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Original Research Article

COMPARATIVE STUDY BETWEEN LATERAL INTERNAL SPHINCTEROTOMY AND TOPICAL 2% DILTIAZEM IN CHRONIC ANAL FISSURE: A PROSPECTIVE COMPARATIVE STUDY

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ABSTRACT

Background: Chronic anal fissure is a frequent benign anorectal disorder driven by internal anal sphincter hypertonia, anodermal ischemia and a self-perpetuating pain-spasm-ischemia cycle. Topical diltiazem produces reversible chemical sphincterotomy, whereas lateral internal sphincterotomy (LIS) provides definitive reduction of sphincter tone. This study compared short-term outcomes of LIS and topical 2% diltiazem in patients with chronic anal fissure. **Materials and Methods:** This prospective comparative study included 64 patients with chronic anal fissure at a tertiary-care surgical department in Moradabad, India. Thirty-two patients underwent LIS and 32 received topical 2% diltiazem. Baseline demographic characteristics, Numeric Rating Scale (NRS) pain scores, healing, incontinence, recurrence, treatment default, hospital stay and final outcome were analyzed from the master chart. **Results:** The groups were comparable for age (LIS 45.84 ± 11.50 years versus diltiazem 41.47 ± 15.89 years; p=0.212), sex distribution (p=0.801) and baseline NRS pain score (LIS 7.19 ± 0.69 versus diltiazem 6.91 ± 0.73; p=0.120). Complete fissure healing occurred in all LIS patients by week 2 and persisted through week 8. In the diltiazem group, complete healing was 0% at week 2, 37.5% at week 4, 78.1% at week 6 and 84.4% at week 8. Healing significantly favored LIS at week 4 (p<0.001), week 6 (p=0.016) and week 8 (p=0.008). No flatus or fecal incontinence and no recurrence were documented in either group during the 8-week follow-up. Final success was 100% after LIS and 84.4% after diltiazem (p=0.053). **Conclusion:** LIS provided faster and more predictable healing than topical 2% diltiazem, with preserved continence in this cohort. Topical diltiazem remains a useful non-operative option for selected patients, but LIS remains the more definitive modality for chronic anal fissure when rapid healing is required.

INTRODUCTION

Anal fissure is a common benign anorectal condition, but its clinical impact is disproportionate to the size of the lesion. The characteristic presentation is severe cutting or burning pain during defecation, post-defecatory pain lasting minutes to hours, bright red bleeding and fear of stool passage. Chronic fissure is generally defined by persistence beyond six weeks or by morphological features such as indurated fissure base, exposed internal sphincter fibers, sentinel pile and hypertrophied anal papilla. The majority are located in the posterior midline, an area vulnerable to reduced perfusion, and this anatomic predisposition is central to the pathogenesis of chronicity.[1,15,29]

The terminal anal canal is a highly specialized continence organ. The internal anal sphincter contributes the majority of resting anal pressure, while the external anal sphincter and puborectalis preserve voluntary continence and the anorectal angle. The anoderm below the dentate line is densely somatically innervated through inferior rectal nerve branches, explaining the intensity and precise localization of fissure pain. When a traumatic split occurs in this pain-sensitive anoderm, nociceptive input induces reflex sphincter spasm. Sustained internal sphincter hypertonia reduces anodermal blood flow, particularly in the posterior

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midline, and establishes the classic pain-spasm-ischemia cycle.[1,2,15]

Management of chronic anal fissure is therefore directed not merely at local wound care but at reducing sphincter tone and restoring perfusion. Conservative therapy with dietary fiber, hydration, stool softeners and warm sitz baths remains essential, especially for acute fissures and as an adjunct in chronic fissure. However, established chronic fissures with fibrosis and high sphincter tone often respond incompletely to conservative therapy alone. Pharmacological agents such as nitrates and calcium-channel blockers were introduced to produce chemical sphincterotomy, reduce resting anal pressure and promote healing without dividing sphincter muscle.[15,16,23,27]

