

COMPARISON OF ROLE OF TOPICAL GLYCERYL TRINITRATE OINTMENT VERSUS LATERAL INTERNAL SPHINCTEROTOMY FOR CHRONIC ANAL FISSURE

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ABSTRACT

Background: Anal fissure is one of the most common distressing disorders in ano-rectal region. Symptoms from anal fissure cause considerable morbidity and reduction in quality of life. Typically it causes symptoms of severe pain after defecation and bright red rectal bleeding.

Objective: This study aimed to determine the effectiveness of glyceryl trinitrate (GTN) versus lateral internal sphincterotomy in treatment of chronic anal fissure.

Material and Methods: This prospective randomized controlled study was conducted at Hayatabad Medical Complex Peshawar between may 2008 to may 2009 after approval from hospital ethical and research committee. Seventy patients with chronic anal fissure were divided into two equal groups. Group A (35 patients) were treated with topical glyceryl trinitrate ointment (0.2%) three times daily and Group B (35 patients) were subjected to lateral internal sphincterotomy. All patients were followed up in the out-patient department at two weeks intervals for eight weeks to evaluate the improvement in symptoms and efficacy of procedures.

Results: Pain relief was noticed in 60% patients in group A versus 80% in group B after four weeks, and 80% in group A and 90% in group B after eight weeks of follow up. Complete fissure healing occurred in 74% and 85% of group A and group B patients respectively after eight weeks follow up.

Conclusion: Application of GTN ointment as a local treatment for chronic anal fissure should be considered first line treatment because it is safe, easily handled, cost effective, reversible, heals about 70% of chronic anal fissures and avoids complications of surgery. Lateral internal sphincterotomy was superior in terms of healing, but it is an invasive procedure and therefore should be reserved for patients not responded to topical GTN therapy.

Key words: Chronic anal fissure, GTN ointment (0.2%), lateral internal sphincterotomy (LIS).

INTRODUCTION

Anal fissure is one of the most painful conditions encountered in surgical practice, and causes considerable morbidity and reduction in quality of life¹.

Anal fissure is a linear tear in the mucosa of the distal anal canal below the dentate line. It affects all age groups, but is seen more in young healthy adults with equal sex incidence. It typically causes significant pain with defecation and bright red rectal bleeding. Pruritus and anal accompaniment up to 50% of anal fissure². The diagnosis is made by a history of pain and bleeding accompanying defecation and is confirmed by visual inspection³.

Anal fissures are most commonly found in the posterior midline, although 10-20% in women and 1-10% in men are found in anterior midline⁴. SCHOUTEN et al⁵, had shown in their study that anodermal blood flow in the posterior midline is less than in the other segments of anal canal, signifying its high incidence in posterior midline.

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The exact cause of anal fissure is not known, but current evidence suggests high sphincter pressure and secondary local ischemia as causative factors⁶. These high anal pressures can impede blood flow to the anoderm as it passes through the internal anal sphincter.

Though the distinction between acute and chronic fissure is somewhat difficult, fissures failing to heal within six weeks despite conservative measures are designated as chronic anal fissure⁷. In chronic fissures the edges become raised with classical triad of a sentinel tag, anal ulcer and hypertrophic anal papilla⁸.

Different modalities employed for anal fissure management includes conservative measures, surgical procedures and various pharmacological agents like glyceryl trinitrate ointment.

OBJECTIVE

This study aimed to determine the effectiveness of glyceryl trinitrate (GTN) versus lateral internal sphincterotomy in treatment of chronic anal fissure.

MATERIAL AND METHODS

This prospective randomized comparative study was conducted at Hayatabad Medical Complex Pe-

shawar between may 2008 to may 2009 after approval from hospital ethical and research committee. A total of seventy patients were included in the study including both males and females. There were forty males (57%) and thirty females (43%) with a mean age of forty years (age range 20-60). All patients primarily diagnosed with fissure in ano of more than six weeks duration by full history and complete examinations in out-patient department were included, according to the following criteria.

INCLUSION CRITERIA

Patients with chronic anal fissure (more than six weeks old)

Adults with age range of 20 -60 years .

Both males and females.

EXCLUSION CRITERIA

Patients with acute anal fissure (less than six weeks old)

Chronic fissure with other anal pathologies like piles, previous anorectal surgery etc.

Pregnant females.

Age less than 20 or more than 60 years.

Systemic diseases like diabetes mellitus, chronic liver disease, crohn disease etc.

Patients under treatment with nitrates for other diseases like ischemic heart problem .

