Original Research

A STUDY OF EFFICACY OF 0.3% TOPICAL NIFEDIPINEOINTMENT IN PATIENTS OF ACUTE AND ACUTE ON CHRONICFISSURE-IN-ANO

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ABSTRACT

Background: Fissure-in-ano is a common surgical problem all over the world & we in our surgical clinics in Gurugram & North India encounter lots of cases of all the age groups. Despite the high prevalence of acute and acute-on-chronic anal fissure in clinical practice, there remains a need for more effective and well-tolerated treatment.Nifedipine, a calcium channel blocker, has shown potential benefits when used topically for this condition. The main goal of treatment is to break the cycle of ischemia, spasm, and discomfort that is hypothesized to have contributed to the formation of fissure in the ano.

Objective: To study the efficacy of 0.3% Topical Nifedipine ointment in patients of ACUTE AND ACUTE ON CHRONIC FISSURE-IN-ANO. All the patients were confirmed cases withclinical diagnosis of ACUTE and ACUTE ON CHRONIC FISSURE-IN-ANO.

Methods: This prospective and comparative clinical study covers 100 cases of ACUTE and ACUTE ON CHRONIC FISSURE-IN-ANO who agreed for the trial in General Surgery outpatient Department at SGT Medical College, Hospital and Research Institute, Budhera, Gurugram,Haryana, India. This study spanned a period of 18 months. All the Cases were confirmed clinical diagnosis of ACUTE and ACUTE ON CHRONIC FISSURE-IN-ANO.Universal Pain Assessment Tool for pain relief and DRESS scoring done to assess Grading of Anal Spasm during follow up visits of 2, 4, 6, 12 weeks respectively. The Patients were classified into two groups, each consisting of 50 patients were subjected to 0.3% Topical Nifedipine Ointment. Finally we took 100 patients (50 patients in each group). GroupI:included patients diagnosed as Acute Anal Fissure and would be treated with topical application of 0.3% Nifedipine ointment thrice a day, for a period of 6 weeks. Group II:included patients diagnosed as Acute on Chronic Anal Fissure and would be treated with topical application of 0.3% nifedipine ointment thrice a day, for a period of 6 weeks.

Results: There was significant reduction in pain in both groups patients over a period of 6 weeks and DRESS scoring showed significant reduction in spasm of anal sphincter in both the groups equally .

Conclusion: The present study demonstrates that topical application of 0.3% Nifedipine ointment is an effective and safe treatment option for both acute and acute on chronic anal fissures. The study found significant reductions in pain scores over 6 weeks, with a low incidence of side effects and high rates of complete healing, particularly in acute fissures. The similar trend in DRESS score improvement between the two groups suggests that topical nifedipine was equally effective in promoting fissure healing, regardless ofwhether the fissure was acute or acute on chronic in nature.

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INTRODUCTION

Fissure-in-ano is a common condition that leads to significant morbidity, characterized by pain, bleeding, and discomfort during bowel movements. The main goal of treatment is to stop the cycle of ischemia, spasm, and discomfortthat is hypothesized to have contributed to the formation of fissure in the ano. Bulkagents, stool softeners, and warm sitz baths are among the first-line treatments forreducing anal trauma. [1-2]

Anal fissures are classified based on their duration and underlying causes, primarilyinto acute, chronic, and acute-on-chronic types.Acute fissuresusually respond well to conservative treatments such as dietary changes, topicalanesthetics, sitz baths, and increased fiber intake. Treatment for chronic fissures mayrequire more aggressive interventions, including topical medications like nifedipine ornitroglycerin, botulinum toxin injections, or surgical options like Lateral internalsphincterotomy. Treatment for acute-on-chronic fissures typically involves a combination of methodsused for both acute and chronic fissures, including topical medications, dietarymodifications, and possibly surgical intervention if conservative measures fail.[3]

Calcium channel blockers like Diltiazem (DTZ) and Nifedipine (NFD), which have

healing rates that are much better than placebo and little side effects, have beenexplored by several authorsfor the treatment of acute anal fissures. [4-6]. They provide relief from anal fissures without the risk of incontinence or side effects like headaches. By decreasing sphincterpressure, nifedipine improves blood flow, promotes healing, and reduces painassociated with fissures. Topical nifedipine, usually formulated as a 0.2% or 0.3%ointment, is applied directly to the affected area.