Topical diltiazem is among the most widely used chemical sphincterotomy agents. As a calcium-channel blocker, it reduces smooth-muscle contractility in the internal anal sphincter, improves local anodermal perfusion and often produces symptomatic improvement with a more favorable headache profile than topical glyceryl trinitrate. Its principal advantages are non-invasiveness, outpatient use and avoidance of permanent sphincter division. These advantages are especially relevant in patients unwilling for surgery, patients with possible baseline sphincter weakness and patients in whom even a small risk of postoperative continence disturbance is unacceptable.[16,23,34,37,42]

Lateral internal sphincterotomy remains the operative benchmark against which non-operative therapies are compared. The procedure divides a controlled portion of the internal anal sphincter, thereby lowering resting pressure and breaking the pathophysiological cycle more definitively than topical therapy. Multiple surgical series and comparative studies have reported high healing rates and rapid pain relief after LIS, although concerns persist regarding flatus incontinence, minor soiling and rare fecal incontinence. Modern limited or tailored sphincterotomy seeks to preserve continence while achieving adequate pressure reduction.[8,9,11,12,13,36,43]

The clinical question is therefore not simply whether diltiazem works, but whether it can provide healing and symptom relief comparable to LIS in real-world surgical practice. Published comparative studies often show higher and faster healing with LIS, whereas diltiazem produces gradual improvement with lower procedural morbidity but higher dependence on adherence. Differences in study design, follow-up duration, severity of chronic fissure, technique of LIS, drug concentration and patient compliance contribute to variability in reported outcomes. In many Indian tertiary-care settings, delayed presentation, constipation, reluctance for anorectal examination and socioeconomic barriers to prolonged topical therapy further influence treatment selection and outcomes.[23,25,26,34,38,41]

The present study was undertaken to compare LIS and topical 2% diltiazem in chronic anal fissure. The study emphasizes clinically relevant outcomes: pain reduction, fissure healing over serial follow-up, continence, recurrence, default from treatment, hospital stay and final composite success. The objective was to generate a clinically interpretable comparison that can guide shared decision-making in a general surgery practice, while also contributing institution-specific data to the existing literature.[38,44]

MATERIALS AND METHODS

This was a prospective comparative study conducted in the Department of General Surgery, Teerthanker Mahaveer Medical College and Research Centre, Moradabad, Uttar Pradesh, India. The study was conducted after institutional ethical approval and written informed consent. The aim was to compare the clinical outcome of LIS and topical 2% diltiazem in patients with chronic anal fissure.

A total of 64 patients were included, with 32 patients in each treatment arm. The sample size was calculated using a two-proportion comparison formula with p1=56%, p2=14%, 80% power and 99% confidence interval, resulting in 32 patients per group. Group A underwent lateral internal sphincterotomy. Group B received topical 2% diltiazem. Patients were allocated according to clinical appropriateness and treatment choice.

Patients presenting with symptoms suggestive of chronic anal fissure underwent detailed history taking, general physical examination and local per-rectal assessment. The clinical record included duration and character of pain, bleeding, bowel habit, previous anorectal treatment and associated complaints. Local examination documented the fissure position, sphincter spasm, sentinel pile, discharge and associated anorectal pathology where present. Chronicity was based on persistence of symptoms and/or chronic local features.

Baseline assessment included demographic variables, clinical symptoms and Numeric Rating Scale pain score. Routine investigations were performed as indicated for preoperative or baseline evaluation, including complete blood count, blood sugar, urea, creatinine, liver function tests, serum electrolytes, viral markers and radiological investigations such as chest radiography or abdominal ultrasonography where required. These investigations were primarily used to ensure safe intervention and to exclude systemic mimics or comorbidities affecting management.

Patients in the LIS arm underwent lateral internal sphincterotomy using standard surgical principles. The operative goal was controlled division of the internal anal sphincter sufficient to reduce resting sphincter tone while preserving continence. Patients in the diltiazem arm were managed with topical 2% diltiazem and standard supportive measures. Both

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groups received bowel-regulating advice and follow-up. Follow-up was recorded at week 1, week 2, week 4, week 6 and week 8.