Patients with chronic anal fissure were divided into Group A and Group B by lottery method after taking written informed consent. Group A patients were treated with topical GTN (0.2%) ointment applied three times daily for eight weeks along with others conservative measures including analgesics, stool softners and ispaghula husk, and Group B patients were treated with lateral internal sphincterotomy performed under general anaesthesia as a day case procedure after taking informed consent, and both groups were followed up in the out – patient department at two weeks interval for eight weeks.

Lateral internal sphincterotomy was performed by open technique in lithotomy position. Anal retractor was inserted and internal sphincter was stretched and made easily palpable. A small incision was then made and intersphincteric plane was developed by scissors and internal sphincter was cut by exposing it. Postoperatively patients were advised oral antibiotics, analgesics, stool softners and daily sitz bath for five days.

FOLLOW UP ASSESSMENT

All patients in each group were followed up at two weeks interval for eight weeks, in order to evaluate the improvement as follows .

Pain assisted by visual analogue score (VAS) in all patients. Patients asked to indicate a point on 100 mm line, one end of the line represent no pain on defecation and the other represent worst pain. Complete absence of pain was considered as symptomatic pain relief.

Fissure healing: was assessed by anal inspection and complete epithelisation of the fissure was labelled as healed fissure.

Appearance of any adverse effect.

RESULTS

Seventy patients were divided into two equal groups, comparable in age and symptoms duration. Both groups were followed up in the out-patient department at second, fourth, sixth and eight weeks of treatment with main emphasis on pain relief and fissure healing.

Complete disappearance of pain was considered successful. At the ends of 2nd weeks, only 14 patients

TABLE 3: COMPLICATIONS

Complications	GTN (n-35)	LIS (n-35)	p-value
Bleeding	0(0%)	7(20%)	0.0112
Headache	4(11%)	0(0%)	0.1142
Flatus incontinence	0(0%)	5(14%)	0.0536
Wound infection	0(0%)	3(8%)	0.2391

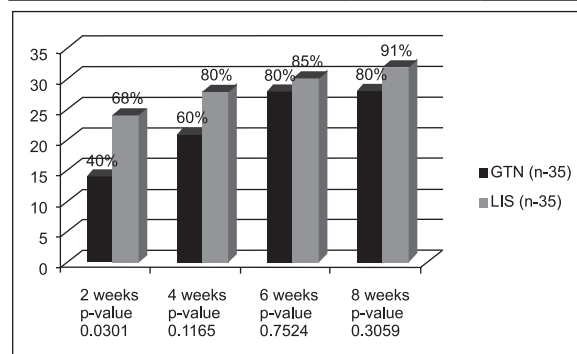


Figure 1: PAIN RELIEF

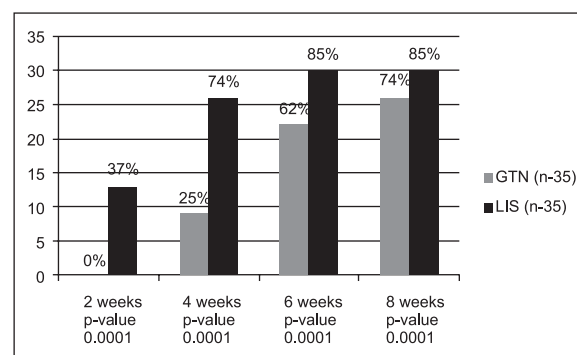


Figure 2: FISSURE HEALING

(40%) in group A had complete pain relief as compared to 24 patients (68%) in group B showed a prompt and early pain relief in LIS group as compared to GTN group. At the ends of 4th weeks, 21 patients (60%) in group A versus 28 patients (80%) in group B had complete pain relief, but at the ends of 6th week, this difference decreases to only 5% as shown in figure 1. At the 8th week follow up, 28 patients (80%) in group A and 32 patients (91%) in group B had complete pain relief as in figure 1.

Fissure was labelled as completely healed when it was found completely epithelialized. At the ends of 2nd week, no patient in group A showed fissure healing as compared to 13 patients (37%) in group B. After 4th week, 9 patients (25%) in group A versus 26 patients (74%) in group B had complete fissure healing as in figure 2. At 6th week follow up, 22 patients (62%) and 30 patients (85%) showed healing in group A and group B respectively. At 8th weeks, 26 patients (74%) in group A and 30 patients (85%) in group B showed complete healing as shown in figure 2.

Headache is the main side effect of GTN ointment. In group A, only 4 patients (11%) had mild to moderate headache which subsides with oral analgesics and does not interfere with daily activities. The main problem with lateral internal sphincterotomy is incontinence, both flatus and faecal. In our study 5 patients (14%) had flatus incontinence subsides with the passage of time in most patients and none of the patients had faecal incontinence at 8th week follow up as shown in Table 3.

