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Comparative Study of Topical 0.3% Nifedipine-Lignocaine Versus 7% Sucralfate-Lignocaine in the Management of Acute Anal Fissure: A Prospective Study

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Abstract: ***Background: Acute anal fissure is a common benign anorectal condition characterized by severe pain after defecation, bleeding per rectum, and sphincter spasm. Pathophysiology of Anal Fissure is hypertonia of internal anal sphincter, elevated resting anal pressure which contributes to reduced anodermal blood flow and relative ischemia. The mainstay of contemporary non-operative management involves Topical pharmacological agents aimed at reducing internal anal sphincter tone and promoting healing remains the first-line treatment. This study compares the effectiveness of Topical 0.3% Nifedipine- lignocaine and Topical 7% Sucralfate- lignocaine in the management of acute anal fissure. Aims and objectives: The study evaluated and compared the effectiveness of Topical 0.3% Nifedipine-Lignocaine and Topical 7% Sucralfate-Lignocaine in Patients with Acute anal fissure. Materials and Methods: Total 200 Patients of Acute Anal Fissure were studied. They were randomly divided into two groups of 100 Patients each. In one group, Patients undergone treatment with Topical Nifedipine (0.3%)- Lignocaine (1.5%) ointment and in second group, Topical Sucralfate (7%)- Lignocaine (4%) Ointment. The Patients were instructed to apply Ointment locally into anal canal twice daily for 3 weeks after passing stools. Patients were assessed for Pain after defecation, Bleeding per rectum, Fissure healing and any side effects at 1st , 2nd and 3rd week of follow up. Results: Pain scores reduced significantly in both groups, with greater reduction in the nifedipine group by 3rd week (Mean VAS ~1.8 vs ~2.4). Fissure healing rates were higher in Group A (≈86%) compared to Group B (≈70%). Bleeding control was also better in the nifedipine group. Conclusion: Topical nifedipine–lignocaine is more effective than sucralfate–lignocaine in reducing pain after defecation, Bleeding per rectum and improving fissure healing in acute anal fissure.***

Keywords: Acute Anal fissure, Topical 0.3% Nifedipine- Lignocaine, Topical 7% Sucralfate- Lignocaine

1. Introduction

Anal fissure is defined as a longitudinal tear in the anoderm of the distal anal canal extending from the anal verge to the dentate line. It is one of the most common benign anorectal condition associated with severe pain after defecation, bleeding per rectum, fear of defecation. Despite being a superficial lesion, the intense pain and chronicity associated with anal fissures significantly impair patients quality of life and daily activities.[1]

The exact etiology of anal fissure remains incompletely understood, however it is widely accepted that mechanical trauma to anoderm, most commonly due to passage of hard stools or prolonged straining during defecation, plays a pivotal initiating role. The posterior midline of anal canal is most frequently affected site. This predilection has been attributed to several anatomical and physiological factors, including increased shearing forces during defecation, relatively poor tissue elasticity, and a higher density of longitudinal muscle extensions in this region of anal circumference. Additionally, posterior midline anoderm has been shown to possess relatively reduced blood flow compared to other areas, predisposing it to ischemic injury and delayed healing.[1]

A central component in the pathophysiology of anal fissure is hypertonia of the internal anal sphincter. Most affected patients demonstrate elevated resting anal pressure, which contributes to reduced anodermal blood flow and relative ischemia. This ischemia impairs tissue repair and perpetuates the fissure. The pain associated with defecation further increases sphincter spasm, resulting in a vicious cycle of pain, spasm, ischemia and non healing. Over time, repeated trauma and inadequate healing may lead to progression from an acute superficial fissure to a chronic deep ulcer.[1]

The primary aim of conservative therapy is normalization of bowel habits to minimize trauma to the anoderm. Dietary modifications with increased fibre intake to bulk and soften stools, adequate hydration, and use of stool softeners are simple yet effective measures. Warm sitz baths help relieve pain by promoting sphincter relaxation, while topical local anaesthetic agents provide symptomatic relief.[1]

The mainstay of contemporary non-operative management involves topical pharmacological agents aimed at reducing internal anal sphincter tone. This approach, often referred to as ‘chemical sphincterotomy’, seeks to interrupt the cycle of sphincter spasm and ischemia, thereby facilitating fissure healing.[1]

Topical nifedipine exerts its therapeutic effect primarily through inhibition of calcium ion entry via blockade of L-type calcium channels in vascular smooth muscle. This results in relaxation of the internal anal sphincter and vasodilation, thereby improving local blood flow and promoting healing of the fissure. When combined with a local anaesthetic such as lignocaine, nifedipine not only facilitates healing but also provides rapid pain relief, improving patient compliance with therapy.

