

A Comparative study of 0.3% Topical Nifedipine Ointment vs Lateral Sphincterotomy in the Treatment of Chronic Anal Fissure

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ABSTRACT

Background: Chronic anal fissure is a common anorectal condition marked by significant discomfort and morbidity. Topical chemical sphincter relaxation and surgical sphincterotomy are both recognized methods for treating this disease. This study aimed to assess the efficacy, analgesic effects, healing outcomes, and adverse effects of topical 0.3% nifedipine with lateral internal sphincterotomy in patients suffering from chronic anal fissure.

Material and Methods: A randomized controlled experiment was conducted over the course of one year in a tertiary care institution. Sixty patients were divided into two groups of thirty. Group I was administered topical 0.3% nifedipine, whereas Group II had lateral internal sphincterotomy. Patients were assessed at 2, 4, 8, and 12 weeks to measure pain (VAS score), healing progression, and adverse events.

Results: The healing rates of both groups improved over time; however, Group II's healing was consistently quicker and slightly more effective. At the conclusion of 12 weeks, 96.7% of patients in Group I and 100% of patients in Group II had achieved healing. The sphincterotomy cohort had significantly reduced pain scores at both 2 and 4 weeks ($p < 0.05$). Headaches and flushes were much more prevalent in the nifedipine cohort, but only the surgical cohort experienced mild incontinence.

Conclusion: Lateral internal sphincterotomy provides rapid pain relief and rapid recovery, whereas topical nifedipine acts as an effective, non-invasive option with few reversible side effects.

Keywords: Nifedipine, LIS, Chronic anal fissure, Comparative study.

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Introduction

Anal fissures are longitudinal or elliptical lacerations or ulcers located in the distal anal canal, extending beneath the dentate line to the anal margin, typically located in the midline.¹ Acute anal fissures exhibit clearly defined, fresh mucosal margins, frequently accompanied by

granulation tissue at the base. Chronic anal fissures are characterized as fissures that persist for more than 4 weeks or recur frequently. Chronic anal fissures exhibit specific anatomical characteristics, including discernible sphincter fibers at the fissure base, anal papillae, sentinel piles, and hardened borders.² The

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pathophysiology is attributed to several factors: mechanical damage, sphincter spasm, and ischemia. Internal sphincter hypertonia or spasm can be a primary or secondary reflex to the pain of the raw ulceration, leading to a vicious cycle of recurrent anal trauma from reflex sphincter spasm brought on by a fear of bowel movements. Anodermal local ischemia, which hinders fissure repair, is the second risk factor.³ A fissure may induce significant pain or be largely asymptomatic, contingent upon the severity of anal sphincter spasm. Low-volume rectal bleeding is frequently related to chronic anal fissure.

Medical management serves as the primary therapeutic approach owing to its safety and ease of administration. The healing rate of chronic anal fissures with medical therapy varies between 8% and 31%.³ Chemical sphincterotomy (CS) utilizing nitrates, calcium channel blockers, or botulinum toxin (BTX) is considered safe, providing prompt analgesic relief, few side effects, and eliminating the risks associated with surgical intervention or anesthesia; nonetheless, it is statistically less effective for chronic anal fissures (CAF) compared to surgical management.⁴

Lateral internal sphincterotomy (LIS), performed through a radial incision in the anoderm and subsequent division of the internal sphincter muscles, has traditionally been considered the preferred gold standard surgical intervention for Anal fissure.^{5,6} However, postoperative impairment of fecal incontinence following LIS has been a source of concern. The prevalence of fecal incontinence documented in the literature varies significantly, ranging from 1.3% to over 30%.⁷

Targeted medical intervention aims to reversibly reduce anal sphincter tone, as sphincter spasm contributes to the persistence and/or emergence of anal fissures, thereby enhancing vascularization of the anoderm, which is crucial for the healing process.³ Glyceryl trinitrate 0.2% or

0.4% rectal ointment may be prescribed to facilitate the healing of anal fissures. Topical nifedipine 0.2–0.5% and topical diltiazem hydrochloride 2% have both been demonstrated to be efficacious alternatives with a reduced side effect profile when compared to glyceryl trinitrate ointment.⁸ So, this study was planned to assess and compare the efficacy and adverse effects of the topical application of 0.3% nifedipine with those of lateral internal sphincterotomy in patients diagnosed with chronic anal fissure.

