
ORIGINAL ARTICLE**A Prospective Randomised Comparative Study on Use of Lignocaine with Zinc with Hydrocortisone Combination Ointment versus Lignocaine with Sucralfate with Metronidazole Combination Ointment in the Treatment of Acute Fissure in Ano**

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Abstract:

Background: An anal fissure is a cut or split in the epithelial lining of the anal canal distal to the dentate line. Various topical ointments been described for its treatment. *Aim and Objectives:* To study Lignocaine (3%) with Zinc (5%) with Hydrocortisone (0.25%) combination (LZH) ointment in comparison to Lignocaine (4%) with Sucralfate (7%) with Metronidazole (1%) combination (LSM) ointment with respect to pain relief, healing, patient satisfaction and safety in Acute Fissure In Ano (AFIA). *Material and Methods:* This was a prospective randomized study. Sixty patients with AFIA were randomly divided into two groups of 30 patients each. In group A, LZH ointment and in group B, LSM ointment was prescribed and followed up weekly for six weeks. *Results:* Our study shows less pain score in group B as compared to group A. The rate of healing was statistically significantly better in group B from 3rd week onwards. The patient satisfaction score was better in group B (P value = 0.0004). No complication was seen in any patient. *Conclusion:* Our study shows that the LSM ointment in comparison to LZH ointment is associated with early pain relief, better healing, better overall patient satisfaction, and equally safe in patients with AFIA

Keywords: Lignocaine, Sucralfate, Metronidazole, Hydrocortisone, Zinc, Fissure in ano

Introduction:

An anal fissure is a cut or split in the epithelial lining of the anal canal distal to the dentate line[1]. Passage of hard stool is considered as the main

cause of anal fissure. A chronic anal fissure is usually categorized when the fissure fails to heal within 4-8 weeks [1]. The aim of treatment in a case of anal fissure is to break the cycle of hard stool, pain, and spasm. Mainstay of treatment of acute anal fissure is with conservative therapies like warm water sitz baths, analgesics, stool softeners and dietary modifications [2-3]. Various topical agents in ointment form for local application been described to relieve the spasm and heal the ulcer such as 0.2% glyceryl trinitrate, 2% diltiazem, 0.3% nifedipine, lignocaine, sucralfate, hydrocortisone etc., either alone or in combination [2,4,5]. A comprehensive review of the published reports lacks the presence of a randomised comparative study comparing conservative treatment with, lignocaine with zinc with hydrocortisone combination ointment as compared to lignocaine with sucralfate with metronidazole combination ointment in the treatment of acute fissure in ano. The aim of the study was to fill this lacuna by comparing these ointments with respect to pain relief, healing, patient satisfaction and safety in patients with acute fissure in ano.

Material and Methods:

This was a prospective randomized comparative study conducted at our centre over a period of one

year, after approval of the institutional ethical committee. A total of 60 cases of acute anal fissure were taken for the study. They were randomized in two groups, A and B, with 30 patients in each group.

Selection and the exclusion of the patients was done according to the criteria given below.

Inclusion Criteria:

1. Presence of Acute fissure in ano.
2. Patients above 18 years of age.
3. Patients willing to participate in the study.

Exclusion Criteria:

1. Patients less than 18 years of age.
2. Patients with recurrent fissure.
3. Patients with fissure of more than 6 weeks duration.
4. Presence of sign of chronicity of anal fissures such as sentinel tag, visible fibres of internal sphincter, suppuration, etc.
5. Pregnant women.
6. Patients operated on for any anorectal pathology in the past.
7. Patients with concomitant inflammatory bowel disease.
8. Patients with co-morbidities such as diabetes, HIV infection, immune suppression.
9. Patients with known allergy to any component of ointments.
10. Patients not willing to participate in the study.

Intervention:

In group A: Lignocaine (3%) with Zinc (5%) with Hydrocortisone (0.25%) combination ointment was prescribed. In group B: Lignocaine (4%) with Sucralfate (7%) with Metronidazole (1%) combination ointment was prescribed. The patients were

advised about the proper application of ointment three times in a day. In addition, patients were encouraged to take high fibre diet and Lactulose syrup 3tsp twice a day. Warm sitz bath was advised thrice in a day before application of the ointments. Patients were followed up weekly upto 6 weeks.

