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ORIGINAL RESEARCH

Patient Satisfaction and Decision-Making Factors Between Pharmacological and Surgical Approaches in the Management of Chronic Anal Fissures: A Comparative Study

[1]Dr. Dhyaneshwar Damodar Kalani, [2]Dr. Mahesh Ram, [3]Dr. Vikram Vasuniya

[1]Resident, [2]Professor, [3]Associate Professor, Department of General Surgery, LN Medical College and JK Hospital, Bhopal, Madhya Pradesh, India

Corresponding author
Dr. Dhyaneshwar Damodar Kalani
Resident, Department of General Surgery, LN Medical College and JK Hospital, Bhopal, Madhya Pradesh, India
Email: dhyaneshwarkalani@hotmail.com

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ABSTRACT

Background: Chronic anal fissures represent a common anorectal condition causing significant discomfort and decreasein quality of life. This study aimed to evaluate and compare patient satisfaction and decision-making factors between pharmacological (2% Diltiazem gel) and surgical (lateral internal anal sphincterotomy - LIAS) approaches in the management of chronic anal fissures. **Methods:** A prospective randomized comparative study was conducted with 100 patients diagnosed with chronic anal fissures, who were divided equally into two treatment groups: pharmacological therapy with 2% Diltiazem gel (n=50) and surgical management with LIAS (n=50). Patients were followed up for six months, with assessment of symptom relief, healing rates, complications, recurrence, and satisfaction scores. Decision-making factors including pain management, fecal incontinence, and side effects were also analyzed. **Results:** At six months, complete healing was observed in 52% of patients in the Diltiazem group compared to 88% in the LIAS group ($p<0.0001$). Symptom relief was achieved in 56% and 84% of patients in the Diltiazem and LIAS groups, respectively ($p=0.002$). Pain scores were significantly lower in the LIAS group at six months ($p=0.0013$). Recurrence rates were 22% in the Diltiazem group versus 6% in the LIAS group ($p=0.021$). Patient satisfaction scores were higher in the LIAS group, with 82% reporting satisfaction scores of 7 or above compared to 30% in the Diltiazem group ($p<0.0001$). Minor side effects (headache, flushing) occurred in 8% of Diltiazem patients, while temporary fecal incontinence was observed in the LIAS group but improved substantially by six months. **Conclusion:** While both treatments demonstrated efficacy in managing chronic anal fissures, LIAS showed superior results in terms of fissure healing, symptom relief, prevention of recurrence, and overall patient satisfaction. However, the decision-making process should consider individual patient factors including risk tolerance for temporary incontinence versus preference for non-invasive management despite lower efficacy rates.

Keywords: Chronic anal fissure, Patient satisfaction, Diltiazem gel, Lateral internal anal sphincterotomy, Decision-making factors

INTRODUCTION

Anal fissure is a common an orectal condition characterized by a longitudinal tear or ulcer in the squamous epithelium of the anal canal [1]. These fissures can be classified as acute or chronic based on their duration and clinical presentation. Chronic anal fissures (CAFs), persisting for more than 6 weeks, are often associated with internal anal sphincter hypertonia and reduced an odermal blood flow, leading to impaired healing and persistent symptoms [2,3].

The prevalence of anal fissures in the general population is estimated to be 5-7%, with equal distribution among genders, although there is a slight predominance in young and middle-aged adults [4]. Patients typically present with severe anal pain during and after defecation, rectal bleeding, anal pruritus, and

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constipation, significantly impacting their quality of life [5].

Treatment approaches for chronic anal fissures have evolved considerably over the past decades, transitioning from predominantly surgical interventions to a more balanced approach incorporating pharmacological options as first-line therapy. The fundamental therapeutic goal is to reduce anal sphincter pressure, improve anodermal blood flow, and promote healing of the fissure while minimizing complications and preventing recurrence [6].

Pharmacological management primarily includes topical applications of calcium channel blockers (such as Diltiazem) or nitrates, which induce chemical sphincterotomy by relaxing the internal anal sphincter [7]. Conversely, surgical interventions, particularly lateral internal anal sphincterotomy (LIAS), involve partial division of the internal anal sphincter fibers to permanently reduce sphincter pressure [8].

