

Original Research Article

Fixed-dose formulation of nifedipine and lidocaine for the treatment of anal fissures: results from a prospective, multicenter, single-arm and post-marketing observational study

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ABSTRACT

Background: Anal fissures are a common cause of severe anorectal pain and impaired quality of life, most often affecting individuals aged 15-40 years. Combination therapy with nifedipine and lidocaine has shown promise for symptom relief and healing, yet Indian clinical data remain scarce, highlighting the need for real-world evaluation of this fixed-dose combination (FDC).

Methods: This prospective, multicenter, single-arm, open-label, post-marketing observational study evaluated the effectiveness and safety of FDC of nifedipine and lidocaine in Indian patients with acute or uncomplicated chronic anal fissures. The primary effectiveness endpoint was improvement in pain management. Secondary endpoints evaluated improvement in fissure healing, number of rescue medications required, global effectiveness and tolerability to therapy. Safety was evaluated by monitoring adverse drug reactions (ADRs).

Results: Fifty patients (male: female, 39:11), with a mean (SD) age of 43.5 (16.1) years were enrolled. Pain intensity decreased significantly from a mean (SD) of 6.6 (0.8) at baseline to 3.7 (1.4) and 1.2 (1.5), respectively at week 3 and 6. At Week 6, 93.0% of patients achieved complete re-epithelialization, with no requirement for rescue medication. The treatment was well tolerated with no incident of ADRs.

Conclusions: The study demonstrated statistically significant pain reduction along with improvements in fissure healing over 6 weeks of treatment with the FDC in Indian patients. The complementary actions of nifedipine and lidocaine contributed to both symptomatic relief and sustained healing, with no ADRs reported. These findings support its effectiveness, acceptability, and suitability as a non-surgical treatment option in routine clinical practice.

Keywords: Anal fissure, Anorectal pain, Nifedipine, Lidocaine, Fixed dose formulations

INTRODUCTION

Anal fissures are a predominant cause of intense anorectal pain in adults, that leads to severe degradation of the quality of life.¹ It is characterized as a chronic ulcerative tear of the anal canal, typically located at the posterior midline, though around one-quarter of cases are found

anteriorly.² The anal fissures affect the region of the anoderm that is densely supplied with pain sensory nerve endings.³ Thus, the excruciating pain experienced during defecation may persist for up to an hour or longer, causing significant distress due to intense, sharp, and tearing sensation.^{4,5} The annual incidence of anal fissures is estimated at 0.11% (1.1 per 1,000 person-years), with the

condition most frequently affecting individuals between 15 and 40 years of age. Anterior fissures are more often seen in women, particularly in the postpartum period.^{1,6} In the Indian population, reported prevalence ranges from 11% to 36.2%, with a higher occurrence in males and in the 15-40-year age group.^{7,9} However, the apparent sex difference and the true burden of disease in India is likely underestimated, as social stigma continues to limit timely reporting and diagnosis.⁷

Careful evaluation of anal fissure remains essential, as atypical presentations-such as lateral fissures or multiple lesions-may indicate underlying conditions like Crohn's disease, human immunodeficiency virus infection, sexually transmitted infections, tuberculosis, hematological malignancies, or other systemic disorders.^{4,10} Anal fissures are broadly divided into acute and chronic forms. The acute type generally manifests as a superficial tear of the mucosa, whereas chronic fissures-persisting for more than 8 to 12 weeks, show characteristic changes such as fibrosis, hypertrophied papillae, sentinel tags, and at times, exposure of internal anal sphincter fibers.² Typical clinical features include severe anal pain, 'bright red rectal bleeding on wiping,' and a history of hard stools or constipation.^{2,11}