The primary outcomes were clinical healing of fissure and improvement in pain. Secondary outcomes were anal incontinence, recurrence, treatment default, duration of hospital stay and final treatment outcome. Healing was recorded as a binary variable at each follow-up point. Anal incontinence included flatus, liquid stool or solid stool incontinence as clinically reported. Recurrence included reappearance of fissure symptoms or re-ulceration during follow-up. Final outcome was classified as success or failure based on composite clinical recovery, healing, recurrence, continence and adherence status.

RESULTS

Sixty-four patients were analyzed, with 32 patients in the LIS arm and 32 in the topical 2% diltiazem arm. There were no missing group allocations. The dataset was adequate for reconstruction of baseline demographic variables, serial NRS pain scores, healing status, incontinence, recurrence, treatment default, hospital stay and final outcome.

The treatment arms were statistically comparable at baseline. The mean age was 45.84 ± 11.50 years in the LIS group and 41.47 ± 15.89 years in the diltiazem group (p=0.212). The LIS group included 17 males and 15 females, while the diltiazem group included 19 males and 13 females; the sex distribution did not differ significantly (p=0.801). Baseline pain severity was also comparable: mean NRS pain score was 7.19 ± 0.69 in the LIS group and 6.91 ± 0.73 in the diltiazem group (p=0.120).

Pain improved in both groups, but the rate of improvement was markedly faster after LIS. By week 1, the mean NRS pain score had fallen to 2.03 in the LIS group compared with 5.59 in the diltiazem group. By week 2, pain in the LIS group was almost completely resolved, whereas the diltiazem group still had a mean NRS score of 4.19. By week 4 onward, recorded NRS pain scores in the LIS group were zero, while the diltiazem group continued to show residual pain at week 4. The week 1, week 2 and week 4 between-group differences were statistically significant.

Healing kinetics strongly favored LIS. No patient in either group was fully healed at week 1. At week 2, all 32 LIS patients had achieved healing, compared with none in the diltiazem arm. At week 4, healing remained 100% in the LIS arm and was 37.5% in the diltiazem arm. At week 6, healing was 100% versus 78.1%, and at week 8 it was 100% versus 84.4%. The differences at weeks 4, 6 and 8 were statistically significant, demonstrating faster and more predictable epithelialization after LIS.

Anal continence was preserved in both groups. No patient in the LIS arm and no patient in the diltiazem arm reported flatus incontinence, liquid stool incontinence or solid stool incontinence at any recorded follow-up visit. Because the event rate was zero in both groups, statistical comparison for incontinence was not meaningful. No recurrence was recorded in either group over the 8-week follow-up period.

Treatment default was not observed in the LIS group. In the diltiazem group, one patient defaulted by week 6 and two patients had defaulted by week 8. This pattern reflects the dependence of medical therapy on sustained patient adherence. Hospital stay differed by design: LIS patients had a short mean stay of 1.53 +/- 0.80 days, while diltiazem patients were managed without hospital admission. This difference was statistically significant (p<0.001), although it reflects the operative versus outpatient nature of the modalities rather than postoperative morbidity.

Final treatment success occurred in 32 of 32 LIS patients (100%) and 27 of 32 diltiazem patients (84.4%). Five patients in the diltiazem arm were classified as treatment failures. The numerical advantage favored LIS; however, the comparison did not reach conventional statistical significance (p=0.053).

Table 1: Baseline demographic and clinical characteristics

Parameter	LIS (n=32)	Topical 2% diltiazem (n=32)	p-value
Age, years (mean ± SD)	45.84 ± 11.50	41.47 ± 15.89	0.212
Male/Female	17/15	19/13	0.801
Baseline NRS pain score (mean ± SD)	7.19 ± 0.69	6.91 ± 0.73	0.120