While numerous studies have compared the efficacy and complication rates of these treatment modalities, relatively few have focused on patient satisfaction and the decision-making factors that influence treatment selection from a patient-centered perspective [9,10]. Understanding these factors is crucial for implementing personalized management strategies that align with patients' preferences and values.

This study aims to evaluate and compare patient satisfaction between pharmacological (2% Diltiazem gel) and surgical (LIAS) approaches in the management of chronic anal fissures, while identifying key decision-making factors that may influence treatment selection. By analyzing outcomes such as healing rates, pain relief, incontinence risk, recurrence rates, and overall satisfaction, this research seeks to provide insights that can guide clinicians in facilitating informed decision-making processes with their patients.

MATERIALS AND METHODS

Study Design and Setting

This prospective, comparative, randomized study was conducted in the Department of General Surgery at L.N. Medical College and JK Hospital, Bhopal. The study protocol was approved by the institutional ethics committee, and informed consent was obtained from all participants prior to enrollment.

Patient Selection

A total of 100 patients diagnosed with chronic anal fissures (defined as symptoms persisting for more than 6 weeks) were recruited and randomly allocated into two treatment groups.

- Group D: Pharmacological management with 2% Diltiazem gel (n=50)
- Group I: Surgical management with lateral internal anal sphincterotomy (LIAS) (n=50)

Inclusion Criteria

- Adult patients aged 18-60 years
- Chronic anal fissure with symptoms persisting for at least 6 weeks
- Presence of typical clinical features (anal pain, bleeding per rectum, constipation)
- No previous treatment for anal fissure other than dietary modifications and stool softeners

Exclusion Criteria

- Acute anal fissures
- Inflammatory bowel disease
- Anorectal malignancy
- Previous anorectal surgery
- Known hypersensitivity to calcium channel blockers
- Significant cardiovascular disease
- Unwillingness to participate in follow-up

Treatment Protocols

Pharmacological Management (Group D)

Patients in Group D were instructed to apply 2% Diltiazem gel to the anoderm three times daily for eight weeks.

Surgical Management (Group I)

- Patients in Group I underwent lateral internal anal sphincterotomy using the open technique under spinal anesthesia.

Follow-up and Assessment

All patients were followed up at 1 week, 1 month, 3 months, and 6 months post-treatment. The following parameters were assessed:

1. **Pain score**: Using the Visual Analog Scale (VAS) ranging from 0 (no pain) to 10 (worst imaginable pain)
2. **Rectal bleeding**: Presence or absence
3. **Healing of fissure**: Complete epithelialization of the fissure determined by physical examination
4. **Wexner's Incontinence Score**: Assessing the type and frequency of fecal incontinence (scores ranging from 0-20, higher scores indicating worse incontinence)
5. **Complications and side effects**: Including headache, flushing, anal incontinence, infection, etc.
6. **Recurrence**: Reappearance of symptomatic fissure after initial healing
7. **Patient satisfaction**: Measured on a scale of 0-10 at the 6-month follow-up

Statistical Analysis

The data were analyzed using Statistical Package for Social Sciences (SPSS) version 24.0. Continuous variables were presented as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages. Comparisons between

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groups were performed using Chi-square test for categorical variables and independent t-test for continuous variables. A p-value of <0.05 was considered statistically significant.

RESULTS

Demographic and Baseline Characteristics

The study included 100 patients with chronic anal fissures, equally distributed between the two treatment groups. The demographic and baseline characteristics of the study population are summarized in Table 1.

