

Review Article

Optimizing outcomes in anal fissure treatment: Indian expert panel consensus on combination strategies

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ABSTRACT

Anal fissures, defined as longitudinal tears in the anoderm, are a common cause of severe anorectal pain, especially during defecation. Despite the availability of both pharmacological and surgical treatments, certain challenges persist in effectively managing chronic anal fissures (CAFs). This manuscript reviews the unmet needs in the management of anal fissures like high recurrence rates, side effects from existing treatments, improper application of topical agents and poor compliance. It also presents the recommendations from an expert panel of surgeons from all over India, aimed at addressing these issues. While standard surgical treatment, such as lateral internal sphincterotomy, is highly effective, it carries the risk of side effects, including fecal incontinence, which can significantly impact quality of life. Consequently, chemical sphincterotomy has emerged as a leading non-invasive approach, with topical agents such as diltiazem and lidocaine serving as key components in the management of anal fissures. The experts recommended the combination of diltiazem and lidocaine for its superior efficacy in promoting healing and reducing anal resting pressure, with fewer side effects than agents like nifedipine and glyceryl trinitrate. This combination offers a promising alternative for patients seeking non-surgical management of anal fissures.

Keywords: Anal fissure, Diltiazem, Lidocaine, Combination therapy

INTRODUCTION

Anal fissures are longitudinal tears in the anoderm, typically located distal to the dentate line, and are a common cause of severe anorectal pain.¹ The pathophysiology of anal fissures involves an initial tear in the anal mucosa, typically caused by trauma such as hard stool or severe diarrhea, leading to local pain and spasm of the internal anal sphincter. This spasm increases resting anal sphincter pressure, which reduces blood flow to the affected area, causing ischemia and hindering healing.^{1,2}

Anal fissures can be classified based on their duration and etiology. Acute fissures are fresh lacerations that typically heal within 4-8 weeks with conservative therapy. If a fissure fails to heal within this period, it becomes chronic, lasting more than 8-12 weeks.^{1,2}

This article reviews the unmet needs in anal fissure management, highlights the benefits of calcium channel blockers (CCBs) with topical anesthetics, and presents expert consensus from a panel of 20 Indian surgeons.

REDEFINING MANAGEMENT OF ANAL FISSURES WITH DILTIAZEM-LIDOCAINE GEL

Current practices and challenges in diagnosis

Diagnosing anal fissures involves a comprehensive approach as directed by current clinical guidelines and research findings. It relies heavily on clinical history and physical examination, yet it presents notable challenges and variations in practice. Clinicians primarily diagnose anal fissures based on the characteristic presentation of severe pain during defecation and the presence of a visible tear. In many cases, further investigations are unnecessary

unless there is suspicion of a secondary fissure, which may necessitate anoscopy, endoscopy, or imaging to rule out underlying conditions like Crohn's disease or malignancy.^{1,2}

One of the primary challenges is the significant discomfort patients experience during physical examinations, often limiting thorough inspection. Examination under anesthesia may be required if the diagnosis remains unclear, especially in cases of atypical fissure location or presentation. Additionally, distinguishing chronic fissures from acute ones is crucial as it influences the treatment approach; chronic fissures often present with more pronounced fibrosis and hypertrophied anal papilla. This complexity underscores the necessity for clinicians to balance diagnostic thoroughness with patient comfort, ensuring accurate identification while minimizing patient distress.^{1,2}

Further, a survey highlights variability among clinicians in diagnostic practices.³ This emphasizes the need for standardized diagnostic criteria to improve consistency in identifying and categorizing anal fissures. Pelvic floor examination also varies widely in clinical practice. It typically involves assessing pelvic muscle tone and function to identify underlying factors contributing to fissure formation or persistence.³ This examination is crucial for tailoring management strategies, such as biofeedback therapy, aimed at improving pelvic floor coordination and reducing sphincter spasm, which are often implicated in the pathophysiology of CAFs.^{2,3}

The experts stressed the importance of investigating the underlying causes of fissures, especially in cases with diverse symptoms or a history of digital evacuation, as this may require considering alternative diagnoses like solitary ulcer syndrome or dyssynergia. Diagnosing acentric or multiple fissures is challenging due to their atypical presentation, and ruling out sexually transmitted diseases (STDs) is crucial due to symptom overlap. Further, the experts agreed that while pelvic examinations are not routinely performed, they become necessary when assessing patients with chronic fissures. In such cases, evaluating bowel habits and conducting further tests for suspected pelvic dysfunction is crucial.

