

Comparative Study of Lateral Internal Sphincterotomy verses Topical Glyceryl Trinitrate for treatment of fissure-in-Ano

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This prospective randomized interventional study was carried in one of surgical unit of Lahore General Hospital Lahore from 1st, January 2002 to 30, December 2002 a total number of 100 patients with both acute and chronic anal fissure were taken and randomly divided in two groups. Group A was treated with 0.2% GTN for 6 weeks and Group B was treated with lateral internal closed sphincterotomy a follow up after 1st, 2nd, 6th weeks and even after 6 months carried out. Peak incidence of disease was observed between 30 and 40 years of age with 56 males and 44 females. 24% patients were with acute fissure and 76% with chronic fissure. In this study with 0.2% GTN overall healing rate of 66.66% for acute fissure and 63.15% for chronic anal fissure was observed. GTN was found less effective in healing the fissure but some what good for initial symptomatic improvement in its comparison 100% healing was observed with lateral internal sphincterotomy with only 10% transient incontinence for flatus. So it was concluded that lateral internal sphincterotomy is superior to GTN and is the procedure of choice for fissure in ano.

Key words: Fissure in Ano, 0.2% GTN, lateral internal sphincterotomy.

Fissure in Ano is a common benign ano rectal problem which is frequently encountered in surgical outpatient department. It is defined as a split in the skin of the anal canal which may extend from the dentate line to the anal verge². Fissures are usually categorized as acute or chronic. Acute fissures have short history and are generally very painful while chronic fissures have longer history usually more than 2 months and characterized by the triad of external skin tag (Sentinel pile), a hypertrophied anal papilla, an ulcer with rolled edges and a base exposing the internal sphincter fibers¹.

Symptoms are usually pain at the time of and subsequent to a bowel movement, sometimes lasting for hours, with small amounts of bright red bleeding occurring fairly frequently. There are several theories of fissure in ano. The most commonly held blames trauma from hard stools, excessive straining or violent diarrhea as the etiology. Another widely accepted theory and the basis for chemical sphincterotomy is that increased resting anal pressure causes ischemia of the internal sphincter which contributes greatly to the continuation of symptoms and chronicity¹. For effective therapy, it is necessary to break the vicious cycle of pain, sphincter spasm and ischemia. Conservative treatment which includes oral or injectible analgesics, local anesthetics as first therapy is almost universally employed, especially in acute fissures. Even chronic fissures are usually managed by local anesthetics, graduated dilators, and bulking agents initially though the likelihood of healing is much less. Because these conservative measure have uncertain results and usually patients do not satisfy with these ultimately more definite form of treatment sooner has to be offered. This was usually anal dilatation under anesthesia followed by internal sphincterotomy. Because of the occasional complications (minor degree of incontinence for flatus), attempts have been made at "chemical sphincterotomy". Local injection (into the external anal sphincter) of

botulinum toxin which paralyzes external sphincter by inhibiting acetylcholine release¹³ is the best known of these but has not achieved wide popularity and is not widely available.

Demonstration that nitric oxide is the inhibitory neurotransmitter of the internal sphincter opened further possibilities and there is new surge for treatment of fissure in Ano with this agent (glyceryl trinitrate) but most surgeons remain faithful to the simple and very effective lateral internal sphincterotomy. Thus there was a need to compare the effectiveness and toxicity of topical glycerol trinitrate with lateral internal sphincterotomy in the treatment of anal fissures.

Aims and Objectives

To compare the topical glyceryl trinitrate (GTN) application with the surgical lateral internal anal sphincterotomy for the 1 effectiveness, 2 symptomatic relief, 3 ulcer healing, 4 complications and 5 recurrence.

Inclusion criteria

Patient between 10-65 years of age with both acute and chronic anal fissures are included.

Exclusion criteria

Patients having fissures associated with other pathologies e.g. Hemorrhoids, fistula in Ano, anal Abscess. Peri anal cancer, inflammatory bowel disease, intestinal carcinoma and previous surgical procedures on anal canal were excluded from study.

Patients and methods

This randomized controlled prospective interventional study was carried out in Lahore General Hospital Lahore from 1st Jan 2000 to 30 Dec 2002. A total number of 100 patients were included in the study.

A detailed history and examination both local and systemic was undertaken and diagnosis was entirely

clinical. Information regarding duration of pain, severity of pain (using visual analogue scale for pain, VAS) along with other associated symptoms like constipation, bleeding, mucous discharge and previous treatment were obtained and carefully recorded in the performa.

Patients were randomly divided into two groups. The patients in group A were advised 0.2% GTN ointment whereas those in group B were subjected to lateral internal anal sphincterotomy. A pea size quantity (0.5 ml) of GTN was applied circumferentially to the anal margin and rubbed gently in a clock wise direction for 5-8 seconds and small quantity was also applied inside the anus. The drug was advised to apply three times daily for 6 weeks.