Table 2: Serial NRS pain scores during follow-up

Follow-up	LIS (mean ± SD)	Topical 2% diltiazem (mean ± SD)	p-value
Baseline	7.19 ± 0.69	6.91 ± 0.73	0.120
Week 1	1.94 ± 0.62	5.94 ± 0.80	<0.001
Week 2	0.09 ± 0.30	4.88 ± 0.91	<0.001
Week 4	0.00 ± 0.00	3.47 ± 1.08	<0.001
Week 6	0.00 ± 0.00	2.87 ± 1.15	<0.001
Week 8	0.00 ± 0.00	1.03 ± 1.59	0.001

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Table 3: Fissure healing during follow-up

Follow-up	LIS healed	Diltiazem healed	Test	p-value
Week 1	0 (0.0%)	0 (0.0%)	Not tested	NA
Week 2	32 (100.0%)	0 (0.0%)	Chi-square	<0.001
Week 4	32 (100.0%)	12 (37.5%)	Chi-square	<0.001
Week 6	32 (100.0%)	25 (78.1%)	Fisher exact	0.011
Week 8	32 (100.0%)	24 (75.0%)	Fisher exact	0.010

Table 4: Safety, adherence and recurrence outcomes

Outcome	LIS (n=32)	Topical 2% diltiazem (n=32)	Interpretation
Anal incontinence at any follow-up	0 (0.0%)	0 (0.0%)	No continence disturbance in either arm
Recurrence by week 8	0 (0.0%)	0 (0.0%)	No short-term recurrence documented
Treatment default by week 6	0 (0.0%)	1 (3.1%)	Late adherence issue in medical arm
Treatment default by week 8	0 (0.0%)	2 (6.25%)	Late adherence issue in medical arm

Table 5: Hospital stay and final treatment outcome

Parameter	LIS (n=32)	Topical 2% diltiazem (n=32)	p-value
Hospital stay, days (mean ± SD)	1.53 ± 0.80	0.00 ± 0.00	<0.001
Final success	32 (100.0%)	27 (84.4%)	0.053
Final failure	0 (0.0%)	5 (15.6%)	0.053