Current clinical guidelines recommend pharmacological agents such as nitric oxide donors or calcium channel blockers (CCBs) as first-line therapy for anal fissures.¹² Although lateral internal sphincterotomy remains the gold standard for management, it is associated with high costs and a considerable risk of long-term anal incontinence.^{1,11} Topical nitrates provide effective pain relief; however, adverse effects such as headache often limit patient compliance.^{2,13} In contrast, CCBs demonstrate comparable efficacy with a lower incidence of side effects.¹⁴ A Cochrane review further confirmed that CCBs achieve similar healing outcomes to glyceryl trinitrate (GTN) but with significantly fewer ADRs.¹¹ Notably, recurrence following GTN therapy may reach 50%, which has led clinicians to prefer CCBs for better compliance and long-term outcomes.¹¹ Commonly used CCBs such as diltiazem and nifedipine are recommended for chronic anal fissures and are available in both oral and topical formulations.^{15,16} However, recent meta-analyses indicate that topical administration is more effective than oral formulations in promoting fissure healing. Alongside agents that promote sphincter relaxation and healing like local anesthetics play an important role in symptom control. Lidocaine, an amide local anesthetic, is widely used to improve pain associated with anal fissures and symptomatic hemorrhoids.¹⁷ Clinical studies further indicate that combining topical lidocaine with nifedipine is both well tolerated and effective in improving healing and symptomatic relief.¹⁸⁻²⁰

Evaluating the efficacy and safety of therapeutic agents is an ongoing process essential to improving the quality and delivery of medical care. Observational studies play a crucial role by focusing on real-world outcomes in large, heterogeneous populations to provide valuable evidence

on clinical effectiveness and tolerability data.²¹ However, there is a notable paucity of Indian clinical data on the efficacy of topical nifedipine-lidocaine combination therapy, since literature search revealed no prospective clinical studies assessing this fixed-dose formulation for anal fissure treatment. Therefore, the present prospective, multicenter, single-arm, post-marketing observational study was undertaken to evaluate the safety and effectiveness of topical nifedipine (0.3% w/w) and lidocaine (1.5% w/w) FDC therapy in Indian patients with acute or uncomplicated chronic anal fissures over a 6-week treatment regimen.

METHODS

Study design

This prospective, multicenter, single-arm, open-label, post-marketing observational study (CTRI/2024/09/073830; registered on 12 September 2024) evaluated the effectiveness and safety of a 6-week treatment with a topical FDC of lidocaine and nifedipine, applied prior to the urge to defecate, for the management of acute or uncomplicated chronic anal fissures. The study was conducted between October 2024 and June 2025 at three sites located in India.

The study adhered to ICH-GCP guidelines, the declaration of Helsinki, relevant local regulatory requirements such as the new drugs and clinical trials rules (2019), and institutional SOPs. The protocol, informed consent form, and amendments were approved by the relevant ethics committee before study initiation.

Patients

Inclusion criteria required patients aged ≥ 18 years with a clinical diagnosis of acute or uncomplicated chronic anal fissure and moderate to severe anal pain, defined as a visual analog scale (VAS) score of ≥ 45 mm (4.5 cm) on a 100 mm (10 cm) scale at screening. Women of childbearing potential were required to have a negative pregnancy test, be 'non-lactating', and agree to use reliable contraception during the study period. Patients were also required to discontinue any concomitant perianal topical preparations before starting the study treatment and for the duration of the trial, comply with study requirements, and give written 'informed consent' before enrollment.

Exclusion criteria included patients unwilling to undergo an examination of anal fissures; those with complicated chronic anal fissures (with infections), anal fistulas, or fissures secondary to Crohn's disease, anal suppuration, or abscesses. Patients with a history of or active gastrointestinal disorders such as inflammatory bowel disease, chronic fecal incontinence, or chronic constipation within 4 weeks preceding screening (characterized by ≤ 2 bowel movements per week along with straining or hard stool passage) were excluded. Patients suffering from anal abscess; fixed anal