However, specific research evaluating the efficacy of 0.3% topical nifedipine ointment remains sparse. The anatomical and physiological complexities of the anal canal, divided into upper and lower regions with distinct nerve supplies and sensitivities, further complicate the understanding and treatment of anal fissures.

Despite the promising results of studies involving nifedipine, including improved healing rates and reduced pain compared to placebo, gaps in knowledge persist regarding regional efficacy, patient-centred outcomes, and long-term follow-up. Therefore, this study aims to evaluate the effects, side effects, and overall efficacy of 0.3% topical nifedipine in patients with acute and acute-on-chronic fissure-in-ano, ultimately contributing to the improvement of patient care and management strategies. [7-8]

MATERIAL AND METHODS

Study Design: This was a clinical, prospective, comparative study conducted over 18 months at the Department of Surgery, SGT Hospital, Gurugram, Haryana, following Ethical Committee approval.

Participants: A total of 100 patients with acute (<8 weeks) and acute on chronic (>8 weeks) anal fissures were included. Participants were recruited from the surgical outpatient department.

Inclusion Criteria: Patients with painful stool passage, with or without bleeding, diagnosed based on history and clinical examination.

Exclusion Criteria: Patients with active tuberculosis, hemorrhoids, anorectal abscesses, anal malignancies, prior anal surgeries, fecal incontinence, anal stenosis, or bleeding diathesis were excluded.

Data Collection Techniques and Tools:

Participants were divided into two groups:

- Group I: 50 patients with Acute Anal Fissure treated with 0.3% Nifedipine ointment thrice daily for 6 weeks.
- Group II: 50 patients with Acute on Chronic Anal Fissure treated with 0.3% Nifedipine ointment thrice daily for 6 weeks.

Follow-Up: Patients were assessed for pain relief and anal spasm grading at 2, 4, 6, and 12 weeks post-treatment.Visual analogue scale was used for grading relief in pain and digital rectal examination was used for grading ofanal spasm during follow up visits.

Grading of Anal Spasm (by Digital Rectal Examination)

Grade – N	Normal Anal Sphincter, 0 anal spasm.
Grade – 1	+1 Anal Spasm.
Grade – 2	+2 Anal Spasm
Grade – 3	+3 Anal Spasm

*This is objective Grading according to Surgeon Index Finger.

Statistical Analysis: Datawas validated and analyzed using SPSS version 20.0. Descriptive statistics summarized the data, and bivariate analyses employed independent t-tests and chi-square tests, with significance set at $p < 0.05$.

RESULTS

The study compared two groups of participants with anal fissures treated with 0.3% Nifedipine ointment over six weeks.

Age and gender distributions were similar in both groups, with no statistically significant differences.

Pain was universally reported in both groups (100.0%), followed by bleeding (80.0%). The occurrence of pruritus showed no significant differences. Majority of anal fissures were located posteriorly in both groups

Visual Analog Scale (VAS) score decreased significantly from baseline across follow ups conducted till 6 weeks in both groups indicating effective pain relief.

Side effects were minimal and no significant difference was observed in both groups. They are in line with current nifedipine safety guidelines.

A higher proportion of complete healing was observed in Group A (84%) compared to Group B (70%), though this difference was not statistically significant.No significant differences were noted in DRESS scores at various time points between the two groups.

Overall, both groups demonstrated similar effectiveness of nifedipine treatment, with a trend favouring the acute fissure group in healing outcomes. Further investigation is warranted to explore these findings in larger cohorts.

Table 1: Age Distribution of Study Participants

Group	Mean	SD	Median	Minimum	Maximum	p-value
A	32.340	7.2043	31.000	20.0	52.0	0.218
B	34.180	7.6310	32.500	20.0	52.0	
Total	33.260	7.4408	32.000	20.0	52.0	

Table 2: Gender Distribution of Study Participants among Both Group

Gender	A		B		p-value
	Count	%	Count	%	
Female	30	60.0%	25	50.0%	0.315
Male	20	40.0%	25	50.0%	
Total	50	100.0%	50	100.0%	

Table 3: Symptoms Distribution of Study Participants among Both Group

Symptoms	A		B		p-value
	Count	%	Count	%	
Pain	50	100.0%	50	100.0%	NA
Bleeding	40	80.0%	40	80.0%	1.000
Pruritis	4	8.0%	5	10.0%	0.727

Table 4: Distribution of Study Participants According To Location of Fissure Amongboth Groups