Specific questions regarding pelvic dysfunctions should be asked for patients with weaker anal sphincter tones. However, the experts indicated that if a young patient presents with straightforward chronic fissures caused by constipation and hard stools, without any history of digital evacuation, a pelvic examination is generally not deemed necessary.

Treatment of anal fissures

Treating anal fissures involves a multifaceted approach typically comprising a combination of non-surgical and surgical methods aimed at alleviating symptoms and promoting healing. Pain management typically includes

conservative measures like topical anesthetics (lidocaine), cortisone-based suppositories, sitz baths, laxatives and analgesics. Topical anesthetics, particularly lidocaine, are used in the management of anal fissures primarily for their ability to provide symptomatic relief by numbing the affected area, thus reducing pain during defecation.^{4,5} Laxatives help relieve discomfort during bowel movements, by keeping the stool soft.⁴ Corticosteroids may also be used cautiously to reduce inflammation, though their potential to exacerbate GI irritation requires careful consideration in this sensitive area.^{1,2,4} Topical calcium channel blockers (CCBs) relax the internal anal sphincter by inhibiting calcium influx into smooth muscle cells.¹

The expert panel recommended dietary guidelines that emphasize fiber intake accompanied by adequate fluid consumption in patient treatment of anal fissure. The experts identified lidocaine, available in both gel and ointment forms, as the most commonly prescribed local anesthetic for anal fissures. They also emphasized that lidocaine causes numbing of the anus before defecation to relieve pain and this relief may temporarily reduce the tone of the internal anal sphincter thereby encouraging proper bowel habits. However, lidocaine majorly only aids in pain management, it does not contribute to the healing process. The experts also highlighted that lidocaine is preferably prescribed in combination with other treatments because it is effective, fast-acting and easy to use.

Conservative treatments offer symptomatic relief but often fail to ensure complete healing, which may require surgery or pharmacological interventions, which will be explored in detail in the subsequent sections.

Surgical intervention

Surgery becomes necessary and considered gold standard when conservative methods fail to heal the fissure. Traditional surgical approaches like lateral internal sphincterotomy (LIS) and fissurectomy aim to reduce anal sphincter pressure, thereby promoting fissure healing.^{3,6} However, this method carries risks of post-operative pain, bleeding and fecal incontinence due to inadvertent damage to sphincter muscles.⁷

Within five years after LIS, the incidence of incontinence decreases significantly to less than 10%, with the gross loss of solid stool occurring in less than 1% cases. The recurrence rate of CAF after LIS is around 5%, and approximately 75% of these cases are successfully treated with conservative pharmacological methods.⁸ The potential adverse outcomes of surgery including incontinence, infection, and longer recovery times have prompted a shift towards non-surgical approaches, with increasing acceptance of pharmacological methods for managing anal fissures.

Experts recommended LIS for patients with high resting anal pressure, while fissurectomy with ano-cutaneous flap

surgery was preferred for low-tone. Complete fissure excision was deemed unnecessary unless secondary changes were present. Anal dilation was discouraged as outdated. The panel emphasized discussing treatment options with patients and following guidelines, which suggest surgery only after failure of two chemical sphincterotomy agents or symptom recurrence. A fissure unhealed after 40 days was considered a treatment failure.

Pharmacological methods

Pharmacological methods include pain management with agents like lidocaine as well as chemical sphincterotomy using topical agents like glyceryl trinitrate (GTN) or CCBs viz. diltiazem and nifedipine. While effective in many cases as an alternative to surgery, their use requires careful monitoring for side effects.^{4,6,7}

Lidocaine was studied by Perotti et al to assess its efficacy in the treatment of CAFs. The study involved 110 patients, and the results demonstrated that 58.2% of patients reported modest pain relief within 3 weeks of treatment with 1.5% lidocaine. However, the healing rate was lower, at around 16.4%, indicating that while lidocaine effectively managed pain, it did not significantly enhance the healing process.⁵ This may be because these treatments do not address the underlying cause of the condition, which is the hypertonicity of the internal anal sphincter.⁴