stenosis/fibrosis; acute hemorrhoidal attacks; anal or perianal cancer; hepatic or renal impairment; or neoplastic disease within the past 5 years, were not included in the study. Patients were also excluded if they had a relevant medical history indicating serious renal, hepatic, neurological, dermatological, immunological, or major psychiatric disorders (including substance or alcohol misuse), or hematological illness, or clinically significant abnormal laboratory findings (as assessed by the investigator). Other exclusion criteria included a history of hypertension or ischemic heart disease treated with oral CCBs, fissures linked to secondary causes such as drug exposure (e.g., nicorandil), trauma, HIV infection, fistula-in-ano, perianal sepsis, or malignancy. Patients with cardiovascular conditions such as impaired left ventricular function, bradycardia, first-degree atrioventricular block, or prolonged PR interval (>200 ms) were also excluded. Patients exhibiting uncontrolled diabetes (HbA1c >8%) and/or hypertension (>140/100 mmHg); prior therapy with nifedipine, other topical CCBs, or topical medicated ointments within 3 days before screening were excluded. Known viral hepatitis; hypersensitivity to amide-type local anesthetics or nifedipine; prior surgical treatment or use of oral CCBs, nitrates, or other vasodilators were taken under exclusion criteria. Further, concurrent use of prohibited medications; symptoms suggestive of urinary tract infection; pregnancy or lactation; women of childbearing potential not practicing reliable contraception; and any patient considered unsuitable for study participation in the opinion of the investigator were excluded from the study.

Study endpoints

The evidence of effectiveness was evaluated based on changes in the severity of anal fissure symptoms in patients with acute or uncomplicated chronic anal fissures.

The primary effectiveness endpoint was the mean change in pain scores, assessed using a 10-point VAS, with 0 denoting the absence of pain and 10 reflecting the maximum pain intensity, from baseline (Day 1) to week 6 following treatment with the FDC of nifedipine and lidocaine in patients with anal fissures.

The secondary endpoints evaluated proportion of patients demonstrating fissure healing using video rectoscopy, where healing determined by extent of re-epithelialization (graded as 0: deep fissure, 1: superficial fissure, 2: partial re-epithelialization, and 3: complete re-epithelialization), following 6 weeks of the study FDC therapy. Additional measures comprised the proportion of patients requiring rescue medication at weeks 3 and 6, along with overall effectiveness and tolerability assessment at week 6, as rated by both physician and patient (categorized as poor, good, very good, or excellent) at week 6.

The exploratory endpoints included assessing the impact of using cream applicator through a 5-item questionnaire administered to patients with anal fissures who had previously used ointments, with/without an applicator.

Safety outcomes encompassed the occurrence of ADRs, other pharmacovigilance-relevant information (OPRI), serious ADRs and OPRI, as well as ADRs resulting in treatment discontinuation during the 6 weeks of treatment with the study FDC.

Statistical analysis

The study was powered to detect a clinically meaningful mean difference of 15 units in anal pain score from baseline to two months, assuming a standard deviation (SD) of 25 units. A minimum of 32 evaluable subjects were required to achieve 90% power with a two-sided paired t test at a 0.05 significance level. To accommodate an anticipated dropout rate of approximately 30%, 50 subjects were enrolled to ensure an adequate sample for the primary effectiveness analysis.

The safety analysis set comprised all participants who had taken at least one dose of the investigational treatment. Patients in the safety population with available post-baseline efficacy data comprised the 'intention-to-treat' (ITT) population. The 'per-protocol' (PP) cohort consisted of patients from ITT group who completed the study without major protocol deviations and was used for the effectiveness analysis.

Continuous variables for the primary endpoint were summarized using mean and SD, while categorical variables for the secondary and exploratory endpoints were presented as counts and percentages (n [%]). Changes in continuous outcomes from baseline to follow-up were analyzed using paired t-tests with a two-sided significance level of 0.05. Mean, SD, and mean change values were rounded to one decimal place. All statistical analyses were conducted using SPSS version 26.