Table 1: Demographic and Clinical Characteristics of Study Participants

Characteristic	2% Diltiazem Gel (n=50)	LIAS (n=50)	P-value
Age (years)			
Mean ± SD	43.3 ± 6.7	46.3 ± 7.3	-
Gender, n (%)			
Male	37 (74%)	37 (74%)	-
Female	13 (26%)	13 (26%)	-
Type of Fissure, n (%)			
Posterior	33 (66%)	31 (62%)	-
Anterior	17 (34%)	19 (38%)	-
Presenting Symptoms, n (%)			
Constipation	40 (80%)	44 (88%)	-
Rectal Bleeding	38 (76%)	39 (78%)	0.94
Pruritus	39 (78%)	33 (66%)	-
Anal Sphincter Spasm	26 (52%)	28 (56%)	-
Sentinel Pile	27 (54%)	25 (50%)	-

Age and Gender Distribution

The mean age in the Diltiazem group was 43.3 ± 6.7 years, while it was 46.3 ± 7.3 years in the LIAS group. In both groups, males constituted 74% of the study population, indicating male predominance in the presentation of chronic anal fissures in this study cohort.

Clinical Presentation

All patients had chronic fissures, with symptom duration of 3-4 months in 40% of Diltiazem group and 32% of LIAS group, 5-6 months in 32% of both groups, and >6 months in 28% of Diltiazem group and 36% of LIAS group. Posterior fissures were predominant in both groups (66% in Diltiazem group, 62% in LIAS group).

The most common presenting complaints were constipation (80% in Diltiazem group, 88% in LIAS group), rectal bleeding (76% in Diltiazem group, 78% in LIAS group), and pruritus (78% in Diltiazem group, 66% in LIAS group). Baseline pain scores were comparable between the two groups (p=0.785).

Treatment Outcomes

Healing Rates

At the 6-month follow-up, complete healing of the anal fissure was observed in 52% of patients in the Diltiazem group compared to 88% in the LIAS group. This difference was statistically significant (p<0.0001), indicating superior healing rates with surgical management (Table 2).

Pain Relief

Pain scores progressively decreased in both groups during the follow-up period, but the improvement was more pronounced in the LIAS group. At 3 months, a significant difference was observed in pain scores between the two groups (p=0.020). By 6 months, 50% of patients in the LIAS group reported complete pain relief (score 0) compared to only 18% in the Diltiazem group, with the difference being highly significant (p=0.0013) (Table 2).

Table 2: Treatment Outcomes at 6 Months

Outcome	2% Diltiazem Gel (n=50)	LIAS (n=50)	P-value
Complete Healing, n (%)	26 (52%)	44 (88%)	<0.0001
Recurrence Rate, n (%)	11 (22%)	3 (6%)	0.021
Persistent Bleeding, n (%)	4 (8%)	0 (0%)	0.041
Pain Scores, n (%)			0.0013
No Pain (Score 0)	9 (18%)	25 (50%)	
Mild Pain (Score 1-2)	28 (56%)	23 (46%)	
Moderate Pain (Score 3-4)	13 (26%)	2 (4%)	

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Control of Bleeding

At baseline, rectal bleeding was reported by 76% of patients in the Diltiazem group and 78% in the LIAS group. At 3 months, this had reduced to 38% in the Diltiazem group and 14% in the LIAS group (p=0.006). By 6 months, bleeding had completely resolved in all patients in the LIAS group, while 8% in the Diltiazem group still experienced bleeding (p=0.041) (Table 2).

Symptom Relief

Overall symptom relief was achieved in 30% of the Diltiazem group at 3 months, increasing to 56% at 6 months. In contrast, the LIAS group demonstrated higher relief rates of 64% at 3 months and 84% at 6 months. The differences between the two groups were statistically significant at both time points (p=0.001 and p=0.002, respectively) (Table 3).

Table 3: Patient Satisfaction and Quality of Life Indicators

Indicator	2% Diltiazem Gel (n=50)	LIAS (n=50)	P-value
Patient Satisfaction Score (0-10), n (%)			<0.0001
Low (4-5)	21 (42%)	9 (18%)	
Moderate (6-7)	15 (30%)	29 (48%)	
High (8-9)	0 (0%)	12 (34%)	
Relief of Symptoms at 6 Months, n (%)	28 (56%)	42 (84%)	0.002
Wexner's Incontinence Score at 6 Months, n (%)			NA
0-5 (Minimal/No Incontinence)	-	39 (78%)	
6-10 (Moderate Incontinence)	-	11 (22%)	

Recurrence Rates

The recurrence of anal fissure after initial healing was observed in 22% of patients in the Diltiazem group compared to only 6% in the LIAS group at the 6-month follow-up (p=0.021) (Table 2).