Location	A		B		p-value
	Count	%	Count	%	
Anterior	8	16.0%	7	14.0%	0.779
Posterior	42	84.0%	43	86.0%	
Total	50	100.0%	50	100.0%	

Table 5: Distribution of Study Participants According To VAS Score among Both Groups

Group		At baseline	2-week	4-week	6-week	p-value (comparison to baseline)	p-value (ANOVA test)
A	Mean	8.26	5.34	3.42	1.54	0.0001	0.0001
	SD	.723	1.099	1.486	1.328		
B	Mean	8.20	5.30	3.36	1.60	0.0001	0.0001
	SD	.756	1.111	1.509	1.309		
p-value (A vs B)		0.686	0.857	0.842	0.821		

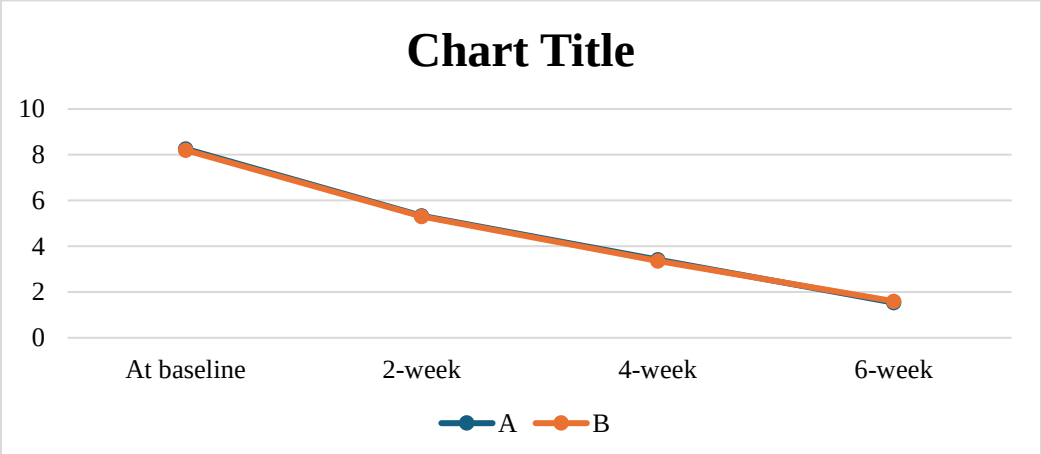

Table 7: Comparison of DRESS Score at Different Times between the Groups

DRESS Score	A		B		p-value
	Count	%	Count	%	
At baseline					
+1	4	8.0%	6	12.0%	0.702
+2	29	58.0%	30	60.0%	
+3	17	34.0%	14	28.0%	
At 2 week					
Normal	4	8.0%	6	12.0%	0.636
+1	27	54.0%	28	56.0%	
+2	14	28.0%	14	28.0%	
+3	5	10.0%	2	4.0%	
At 4 week					
Normal	31	62.0%	36	72.0%	0.554
+1	18	36.0%	13	26.0%	
+2	1	2.0%	1	2.0%	
At 6 week					
Normal	37	74.0%	40	80.0%	0.476
+1	13	26.0%	10	20.0%	

DISCUSSION

Historically, the management of anal fissures has evolved significantly. Recamier first described anal dilatation for fissures in 1838, and Miles later reported on sphincterectomy in 1939. While midline sphincterectomies were initially employed, high complication rates led to the adoption of lateral internal sphincterotomy (LIS), introduced by Eisenhammer in 1959. LIS has since remained the cornerstone of surgical therapy for chronic anal fissures. [9-10]

This study evaluated the safety and efficacy of topical 0.3% nifedipine ointment for treating acute (Group A) and acute on chronic (Group B) anal fissures.Age, gender, symptoms, fissure location, side effects, VisualAnalog Scale (VAS) score, and complete healing at 6 weeks were among the factorsevaluated in the study.

Demographics: Group A participants had an average age of 32.340 ± 7.2043 years, whereas Group B had an average age of 34.180 ± 7.6310. The two sets of datashowed no noticeable difference in age distribution. Group A had more female participants (60.0%) than Group B (50.0%), whereas Group B had more male participants (50.0%) than Group A (40.0%). No significant differences in age or gender were observed between the groups, ensuring that treatment outcomes could be reliably attributed to the intervention rather than demographic factors.