Review of literature

The widely recognized definition of an anal fissure is: "A linear ulcer of the anoderm, situated distal to the dentate line, typically found in the posterior midline." Patients with primary chronic anal fissures are recommended to consume liquids and fiber supplements, as well as bulk-forming emollient laxatives, and to utilize warm sitz baths. The fiber intake should be incrementally elevated to prevent issues of flatulence. The objective of medical intervention for chronic anal fissure is to attain a transient decrease in anal canal pressure to promote fissure healing ("reversible sphincterotomy"), therefore diminishing muscular tone. Diverse techniques may be employed: augmentation of nitric oxide, direct reduction of intracellular calcium, activation of muscarinic receptors, inhibition of alpha-adrenergic receptors, or activation of beta-adrenergic receptors. Calcium channel blockers diminish muscular tone. At present, there are only two industrial formulations of the channel blockers nifedipine and diltiazem available in topical form on the market. Lateral internal sphincterotomy (LIS), executed using an open or closed approach, entails an incision of the internal sphincter, variably extensive, distal to the dentate line, potentially accompanied by the excision of the sentinel node and hypertrophied papillae.⁶

In the study by Shahi et al⁹., fissures healed in 78%, 86%, 92%, and 90% of

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patients at 4, 6, 8, and 12 weeks, respectively, in the nifedipine ointment group. In contrast, the lateral sphincterotomy group exhibited healing rates of 88%, 92%, 98%, and 98% at the same intervals. Nineteen patients (38%) experienced side effects in the nifedipine cohort, whereas 10 patients (20%) in the sphincterotomy cohort did. Samson et al¹⁰. demonstrated that the healing rate was superior in the surgical group (96.7%) compared to the nifedipine group (83.3%). Surgical intervention resulted in superior pain alleviation and reduced recovery duration. Conversely, the nifedipine cohort had an insignificant risk of incontinence, while the surgical cohort experienced transient and minor permanent incontinence. The recurrence rate was greater with nifedipine (10%) in contrast to none observed in surgery. Perrotti et al¹¹. discovered that 94.5 percent of patients treated with nifedipine achieved healing of chronic anal fissures after 6 weeks of therapy ($P < 0.001$), compared to 16.4 percent of the control group.

Material and Methods

A randomised controlled trial was conducted in a tertiary care centre over the course of one year to determine the efficacy and adverse effects of topical 0.3% nifedipine compared to lateral internal sphincterotomy in patients diagnosed with chronic anal fissure. The study population included patients diagnosed with chronic anal fissure who presented to the Department of General Surgery, SRM Medical College Hospital and Research Centre.

Patients of both genders who were 18 years of age or older and had a confirmed diagnosis of an anal fissure with symptoms that lasted longer than six weeks were included in the study. Eligible patients gave their written and informed consent to participate, and their physical examination confirmed that they had an anal ulcer with indurated edges. Individuals who did not give their consent, had a history of allergic responses to topical medications, had

recurring anal fissures, or were younger than 18 years old were not included in the study. People having concomitant illnesses or conditions, such as leukemic ulcers, HIV-related anal ulcers, TB-related ulcers, Crohn's disease, anal fistulas, abscesses, or severe anemia, were not included. The study also excluded patients with a history of hemorrhoids or prior anal operations.

Following informed consent and in accordance with the inclusion criteria, all patients with anal fissures detected at the Surgery Department OPD were added to the study. Patient's basic demographic details and clinical history were recorded using semi structured questionnaire. A randomization process was used to divide the enrolled patients into two groups of 30. Group I patients received instructions on how to apply 0.3% nifedipine ointment locally around the anal orifice and at the site of the anal fissure. The study employed block randomization to ensure that each therapy group had an equal number of participants. Patients were divided into two groups in a 1:1 ratio within each block: Group I (medical care with 0.3% nifedipine ointment) and Group II (surgical management with lateral anal sphincterotomy). A block size of six was chosen. A computer-based random number generator was used to create randomization sequences. After the patient fulfilled all eligibility requirements and gave their informed consent, sealed, opaque envelopes were opened one after the other to maintain allocation concealment.

