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Original Research Article

Comparative evaluation of 5% lignocaine ointment and a combination of 0.2% glyceryl trinitrate and 5% lignocaine in management of acute fissure in ano.

Vundavalli Sattibabu, Satish Dalal, Mahavir Singh, Chisel Bhatia*

Department of Surgery, Pandit Bhagwat Dayal Sharma PGIMS, Rohtak, Haryana, India

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***Correspondence:**
Dr. Chisel Bhatia,
E-mail: chiselbhatia@gmail.com

ABSTRACT

Background: Anal fissure is one of the most common anorectal problem and presents as a tear in the anoderm distal to the dentate line. It is a common proctologic problem and accounts for 10-15% of proctological consultations and seen frequently in young and middle-aged patients. Presently wide range of medical and surgical treatment options were available. Present study was aimed to evaluate the therapeutic efficacy of 5% lignocaine ointment and a combination of 0.2% glyceryl trinitrate and 5% lignocaine in management of acute fissure in ano.
Methods: In the present study, a total of 100 patients diagnosed with acute fissure in ano were randomly allocated into two groups (I, II) of 50 patients each and were managed by local application of 5% Lignocaine (LIG) ointment and a combination of both 0.2% Glyceryl trinitrate (NTG) and 5% Lignocaine (LIG) ointment respectively.
Results: In the present study, the incidence of anal fissure was higher in males than in females with mean age of occurrence of 35.12 years. Pain was the most common symptom to present with. After six weeks, complete pain relief was seen in most of the patients and was comparable in both the groups but healing was superior in group II when compared to group I. Headache and dizziness were the side effects only noticed in group II.
Conclusions: To conclude the study, we can say that the treatment of anal fissure is becoming increasingly medical as it can be carried out on outpatient basis and is cost effective and there is no loss of man hours. Lignocaine may be preferred as the first line treatment as there are no side effects and if there is failure to heal then we can prescribe the combination of both drugs owing to their risk benefit ratio.

Keywords: Acute fissure in ano, Healing, LIG, NTG, Pain relief

INTRODUCTION

Anal fissure is one of the most common anorectal problem and presents as a tear in the anoderm distal to the dentate line.[1] It is a common proctologic problem and accounts for 10-15% of proctological consultations and seen frequently in young and middle-aged patients around 15 to 40 years of age with an incidence of 1 in 350 and equal incidence in both sexes.[2,3]

Approximately 90% of anal fissures in both men and women are located posteriorly in the midline. Anterior fissures occur in approximately 10% of patients and are more common in women. Less than 1% of fissures are located off a midline position or are multiple in number. These atypical fissures may be associated with Crohn's disease, sexually transmitted diseases, anal cancer or tuberculosis.[1]

The exact mechanism surrounding the pathophysiology of anal fissures has not been clearly established and is fairly complex and multifactorial. It involves anodermal ischemia, infection, chronic constipation, hypertonicity of smooth muscle of the internal anal sphincter (IAS) and

elevated maximal anal resting pressure (MARP) being involved.[4]

Fissure in ano is typically a painful condition as it involves the highly sensitive squamous epithelium. With defecation, the ulcer is stretched, causing pain and mild bleeding. Pain is the most incapacitating feature of fissure with or without bleeding during and after defecation for which the patient presents to the surgeon. The diagnosis can typically be confirmed by physical examination in an office setting. By gentle separation of the buttocks and examination of the anus, a linear separation of the anoderm can be identified usually at the lower half of the anal canal.[1]

The principal aim of treatment of anal fissure is to decrease internal anal sphincter tone and hence increase the blood flow with subsequent tissue healing. Treatment options include pharmacological and surgical means.

First line therapy generally used to manage acute anal fissure is nonspecific and includes stool softeners, bulk agents and warm Sitz's bath. In patients not relieved with this management, chemical sphincterotomy is attempted. This includes the usage of various pharmaceutical like analgesics, local anaesthetic and smooth muscle relaxants.