Sucralfate, traditionally used in management of peptic ulcer disease, has gained interest as a topical agent in anorectal disorders due to its cytoprotective properties. When applied locally, sucralfate forms a viscous polyanionic gel that adheres to the ulcer base, creating a protective barrier against mechanical trauma and bacterial contamination. Additionally, sucralfate enhances mucosal defense by increasing mucus production and stimulating tissue repair through the activation of growth factors, including epidermal growth factor and fibroblast growth factor. These properties make topical sucralfate a promising agent in promoting epithelial healing of anal fissures, particularly when combined with lignocaine for pain relief.

Lateral internal sphincterotomy is the most commonly performed surgical procedure and is associated with high cure rates. In this operation, the internal anal sphincter is divided laterally, away from the fissure, to reduce resting anal pressure and allow healing. Lateral sphincterotomy is highly effective, it carries a risk of fecal incontinence, particularly in elderly patients and multiparous women. Therefore, surgery is generally reserved for cases that fail medical management.

Aim:
To Compare the effectiveness of Topical 0.3% Nifedipine-lignocaine and Topical 7% Sucralfate-Lignocaine in Acute Anal Fissure

Objective:
1) To evaluate the efficacy of Topical 0.3% Nifedipine-Lignocaine and Topical 7% Sucralfate- Lignocaine in Acute Anal Fissure.
2) To evaluate the patients requiring surgical intervention after not relieved by conservative management with Topical 0.3% Nifedipine- lignocaine and Topical 7% Sucralfate-Lignocaine.

2. Materials and Methods

This prospective, randomized Study was Undertaken from April, 2024 to September, 2025 on patients presenting to Department of General Surgery, American International Institute of Medical Sciences, Udaipur. The study protocol was approved by Institutional Ethics committee. The study group was of 200 patients of acute anal fissure divided into two groups of 100 each and recruited into study after taking the written informed consent. The diagnosis of acute anal fissure was established on basis of history and clinical examination of the patient.

Inclusion Criteria:
- Patients of Age ≥18 years diagnosed with acute anal fissure (<6 weeks)
- Patients willing to participate, willing to follow up in the study and provide informed consent.

Exclusion Criteria:
- Patients with Chronic Anal fissure
- Secondary fissures (Crohn's disease, TB, malignancy).
- Any History of Previous anorectal surgery.
- Patients with known cardiac disease.
- Immunocompromised patients.

The selected patients were randomly assigned to two groups.
Group A: Patients undergoing treatment with Topical (0.3%) Nifedipine- Lignocaine.
Group B: Patients undergoing treatment with Topical (7%) Sucralfate- Lignocaine.

In both groups, patients were instructed to apply ointment locally into the anal canal twice daily for 3 weeks after defecation. The therapeutic efficacy of both combinations were evaluated and compared based on predefined clinical parameters. The patients were assessed for symptoms like Pain after defecation, Bleeding per rectum, Constipation, Fissure healing and any side effects at 1st, 2nd and 3rd week of follow up.

Pain was assessed according to visual analogue scale and was classified as mild, moderate and severe. Symptomatic relief in terms of pain and bleeding was assessed on follow up.

Healing of fissure assessed by measuring visually and again reassessed on follow up. All results were statistically analysed.

3. Results

The maximum number of patients belonged to the 41–50 years age group (60; 30.0%), followed by 51–60 years (52; 26.0%) and 31–40 years (36; 18.0%). Patients aged >60 years were 34 (17.0%), while the least number were in 18–30 years (18; 9.0%). Overall, the study included 200 participants.

The study showed male predominance, with 138 males (69.0%) and 62 females (31.0%), indicating that anal fissure cases were more commonly observed among males in the study population.

In the nifedipine group, symptoms showed steady improvement over 3 weeks. Pain reduced from 78% (1st week) to 46% (2nd week) and 18% (3rd week). Burning sensation reduced from 72% to 40% and 14%, while bleeding per rectum reduced from 42% to 20% and 6%. Fissure healing improved from 28% in week 1 to 62% in week 2 and 86% by week 3. Side effects decreased from 6% to 4% and 2%.

In the sucralfate group, improvement was also observed but comparatively less. Pain reduced from 82% to 54% and 24% over 3 weeks. Burning sensation decreased from 76% to 48%and 20%, and bleeding reduced from 46% to 24% and 10%. Fissure healing improved from 24% to 54% and 78% by the third week. Side effects were minimal and remained low (4% → 2% → 2%).