The patients in Group I were instructed on how to apply 0.3% nifedipine ointment locally at the site of the anal fissure and around the anal opening. Basic standard examinations, including complete blood counts, renal function tests, electrocardiograms, and chest X-rays, were conducted on patients in Group II. After determining the patients' pre-anesthesia fitness, a lateral anal sphincterotomy appointment was set. Before the procedure, intravenous antibiotics (cefotaxime 1 g IV) were administered, and patients were

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instructed to fast starting at midnight. A lateral internal sphincterotomy, which typically takes 15 to 30 minutes while under local or regional anesthesia, involves making a small intersphincteric incision to split the lower internal sphincter.¹²

All patients were monitored for three months, at two-week intervals from the date of surgery or the commencement of medicinal treatment (i.e., at the second, fourth, sixth, eighth, and twelfth weeks). Patients were evaluated for healing status, Visual Analogue Scale (VAS) ratings, symptomatic alleviation, and therapy adverse effects, including headache and perineal discomfort, during follow-up visits. Patients were evaluated for several clinical parameters at each follow-up appointment, which was planned for 2, 4, 8, and 12 weeks. The degree of bleeding was noted and classified as mild, moderate, or severe. The anal fissure's level of healing was assessed and categorized as either adequate, inadequate, or no healing. Over time, the Visual Analogue Scale (VAS) was used to measure the patient's sense of pain. Drug-related adverse effects were also recorded, with particular attention paid to the occurrence of headache, hypotension, hot flashes, or rashes.

The IBM SPSS Statistics software, version 26.0, was used to analyze the data. The distribution of continuous variables determined which statistical techniques were used, and their normality was checked. Normal distribution variables were shown as mean $\pm$ standard deviation, and non-normally distributed variables were shown as median with interquartile ranges. The chi-square test was used to compare the patient distribution across the surgical and medical management groups. The independent t-test was used to compare the two groups' mean values. At each follow-up interval, the distribution of optimal fissure healing was also assessed using the chi-square test. A two-sided probability value of $P < 0.05$ was deemed statistically significant for all statistical tests.

This research was authorized by the Trichy SRM Medical College Hospital and Research Center's Institutional Ethics Committee (IEC). All participants provided their signed and informed consent after being fully informed about the study's goals, methods, potential risks, and benefits. Participants were free to choose whether they wanted medical or surgical care, and their autonomy was completely respected. All patients, especially those in the medical management group, were closely monitored for any drug-related side effects to ensure the quality of care was maintained. Any adverse reactions, such as rash, headache, or hypotension, were quickly recognized and treated to ascertain patient safety and well-being during the trial.

Results

This study was conducted among 60 individuals with chronic anal fissure, who were randomly divided into two groups. Group I was administered 0.3% nifedipine topically, whereas Group II underwent a lateral internal sphincterotomy.

An overview of the basic characteristics of the study participants is provided in Table 1. The mean age of patients in Group I was 38.03 ± 6.34 years, while the mean age of patients in Group II was 39.57 ± 5.16 years. This indicates that the age distribution was comparable in both groups. In both groups, the majority of participants were male: 60% in Group I and 70% in Group II. Both groups had a slightly higher prevalence of posterior anal fissures compared to anterior anal fissures. In Group I, the mean duration of symptoms was 12.53 ± 4.51 weeks, but in Group II, it was 14.57 ± 3.87 weeks. The two groups exhibited comparable demographic and clinical baseline characteristics.

Table 1: Descriptive data of participants

S N o	Variables	Group I (n = 30)	Group II (n = 30)
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1	Age in years		38.03±6.338	39.57±5.164
2	Gender	Male	18 (60%)	21 (70%)
		Female	12 (40%)	9 (30%)
3	Location of fissure	Anterior	21 (70%)	19 (63.4%)
		Posterior	9 (30%)	11 (36.6%)
4	Mean duration of symptoms in weeks		12.53±4.508	14.57±3.866

Figure 1 exhibits the preoperative symptoms among groups. The preoperative symptoms were analogous in both groups. Eight percent of patients in Group I and seventy-six percent of patients in Group II reported experiencing perianal pain. Rectal bleeding was observed in 63.3% of individuals in Group I and 60% of participants in Group II. Seventy percent of patients in Group I and sixty-six percent of patients in Group II experienced pruritus ani, indicating that both groups exhibited comparable symptoms initially.