Although the debate about optimum first-line therapy for acute anal fissure continues, treatment is increasingly medical. Surgical techniques like anal dilatation, open or closed sphinterectomy available for treating anal fissure permanently lower resting anal pressure and result in healing of the ulcer in majority of the patients but these surgical procedures may be complicated by non-healing wounds and a higher incidence of flatus or faecal incontinence. Medical treatment avoids all the complications related to surgical procedures and it can be carried out as an outpatient procedure. It is cost effective, does not require hospitalization and there is no loss of man hours.

The present study is designed to comparatively evaluate the topical efficacy of pharmacological drugs i.e. 5% Lignocaine versus combination of both drugs in reference to early pain relief, healing of fissure, side effects and persistence of fissure in the management of acute anal fissure.

METHODS

The present prospective study was conducted in Department of General Surgery, Pt. B. D. Sharma Institute of Medical Sciences, Rohtak. 100 patients with diagnosis of acute fissure in ano who presented to the OPD of department of general surgery were included in the study. These patients were allocated into one of the two groups (I, II) of 50 each. Group I was managed by local application of 5% Lignocaine ointment and Group II was managed by application of both 0.2% Glyceryltrinitrate and 5% Lignocaine ointment. An informed consent was taken from all patients for inclusion in the study.

- Group I patients were prescribed a single brand of 5% Lignocaine ointment. This ointment was applied by fingertip twice daily, once in the morning after passing stool and then again during at night before going to bed. Patient were advised to squeeze 2 cm of ointment from tube onto the device provided by manufacturer and applied circumferentially 1.5-2 cm inside the anal canal and to the anal margin.
- Group II were prescribed both 0.2% Glyceryltrinitrate and 5% Lignocaine. This ointment was applied by fingertip twice daily, once in the morning after passing stool and then again during at night before going to bed. Patient were advised to squeeze 2 cm of ointment from tube onto the device provided by manufacturer and applied circumferentially 1.5-2 cm inside the anal canal and to the anal margin. Both the ointments were applied over 15 minute's gaps twice daily.

All patients were advised to follow a high fiber diet, stool softener and advice on perianal hygiene (Sitz's bath) at initial assessment. During the course of treatment, the patient under study was followed initially at one week, then at two, four and six weeks and examined for symptomatic relief of pain (VAS), healing of fissure, bleeding per rectum and side effects of drug if any.

Anal pain was assessed before starting treatment and at weekly follow up visits using a linear Visual Analogue Pain score (range 0-10, with 0 representing no pain and 10 indicating the worst possible pain). Bleeding per rectum was assessed subjectively at baseline and at every visit. Side effects like headache, dizziness, burning sensation and allergy to the drug were recorded at each visit.

The primary end point was complete healing of anal fissure, defined as presence of scar at six weeks of treatment. Partial healing defined as persistence of fissure but with improvement in symptoms was noted. Non-healing of fissure will be taken as persistence of fissure and symptoms at the end of six weeks.

RESULTS

100 patients with diagnosis of acute fissure in ano who presented to the OPD of department of general surgery were included in the study. These patients were allocated into one of the two groups (I, II) of 50 patients each. In the present study, maximum incidence of acute fissure is seen in 4th decade of life and then it is closely followed by 3rd decade. Extremes of ages are having the least incidence. The decreased incidence with advancing age is probably because of the reason that with the advancing age sphincter muscle relaxes along with other muscles of the body (Table 1).

Table 1: Age distribution of the patients included in the three groups.

Age	Group I	Group II	P-value
<20 years	4	6	
21-30 years	20	16	
31-40 years	10	12	0.955
41-50 years	6	8	
51-60 years	10	8	
Total	50	50	

In the present study, total of 58 (58%) patients out of 100 patients with anal fissure are males in all the two groups. The incidence of anal fissure was slightly higher in males than in females. The most common symptoms of patients with anal fissure are painful defecation, bleeding per rectum, pruritus, anal spasm and constipation at the time of presentation.