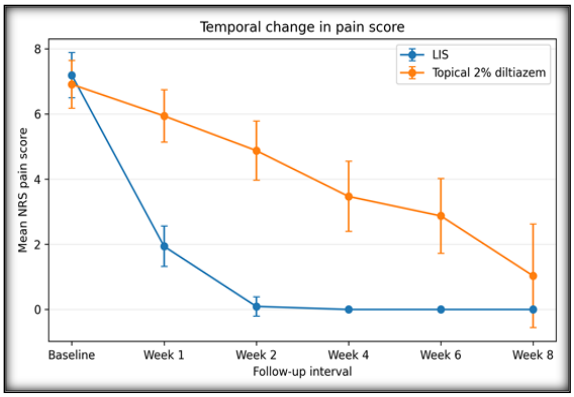

Figure 1: Temporal change in NRS pain score during follow-up

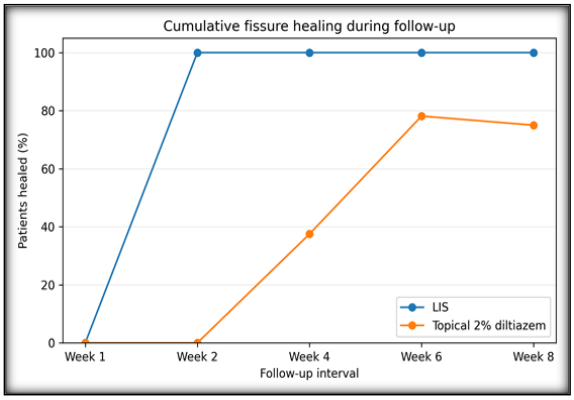

Figure 2: Cumulative fissure healing during follow-up

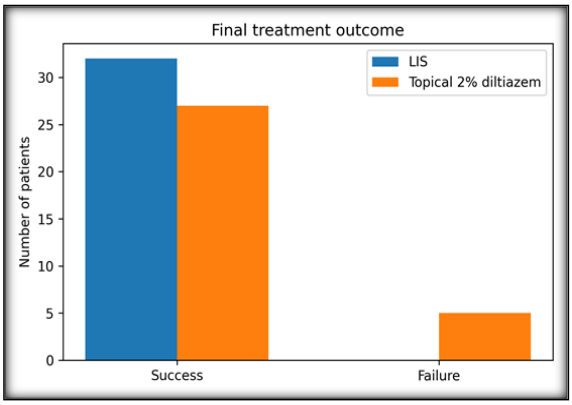

Figure 3: Final treatment outcome by treatment group

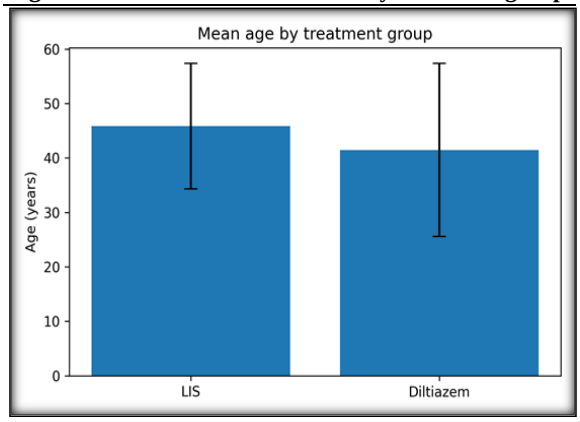

Figure 4: Mean age by treatment group

DISCUSSION

This prospective comparative study demonstrates that LIS produces faster healing and more rapid pain relief than topical 2% diltiazem in chronic anal fissure. The two groups were comparable at baseline for age, sex and pain severity, strengthening the interpretation that the observed divergence in outcomes was attributable primarily to the treatment modality. The most striking finding was the speed of healing: all patients in the LIS group were healed by week 2, whereas the diltiazem group showed

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delayed and incomplete healing during follow-up.[11,12,23,26]

The results align with the fundamental pathophysiology of chronic fissure. Chronic fissure is maintained by internal anal sphincter hypertonia and reduced anodermal perfusion. LIS directly addresses this mechanism by dividing a portion of the internal sphincter and reducing resting pressure. The immediate reduction in sphincter tone explains the rapid fall in pain scores and early epithelialization observed in the present surgical arm. Ram et al. documented functional changes in the internal sphincter after LIS, and Brown et al. reported durable healing advantages of sphincterotomy over topical treatment in long-term follow-up.[11,12]

The diltiazem arm also improved, which confirms the clinical value of chemical sphincterotomy. However, its effect was slower and less complete. Topical diltiazem depends on repeated application, adequate local absorption, patient adherence and ongoing stool regulation. A proportion of patients may have chronic fibrotic fissures or marked sphincter hypertonia that are insufficiently corrected by topical pharmacological relaxation. This explains why diltiazem reached 78.1% healing at week 6 but did not match the complete and early healing observed in the LIS group.[16,23,34,37]

Published comparative studies support this pattern. Kenche and Reddy reported better outcomes with surgical sphincterotomy than with 2% diltiazem cream. Sritharan et al. similarly compared LIS with 2% diltiazem and found higher efficacy with the operative approach. Kulkarni et al. reported prospective comparative data favoring LIS over local diltiazem gel. Shukla et al., while using fissurectomy with diltiazem as an intermediate approach, also reported lower healing than LIS. The present cohort fits this broader evidence base: diltiazem is useful and safe, but LIS is more reliable when complete healing is the primary goal.[23,25,34,38]

The absence of anal incontinence in the LIS group is clinically important. Continence disturbance remains the principal concern limiting universal acceptance of LIS, especially in young women, multiparous women and patients with prior sphincter injury or baseline continence symptoms. In this cohort, no patient reported flatus, liquid or solid stool incontinence during 8 weeks of follow-up. This finding is consistent with modern studies suggesting that controlled, limited or tailored sphincterotomy can preserve continence when performed carefully. However, the limited sample size and short follow-up period must be considered before generalizing the continence findings.[8,9,13,36,43]