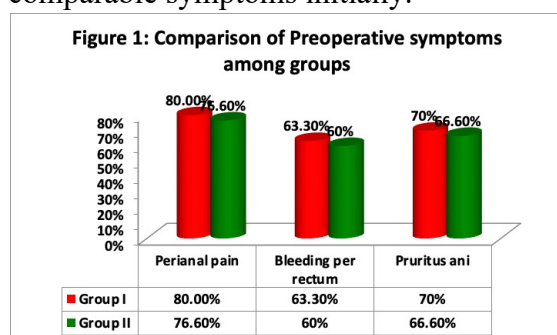


Figure 2 shows the proportion of patients who had adequate healing postoperatively. Periodic follow-up appointments were conducted to monitor the healing process. During the second week, 73.30% of patients in Group I exhibited sufficient healing, but 86.70% of patients in Group II showed adequate

healing. This indicates that the surgical group exhibited a more rapid first response. By the fourth week, the healing rates increased to 76.70% in Group I and 90% in Group II. Both groups continued to improve, although Group II had superior results. By the eighth week, 90% of patients in Group I and 96.70% of patients in Group II had achieved satisfactory healing. During the twelfth week, 96.70% of patients in Group I and 100% of patients in Group II had indications of healing. Lateral internal sphincterotomy consistently showed superior and accelerated healing rates; however, topical nifedipine also revealed significant efficacy with incremental improvement over time.

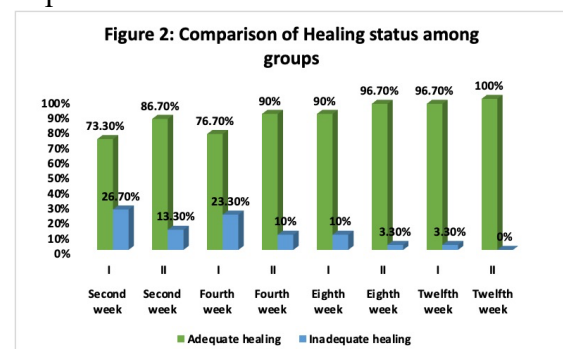


Table 2 illustrates time-related variations in the healing status of Group I (topical 0.3% nifedipine) and Group II (lateral internal sphincterotomy). Group II demonstrated slightly increased and accelerated healing rates at all follow-up evaluations. However, the disparities among groups at 2, 4, 8, and 12 weeks were not statistically significant. At the conclusion of 12 weeks, both groups exhibited nearly complete healing, indicating their general equivalence in efficacy.

Table 2: Comparison of Healing status among patients					
S No	Variables		Group I (n = 30)	Group II (n = 30)	p value
1	Healing at 2	Adequate	22 (45.8%)	26 (54.2%)	0.197

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	weeks	Inadequate	8 (66.7%)	4 (33.3%)	
2	Healing at 4 weeks	Adequate	23 (46%)	27 (54%)	0.166
		Inadequate	7 (70%)	3 (30%)	
3	Healing at 8 weeks	Adequate	27 (48.2%)	29 (51.8%)	0.301
		Inadequate	3 (75%)	1 (25%)	
4	Healing at 12 weeks	Adequate	29 (49.2%)	30 (50.8%)	0.313
		Inadequate	1 (100%)	0	

Table 3 illustrates the disparities in adverse events between Group I (topical 0.3% nifedipine) and Group II (lateral internal sphincterotomy). Five individuals with topical 0.3% nifedipine experienced headache; none of the patients who underwent sphincterotomy reported such symptoms. The change was statistically significant ($p = 0.020$). Flushing was exclusively observed in the nifedipine group ($p = 0.038$), perhaps due to its vasodilatory effects. Both groups experienced anal irritation, with no statistically significant difference observed ($p = 0.389$). Minor incontinence was only noted in the lateral internal sphincterotomy cohort, signifying an acknowledged surgical risk; the difference lacked statistical significance ($p = 0.076$). Topical nifedipine induced mild, transient systemic effects, whereas surgery presented a

minimal risk of complications related to the sphincter.