DISCUSSION

Anal fissure is a linear tear in the mucosa of the anal canal normally extending distally from the dentate line to the anal verge. An acute tear in the mucosa if fails to heal, then it progresses to a chronic anal fissure⁹. Although there is no defined time period distinguishing acute from chronic fissure, some authors suggest a chronic fissure should be present for at least 6-8 weeks^{10,11}.

Although the exact mechanism surrounding the pathophysiology of anal fissure has not been clearly established, current theories revolve around the tonicity of anal sphincter and blood flow. Most patients with chronic anal fissure has raised resting anal pressure caused by hypertonicity of internal anal sphincter which results in decrease blood flow at posterior commissure of anal canal and fissure formation¹². Nitric oxide (NO) causes relaxation of the smooth muscles including internal sphincter muscles, and is the most important inhibitory neurotransmitter of the internal sphincter muscle. Derangement in the NO regulation may underlie the anal sphincter hypertonicity associated with anal fissure¹³. GTN is one of the group of organic nitrates release NO, leading to fall in maximum anal resting pressure and increase anal blood flow to heal fissure.

Various treatment modalities are available for the treatment of chronic anal fissure. Non surgical options include conservative measures (increase fibre diet and water intake, pain control), pharmacological therapies e.g GTN ointment, calcium channel blockers and local botulinum toxin injection. If the use of topical GTN has not improved symptoms or where adverse effects of nitrates are intolerable, topical Diltiazam 2% two to three times daily may be used¹⁴. Surgical procedures commonly used for chronic anal fissure which aims to relax the internal sphincter includes, manual anal dilatation, open lateral internal sphincterotomy, closed lateral sphincterotomy, posterior midline sphincterotomy and anoplasty with varying success rates¹⁵. Surgery is consistently superior to medical management, although it should only be considered in patients with chronic, non healing anal fissure where medical treatment failed¹⁵. About 10-30 % of chronic anal fissure do heal with conservative measures alone but most will require further intervention. Among various treatment options, GTN ointment and LIA are the most commonly used for chronic anal fissure treatment.

Some studies showed GTN role in healing chronic anal fissures as high as 80-86%^{16,17}. Others randomized controlled trials showed lower healing rates between 49-68%^{18,12}. Another study showed that local application of GTN can avoid surgery in more than 80% of patients with chronic anal fissure¹⁹. One study showed very prompt symptomatic relief and fissure healing in upto 95% of chronic anal fissures²⁰.

In one study²¹, 66.6% patients with topical GTN ointment treatment and 86.5% with LIS patients had healed chronic anal fissures at the end of 8th week treatment. This is comparable to our study of 74% and 85% healing rates in GTN and LIS groups at the end of 8th week follow up. In another study²², 70 % patients with chronic anal fissure had healed fissures in GTN group at the end of 8th week follow up, as compare to 74 % healing rates in GTN group in our study. The same study also showed 97 % healing rates in LIS group at the end of 8th week, as compare to 85 % healing rates in our study.

Another study by Samad and his colleagues²³, showed early complete pain relief in 72% and 44% in LIS and GTN group at the ends of 2nd week, but this became equal of 92% and 92% in both groups at ends of 6th week. Our study also showed comparable results of 80% and 85% pain relief in GTN and LIS groups at the ends of 6th weeks. Same study also showed fissure healing rates of 92% and 88% at the ends of 6th week follow up in GTN versus LIS groups as compared to 62% and 85% in GTN versus LIS groups in our study at 6th weeks follow up.

In one study by Richard and his colleagues²⁰, showed that sphincterotomy had a higher rate of fissure healing at 6th month than did the GTN group (92.1% vs 27.2%). Our study also showed the higher rates of

healing in LIS group than GTN (85% vs 74%). Another study of 70 patients by Libertiny and his colleagues²⁴, comparing topical GTN vs LIS with 24th month follow up, concluded that many anal fissures healed with topical GTN, and LIS remains effective but should be reserved for patients who fails to respond to initial GTN.

Headache is the major side effect of topical GTN treatment and is seen in 19-44% of patients in various studies. In one study²¹, 26% patients had moderate to severe headache responded to oral analgesics, as compare to 11% in our study, also responded to oral analgesics. The main complication in LIS patients is incontinence both flatus and faecal. In one study by Hussain and his colleagues²¹, showed 13.2 % had flatus incontinence as compare to 14% in our study at follow up. Another study²³, showed flatus incontinence of about 16% in LIS patients.

CONCLUSION

Application of GTN ointment as a local treatment for chronic anal fissure should be considered first line treatment because it is safe, easily handled, cost effective, reversible, heals about 70% of chronic anal fissures and avoids complications of surgery. Lateral internal sphincterotomy was superior in terms of healing, but it is an invasive procedure and therefore should be reserved for patients not responded to topical GTN therapy .

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