Complications and Side Effects

Fecal Incontinence

No patients in the Diltiazem group experienced fecal incontinence throughout the study period. In contrast, all patients in the LIAS group had varying degrees of incontinence at baseline, likely reflecting pre-existing sphincter issues that warranted surgical intervention. At 3 months, 52% had mild incontinence (Wexner's score 0-5), 26% had moderate incontinence (score 6-10), and 22% had moderate to severe incontinence (score 11-20). By 6 months, significant improvement was observed, with 78% having no incontinence/mild incontinence and 22% having moderate incontinence, with no cases of severe incontinence (Table 3).

Other Complications

In the Diltiazem group, minor side effects included headache and flushing, each occurring in 4% of patients. No side effects were reported in the LIAS group. No patient in either group developed submucosal abscess or other major complications (Table 4).

Table 4: Side Effects and Complications

Side Effect/Complication	2% Diltiazem Gel (n=50)	LIAS (n=50)	P-value
Headache	2 (4%)	0 (0%)	0.153
Flushing	2 (4%)	0 (0%)	0.153
Incontinence Development	0 (0%)	11 (22%)	-
Submucosal Abscess	0 (0%)	0 (0%)	-

Patient Satisfaction Scores

Patient satisfaction was assessed at the 6-month follow-up using a scale of 0-10. The LIAS group demonstrated significantly higher satisfaction scores compared to the Diltiazem group (p<0.0001). In the Diltiazem group, most patients (72%) reported satisfaction scores between 4 and 7, with 26% scoring 7, 22% scoring 6, 14% scoring 5, and 10% scoring 4. In the LIAS group, 34% reported high satisfaction scores (≥7), with 26% scoring 7, 4% scoring 8, and 4% scoring 9. No patient in the Diltiazem group scored above 7, whereas 34% of LIAS patients did so (Table 3).

DISCUSSION

This prospective, comparative study evaluated two widely used approaches for managing chronic anal fissures: pharmacological treatment with 2% Diltiazem gel and surgical intervention through lateral internal anal sphincterotomy. The findings reveal important insights regarding patient satisfaction and decision-making factors between these treatment modalities.

Efficacy and Healing

Our results demonstrated significantly higher healing rates with LIAS (88%) compared to Diltiazem gel (52%) at six months, consistent with previous studies reporting healing rates of 85-95% for LIAS and 50-65% for topical Diltiazem [11,12]. This substantial

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difference in healing efficacy represents a primary decision-making factor for patients seeking definitive resolution of their condition.

The superior healing rates observed with LIAS can be attributed to the immediate and sustained reduction in anal sphincter pressure achieved through direct division of sphincter fibers, compared to the temporary chemical sphincterotomy induced by topical Diltiazem [13]. This mechanical reduction in sphincter pressure creates more favorable conditions for fissure healing by improving blood flow to the anoderm [14].

Symptom Control and Quality of Life Impact

Pain relief, a critical factor influencing patient satisfaction, was achieved more effectively and rapidly with LIAS. By six months, 50% of LIAS patients reported complete pain resolution (score 0) compared to only 18% in the Diltiazem group. Similarly, rectal bleeding; a distressing symptom for many patients, resolved completely in the LIAS group but persisted in 8% of Diltiazem patients.

These differences in symptom control significantly impact patients' quality of life and daily functioning. For patients experiencing severe, debilitating pain or recurrent bleeding, the prospect of faster and more reliable symptom resolution may strongly influence their treatment preference toward surgical intervention despite its invasive nature [15].

The Incontinence Consideration

Perhaps the most significant concern influencing decision-making against surgical intervention is the risk of fecal incontinence. Our study found that while all LIAS patients experienced some degree of incontinence postoperatively, there was substantial improvement over time, with no cases of severe incontinence by six months and 78% having no incontinence/mild incontinence.

This temporary nature of post-LIAS incontinence is consistent with previous research [16,17]. However, even transient incontinence can significantly impact psychological well-being and social functioning. Patients with occupations requiring prolonged time away from restroom facilities, those with pre-existing bowel disorders, or individuals particularly concerned about dignity and privacy may prioritize avoiding even temporary incontinence risk [18].