Table 3: Comparison of Adverse events in groups

S No	Adverse events		Group I (n = 30)	Group II (n = 30)	p value
1	Headache	Yes	5 (100%)	0	0.020
		No	25 (45.5%)	30 (54.5%)	
2	Flushing	Yes	4 (100%)	0	0.038
		No	26 (46.4%)	30 (53.6%)	
3	Anal irritation	Yes	4 (66.7%)	2 (33.3%)	0.389
		No	26 (48.1%)	28 (51.9%)	
4	Minor Incontinence	Yes	0	3 (100%)	0.076
		No	30 (52.6%)	27 (47.4%)	

Postoperative pain scores showed a significant reduction from 2 weeks to 4 weeks in both cohorts. The average VAS pain score in the nifedipine group decreased from 3.80 ± 0.81 at 2 weeks to 2.17 ± 0.38 at 4 weeks. This indicates a significant improvement in the symptoms. Similarly, in the lateral internal sphincterotomy group,

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pain levels decreased from 3.17 ± 0.75 at 2 weeks to 1.83 ± 0.38 at 4 weeks. While both groups exhibited substantial pain alleviation over time, the sphincterotomy group consistently achieved better pain reduction at both intervals, indicating more rapid and effective postoperative pain management. No moderate to severe bleeding was observed in either group.

Discussion

This study was done among patients with chronic anal fissure to determine the efficacy of 0.3% nifedipine compared with LIS. Among the 60 patients included in this study, thirty of them were treated with 0.3% of nifedipine local application, and the rest underwent surgical management.

Healing Status

Our study found that healing improved progressively in both groups at 2, 4, 8, and 12 weeks. Group II consistently showed earlier and marginally higher healing rates. By 12 weeks, adequate healing was achieved in 96.7% of Group I and 100% of Group II patients, indicating comparable long term efficacy of both modalities.

Shaki et al.⁹ from Bihar observed that healing progressively improved in both groups. At four weeks, 78% of the nifedipine cohort and 88% of the sphincterotomy cohort exhibited healing, while at twelve weeks, 90% of the nifedipine cohort and 98% of the sphincterotomy cohort showed healing. Katsinelos et al.¹³ in Greece, complete healing was observed at 8 weeks in 96.7% of patients administered nifedipine and 100% of those who underwent sphincterotomy, with comparable total healing rates at the end of the follow-up period. Kanojiya et al.¹⁴ from Jaipur discovered that 86.48% of patients treated with nifedipine and lignocaine healed after four weeks, whereas 100% of patients who had sphincterotomy achieved healing. Chauhan et al.¹⁵ from Rewa discovered that 84% of individuals with nifedipine achieved complete healing within 12 weeks, whereas 98% of those who

underwent sphincterotomy experienced total recovery, which shows similar results.

Khaledifar et al.¹⁶ from Iran demonstrated that topical nifedipine (77.1%) was significantly more effective in wound healing compared to isosorbide dinitrate (51.4%) during a 21-day follow-up period. Golfam et al.¹⁷ established that topical nifedipine produced markedly higher ulcer healing rates than oral nifedipine. A systematic review by Sierro et al.¹⁸ demonstrated that nifedipine displayed a more effective healing response than lidocaine alone. Li et al.¹⁹ performed a systematic review and meta-analysis demonstrating that topical calcium channel blockers significantly reduced the probability of unhealed fissures compared to oral formulations, while showing similar recurrence rates. Nelson et al.²⁰ concluded that nifedipine and diltiazem exhibited no significant difference in efficacy compared to glyceryl trinitrate for the treatment of anal fissures in their meta-analysis. In comparison to studies assessing other medical therapies, such as those by Khaledifar et al. and Golfam et al., our research further substantiates the superiority of topical nifedipine over alternative pharmacological treatments, including nitrates and oral calcium channel blockers. Li et al. and Nelson et al. performed systematic reviews and meta-analyses demonstrating that topical calcium channel blockers are efficacious and similar to recognized medical therapies such as glyceryl trinitrate, with acceptable recurrence rates.

Nifedipine may have elevated healing rates due to multiple factors. Nifedipine reduces the tone of the internal anal sphincter by inhibiting calcium influx, while simultaneously enhancing blood circulation to the anoderm and exhibiting local anti-inflammatory properties. Chronic anal fissures are thought to indicate ischemic ulcerations, particularly near the posterior midline, where sphincter hypertonia worsens perfusion insufficiency. Experimental research

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suggests that nifedipine may affect microcirculation and demonstrate free radical-scavenging and cytoprotective properties, potentially aiding in ulcer healing. Additional research is required to elucidate these adjunctive treatment processes in both acute and chronic anal fissures.²¹