Patients assigned to surgery were examined under anesthesia, their findings noted and then proceeded for internal sphincterotomy by an experienced surgeon. A closed left lateral internal anal sphincterotomy was performed under general or regional anesthesia (spinal or caudal). Internal anal sphincter was divided for a length of approximately 2 cm. The anal skin tag or fibrinous polyp if present was excised. Hemostasis secured and a gauze dressing applied. No prophylactic antibiotic was given. Patient were discharged after 24 hours. A follow up at the end of 1st, 2nd and 6th week and even after 6 months was carried out. All patients were informed about the potential side effects of both the treatment modalities and their remedial measures.

To assess the effectiveness of both treatment modalities the assessment criteria of visual analogue scale for pain was used for subjective assessment and objectively, the fissure healing was assessed by looking for epithelization at the base of the fissure. Both groups were also analyzed with respect to the range of complications.

Results

100 patients with the diagnosis of fissure in ano were included in the study. The age range of the patients was between 12-65 years with mean age of 35.25 years. Peak incidence of disease was between 30-40 years of age. As shown in table 1 and figure 1. Out of 100 patients, 56 were male and 44 were females. Male to female ratio was 1.2:1 as shown in table 2 and fig 2.

Twenty-four patients presented with acute anal fissure among which 16 were male and 8 were females. 76 patients presented with chronic anal fissure among which 40 were males and 36 were females as shown in table 3.

Presenting complaints in these patients were painful defecation in all 100 patients, constipation in 20 patients with acute anal fissure and in 66 patients with chronic anal fissure, bleeding per rectum in 16 patients with acute anal fissure and in 60 patients with chronic anal fissure while discharged and peri anal soiling was present in 10 patients with acute anal fissure and in 30 patients with chronic anal fissure as shown in table 4 and fig 3. Finding of peri anal examination are elaborated in table 5.

The patients in group A were treated with 0.2% glyceryl trinitrate while group B patients underwent a closed left lateral internal anal sphincterotomy. All patients turned up for follow up at 1st and 2nd visit after one and two weeks respectively. 96 patients were available at 3rd visit after six weeks while 92 patients came after 6 months.

Discussion

The encouraging results of early clinical trials of glyceryl trinitrate (chemical sphincterotomy) suggested it might find a role in the treatment of fissure in ano. Before widely adopting this form of treatment a comparison with the current standard lateral internal sphincterotomy (surgical sphincterotomy), must be made. This study was carried out to compare the effectiveness of topical glyceryl trinitrate (GTN) with surgical lateral internal anal sphincterotomy, regarding symptomatic relief, ulcer healing. 100 patients presenting to surgical outpatient department of Lahore General Hospital Lahore were taken and randomly divided into two groups. Group A was offered 0.2% GTN ointment and the patient in Group B underwent lateral internal sphincterotomy and their results compared.

In this study with the dose of 0.5 ml of GTN for 6 weeks we observed overall healing rate of 66.66% for acute fissure and 63.15% of chronic anal fissure which is very much comparable with the results of lund and scholefield and other studies^{1, 3, 5, 8, 12, 14}.

Although GTN was less effective in healing anal fissure, it was quite effective in reducing the symptoms or minimizing the pain while the patient was using it. The symptoms were improved in approximately 78.25% of patients in GTN group at six weeks. However once GTN was discontinued pain recurred in some patients. Furthermore almost more than one fourth of patients required surgery in this group. Thus GTN may be effective in the short term for providing symptomatic relief but does not seem to be as effective in healing the fissure in the long term as surgery. Most of the studies tried to establish the role of GTN as an exogenous nitric oxide donor which is an important neurotransmitter mediating internal anal sphincter relaxation in those studies anal manometry and the assessment of squeeze pressure were the methods to evaluate the effectiveness of 0.2% GTN, manometry showed 2% reduction in MRP and squeeze pressure fell by 11% this is parallel to the criteria used in this study where in place of objective evidence, improvement in pain and healing of the anal fissure were used to assess the efficacy of treatment modalities. Same methodology was adopted by Gorfine in 1995⁵ who used only clinical evidence to assess the efficiency of treatment therapy. Visual analogue scale (VAS) for pain adopted from Salim¹³ proved to be simple and effective way to evaluate the subjective improvement. It was seen that the pain scored fell more progressively and permanently from 10 to 2 with lateral internal sphincterotomy as compared to GTN therapy

which was from 10 to 4 initially but after 6 weeks it again raised to 6 or 7.

Although there was initial enthusiasm for GTN for the treatment of fissure in Ano, our results are more in the favor of lateral internal sphincterotomy (the current standard). In its comparison, the overall healing ratio of 100% was observed with lateral internal sphincterotomy in both types of fissure which is also very much comparable with the results of various studies in the literature in which healing was reported in 95 to 100% of patients^{9, 10, 11}. Richard et al¹² concluded that surgical sphincterotomy significantly improved healing rate at six weeks (89 vs 29%) and reduced the requirement for further surgery (3vs 45%) in his trial of 82 patients.