- Pain score was assessed weekly using 10 cm visual analogue pain scale with 0 representing no pain and 10 indicating the worst possible pain [5].
- Healing of fissure was assessed weekly by local examination.
- Patients were also checked for any side effects like skin excoriations, perianal burns, pruritus or dizziness, etc., after application of ointment to check the safety of ointment.
- At six weeks, patient satisfaction with overall treatment was recorded using Patient Satisfaction (PS) scale with score as 1 (extremely dissatisfied), 2 (dissatisfied), 3 (neither dissatisfied nor satisfied), 4 (satisfied) and 5 (extremely satisfied).

Statistical Analysis:

Data were summarized using mean and standard deviation for quantitative variables or frequency and percentage for qualitative ones. Comparison between groups was performed using unpaired student's 't' test for quantitative variables while comparison for qualitative variables was performed through Chi square or Fisher's exact test. P values < 0.05 were considered statistically significant. The Statistical analysis Package for the Social Science Software (SPSS) program, version 24 was used for statistical analysis.

Results:

Demographic and Pre-treatment Data between Two Groups:

The two groups were equally matched in terms of age, gender, baseline pain score and position of fissure and the data is presented in Table 1.

Pain Score Comparison between Two Groups:

The comparison of pain score data on intervention is presented in Table 2 and Fig. 1. On weekly follow up, our study showed less pain score in group B as compared to group A, but it was not statistically significant (P value > 0.05). All patients showed pain relief by 3rd week in group B and by 5th week in group A.

Weekly Comparison of Number of Patients Healed between Two Groups:

As shown in Table 3 and Fig. 2, the rate of healing

was better in group B from 3rd week onwards as compared to group A and the difference was statistically significant. At the end of 6th week healing was seen in all patients in group B, but in group A, six (20%) patients did not show healing of fissure.

Patient Satisfaction Score:

Mean ± SD patient satisfaction score at the end of 6 weeks was 3.80±0.81 in group A and 4.5±0.63 in group B, which was statistically significant (P value = 0.0004).

Complication:

No complication was seen in any patient in both the groups.

Table 1: Demographic and Pre-treatment Data Between Two Groups

Characteristics		Group A	Group B	p-value
Age	Years	35.06±8.95	34.00±9.95	0.664
Gender	Male	18(60.0%)	19(63.33%)	0.790
	Female	12(40.0%)	11(36.67%)	
Base Line Pain Score	Score	7.43±1.59	7.90±1.60	0.317
Position of fissure	Posterior midline	26(86.67%)	29(96.67%)	0.353
	Anterior midline	4(13.33%)	1(3.33%)	

*- significant at p<0.05; Values expressed in Mean±SD

Table 2: Pain Score Comparison Between Two Groups

Follow-up	Group A (Mean ± SD)	Group B (Mean ± SD)	t value	p-value
1 st week	2.03±1.82	1.86±1.59	0.367	0.707
2 nd week	0.86±1.57	0.36±0.85	1.53	0.130
3 rd week	0.36±0.92	0.00	NA	NA
4 th week	0.10±0.00	0.00	NA	NA
5 th week	0.00	0.00	NA	NA
6 th week	0.00	0.00	NA	NA