At the end of 3 weeks, pain, burning sensation, and bleeding per rectum were lower in the nifedipine group compared to the sucralfate group; however, these differences were not statistically significant ($p > 0.05$). Pain persisted in 18% vs 24% ($p = 0.28$), burning in 14% vs 20% ($p = 0.24$), and bleeding in 6% vs 10% ($p = 0.30$).

Fissure healing was significantly better in the nifedipine group, with 86% healed compared to 78% in the sucralfate group. This difference was statistically significant ($p = 0.04$), suggesting superior healing efficacy with 0.3% Nifedipine + Lignocaine.

The mean VAS score was significantly lower in the nifedipine group (1.8 ± 0.9) compared to the sucralfate group (2.4 ± 1.1). This difference was statistically significant ($p = 0.002$), indicating better pain relief with nifedipine.

Adverse effects were minimal and similar in both groups. In the nifedipine group, headache (4%), perianal irritation (2%), and dizziness (2%) were reported. In the sucralfate group, headache (2%) and perianal irritation (4%) were noted, with no dizziness. Overall, any adverse effect occurred in 6% of patients in both groups, with no statistically significant difference ($p = 1.00$), showing both regimens were equally safe and well tolerated.

In this study of 200 patients with anal fissure, topical 0.3% Nifedipine-Lignocaine was compared with 7% Sucralfate-Lignocaine after conservative management for 3 weeks. Both treatments improved symptoms, but Nifedipine showed better pain relief and higher healing rate (86% vs 78%). Consequently, fewer patients required surgery in the Nifedipine Group (14%) compared to the Sucralfate Group (22%). Both regimens were safe with minimal side effects.

Table 1: Mean VAS Score after treatment in Group A and B

Time interval	Group A	SD	Group B	SD	p-value	significance
1st Week	5	0.9	5.4	0.8	0.12	>0.05
2nd Week	3.2	0.9	3.8	0.8	0.04	<0.05
3rd Week	1.8	0.9	2.4	1.1	0.002	<0.05

Table 2: Bleeding after treatment in Group A and B

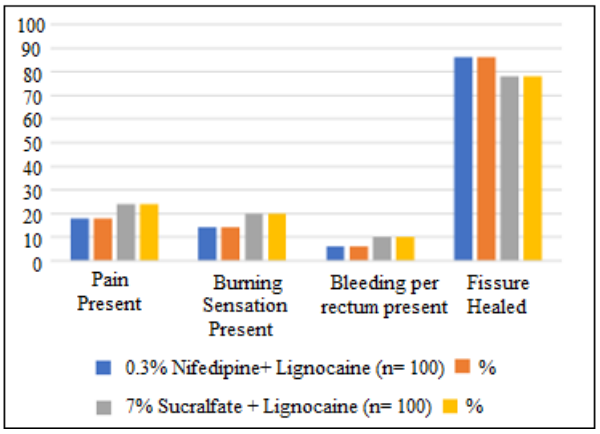
Time Interval	Group A	Group B	p- value
1st week	42%	50%	>0.05
2nd week	20%	32%	>0.05
3rd week	6%	14%	>0.05

Table 3: Fissure Healing after treatment in Group A and B

Time Interval	Group A	Group B	p- value
1st week	28%	22%	>0.05
2nd week	62%	48%	>0.05
3rd week	86%	70%	0.04

Table 4: Comparison of 3rd Week Clinical Outcomes (n = 200)

Outcome at 3rd week	Group A	%	Group B	%	p- value
Pain Present	18	18	24	24	0.28
Burning Sensation	14	14	20	20	0.24
Bleeding per rectum	6	6	10	10	0.3
fissure healing	86	86	78	78	0.04



Graph 1: Comparison of 3rd Week Clinical Outcomes (n = 200)

4. Conclusion

The present study was conducted on 200 patients diagnosed with anal fissure to compare the clinical effectiveness and safety of two topical treatment regimens: 0.3% Nifedipine + Lignocaine (n=100) and 7% Sucralfate + Lignocaine (n=100). Both 0.3% Nifedipine + Lignocaine and 7% Sucralfate + Lignocaine are effective and safe topical treatments for anal fissure, producing significant symptomatic improvement over 3 weeks. However, 0.3% Nifedipine + Lignocaine is superior, as it provides better pain relief and significantly higher fissure healing rates at the end of 3 weeks, while maintaining a similar safety profile. Hence, topical nifedipine with lignocaine can be recommended as a more effective first-line medical therapy for anal fissure in routine clinical practice.

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