Original Research Article

DOI: https://dx.doi.org/10.18203/2349-2902.isj20221326

Zinc oxide, lidocaine, and lateral internal sphincterotomy for fissure-inano: a comparative study

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Received: 19 April 2022 Revised: 03 May 2022 Accepted: 04 May 2022

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ABSTRACT

Background: The aim of the study was to choose best method for management of fissure-in-ano. By comparing among zinc oxide pomade, lidocaine pomade and lateral internal sphincterotomy for treatment of anal fissure.

Methods: 90 patients who were diagnosed with anal fissure between 2019 and 2021 at our MGM Medical College and M. Y. Hospital were undertaken for this prospective randomized trial. All cases randomized into three groups. Group 1 were the patients who applied 15% of zinc oxide pomade twice a day. Group 2 were the patients would apply 5% of lidocaine pomade twice a day. Group 3 were those undergone with lateral internal sphincterotomy. Healing rates, pain relief, recurrences, changes in symptoms after the treatment and complications were recorded.

Results: There were no statistical difference among groups in terms of age and gender. The healing and symptomatic relief in the sphincterotomy group significantly much more when compared to the other groups (p=0.05). Recurrence rate is very less in sphincterotomy group.

Conclusions: Lateral internal sphincterotomy is better treatment option when compared to zinc oxide and lidocaine. There was no difference between zinc oxide and lidocaine treatments.

Keywords: Lateral internal sphincterotomy, Zinc oxide, Anal fissures, Lidocaine treatment

INTRODUCTION

Anal fissure is a typical issue that causes considerable horribleness in who are generally sound. An anal fissure is among the most common disease of the anal region and is an ulcer in the form of a linear cut or tear between the anal verge and linea dentata. The most incessant site for anal fissure is midline posteriorly followed by midline anteriorly. The sickness is more normal in men while it is exceptional in youngsters and old. It causes extreme agony during passing flatus and stools. The pathogenesis of ongoing anal fissure remains deficient but most are related with a high resting external anal sphincter tension and decreased perfusion at the posterior midline site because of tenacious hypertonia of the inside anal sphincter. Medical and surgical treatments have been mainly used in the treatment of fissures. Surgery has typically been used

to treat chronic anal fissures, which is an effective and routine operation that heals 90-95 percent of the time.1 There have been a variety of pharmacological sphincter relaxants introduced with promising outcomes, but surgical therapy is frequently required. In almost 90% of cases, lateral internal sphincterotomy repairs the chronic anal fissure, although surgery comes with the risk of longterm consequences. Incontinence due to flatus and fecal soiling are distressing sphincterotomy consequences, and some of them had delayed wound healing and disease recurrence.² To date, 15 pharmacological treatments have been evaluated to treat chronic anal fissure disease, according to a review by Nelson et al.3 Zinc repairs tissues and facilitates quick healing of wounds and is a necessary trace element for the human body.4 Zinc can be administered orally or topically.5 Zinc oxide pomade was used for the skin irritations, external ulcers (decubitus,

varicose, diabetic), sunburn, non-infected wounds and burns.^{5,6} There are lacunae in the literature comparing the effectiveness of zinc oxide pomade, lidocaine pomade and internal sphincterotomy in the management of anal fissures. The aim of the study was undertaken to evaluate and compare the effectiveness of zinc oxide, lidocaine and lateral internal sphincterotomy in the management of patients with fissure-in-ano.

Aim and objectives

The aim of the study was to compare the effect of zinc oxide pomade, lidocaine pomade and lateral internal sphincterotomy for treatment of chronic anal fissure in terms of healing and complications.

Primary objective

The primary objective of the study was to choose best method for management of fissure-in-ano.

Secondary objective

The secondary objective of the study was to compare zinc oxide, lidocaine and lateral internal sphincterotomy.

METHODS

Source of data

All cases of anal fissure operated and admitted in department of surgery, MGM Medical College and MY Hospital, Indore. The study will include prospective cases for 1 year from date of approval.

Method of collection of data

Study design

The study design was prospective and comparative study.

Study period

The study period was from January 2020 to January 2021.

Place of study

The study place was department of surgery, MGM Medical College and MY Hospital, Indore.

Sample size

The sample size was minimum 90 cases (30 in each group).

Inclusion criteria

The study included patients with age18-60 years; and patients who give written informed consent.

Exclusion criteria

The study excluded patients who were not willing to give written consent; with haemorrhoids, Crohn's disease, tuberculosis, sexually transmitted disease and cancer patients; and pregnant and lactating women.

Informed consent was taken from all patients included in the study.

All patients in study underwent a detailed history taking including general examination and investigations. Patients were categorized into groups 1, 2 and 3.