RESULTS

Patients disposition

The study enrolled 50 patients, of whom 43 completed the study per protocol, while 7 patients (14.0%) discontinued 6 (12.0%) were lost to follow-up and 1 (2.0%) withdrew consent. Both the ITT and PP analysis sets, therefore, comprised 43 patients.

Demographics and baseline characteristics

A total of 50 patients (39 males and 11 females) with a mean (SD) age of 43.5 (16.1) years were enrolled. The mean (SD) baseline pain intensity on the VAS was 6.5 (0.9). Superficial and deep fissures were present in 52.0% and 40.0% of patients, respectively. The fissure was located posteriorly in 60.0% of patients and anteriorly in 40.0%. Induration was present in 82.0% of patients, lesions in 62.0%, lacerations in 30.0%, and sentinel piles in 16.0%. The demographic and baseline characteristics of the subjects are summarized in Table 1.

Effectiveness of FDC of nifedipine and lidocaine cream

Significant improvement in anal fissure symptoms was reported, post 6 weeks of treatment with the study FDC.

Primary effectiveness outcome

The mean (SD) pain intensity score, measured by VAS, decreased significantly from a baseline of 6.6 (0.8) to 3.7 (1.4) at Week 3, representing a mean (SD) reduction of 2.9 (1.2) (95% CI, -3.2 to -2.5; $p < 0.001$), and to 1.2 (1.5) at week 6, corresponding to a mean (SD) reduction of 5.3 (1.4) (95% CI, -5.8 to -4.9; $p < 0.001$) (Figure 1).

Secondary effectiveness outcome

At baseline, superficial and deep fissures were observed in 48.8% and 46.5% of patients on video rectoscopy, respectively. By visit 3 (Week 6), 93.0% of patients achieved complete healing and re-epithelialization of the fissure, while 7.0% demonstrated partial re-epithelialization (Figure 2). Notably, no patients required rescue medication during the 6-week treatment period with the topical FDC of nifedipine and lidocaine.

The effectiveness of 6 weeks of treatment with the topical FDC of nifedipine and lidocaine was rated as “Excellent” or “Very good” in 90.7% of patients by investigators, and in 93.0% of patients by self-assessment (Figure 3). The treatment was also well tolerated: investigators rated tolerability as “Excellent” or “Very good” in 48.8% of patients and “Good” in 51.2%, whereas 97.7% of patients rated tolerability as “Excellent”/“Very good,” indicating a high level of patient-perceived acceptability (Figure 4).

Exploratory effectiveness outcome

The exploratory endpoint could not be evaluated, as none of the enrolled patients had a prior history of using topical ointments for the treatment of anal fissures.

Safety and tolerability

Safety was assessed through monitoring and recording all ADRs, OPRIs. During the 6-week treatment regimen, no ADRs or OPRIs were reported among Indian patients treated with the study FDC for anal fissures. These findings indicate that the treatment was well tolerated in this patient population.

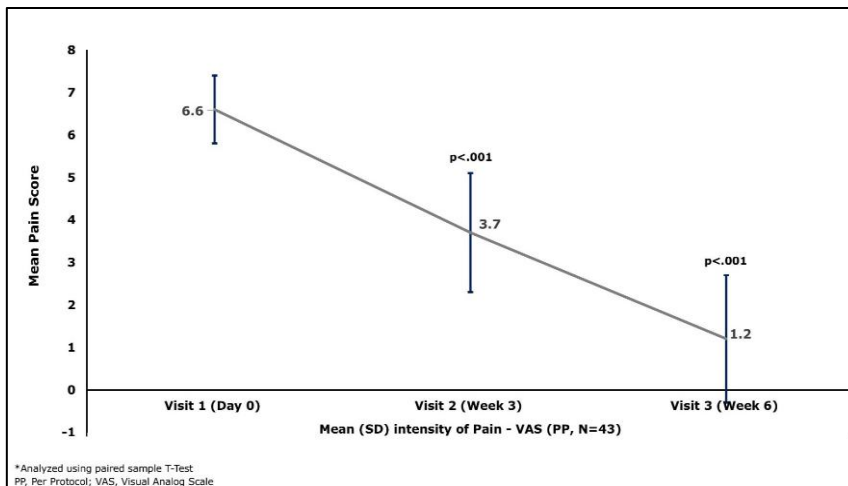


Figure 1: Mean (±SD) intensity of pain (VAS)-(PP set, n=43).