GTN works by relaxing the internal anal sphincter through the release of nitric oxide, which decreases anal pressure and facilitates healing.^{4,9} Although GTN is effective, its use is often restricted due to adverse effects, with headaches being the most reported side effect. In 19 trials involving a total of 775 participants, the incidence of headache ranged from 16% to 100% of patients.⁴ This limits its use in treatment of anal fissures. Additionally, the recurrence rate with GTN post-therapy is about 50%, posing a significant challenge for sustained management.¹⁰

Another pharmacological method for treating anal fissures is chemical sphincterotomy using botulinum toxin injections. This approach allows the fissure to heal without the risks associated with surgical sphincterotomy. However, the effectiveness of botulinum toxin injections may vary, and repeated treatments may be necessary to maintain symptom relief.^{1,2,7,11}

Nifedipine, a CCB, is commonly used in the management of CAFs due to its ability to relax the internal anal sphincter. This pharmacological action helps reduce sphincter pressure, alleviating pain and promoting healing. It also has anti-inflammatory action. Topical nifedipine, effectively reduces internal anal sphincter pressure and improves local blood flow, promoting fissure healing. Applied as a 0.2–0.3% ointment twice daily, it offers a non-invasive alternative to surgery, with minimal side effects and favorable outcomes in chronic anal fissure management.^{4,5}

A double-blind RCT by Perotti et al compared 1.5% lidocaine + 0.3% nifedipine with an active placebo (1.5% lidocaine + 1% hydrocortisone acetate) in 110 CAF patients. After 6 weeks, complete healing occurred in 94.5% of the combination therapy versus 16.4% of control group. After 3 weeks, 87.3% of the therapy group reported no pain versus 10.9% of control group, underscoring lidocaine's role in pain relief.⁵

Diltiazem, another CCB, has gained prominence in the non-surgical management of CAFs due to its ability to relax the internal anal sphincter, thereby reducing sphincter pressure and promoting healing.^{4,12} The pharmacological action of diltiazem involves inhibiting the influx of calcium ions during membrane depolarization of smooth muscle cells, leading to muscle relaxation.¹³

A study by Kujur et al compared topical nifedipine, diltiazem, and lidocaine in 90 CAF patients. One group received 0.3% nifedipine + 2% lidocaine, another 2% diltiazem + 2% lidocaine, and the control 2% lidocaine alone. After 4 weeks, nifedipine and diltiazem showed significantly better pain and bleeding reduction vs. control, with healing rates of 93.33% ($p < 0.0001$) and 86.67% ($p = 0.0002$) versus 36.67%. No significant difference was seen between nifedipine and diltiazem in visual analog scores (VAS) scores ($p = 0.4738$) or bleeding improvement ($p = 0.5769$). The study concluded that topical CCBs are superior to lidocaine alone in pain relief and healing.¹⁴

A randomized phase 4 trial by Mital et al compared 2% diltiazem alone versus diltiazem with 2% lidocaine in CAFs, hemorrhoids, and post-surgical anorectal pain. Both reduced means resting pressure (MRP) at 15-, 30-, and 60-minutes post-application, but the combination showed greater MRP reduction and superior pain relief. VAS scores and patient comfort were consistently better in the combination group. The study emphasized the advantage of combining diltiazem with lidocaine for enhanced symptom control in anal conditions.¹⁵⁻¹⁷

Therefore, such a combination is important to address the underlying muscular tension by reducing sphincter pressure (through the action of diltiazem) as well as provide immediate pain relief (due to the anesthetic effects of lidocaine). This dual action is preferred as a superior therapeutic option for treating conditions like chronic anal fissures.