*- significant at $p < 0.05$

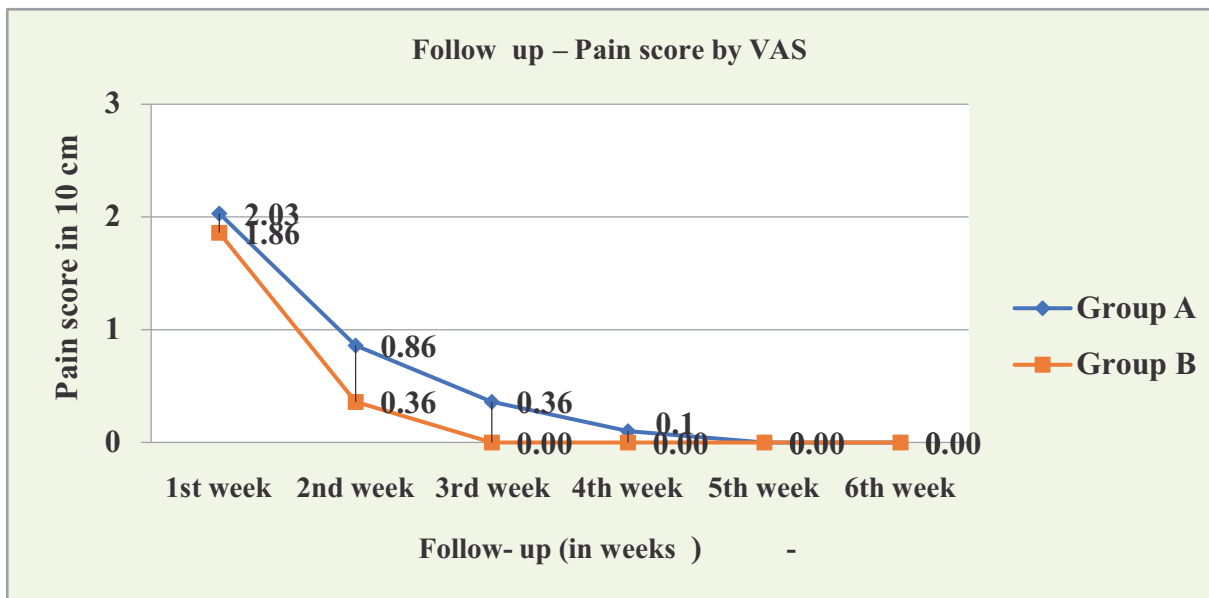


Fig. 1: Graph Comparing Mean Pain Score Between Two Groups

Table 3: Weekly Comparison of Number of Patients Healed between Two Groups

Follow-up	Group A		Group B		p-value
	Healed (%)	Not healed (%)	Healed (%)	Not healed (%)	
1 st week	00 (0.0%)	30 (100%)	00 (0.0%)	30 (100%)	NA
2 nd week	02 (6.67%)	28 (93.33%)	06 (20.0%)	24 (80.00%)	0.254
3 rd week	04 (13.33%)	26 (86.67%)	18 (60.0%)	12 (40.0%)	0.0004*
4 th week	11 (36.67%)	19 (63.33%)	27 (90.0%)	03 (10.0%)	<0.0001*
5 th week	19 (63.33%)	11 (36.67%)	28 (93.33%)	02 (6.67%)	0.010*
6 th week	24 (80.00%)	06 (20.00%)	30 (100.0%)	00 (0.0%)	0.023*