Group 1

Patients were instructed to sit in sitz baths twice a day for 10 minutes at a time for 6 weeks, after drying themselves, apply 15% zinc oxide pomade the size of a rice grain around the anus and up to 1 cm into the anal canal twice a day.

Group 2

Patients were also instructed to sit in sitz baths for 10 minutes a day for 6 weeks and were told to apply 5% lidocaine pomade the size of a rice grain around the anus and up to 1 cm into the anal canal twice a day.

Group 3

Patients undergoing lateral internal sphincterotomy.

All groups were instructed to feed on fiber-rich food and, if necessary, stool softeners were prescribed. All patients were invited for controls at 3 and 6 weeks and were evaluated for symptoms (pain, bleeding and itching), physical examination and complications. Recovery was considered as the absence of symptoms and the absence of (in the physical examination) fissures (re-epithelization) Patients with improvement were evaluated for recurrence after 3, 6 months.

Assessment tools

The assessment tools were (a) NRS score/visual analogue pain scale; (b) incontinence (faecal/flatus); (c) number of work days lost; (d) wound infection; (e) recurrence; and (f) per rectal digital examination.

Statistical analysis

The data was initially entered into the customized proforma and then transferred to Microsoft excel for analysis. Statistical software IBM SPSS was used for calculating the p values. Chi-square test was applied for comparing the groups. A p value of <0.05 was taken as statistically significant. The final data was presented in the form of tables and graphs.

RESULTS

Group 1 consisted of 30 patients treated with zinc oxide; group 2 consisted of 30 patients treated with lidocaine pomade; and group 3 consisted of 30 patients treated with sphincterotomy.

There were no gender differences between the groups (p>0.05). There were no age differences between the groups (p>0.05) (Table 1). Pain is the most common symptom in all groups. There was no significant difference

between the groups in terms of symptoms (pain) (p>0.05). In the evaluation of all groups, the fissure was usually found to be located posteriorly at 6 o'clock position. However, there was no statistically significant difference in the location of the fissure among the different groups (p>0.05). There was no statistically significant difference between groups according to pain scores before and after treatment (NRS) (p>0.05) (Table 2). The satisfaction of pain relief at both the 1st month and the 3rd month after treatment when compared to the pain scores before treatment in all groups was statistically significant (p<0.05).

Table 1: Demographic information of the patients.

Parameters	Group A (n=30)	Group B (n=30)	Group C (n=30)	P value
Age (years)	36.6±11.6	37.4±11.6	40.4±12.7	0.5525
Sex				
Male	12	16	17	- 0.393241
Female	18	14	13	

Table 2: Characteristics of fissures.

Characteristics	Group A (n=30)	Group B (n=30)	Group C (n=30)	P value
Tone of external	Increased=23	23	25	
anal sphincter pre-	Decreased=0	0	0	0.553
treatment	Normal=7	07	05	
Pain	24/30	23/30	25/30	0.837
Bleeding	24/30	24/30	26/30	0.823
Constipation	20/30	22/30	23/30	0.645



Figure 1: Anal fissure at 6 o clock position with proctoscopy.



Figure 2: Anal fissure on external examination.

DISCUSSION

Anal fissure is a painful linier ulcer formed in the anal mucosa between the mucocutaneous junction and the linea dentate most commonly at posterior aspect of anal canal.

Demographic variables of anal fissure age: it is a most common anorectal disease that can be seen in any age group. It is most commonly observed in patients in around 30s and 40s age groups. Ay et al in their study reported a mean age of 35.1±11.3 years, while in our study the mean age of the patients was 38.7±12.11 years. Mean age is comparable with the study done by Ay. Gender was seen in equal distribution among men and women. In our study, the age and gender of the patients were in accordance with the literature.

Location of fissure

The most popular theory on the development of anal fissure posits that their development is due to ischemia. Autopsy studies most commonly showed fissures in the posterior aspect of the distal anal canal as there is reduced blood flow in this region.

This is especially pronounced in patients with fissures was studied in study done by Acheson et al which supports our study finding that 6 O'clock position is the most common location for fissure. ¹²

Anal tone

In almost all patients with chronic anal fissure, the anal canal resting pressure is high, which decrease blood flow from the sphincter to the anal mucosa and impairs the healing of the fissure and increasing chronicity. The main aim in treatment of fissure is to reduce the anal tone created by the anal sphincter mechanism, to increase blood flow and to improve fissure healing, according to the study done by Ho et al.¹⁴ In our study 71 out of 90 individuals have increased anal tone which is comparable with the above study.¹⁴

