital dilation was performed by controlled stretching. Use of four to six fingers inserted into anal canal for atleast 4 minutes.

Lateral Sphincterotomy Group: performed under spinal anaesthesia. Internal sphincterotomy was done either in right or left lateral side. The internal sphincter was placed on a slight stretch and closed anal sphincterotomy was done.

All the patients were followed up to 6 weeks and comparison was done with respect to pre-treatment symptoms. Patients were also assessed for fissure healing, complications and compliance.

Results

Table 1: Distributions of patients according to age and sex.

S. No.	Age	Male	Female	Total	0/0
1	0-10	0	0	0	0
2	11-20	2	1	3	2.97%
3	21-30	18	4	22	21.78%
4	31-40	28	16	44	43.56%
5	41-50	14	5	19	18.81%
6	51-60	4	3	7	6.93%
7	61-70	6	0	6	5.94%
	Total	72	29	101	
		(71.28%)	(28.72%)		

Mean age was 37.27 years (Table 1).

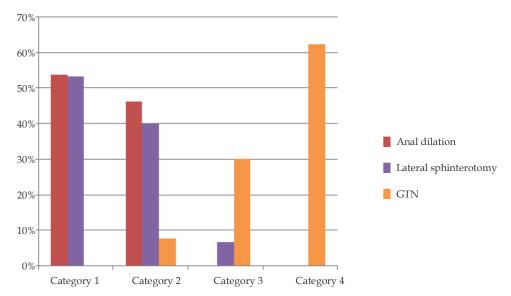


Fig. 1: Distribution of patients according to duration and pain relief post treatment in various groups.

Table 2: Distribution of patients according to chief presenting complaint.

S. No	Complaint	No. of Patients	0/0
1	Anorectal pain	101	100%
2	Rectal bleeding	79	78.2%

Anorectal pain and blood in stool were chief presenting complaints (Table 2).

Table 3: Distribution of patients according to associated complaints.

S. No.	Associated complaints	No. of patients	0/0
1	Pruritis	23	22.77%
2	Prolapsed	32	31.68%
3	Constipation	72	71.28%
4	Diarrhoea	3	2.97%
5	Child birth	4	3.96%

Mean duration of pain relief was 1.46 weeks with anal dilation, 1.53 weeks with lateral sphincterotomy and 3.54 weeks with 0.2% GTN application. Pain relief at 2 weeks was in 100% patients of anal dilation, 93.3% of lateral sphincterotomy and only 7.5% of GTN patients (highly significant; p < 0.001) (Fig. 1).

Discussion

This study consists of 101 cases of chronic anal fissure treated by different modalities at Geetanjali Medical College and Hospital, Udaipur in surgery outdoor and indoor during the year 2015 to 2017.

Majority of patients were between 30 and 50 years of age group. In our study, all patients were between 15 and 70 years of age, with mean age

of 37.27 years. Maximum number of patients 62% were in between 30 and 50 years of age group while 2.97% below 20 years and 5.94% above the age of 60.

Similar age incidence was reported by Lund JN *et al.* (1996)–36 years, Richard *et al.* (2000)–40.3 years, U K Srivastav *et al.* (2001)–40 years, garcea G *et al.* (2004)–33 years.

In our study it was observed that males were more affected than females. Ratio being 2.48:1. Maximum numbers of male and female patients were of 31-40 years of age. It was observed that almost 100% of patients had experienced anorectal pain during and after defecation for few minutes to few hours. It was due to spasm of anal sphincter and anal passage of hard stool.

In our study, pain was classified as mild, moderate and severe with 70.3% moderate and 9.9% had severe pain. Maximum number of patients 81.15% experienced pain during and after defecation for few minutes to half hour while 8% patients had pain lasting for more than 3 hours. Blood on stool is a common symptom. Bleeding is in the form of streak not mixed with the stool and bright red color.

In our study, approximately 78% of patients had blood on stool in the form of streak. About 22.7% had pruritis and 32% complaints of prolapsed as associated complaint.

Constipation is considered as a causative factor as well as aggravating factor of anal fissure. In our study, history of constipation was present in about 71.28% patients. Similar observation of approximately 88% cases in study by Jensen SL

et al. (1988). F.F. Ammari *et al.* (2004) reported 78.5% patients of anal fissure had constipation.

In our study, anal tags were associated in 84% cases and internal haemorrhoids in 19.8% patients.

Similar observation made by Pravin J Gupta *et al.* (2003) observed 51.6% of patients having anal tags and 17% with internal haemorrhoids.

Majority of fissures are usually single and present in posterior mid line in our study 83.17% patients had posterior fissure and 11.8% with anterior fissure.

Sajith Babu SM, Rachna Gupta, Lalmani Singh, Effectiveness of conservative management of acute fissure in ano: A prospective clinical study of 165 patients. Most of the patients were young adults with a slight female dominance. Pain during defecation and bleeding per rectum were the major presenting complaints. 73.94% of patients achieved symptom relief within 2 weeks of conservative treatment. At 6 weeks follow up after giving conservative line of management, 97.58% achieved symptom relief with healing of ulcer. Mean pain score was reduced from 9.5 ± 0.71 at the start of therapy to 1.33 ± 0.69 at the end of 6 weeks of conservative therapy.

Tayfun Yucel and Dogan Gonullu concluded that two months postoperatively, 18 patients in the CIAD group and 17 patients in the LIS group had healed completely, and had no anal incontinence or other complications. The postoperative improvement in pain, bleeding, and constipation did not differ significantly between the two groups. In the CIAD and LIS groups, the pre-operative MACRPs were 89.7 ± 16.5 and 87.6 ± 12.3 mmHg, respectively; 2 months postoperatively, the MACRPs had significantly decreased to 76.9 ± 13.7 and 78.1 ± 11.3 mmHg in the CIAD and LIS groups, respectively. No statistical difference existed in the pre- or post-treatment MACRPs between the groups.