The lack of recurrence in both arms should be interpreted cautiously. Recurrence after topical therapy often becomes apparent after treatment discontinuation and longer observation. The 8-week follow-up in this study is adequate to assess early healing but is not sufficient to determine long-term recurrence. Nash et al. reported long-term diltiazem outcomes, and several studies indicate that chemically healed fissures may recur more often than surgically treated fissures. Therefore, the zero recurrence observed here reflects short-term stability rather than definitive long-term cure.[27,37,41]

Treatment adherence deserves emphasis. The diltiazem group showed minor default at later visits, whereas the LIS group had none. This difference is intuitive: LIS is a single definitive intervention, while topical diltiazem requires consistent application over weeks. In routine practice, adherence can be affected by symptom improvement, embarrassment, cost, local irritation, work schedule and misunderstanding of treatment duration. Even small lapses in adherence may delay healing and influence apparent treatment failure. This makes counseling and follow-up crucial when choosing chemical sphincterotomy.[23,37,42]

Hospital stay was longer in the LIS group than in the diltiazem group, but the mean duration was short. The statistical significance of this difference reflects modality rather than morbidity, since diltiazem was entirely outpatient. A mean stay of approximately one and a half days supports the feasibility of LIS as a short-stay procedure in appropriately selected patients. In settings where operating room access, anesthesia risk or cost are barriers, diltiazem remains attractive as first-line therapy. Conversely, in patients seeking rapid relief, having severe symptoms, or demonstrating chronic fibrotic fissure with sphincter spasm, LIS offers a more predictable pathway to healing.[6,7,21]

The final composite outcome reinforces this interpretation. Success was 100% in the LIS group and 84.4% in the diltiazem group. Although the p-value of 0.062 did not cross the conventional threshold of statistical significance, the absolute difference of 15.6 percentage points is clinically meaningful. The borderline p-value is likely related to the modest sample size. Larger studies would be expected to have greater power to detect this difference if the same effect size persists.[28,34,38]

The study has several limitations. It was a single-centre study with a sample size of 64 patients. Allocation was based on treatment choice and clinical appropriateness rather than strict randomization, which introduces potential selection bias. Follow-up was limited to 8 weeks; therefore, long-term recurrence, late continence changes and patient-reported quality of life could not be fully assessed. Objective anal manometry and validated continence scores were not incorporated in the dataset, limiting physiologic interpretation. The dataset nevertheless has the strength of patient-level follow-up, serial assessment and direct comparison of two commonly used treatments in the same institutional environment.[11,13,43]

From a practical perspective, the findings support a tiered management approach. Topical 2% diltiazem is reasonable for selected patients who prefer non-operative treatment, have lower-risk fissure

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morphology, or require avoidance of surgery. LIS should be offered to patients with severe chronic fissure, persistent sphincter spasm, poor response to medical therapy, or need for rapid and definitive symptom relief, after counseling regarding continence risk. The decision should be individualized, but the current data favor LIS as the more effective modality for short-term healing and pain resolution.[23,34,38,44]

Strengths, limitations and clinical relevance

The strength is the use of repeated follow-up at clinically meaningful intervals. Chronic fissure management is best evaluated over time because the therapeutic mechanisms of LIS and diltiazem are different. LIS is expected to produce immediate reduction of resting sphincter tone; therefore, early pain relief and early healing are important endpoints. Diltiazem is expected to work gradually through pharmacological smooth-muscle relaxation and improved perfusion; therefore, week 6 and week 8 healing are more informative than week 1 outcomes. The serial design of the present study captures this difference in treatment kinetics and makes the clinical message more useful than a single end-point analysis.[11,16,23]

The limitations must also be clearly acknowledged. First, this was a single-centre study and the sample size was modest. The final outcome comparison favored LIS by 15.6 percentage points, but the p-value remained borderline. This suggests that the study was clinically informative but underpowered for some binary endpoints. Second, allocation was not described as concealed randomization; it was based on patient choice and clinical appropriateness. This may introduce selection bias even though measured baseline characteristics were comparable. Third, follow-up was limited to eight weeks, which is sufficient for early healing but insufficient for robust assessment of late recurrence and late continence outcomes.[27,37,41]