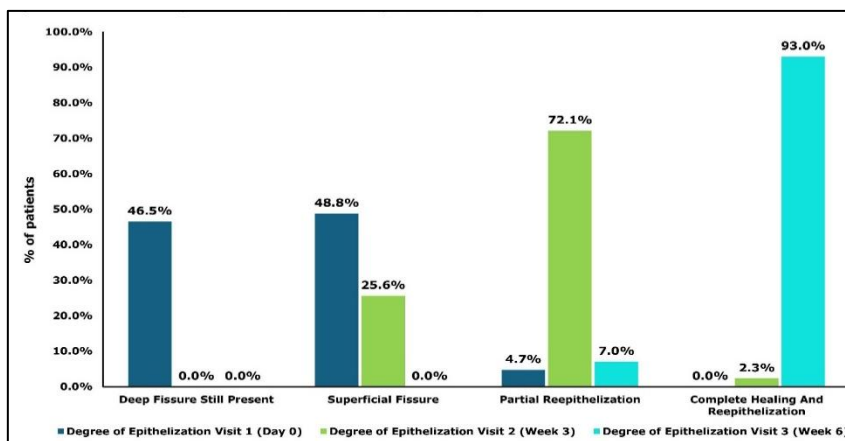


Figure 2: Assessment of epithelialization of the fissure-(PP set, n=43).

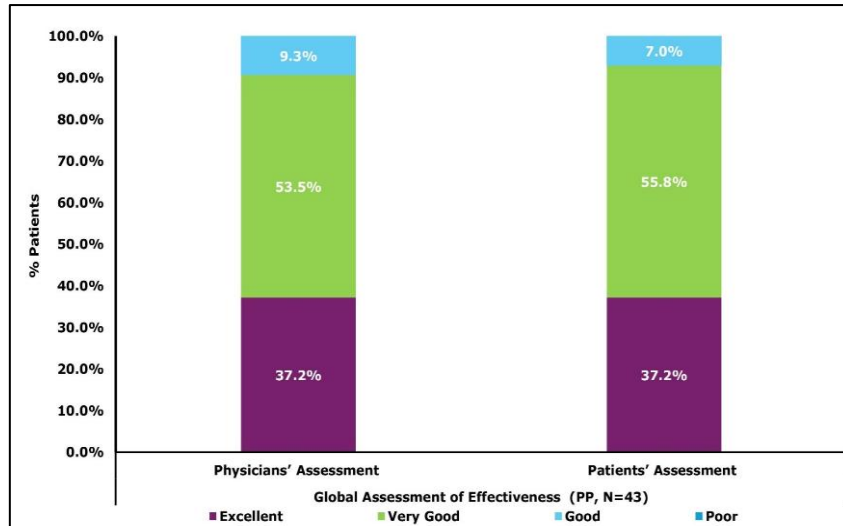


Figure 3: Global assessment of effectiveness by physician and patient (PP set, n=43).