Majid Aziz and Faran Kiani in a study of comparison between lateral internal anal sphincterotomy and diltiazem in the treatment of chronic anal fissure concluded that in group A six patients had healing of fissure after 4 weeks and a further 4 at 6th week. In group B 14 patients had healing at 2 weeks, 10 at 4 weeks, and 5 at 6 weeks. One patient in group B and 20 in group A had no healing. In this study overall healing rate after 6 weeks with diltiazem was 33.33% and 96.66% with LIS.

Out of 101 cases, 26 cases were treated by anal dilation, 15 by lateral sphincterotomy and 60 cases by 0.2% GTN application. These were followed up

for 6 weeks.

In GTN group, 20 out of 60 patients did not come for follow-up.

Blood on stool was absent after a mean duration of 4.4 days with anal dilation v/s 1.3 days with lateral sphincterotomy, whereas with GTN mean duration was 3.4 days. After one-week bleeding were absent in 79% patients treated with GTN, 66% with anal dilation and 100% with sphincterotomy. Thus, absence of bleeding was earlier with lateral sphincterotomy followed by 0.2% GTN application and anal dilation.

Mean duration of pain relief with GTN was 3.55 weeks whereas 1.46 weeks with anal dilation and 1.53 weeks lateral sphincterotomy, showing earlier pain relief with anal dilation and lateral sphincterotomy.

Pain relief at two weeks was in 100% patients with anal dilation, 93.3% with lateral sphincterotomy while 37.5% with GTN (highly significant; p < 0.001).

Pain relief at three weeks was in 100% with anal dilation and lateral sphincterotomy while 37.5% with GTN (highly significant; p < 0.001).

Lund and Armitage *et al.* (1996) reported that pain relief was in 100% cases of lateral sphincterotomy.

D. Khetan *et al.* (2000) reported pain relief in 94% cases of lateral sphincterotomy v/s in 80% cases of anal dilation at 4 weeks.

Janson S.L. *et al.* (1984) reported pain relief in 90% cases with anal dilation v/s in 100% cases of lateral sphincterotomy.

At the end of 6 weeks, 70% patients got their fissure healed while 30% failed to heal with 0.2% GTN.

It was seen that 80.76% of fissures healed by anal dilation while 100% fissures healed by lateral sphincterotomy.

In our study, mean duration of healing of fissures with anal dilation was 4 weeks, 2.6 weeks with lateral sphincterotomy and 4.6 weeks with GTN application.

Fissure healing at 2 weeks was in 40% patients of lateral sphincterotomy v/s 0 in anal dilation and GTN group (highly significant; <0.001). whereas at 4 weeks, healing of fissure was in 100% patients of lateral sphincterotomy, in 65.4% of anal dilation and only 35% cases of GTN (highly significant; <0.001).

At the end of 6 weeks, 80.7% of patients in anal

dilation group got their fissure healed v/s 70% in GTN group (significant; <0.05).

With lateral sphincterotomy, Richard CS *et al.* (2000) reported healing rate of 89.5% patients at 6 weeks, D. Khetan (2000) – 100% at 4 weeks, Simkovic D (1989) – 100% at 3 weeks, Notaras (1971) – 100% at 3 weeks, Milito (1983) – 100% at 4 weeks. Liratzopoulous *et al.* (2005) – 92.5%.

Healing rate with anal dilation, NA Strugnell *et al.* (1999) reported 89%, D Khetan *et al.* (2000) 84% at 4 weeks and Pravin J Gupta *et al.* (2003) 93%.

Our study shows that healing of fissure was early with lateral sphincterotomy followed by anal dilation and GTN application. Fissure healing was in 100% cases undergoing lateral sphincterotomy while 80.7% and 70% cases healed at the end of 6 weeks follow up with anal dilation and GTN application (significant; p < 0.05). Thus results are comparable with previous studies.

This shows lateral sphincterotomy is the treatment of choice for chronic anal fissure followed by anal dilatation whereas chemical sphincterotomy as conservative treatment to avoid surgery in majority of patients.

Non healing of fissure was seen in 19% patients of anal dilatation and 30% patients of 0.2% GTN application group.

Summary

A follow up of 101 patients was done for 6 weeks. Majority of patients were between 30 to 50 years of age with male and female ratio of 2.48:1. Patients presented with main complains of pain in anal region during defecation with blood streak on stool. History of constipation was presented in 71% patients. Out of 101 patients only 81 patients could be followed up to 6 weeks. Rest 20 lost were belonging to GTN application group.

Mean duration of pain relief was comparable in anal dilatation and lateral sphincterotomy and 3.54 weeks with GTN application at 2 weeks. 100% and 93.3% patients were relieved of pain in anal dilatation and lateral sphincterotomy as compared to 75% patients with GTN application (highly significant; p < 0.001).

Conclusion

This study concludes that pain relief is early with lateral sphincterotomy anal dilatation.

Healing of fissures was early and 100% by lateral sphincterotomy only. Postoperative stay in hospital was short. Incidence of anal incontinence were present with anal dilatation and lateral sphincterotomy which was absent with GTN. Also, healing of fissure was seen in 70% patients at 6 weeks after GTN application with minor side effects of headache, itching; etc. lateral sphincterotomy is the best choice in terms of surgical treatment but GTN application is a good medical treatment in majority of patients and surgery can be offered to those failures with medical treatment.

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