Topical diltiazem has demonstrated greater efficacy and fewer side effects compared to oral treatments, leading to improved patient compliance. Its localized action minimizes systemic exposure, reducing the risk of adverse effects. This evidence favors the use of topical over oral diltiazem for managing CAFs.^{8,19}

Several trials have shown diltiazem to be effective for CAFs. Jonas et al studied 50 patients treated with either oral diltiazem (60 mg) or 2% topical gel twice daily for 8 weeks. Maximum resting anal pressures (MARP)

decreased by 15% in the oral group (95±4 to 81±4 cm H₂O) and 23% in the topical group (102±5 to 79±5 cm H₂O). Complete healing occurred in 38% of oral and 65% of topical patients. Notably, topical diltiazem caused no side effects.¹²

Another significant double-blind, randomized controlled trial study by Knight et al demonstrated that topical 2% diltiazem is highly effective, with 51 patients (75%) experiencing initial healing. Follow-up data revealed that 59 of 67 patients (88% of those with follow-up data) remained healed, while 6 of 7 patients had mild recurrent symptoms but no fissures.²⁰

The experts' panel noted that acute fissures typically heal within 4–8 weeks with conservative management and chemical sphincterotomy, while chronic fissures may require surgical intervention if complications like hypertrophic papillae or skin tags develop. They noted that, chemical sphincterotomy, prescribed for 1.5 to 2 months, results in significant improvement for 90% of patients, with surgery needed in only a few cases. Treatment should continue for at least 6 weeks if 50% improvement is seen in the first week.

Subsequently, the experts noted that the adverse effects of GTN, particularly headaches, have led to increased use of alternative agents like CCBs, which are as effective as nitroglycerin with healing rates of 65% to 95% but a much lower incidence of headaches.^{11,21} The panel emphasized that American College of Gastroenterology and The American Society of Colon and Rectal Surgeons guidelines recommend CCBs as the first-line treatment for CAFs. Majority of the experts on the panel preferred diltiazem due to its favorable tolerability profile compared to nifedipine. According to experts, CCBs are also useful in cases with spasms and can help patients with severe pain post-hemorrhoidectomy or fistulectomy.

Medication application frequency and technique

The expert panel had mixed opinions on whether to apply the medication twice or thrice daily, but preferred thrice daily, with the night dose reducing morning defecation pain and the morning dose applied after defecation. Patients often fear insertion, leading to ineffective application with the product remaining outside, but using a finger helped them understand the anal canal's direction and aided dilation. Application methods included a finger, conical applicator, or syringe, with the ointment applied to the anoderm, not too deep or on the outer skin. The preferred method was using a finger, as applicators could cause injury.

In cases of diltiazem gels, the experts advised applying the gel three times daily due to the 4-hour half-life of diltiazem. To ensure proper dosage, patients should use about 1 gm or 1 inch of gel on the finger if the tube lacks markings. Compliance is crucial, as adherence to local

application determines the necessity for surgery. Patients should be informed that using three 30 gm tubes per month indicates proper dosage.

The expert panel highlighted inaccurate dosing—often from incorrect application—as a key issue in anal fissure treatment. They emphasized that pain can hinder proper application. To address this, lidocaine gel before CCBs was advised to prevent burning. Gels were preferred over creams or ointments for better absorption and ease of application.

Notably, while older pharmacological treatments and CCBs play a role in managing anal fissures, significant challenges remain despite their wide use.^{2,4,11} Traditional methods like topical anesthetics, corticosteroids, and sitz baths offer limited efficacy, especially in chronic cases, with only 50% success. These treatments primarily provide symptom relief without addressing the root cause, hypertonicity of the internal anal sphincter.⁴

The adverse effects with GTN (headaches in 25% of patients) or high recurrence with nifedipine, (reported in 42% of patients) pose another challenge.^{10,22} Thus, medical therapies have their limitations in terms of side effects and recurrence rates. The surgical approach, although effective, requires careful consideration of risks such as incontinence.¹¹ Botulinum toxin injections face challenges due to inconsistent dosing, high recurrence rates (40-55%), and a 10% risk of fecal incontinence.¹⁰ Delayed consultations, lack of fast-acting pain relief options, and non-compliance further complicate treatment, while adverse effects like headaches impact patient quality of life.^{4,11,18}

Building on the previous discussion and expert insights, diltiazem has emerged as a preferred option for the treatment of anal fissures. Studies have also highlighted the need and preference towards combining diltiazem with lidocaine for treating CAFs.¹⁵ While lidocaine offers immediate pain relief, it lacks healing properties. The combination of 2% diltiazem and 2% lidocaine, help with pain relief as well as healing of the fissure, providing a combined action for the holistic management of anal fissures. A comparison of topical diltiazem versus lidocaine versus the combination of diltiazem and lidocaine is shown in Table 1.^{10,12-17}