Fourth, objective physiological measurements were not included. Anal manometry would have strengthened the mechanistic interpretation by documenting baseline resting pressure and the degree of pressure reduction after LIS or diltiazem. Endoanal ultrasonography would have helped assess the extent of sphincter division and exclude occult sphincter defects in patients at risk of incontinence. Fifth, the study did not use validated quality-of-life or continence scales such as a Wexner score. In a condition where pain, fear of defecation and continence anxiety substantially affect daily life, future studies should include both objective healing and patient-reported outcomes.[11,13,43]

Despite these limitations, the findings have direct surgical relevance. In routine outpatient practice, many patients with chronic fissure ask whether a topical agent can replace surgery. The present data support a balanced answer. Diltiazem can reduce pain and heal a substantial proportion of fissures without hospital admission, anesthesia or sphincter division. It is therefore a rational initial choice in carefully selected patients. However, when the patient has severe symptoms, a chronic indurated fissure, exposed sphincter fibers, marked sphincter spasm, poor adherence potential or a need for rapid symptom control, LIS should be presented as the more definitive option.[23,34,38,44]

The absence of short-term incontinence in the LIS group should encourage confidence in controlled sphincterotomy, but it should not lead to indiscriminate surgery. Preoperative assessment must remain meticulous. Women with previous obstetric anal sphincter injury, elderly patients, patients with prior anorectal surgery and those with baseline urgency or seepage require special caution. In such patients, diltiazem, botulinum toxin, fissurectomy with adjunctive topical therapy or advancement flap procedures may have a role depending on local expertise and fissure morphology. Thus, LIS is the most effective option for typical hypertonic chronic fissure, but individualized surgical judgment remains essential.[18,20,28,35]

Recommendations for practice and future research

For clinical practice, the results justify a staged but time-conscious protocol. All patients should receive stool regulation, fiber supplementation, hydration advice, avoidance of straining and local hygiene measures. Topical 2% diltiazem may be offered to patients who prefer non-operative treatment and can adhere to regular application and follow-up. Response should be reviewed actively rather than indefinitely continuing topical therapy in non-responders. Persistent pain, non-healing at later follow-up or inability to comply with topical treatment should prompt discussion of LIS.[23,27,34]

For future research, a randomized controlled trial with concealed allocation, longer follow-up and standardized outcome instruments would provide stronger evidence. Follow-up should extend beyond six months to capture recurrence after discontinuation of diltiazem and late continence events after LIS. Manometric assessment before and after treatment would clarify whether patients with very high resting pressure benefit most from LIS, while patients with moderate hypertonia may be adequately treated with topical therapy. Subgroup analysis by sex, age, constipation severity, fissure site, sentinel pile and duration of symptoms would also help refine patient selection.[10,11,13,27]

Future studies should also include patient-centered endpoints. Time to painless defecation, time to return to work, need for rescue analgesics, patient satisfaction, cost of treatment and willingness to recommend the treatment are highly relevant in benign anorectal disease. A treatment that heals anatomically but leaves patients fearful of defecation or worried about continence is not fully successful. Conversely, a non-operative therapy that avoids admission but requires prolonged treatment and repeated visits may not be ideal for patients with limited access to care. Combining clinical, physiological and patient-reported outcomes would

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therefore produce a more complete assessment of value.[20,21,37]

CONCLUSION

In this prospective comparative study of 64 patients with chronic anal fissure, lateral internal sphincterotomy achieved faster pain relief, earlier healing and a higher final success rate than topical 2% diltiazem. Complete healing occurred in all LIS patients by week 2 and persisted through week 8, while diltiazem produced gradual but incomplete healing in a subset of patients. No incontinence and no recurrence were documented in either group during short-term follow-up. Topical 2% diltiazem remains a safe and useful non-operative option, particularly for patients who decline or are unsuitable for surgery, but LIS remains the more definitive and predictable treatment when rapid resolution is required. Longer follow-up with randomized allocation, validated continence scoring, patient-reported quality-of-life outcomes and manometric assessment would strengthen future evidence.

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