Adverse Events

The present study revealed that adverse effects differed across the two treatment modes, highlighting their distinct mechanisms of action. Headache and flushing were considerably more prevalent in the nifedipine group, although anal discomfort was comparable in both groups. Minor incontinence was exclusively noted in individuals who underwent lateral internal sphincterotomy. The results illustrate the trade-off between systemic drug-related effects from medical treatment and complications associated with sphincter surgery. Our findings resemble those of Shaki et al.⁹, where 12% of patients with topical nifedipine had headaches, whereas none in the sphincterotomy cohort experienced this side effect. The study revealed that only the nifedipine cohort had flushing, although this finding was not statistically significant. Nifedipine, when applied topically, can lead to significant systemic absorption, resulting in headaches and flushing due to its vasodilatory effects on cerebral and peripheral blood vessels. The modest nature of these symptoms and their spontaneous resolution indicate that they are manageable. Both groups experienced anal irritation at a comparable frequency, indicating that the use of nifedipine topically does not significantly exacerbate perianal discomfort relative to surgical intervention. The sphincterotomy group was the sole cohort to experience minimal flatus incontinence. This aligns with existing knowledge regarding the risk of transient sphincter dysfunction following the incision of the internal sphincter. This remains a critical consideration in a clinical context, although lacking statistical significance. Verma et al.²² identified

modest adverse effects, including headaches in 3% of patients administered nifedipine. This additionally indicates the efficacy of topical nifedipine. The adverse event profile in this investigation indicates that topical nifedipine induces only modest, reversible systemic effects. Lateral internal sphincterotomy carries a minor yet significant risk of problems associated with the sphincter.

Postoperative Pain

The present study exhibited a notable decrease in postoperative pain, as quantified by the VAS score, from 2 to 4 weeks in both therapy cohorts. This signifies proficient symptom management with both topical nifedipine and lateral internal sphincterotomy. However, the sphincterotomy cohort experienced significantly greater and more rapid analgesia, indicating that the surgical intervention is superior for early symptom alleviation. The significance of this discovery for physicians is that pain is the primary symptom that impacts the quality of life and comfort of patients with chronic anal fissures. Our results correspond with those of Kanojiya et al.¹⁴ from Jaipur, who reported higher percentages of pain-free patients at four weeks in the lateral internal sphincterotomy group (86.28%) compared to the nifedipine and lignocaine group (77.46%). Chauhan et al.¹⁵ from Rewa saw significantly improved long-term pain results following sphincterotomy. For instance, 96% of patients experienced a complete absence of pain after three months, whereas just 80% of those administered nifedipine did. All of these findings substantiate the hypothesis that sphincterotomy is a more rapid and comprehensive method for alleviating pain. Lateral internal sphincterotomy provides superior pain relief by directly and promptly alleviating internal anal sphincter hypertonia, so interrupting the pain–spasm–ischemia loop associated with chronic anal fissures. Topical nifedipine gradually relaxes the sphincter by inhibiting calcium influx into smooth muscle cells.

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This results in a gradual yet consistent decrease in pressure within the sphincter. This delayed process likely accounts for the slower pain alleviation observed in the medical management group compared to the other groups. Both treatments effectively alleviate pain; however, lateral internal sphincterotomy is more rapid and comprehensive in its efficacy. Topical nifedipine remains an effective non-invasive alternative for alleviating symptoms over time.

Conclusion

Topical nifedipine and lateral internal sphincterotomy are both safe and effective treatments for chronic anal fissure; they have distinct side effect profiles. Topical nifedipine primarily induces minor, transient vasodilatory effects such as headache and flushing. Lateral internal sphincterotomy carries a minimal risk of problems associated with the sphincter, including mild incontinence. Although non-invasive medical treatment is usually the first choice, surgical sphincterotomy is still the most effective treatment for persistent anal fissures. Nifedipine ointment, demonstrating favorable treatment outcomes, has the potential to serve as the first-line therapy for chronic anal fissures. If pharmaceutical therapy is unsuccessful, lateral sphincterotomy is the preferred surgical intervention.

Limitations

The sample size was relatively small and was conducted at a single tertiary care center, which may restrict the generalizability of the findings. The follow-up duration was limited to 12 weeks, and long-term outcomes, including recurrence rates and sustained continence, were not evaluated. Some of the pain and symptom assessments were based on subjective measures, which could have led to reporting bias.

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