A mean healing time of 3.7 weeks (min 2, max 6) was observed in internal and sphincterotomy group and of 4.1 weeks (min 2, max 6) was observed in GTN group, which is compatible to the results achieved by A, Coher⁹, Gorfice⁽⁵⁾ and Lund^(1, 4, 7) where the healing time was between 2 to 6 weeks. There was continence disturbances for flatus observed in 10% patient in the internal sphincterotomy group in this trial which is quite comparable to the other studies in which disturbances in which continence was also a significant complaint in individual having surgery for fissure in ano. One might argue that a more objective measure, perhaps anal manometry, should have been performed to assess anal sphincter status, we felt that clinical symptoms status was more relevant. Although this study suggests that continence is not adversely affected in the short term, further prospective evaluation with a comparison control group is warranted to determine the long term effect on continuance. Different studies show high rate of head ach with GTN, in our study it was also significant which was 76% but easily controllable with simple analgesics.

Conclusion

This randomized, controlled trial demonstrates that internal sphincterotomy is superior to topical glyceryl trinitrate for the treatment of anal fissure, with a good symptomatic relief, high rate of healing, few side effects and a very low rate of early continence disturbances.

Table 1: Age distribution of patients with fissure in ano (n=100)

Age (Years)	n=	%age
11-20	8	8
21-30	24	24
31-40	44	44
41-50	12	12
51-60	8	8
61-65	4	4
Total	100	100

Fig. 1: Age distribution of patients with fissure in ano (n=100)

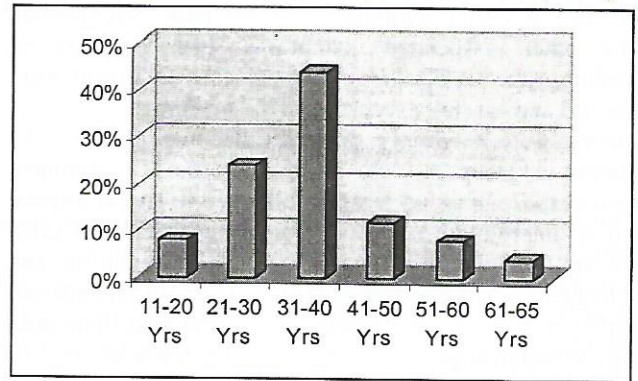


Table 2: Sex distribution of patients with fissure in ano (n=100)

Sex	n=	%age
Male	56	56
Female	44	44
Total	100	100

Figure 2: Sex distribution of patients with fissure in ano (n=100)

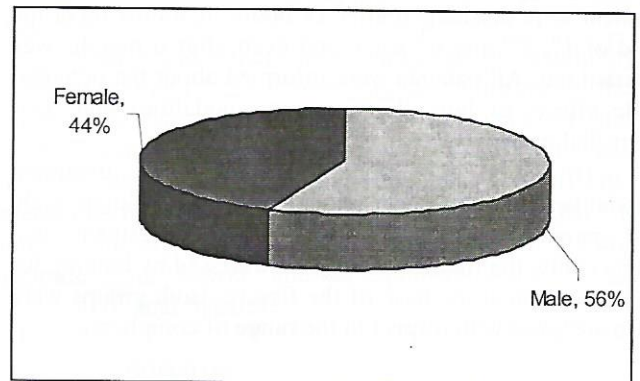


Table 3: Presentation of Fissure in ano (n=100)

Fissure	Sex	n=	%age	Grand %age
Acute	Male	16	16	24
	Female	8	8	
Chronic	Male	40	40	76
	Female	36	36	

Table 4: Symptomatology of fissure in ano (n=100)

Symptoms	Acute fissure(n=24)		Chronic fissure(n=76)	
	No	%	No	%
Pain	24	100	76	100
Constipation	20	83	66	87
Bleeding P/R	16	67	60	79
Discharge and soiling	10	42	38	50

Figure 3: Symptomatology of fissure in ano (n=100)

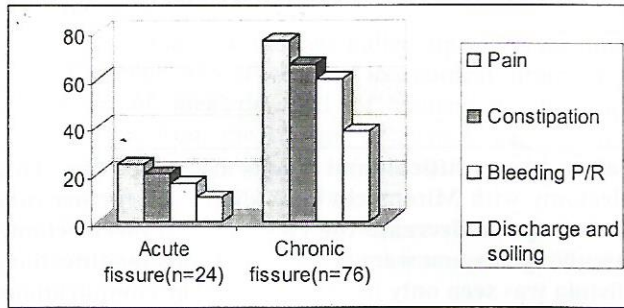


Table 5: Findings of peri-anal examination of patients with fissure in ano

Site of fissure	Acute Fissure (n=24)		Chronic fissure (n=76)		Total (n=100)	
	No	%	No	%	No	%
Anterior	4	17	6	8	10	10
Posterior	20	83	70	92	90	90
Lateral	0	0	0	0	0	0
Sentinal pile	0	0	42	55	42	42
Hypertrophied anal papilla	0	0	18	24	18	18
Induration of margins	0	0	66	87	66	66
Base of fissure						
Red	24	100	2	3	26	26
White	0	0	74	97	74	74
Digital rectal examination						
Possible	0	0	6	8	6	6
Not Possible	24	100	70	92	94	94

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