There is a correlation between pain, bleeding per rectum and constipation. The presence or thought of pain makes the patient to suppress the urge of defecation and thus constipation occurs. Constipation in turn leads to hard stools and hence bleeding per rectum occurs while passing stool. This way a vicious cycle of pain, spasm, bleeding and constipation is propagated. Pain being the most common symptom noticed in our study. In the present study, all the patients presented with pain at the time of defecation which persisted variably after defecation.

In the present study, the anal fissure was most commonly located in posterior half of anal verge, the most common location being 6'0 clock position. 72 out of 100 patients in the present study had posterior anal fissure and 28 patients had anterior anal fissure.

After six weeks, complete pain relief was seen in 38 patients out of 50 patients in Lignocaine group and 46 patients out of 50 patients in Combination group (Table 2).

Table 2: Frequency of pain relief at six weeks in two groups.

Pain relief	Group I	Group II
Present	38 (76%)	46 (92%)
Absent	12 (24%)	4 (8%)
Total	50	50

After six weeks healing was seen in 28 patients out of 50 patients in lignocaine group and 44 patients out of 50 patients in combination group (Table 3).

In combination group 22 (44%) patients out of 50 patients complained of headache. But there were no such complaints in patients treated with lignocaine. In almost all the patients headache gradually subsided (Table 4).

Table 3: Healing at six weeks in three groups.

Headache	Group I	Group II
Present	0	22 (44%)
Absent	50 (100%)	28 (56%)
Total	50	50

Table 4: Frequency of headache in the two groups.

Headache	Group I	Group II
Present	0	22 (44%)
Absent	50 (100%)	28 (56%)
Total	50	50

Burning sensation was seen in 4 patients out of 50 patients in lignocaine group and 4 patients out of 50 patients in combination group. The incidence of burning sensation was equal in all both the groups.

Persistence of fissure after six weeks was seen in 22 patients out of 50 patients in lignocaine group and 6 patients out of 50 patients in combination group.

DISCUSSION

In the present study, the mean age of occurrence of fissure is 34.88±12.35 years for lignocaine group and 35.24±12.70 for combination group. The two groups were comparable in age distribution as p-value of the present study is 0.955. The incidence of anal fissure was slightly higher in males than in females which is comparable to Kocher et al study where incidence of anal fissure is slightly higher in males.[5]

After six weeks, complete pain relief was seen in 38 patients out of 50 patients in Lignocaine group and 46 patients out of 50 patients in Combination group. Results of the present were similar to study conducted Lund et al where 18 out of 21 patients were asymptomatic after second week of treatment and Mann et al where 15 out of 16 patients were asymptomatic after four weeks.[6,7] Lund and Scholefield conducted a randomized, prospective, double-blinded, placebo controlled trial of GTN ointment and found that there is marked pain relief after using GTN ointment in comparison to placebo.[8]

After six weeks healing was seen in 28 patients out of 50 patients in lignocaine group and 44 patients out of 50 patients in combination group. Overall it was seen that healing was equally good in both nitroglycerine and combination group and were superior to lignocaine group. In a study done by Sanei et al, complete remission of anal fissure occurred in 54.9% patients in nitroglycerine group which shows no significant difference.[9]

In combination group 22 (44%) patients out of 50 patients complained of headache. But there were no such complaints in patients treated with lignocaine. In almost

all the patients headache gradually subsided. It is reflected in Kocher et al study that headache was the most common side effect reported in 56% of the people in nitroglycerine group.[5]

CONCLUSION

To conclude the study, we can say that the treatment of anal fissure is becoming increasingly medical as it can be carried out on outpatient basis and is cost effective and there is no loss of man hours. Lignocaine may be preferred as the first line treatment as there are no side effects and if there is failure to heal then we can prescribe the combination of both drugs owing to their risk benefit ratio.

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