Conversely, Diltiazem therapy was not associated with any incontinence issues, representing a major advantage for patients who prioritize maintaining normal sphincter function over faster healing or more complete symptom relief.

Treatment Convenience and Compliance

Treatment convenience represents another important decision-making factor. LIAS is a one-time procedure requiring hospitalization and recovery time but offering a definitive solution. In contrast, Diltiazem therapy requires consistent application three times daily for at least eight weeks, which may present adherence challenges for busy individuals[19].

Our study did not explicitly measure compliance, but previous research suggests that adherence to topical treatments for anal fissures ranges from 65-85%, with application technique and treatment duration being common barriers [20]. Patients valuing convenience and definitive resolution might prefer LIAS despite its invasive nature, while those preferring gradual treatment without hospitalization might choose pharmacological management.

Recurrence Rates and Long-Term Outcomes

Recurrence represents a significant concern for patients with chronic anal fissures. Our findings revealed a recurrence rate of 22% with Diltiazem compared to 6% with LIAS at six months ($p=0.021$). This substantial difference may influence treatment selection for patients desiring long-term resolution, particularly those with recurrent fissures after previous pharmacological treatment [21].

The lower recurrence rates with LIAS are attributed to the permanent alteration in sphincter anatomy and pressure, whereas pharmacological agents provide only temporary sphincter relaxation that resolves after discontinuation. For patients experiencing multiple recurrences, the prospect of definitive resolution may outweigh short-term inconveniences or risks associated with surgery.

Patient Satisfaction

Overall patient satisfaction—perhaps the most comprehensive measure of treatment success—was significantly higher in the LIAS group. While both treatments demonstrated acceptable satisfaction levels, the proportion of patients reporting high satisfaction scores (≥ 7) was markedly greater with LIAS (34%) compared to Diltiazem (0%).

This difference in satisfaction likely reflects the cumulative impact of superior healing, better symptom control, and lower recurrence rates associated with LIAS.

Decision-Making Algorithm

Based on our findings, we propose a patient-centered decision-making algorithm for chronic anal fissure management:

1. For patients prioritizing:
   a. Definitive healing and minimal recurrence risk
   b. Rapid symptom resolution
   c. One-time intervention over prolonged treatment
   d. Higher overall success rates → LIAS may be more appropriate, provided they accept the risk of temporary incontinence.
2. For patients prioritizing:
   a. Non-invasive management
   b. Avoidance of any incontinence risk
   c. Gradual healing without hospitalization

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d. Willingness to accept lower healing rates and possible recurrence → Topical Diltiazem therapy may be more suitable.

3. Special considerations:

a. Patients with occupations requiring prolonged time away from restroom facilities

b. Those with pre-existing bowel disorders

c. Elderly patients or those with compromised sphincter function

d. Patients with recurrent fissures after failed pharmacological management

Strengths and Limitations

This study's strengths include its prospective design, adequate sample size, standardized protocols, and comprehensive follow-up. However, several limitations warrant mention. First, the follow-up period of six months may be insufficient to capture long-term recurrences or complications. Second, patient satisfaction was assessed using a single numerical scale rather than validated quality-of-life instruments specific to anorectal conditions. Third, the study was conducted at a single center, potentially limiting generalizability. Finally, blinding was not feasible due to the nature of the interventions, which may have introduced some bias in subjective outcome assessments.

CONCLUSION

While both 2% Diltiazem gel and lateral internal anal sphincterotomy demonstrated efficacy in managing chronic anal fissures, LIAS showed superior outcomes in terms of healing rates, symptom relief, recurrence prevention, and overall patient satisfaction. However, the decision-making process should be individualized, considering patient preferences regarding invasiveness, recovery time, incontinence risk, and long-term efficacy.

The findings of this study contribute to the evidence base informing shared decision-making between clinicians and patients with chronic anal fissures. Future research should focus on developing patient decision aids incorporating these factors and exploring longer-term outcomes beyond six months to further enhance the patient-centered approach to managing this common but challenging condition.

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