Symptoms and Fissure Location: Both groups presented with similar symptoms. All participants in the current study reported primarily pain (100.0%) and a high proportion reported bleeding (80.0%), with the majority of fissures located posteriorly, consistent with anatomical predispositions. Anterior fissures were less common. The difference in fissure location between the two groups was not statistically significant ($p = 0.779$).

Topical nifedipine is an effective treatment for anal fissures. MomayezSanat et al. (2023) found a higher remission rate with nifedipine (77.4%) versus diltiazem (54%) and quicker pain relief. Shahi et al. (2020) noted similar outcomes between Nifedipine and Lateral internal sphincterotomy. Additional studies by Kujur et al. (2020) and Chandrashekaraiahet. al. (2019) also reported significant pain reduction and healing rates, supporting nifedipine's effectiveness and low complication risk. [11-14]

Pain Reduction: Initial VAS scores were comparable. At baseline, the mean VAS scores were similar between Group A (8.26) and Group B(8.20), indicating that both groups experienced comparable levels of pain prior to theintervention. Both groups experienced significant pain reduction over six weeks, for Group A to 1.54 and Group B to 1.60. The observed reduction in VAS scores within each group was statistically significant($p = 0.0001$), indicating that the topical application of 0.3% Nifedipine ointment waseffective in alleviating the pain associated with anal fissures, regardless of whetherthey were acute or chronic in nature.Importantly, the study found no significant difference in the mean VAS scoresbetween the two groups at any time point ($p > 0.05$).The comparable pain reduction observed in both groupssupports the use of topical nifedipine as a treatment option for anal fissures, regardlessof their chronicity.

Healing Rates: Complete healing was achieved in 84% of Group A and 70% of Group B, with no statistically significant difference, suggesting that nifedipine is effective across both types of fissures.The lower healing rate in the acute on chronic fissure group, though not statistically significant, may stem from longer chronic fissure duration and possible fibrosis or scarring that hinders healing.

Side Effects: Side effects were minimal, namely headache and hypotension and comparable between groups. These results are consistent with the known safety profile of topical nifedipine, whichhas been reported in several previous studies, reinforcing the safety profile of topical nifedipine.The low incidence of side effects observed in this study is in line with the findingsreported by Shrestha et al. (2017) [15] and Agrawal et al. (2013) [16] who noted that nifedipine is better tolerated to other pharmacological agents.

These findings align with MomayezSanat et al. (2023), who reported a 77.4% remission rate with nifedipine versus 54% with diltiazem after 8 weeks. They also support Shahi et al. (2020), which showed comparable healing outcomes between nifedipine and lateral internal sphincterotomy. [11-12]

DRESS Scores: At baseline, the majority of patients in both groups had a DRESS score of +2. Improvements in DRESS scores were similar in both groups, indicating effective healing.

In conclusion, topical 0.3% nifedipine ointment is a safe and effective first-line treatment for both acute and acute on chronic anal fissures. Further long-term studies are recommended to assess recurrence rates and sustained efficacy.

The lack of a statistically significant difference in DRESS scores between the acuteand acute on chronic fissure groups indicates that the chronicity of the fissure did notsignificantlyinfluence the response to topical nifedipine treatment. This is animportant consideration, as it suggests that clinicians can consider topical nifedipineas a first-line treatment option for both acute and chronic anal fissures, without theneed for additional interventions or monitoring based on fissure duration.

CONCLUSION

In the present study, we have shown that topical application of 0.3% nifedipine ointment for both acute anal fissure and acute on chronic anal fissure is promising. Patients in both groups received significant reduction in pain within six weeks and achieved an excellent rate of complete healing with low side effects incidence. The similar trend in DRESS score improvement between the two groupssuggests that topical nifedipine was equally effective in promoting fissure healing,regardless of whether the fissure was acute or acute on chronic in nature.Due to its direct comparison of efficacy and safety of topical nifedipine in acute and acute on chronic anal fissures, this study was a contribution to the management of anal fissures due to the comparative design,reviewofvariousoutcomesoftreatment,andreasonablesamplesize.

However, even these results are relatively limited; therefore, a great need exists to perform more research with multicentred designs and control groups to confirm the results over a more extended period, including the ability to find predictors of response to treatment. Overall, this study confirms the effectiveness and safety of topical nifedipine in the treatment of anal fissures, which can guide clinical practice in the management of this condition.

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