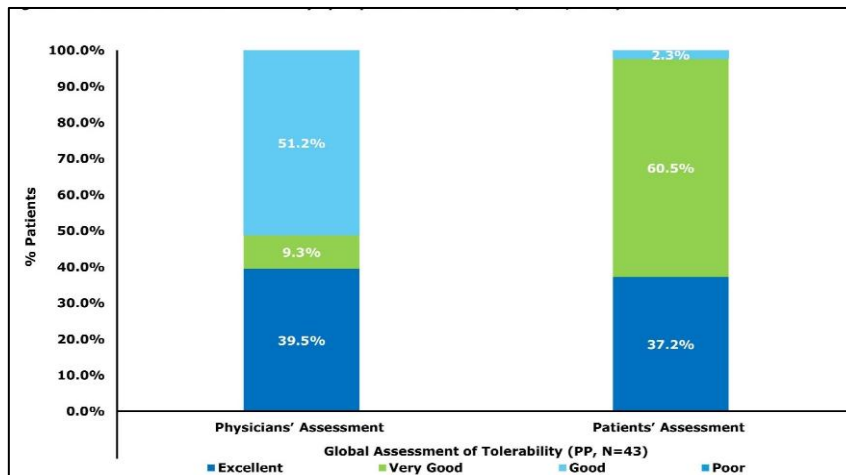


Figure 4: Global assessment of tolerability by physician and patient-(PP set, n=43).

Table 1: Demographics and baseline characteristics of patients-safety population.

Parameters	Overall, (n=50) (%)
Sex	
Male	39 (78.0)
Females	11 (22.0)
Age (in years), mean (SD)	43.5 (16.1)
Duration of disease (months), mean (SD)	4.6 (7.7)
Intensity of pain (VAS), mean (SD)	6.5 (0.9)
Degree of epithelization	
Deep fissure present	20 (40.0)
Superficial fissure	26 (52.0)
Partial re-epithelization	04 (8.0)
Site of fissure	
Posterior	30 (60.0)
Anterior	20 (40.0)
Position of fissure	
6 o'clock	20 (40.0)
12 o'clock	30 (60.0)

*N=Number of patients in safety set, n=Number of patients with data available, SD=standard deviation; VAS=visual analog scale, percentages are calculated using 'N' as the denominator.

DISCUSSION

Management of anal fissures remains challenging, and in recent years the focus has shifted from surgical to medical approaches because of the risks of incontinence, infection, and other complications associated with surgery.²² Combination therapy with the CCB nifedipine, which reduces anal sphincter tone to improve blood flow and promote healing, and the local anesthetic lidocaine, which provides symptomatic relief, has shown clinical promise.²³ Accordingly, this prospective, multicenter, single-arm, open-label observational study evaluated the safety and effectiveness of a topical FDC of lidocaine and nifedipine in Indian patients with acute or uncomplicated chronic anal fissures.

The topical application of study FDC demonstrated a clinically and statistically significant reduction in mean (SD) pain intensity score, measured by VAS, by 2.9 (1.2) and 5.3 (1.4) points, respectively at week 3 and 6, relative to a baseline score of 6.6 (0.8). The results of video rectoscopy also indicated notable improvements in superficial and deep fissures that were present in 48.8% and 46.5% of patients, respectively at visit 1. By week 6, 93.0% of patients demonstrated complete re-epithelialization, while the rest of the 7.0% achieved partial re-epithelialization. The results are consistent with a pilot study which demonstrated that 88.9% of patients receiving nifedipine combined with lidocaine achieved complete healing within 2-6 weeks of treatment.¹⁸ These results were corroborated by an independent study, in which 94.5% of patients with chronic anal fissure showed healing after 6 weeks of the same therapy.²⁰ Additionally, twice-daily application of the combination for 6 weeks has been reported to significantly enhance fissure healing and provide symptomatic relief.¹⁹ A comparative study reported re-epithelialization in 70% of patients treated with nifedipine and 12% with lidocaine after 2 weeks, highlighting the better efficacy of nifedipine.²⁴ Consistent findings were noted in previous literature, where 96.7% of patients achieved fissure healing following 8 weeks of nifedipine therapy.²⁵

The treatment benefit was supported by investigator assessments, which rated treatment efficacy as “Excellent” or “Very good” in 90.7% of cases, and by patient-reported self-assessment, where 93.0% of patients reported similar ratings. Further, investigator-assessed tolerability was rated as “Excellent” or “Very good” in 48.8% of patients, while patient self-assessments reported similar ratings in 97.7% of cases. No ADRs or OPRIs were reported during the study period. The absence of safety concerns, combined with high tolerability ratings, suggests that the study FDC is a tolerable therapeutic option for Indian patients with anal fissures.