Adjunct practices in management of anal fissures

A high-fiber diet is highly recommended as it softens stool, reduces strain during bowel movements, prevents further trauma, improves symptoms and is linked with faster healing.^{1,2,11} Recurrence rates range from 30-70% if a high-fiber diet is discontinued after fissure healing, but drop to 15-20% if the diet is maintained.²³ Adequate hydration is essential to keep stools soft, while regular physical activity and a consistent bowel routine help prevent constipation.⁶

Table 1: Comparison of topical diltiazem versus lidocaine versus combination.

Variables	Topical Diltiazem	Topical Lidocaine	Topical Diltiazem–Lidocaine combination
Drug class	Non-dihydropyridine calcium channel blocker ¹³	Local anesthetic ¹⁵	Calcium channel blocker + local anesthetic ¹⁶
Mechanism of action	Causes relaxation of vascular smooth muscle and vasodilatation, lowers anal resting pressure ¹²	Acts as analgesic, lowers resting anal pressure ^{10,15}	Synergistic effect: reduces anal pressure via muscle relaxation and provides immediate analgesia ^{16,17}
Pain	Alleviates pain ¹⁶	Reduces pain in anal fissures ¹⁵	Provides superior pain reduction and early pain relief compared to either agent alone ^{16,17}
Healing	Proven to heal chronic anal fissures (first-line treatment) ¹²	Helps with healing chronic anal fissure ¹⁷	Higher rates of partial healing by day 5 and 10 versus monotherapy; comparable complete healing by day 40 ¹⁶
Effectiveness	Effectively heals fissures and improves quality of life. Also effective in patients unresponsive or non-adherent to glyceryl trinitrate ¹⁷	Effective in relieving pain, reducing resting anal pressure, healing chronic anal fissures, resolving thrombosed hemorrhoids, and controlling post-hemorrhoidectomy pain ¹⁷	Superior in reducing pain intensity, faster onset (within 0.5 hour), and significant improvement in REALISE score and VAS ^{16,17}
Tolerability	Well tolerated ¹⁶	Well tolerated ¹⁷	Comparable tolerability to monotherapy; very low incidence of mild, non-drug-related TEAEs ^{16,17}
Use in special population	-	-	Shown effective in general adult population; including childbearing age group without added risk ¹⁷

REALISE: ScoRing systEm for AnaL flsSurE, VAS: visual analog scale, TEAE: treatment emergent adverse events

Sitz baths are also a commonly advised adjunct practice for anal fissure management, involving sitting in warm water for 10-15 minutes twice a day, especially after bowel movements. This soothes the area, promotes healing, relieves pain, and reduces the risk of infection by keeping the affected area clean.^{1,4,6}

Hard stools and straining can exacerbate fissures or hinder their healing.^{4,6,7} Stool softeners and laxatives, including combinations of osmotic and stimulant laxatives like milk of magnesia and sodium picosulfate help improve stool consistency and frequency, preventing further straining.²⁴

The expert panel also advised dietary recommendations, especially adequate fiber and fluid intake. The panelists recommended sitz bath, but only with warm water, as adding agents like Betadine or Potassium permanganate can cause staining or burns. Moreover, continued sitz baths should be avoided as they may lead to fungal infections.

The expert panel further agreed on the importance of stool softeners and laxatives, especially those having sodium picosulfate and liquid paraffin. Caution was advised against using bulking agents in cases of severe spasm, as they may intensify pain. Instead, one should start with a combination of stimulant, osmotic, and lubricant laxative until the pain diminishes and use bulking agents for gentle dilatation only when stools can be passed normally.

In conclusion, these adjunct strategies not only support the primary treatments but also contribute to improved patient outcomes by addressing underlying factors that contribute to the condition.

CONCLUSION

In conclusion, the panel highlighted key challenges and progress in anal fissure management. Calcium channel blockers, particularly the diltiazem-lidocaine combination, were preferred for their better tolerability compared to nifedipine. The combination was also favored over plain lidocaine, as it offers both effective pain relief and promotes fissure healing, making it a more comprehensive treatment option.

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