*- significant at $p < 0.05$

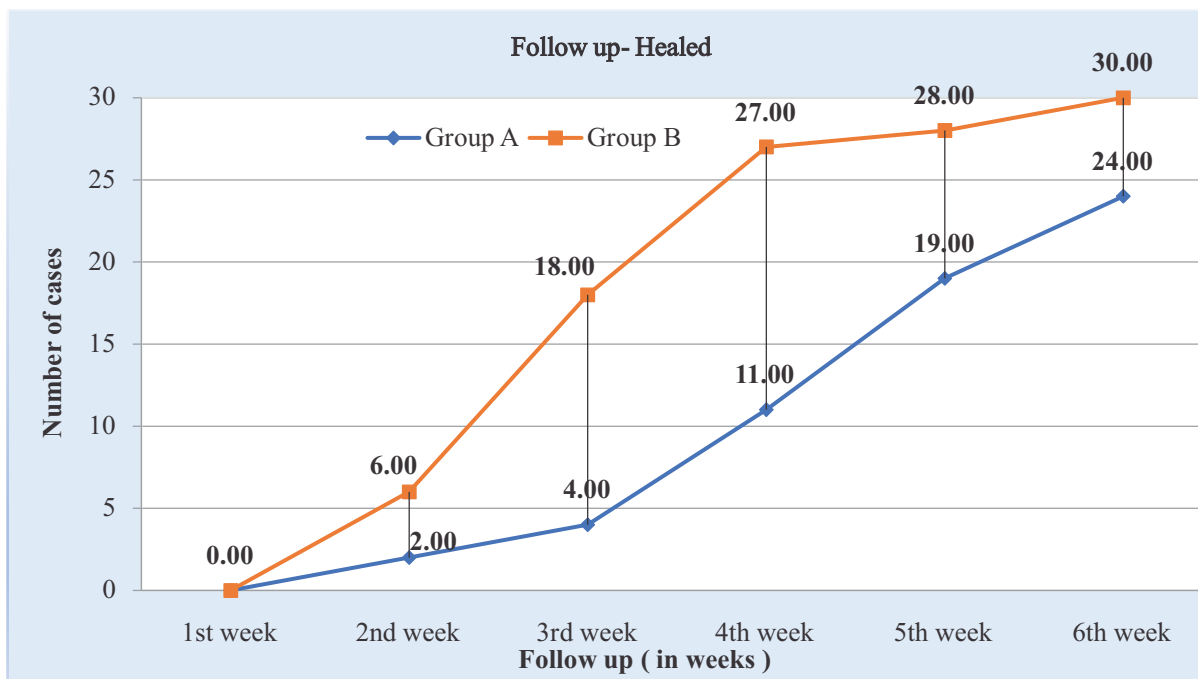


Fig. 2: Graph Comparing Number of Patients Healed between Two Groups

Discussion:

Lignocaine with its local anaesthetic and anti-inflammatory property has been proven to be efficacious in the management of anorectal disorders. Sattibabu *et al.* recommended that lignocaine may be preferred as the first line treatment in the management of acute fissure in ano [5]. Sucralfate with its angiogenic and antibacterial property has ulcer healing capacity. In the study done by Gupta *et al.* it was shown that topical sucralfate is a safe and effective aid for mucosal healing and providing analgesia during wound treatment, after undergoing anal fistulotomy and open hemorrhoidectomy [6-7].

Metronidazole with its antimicrobial and anti-inflammatory properties helps in healing of ulcer in anorectal conditions. In the study done by Karapolat, it was shown that topical metronidazole serves as an effective and safe option resulting in low pain and increased healing rate in a case of acute fissure in ano [8]. The study done by Grekova *et al.* showed the efficacy of topical metronidazole in the treatment of chronic anal fissure [9]. In the studies done by Ala *et al.* and Nicholson *et al.* it was found that topical 10% metronidazole remarkably reduced post hemorrhoidectomy pain and it helped in ulcer healing [10-11].

Combination of these three has analgesic, antimicrobial and ulcer healing properties. Our study showed less pain score in group B as compared to group A, but there was no statistically significant difference. All patients showed pain relief by 3rd week in group B and by 5th week in group A (Table 2) (Fig 1). This can be explained by the presence of lignocaine, which is a local anaesthetic agent, in both the ointments. The lignocaine may have been responsible for the pain

relief felt by the patients in both the groups. Additionally, the conservative treatment measures such as, warm sitz bath, lactulose syrup and high fibre diet which were advised to all patients in both the groups might have been also responsible for the pain relief felt by the patients in both the groups.

On comparing the healing process in the two groups, statistically significant more number of patients were healed from 3rd week onwards in group B as compared to group A (Table 3) (Fig. 2). At the end of 6 weeks healing was seen in all patients in group B, but in group A six (20%) patients did not show healing of fissure. This shows the superior healing rate with lignocaine with sucralfate with metronidazole combination ointment.

At the end of 6 weeks, we found better mean patient satisfaction score in group B who were given lignocaine with sucralfate with metronidazole combination ointment as modality of therapy (P = 0.0004). This can be explained by the better pain relief and early and complete healing seen in this group.

Our study showed both ointment combinations are equally safe as there was no complication seen in any patient in both the groups.

Conclusion:

The findings of our study shows that the lignocaine with sucralfate with metronidazole combination ointment in comparison to lignocaine with zinc with hydrocortisone combination ointment is associated with early pain relief, better healing, better overall patient satisfaction and equally safe in patients with acute fissure in ano.

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How to cite this article:

Dewanda NK, Siddesh HV, Chawla D. A Prospective Randomised Comparative Study on Use of Lignocaine with Zinc with Hydrocortisone Combination Ointment versus Lignocaine with Sucralfate with Metronidazole Combination Ointment in the Treatment of Acute Fissure in Ano. *J Krishna Inst Med Sci Univ* 2021; 10(2):123-129

Submitted: 08-Feb-2021 Accepted: 16-Mar-2021 Published: 01-Apr-2021