This study has certain limitations, including its open-label design, short follow-up, and lack of a control group, all of which may introduce bias. However, the adequately powered sample size, use of validated outcome measures,

and standardized definitions enhance the robustness of the findings. The conduct of the study in routine clinical practice further supports its external validity and real-world applicability. Although observational designs lack the methodological rigor of randomized controlled trials, they offer valuable insights and reflect outcomes across heterogeneous patient populations. The absence of reported ADRs also reinforces the favorable tolerability profile. Given the scarcity of long-term evidence in anal fissure management, larger controlled studies with extended follow-up are warranted to confirm these results and guide optimization of clinical care.

CONCLUSION

This study demonstrates that topical FDC therapy with nifedipine and lidocaine offers significant clinical benefits for Indian patients with acute or uncomplicated chronic anal fissures. Over 6 weeks of treatment, patients reported clinically relevant pain relief, accelerated fissure healing, and improved quality of life, with no ADRs observed. The complementary mechanisms of nifedipine, which reduce sphincter tone and enhance perfusion, and lidocaine, which provides analgesia, collectively contribute to both symptomatic relief and mucosal healing. Use of high-definition video rectoscopy strengthened the objectivity and reliability of outcome assessment, while high patient-reported tolerability underscores the formulation's acceptability in routine care. Collectively, these findings support nifedipine-lidocaine combination therapy as an effective, tolerable, and practical non-surgical option for managing anal fissures in clinical practice.

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Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Mapel DW, Schum M, Von Worley A. The epidemiology and treatment of anal fissures in a population-based cohort. *BMC Gastroenterol.* 2014;14:129.
2. Nelson RL. Anal fissure (chronic). *BMJ Clin Evid.* 2014;2014:0407.