Surgical treatment

Surgical treatment includes fissurectomy, anal dilatation, posterior sphincterotomy, closed lateral sphincterotomy, open lateral internal sphincterotomy and flap applications. Due to permanent anal incontinence after surgical treatment. Most commonly used surgical treatments are like sphincterotomy and anal dilatation alternative treatments have been sought. 12,15-18 In our study we have used lateral internal sphincterotomy as surgical procedure in which 5 patients have developed postop wound infection and 3 patients have developed postop incontinence for flatus and 2 had developed postop incontinence for motion. Cure rate/relief was maximum at 1st month of follow up and it was continued even in 3rd month of follow up. There is no recurrence in any patient compared to medical treatment given in other groups. Medical treatment/conservative management: In many medical facilities, GTN is used as the initial treatment of chronic anal fissures. However, adverse effects such as tachyphylaxis and headache have been reported. 15-21 Botulinum toxin (BT) acts by inhibiting release of acetylcholine from the presynaptic terminals. Nelson et al reported that overall BT recurrence was around 40-50% and recovery was 67.5% in all BT-based studies. 3,22,23 BT has complications such as anal incontinence (5-10%) and perianal thrombosis.

From above studies we have noted that each of the methods such as BT nitric oxide (GTN), topical calcium channel blockers are effective; but surgical treatment is still the gold standard with achievement rates of 95-100%.16,24 In our study, the group treated with sphincterotomy was, similar to the literature with a recovery rate of 99.7% and statistically significant when compared to recovery of the other groups. Our study showed that the recovery rates were very low with the medical treatments (lidocaine, zinc oxide) comparing with surgical treatment. Zinc oxide and lidocaine application in treatment of anal fissure: zinc repairs tissues and helps in quick healing of wounds and is one of the necessary trace element in the human body.4 Zinc can be administered orally or topically.⁵ In a double-blind trial, leg ulcers were reported to improve better with zinc oxide pomade compared to placebo. Immunomodulator, anti-microbial and cytoprotective properties indicates the clinical efficacy of zinc oxide. 6,25 In Ay et al study, zinc oxide, lidocaine,

hot water, and lateral internal sphincterotomy for fissure-in-ano: randomized controlled study, zinc was chosen for its anti-inflammatory properties and as an agent that facilitates tissue healing and tissue repair and thus zinc oxide was compared with lidocaine pomade. Recovery rate with treatment zinc pomade was 42.1%, although higher than lidocaine pomade application (37.8%) and, the difference is not statistically significant.

In our study 30 patients were treated with zinc oxide, recovery rate was 23.3% and 30 patients were treated with lidocaine pomade in which recovery rate was 26.66% slightly higher than zinc oxide treated patient but it is not statistically significant. This suggest that reduction in the sphincter pressure alone also leads to recovery in patients. Other studies have shown that in groups administered with GNT and lidocaine for anal fissure treatment, the patients reporting relief of symptoms is higher than the rate of recovery, this shows that even though relief from symptoms is achieved, the fissures do not heal.8,13 This brings to mind the need for a treatment that not only reduce sphincter spasms but also facilitate healing of fissure. The main goal of anal fissure treatment is relieving anal sphincter pressure, facilitating wound healing and relieving inflammation in the region. It was for this reason that anal sphincter pressure was decreased with sitz baths and a pharmacologic agent to improve healing such as zinc oxide was chosen in this study. Even though higher recovery rates were achieved with patients treated with lidocaine to patients treated with zinc oxide, the difference is not statistically significant. We assume that for improving recovery rates, the use of pomades reducing anal sphincter pressure (such as diltiazem, ISDN, BT, GTN etc.) in addition to zinc oxide pomades can be more beneficial. When compared to all groups the patients treated lateral internal sphincterotomy have showed 97% recovery when compared to conservative methods zinc oxide and lidocaine which have showed 23.3% and 26.66% recovery respectively. Therefore, from the above study we come to know that zinc oxide and lidocaine are effective; but surgical treatment is still the gold standard with recovery achievement rates of 95-100%.

Limitations

We were comparing conservative treatment (zinc oxide and lidocaine) along with surgical treatment, we found out that there was less compliance with the conservative treatment so the number of recurrence rate might be less than the actual study reported, single center study, and was done in COVID period. These should be kept in mind before going for treatment.

CONCLUSION

90 patients have enrolled in study in which patients were put into different groups by simple randomization. The patients treated with zinc oxide pomade with sitz bath have shown 23.33% recovery rate. The patients treated with lidocaine pomade with hot sitz bath have shown 26.66%

recovery rate as compared to patients who were treated with lateral internal sphincterotomy had shown 99-100% of recovery rate. So lateral internal sphincterotomy is superior than zinc oxide and lidocaine pomade application in treatment of anal fissure. There was no significant difference in recovery rate between non-operative treatment.

Funding: No funding sources Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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Cite this article as: Kaushal M, Shukla A, Kovarthanan P, Shivaprasad YH. Zinc oxide, lidocaine, and lateral internal sphincterotomy for fissure-in-ano: a comparative study. Int Surg J 2022;9:1146-50.