3. Altomare DF, Binda GA, Canuti S, Landolfi V, Trompetto M, Villani RD. The management of patients with primary chronic anal fissure: a position paper. *Tech Coloproctol.* 2011;15(2):135-41.
4. Cross KLR, Brown SR, Kleijnen J, Bunce J, Paul M, Pilkington S, et al. The Association of Coloproctology of Great Britain and Ireland guideline on the management of anal fissure. *Colorectal Dis.* 2023;25(12):2423-57.
5. Lu Y, Kwaan MR, Lin AY. Diagnosis and Treatment of Anal Fissures in 2021. *JAMA.* 2021;325(7):688.
6. Abramowitz L, Sobhani I, Benifla JL, Vuagnat A, Daraï E, Mignon M, et al. Anal Fissure and Thrombosed External Hemorrhoids Before and After Delivery. *Dis Colon Rectum.* 2002;45(5):650-5.
7. Chaudhary R, Dausage CS. Prevalence of Anal Fissure in Patients with Anorectal Disorders: A Single-centre Experience. *JCDR.* 2019;13(2):PC05-07.
8. Sharma R, Kaur A, Mittal S, Goyal R, Neki NS. Clinical study of perianal disorders and their management: A study of 200 cases. *IJMHR.* 2017;3(3):2454-9142.
9. Varadarajan MS, Sony PS, Anandan H. Prevalence and Clinical Presentation of Fissure-in-ANO in A Tertiary Care Centre. *Int J Sci Study.* 2018;70:12.
10. Davids JS, Hawkins AT, Bhama AR, Adina EF, Michael JG, Amy LL, et al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anal Fissures. *Dis Colon Rectum.* 2023;66(2):190-9.
11. Nelson RL, Thomas K, Morgan J, Jones A. Non surgical therapy for anal fissure. *Cochrane Database Syst Rev.* 2012;2012(2):CD003431.
12. Stewart DB, Gaertner W, Glasgow S, Migaly J, Feingold D, Steele SR. Clinical Practice Guideline for the Management of Anal Fissures. *Dis Colon Rectum.* 2017;60(1):7-14.
13. Bailey HR, Beck DE, Billingham RP, Binderow SR, Gottesman L, Hull TL, et al. A study to determine the nitroglycerin ointment dose and dosing interval that best promote the healing of chronic anal fissures. *Dis Colon Rectum.* 2002;45(9):1192-9.
14. Bielecki K, Kolodziejczak M. A prospective randomized trial of diltiazem and glyceryltrinitrate ointment in the treatment of chronic anal fissure. *Colorectal Disease.* 2003;5(3):256-7.
15. Jonas M, Neal KR, Abercrombie JF, Scholefield JH. A randomized trial of oral vs. topical diltiazem for chronic anal fissures. *Dis Colon Rectum.* 2001;44(8):1074-8.
16. Golfam F, Golfam P, Golfam B, Pahlevani P. Comparison of Topical Nifedipine with Oral Nifedipine for Treatment of Anal Fissure: A Randomized Controlled Trial. *Iran Red Crescent Med J.* 2014;16(8):e13592.
17. Perrotti P, Dominici P, Grossi E, Cerutti R, Antropoli C. Topical nifedipine with lidocaine ointment versus active control for pain after hemorrhoidectomy: results of a multicentre, prospective, randomized, double-blind study. *Can J Surg.* 2010;53(1):17-24.
18. Patel YR, Foronda ML, Pathmarajah. Treatment of anal fissure with nifedipine/lidocaine ointment: 344. *Am J Gastroenterol.* 2004;99.
19. Merenstein D, Rosenbaum D. Is topical nifedipine effective for chronic anal fissures? *J Fam Pract.* 2003;52(3):190-2.
20. Perrotti P, Bove A, Antropoli C, Molino D, Antropoli M, Balzano A, et al. Topical nifedipine with lidocaine ointment vs. active control for treatment of chronic anal fissure: results of a prospective, randomized, double-blind study. *Dis Colon Rectum.* 2002;45(11):1468-75.
21. Ligthelm RJ, Borzi V, Gumprecht J, Kawamori R, Wenying Y, Valensi P. Importance of Observational Studies in Clinical Practice. *Clin Ther.* 2007;29(6 PART 1):1284-92.
22. Sanei B, Mahmoodieh M, Masoudpour H. Comparison of Topical Glyceryl Trinitrate with Diltiazem Ointment for the Treatment of Chronic Anal Fissure: a Randomized Clinical Trial. *Acta Chir Belg.* 2009;109(6):727-30.
23. Wang C, Ni J, Xiong Y, Chen J, Li B, Xu L. The efficacy of diltiazem, glyceryl trinitrate, nifedipine, minoxidil, and lidocaine for the medical management of anal fissure: a systematic review and network meta-analysis of randomized controlled trials. *Int J Surg.* 2025;111(4):3020-9.
24. Golfam F, Golfam P, Khalaj A, Sayed Mortaz SS. The effect of topical nifedipine in treatment of chronic anal fissure. *Acta Med Iran.* 2010;48(5):295-9.
25. Katsinelos P, Papaziogas B, Koutelidakis I, Paroutoglou G, Dimiropoulos S, Souparis A, et al. Topical 0.5% nifedipine vs. lateral internal sphincterotomy for the treatment of chronic anal fissure: long-term follow-up. *Int J Colorectal Dis.* 2006;21(2):179-83.
26. Muthukumarassamy R, Robinson SS, Sarath SC, Raveendran R. Treatment of anal fissures using a combination of minoxidil and lignocaine: a randomized, double-blind trial. *Indian J Gastroenterol.* 2005;24(4):158-60.

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