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ORIGINAL RESEARCH

A comparative study between topical application of nifedipine 0.3% with lignocaine and partial lateral internal sphincterotomy in the treatment of chronic fissure in ano

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ABSTRACT

Background: The common condition of chronic fissure in ano develops as a tear within the distal anal canal which stems from raised anal sphincter tone that leads to such injuries during bowel movements [1]. Medical professionals use topical agents for sphincter relaxation through chemical means while surgical professionals perform partial lateral internal sphincterotomy (LIS). This study compares the efficacy and morbidity of local application of Nifedipine 0.3% with Lignocaine versus partial LIS in patients with chronic anal fissure. **Methods**: This study analyzed 60 patients who had chronic fissure in ano through clinical assessments and per-rectal evaluations. Research participants were assigned to either Group A for receiving topical Nifedipine 0.3% with Lignocaine treatment or Group B for partial LIS treatment. The patients in both treatment groups received combined standard supportive measures that comprised sitz baths along with high-fiber diet and stool softeners. The clinical evaluation of patients happened at weeks two, four, six, and eight. The study evaluated three measurements comprised of VAS for pain reduction together with bleeding volume through rectal outlet and fissure healing status. **Results**: Of the 60 patients, 37 were female and 23 were male, predominantly aged 20–50 years. Pain was the most common presenting symptom (100%). Patients who underwent partial LIS experienced faster pain relief (96% by postoperative day 1) compared to those on topical therapy. However, complete healing at final follow-up was achieved in 96% of the surgical group and 86% in the topical therapy group. Minor bleeding was noted in both groups but resolved by the later follow-ups. Adverse events were minimal; only one patient in the surgical arm reported mild incontinence, and none in the topical therapy group reported serious side effects. **Conclusion:** Both partial LIS and topical Nifedipine 0.3% with Lignocaine are effective treatments for chronic fissure in ano. Surgical intervention provides more rapid symptomatic relief, while topical therapy avoids operative risks. Long-term follow-up is recommended to monitor recurrence and late complications.

Keywords: Chronic anal fissure, partial lateral internal sphincterotomy, Nifedipine 0.3%, Lignocaine, chemical sphincterotomy, anorectal disorders

INTRODUCTION

The disorder known as chronic fissure in ano presents as one of the most common non-cancerous conditions among patients undergoing surgical procedures [1]. The anal channel displays a longitudinal tear known as chronic fissure in ano that normally develops on the posterior midline but anterior fissures exist more frequently in female patients [2]. The pathologic process includes high tension in the internal anal sphincter causing reduced blood delivery to the anoderm and hindered wound mending and next the tearing which continues during defecation [3]. During defecation patients experience extreme pain along with rectal bleeding and constipation as well as

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intensified pain after their bowel movement. Chronic fissures which form after six weeks of duration include symptoms of sentinel tags and exposed internal sphincter fibers together with hypertrophied anal papilla [4]. Management strategies for chronic anal fissures revolve around addressing the elevated resting anal sphincter pressure. Conservative or "chemical sphincterotomy" methods include topical application of calcium channel blockers such as diltiazem or nifedipine, as well as nitrate ointments [5]. These agents reduce the sphincter tone by inducing local smooth muscle relaxation, promoting improved blood flow and facilitating healing. The combination of Nifedipine 0.3% with Lignocaine aims to alleviate pain and reduce sphincter spasm without exposing patients to the risks associated with surgery [6]. The standard treatment procedure for treatment failures requires surgical correction. Improved healing of anal fissures can be achieved through a surgical technique named partial lateral internal sphincterotomy (LIS) that requires precise muscle division of the internal anal sphincter. Patients benefit from reduced resting anal pressure together with decreased pain as well as accelerated fissure healing at a high rate [7]. Surgeons seek to optimize their procedure because of incontinence worries yet they need to maintain continence capacity[8]. Clinicians require study results of chemical sphincterotomy with topical nifedipine-lignocaine and partial LIS to make informed decisions about patient care. The rapid relief of symptoms through partial LIS remains well known but topical therapies provide patients with a noninvasive treatment that addresses their concerns about surgical risks together with anesthesia. A study was designed to measure therapeutic achievements between Nifedipine 0.3% with Lignocaine application and partial LIS intervention in chronic anal fissure patients. The assessment included healing of fissures together with symptom relief and complications experienced by patients. The research aims to advance the community understanding of suitable treatments for chronic fissure in ano through clear assessment of intervention advantages and limitations.

MATERIALS AND METHODS

Study Design and Setting

A prospective interventional study took place at the General Surgery department within Index Medical College Hospital Research Center located in Indore (M.P.). The research enrolled patients who received chronic fissure in ano diagnoses when visiting the outpatient department (OPD).

Inclusion Criteria

1. Patients diagnosed with anal fissure persisting for more than six weeks.
2. Presence of sentinel piles and/or exposed internal sphincter fibers indicating chronicity.
3. Patients who failed conservative treatment with topical Nifedipine 0.3% and Lignocaine, and subsequently underwent surgical management.

Exclusion Criteria

1. Fistula in ano.
2. Fissures associated with inflammatory bowel diseases.
3. Pregnant females.
4. Patients aged below 15 years.

Sample Size and Randomization

A total of 60 patients who met the inclusion criteria were enrolled after providing informed written consent. The patients were randomized into two groups (Group A and Group B) using a table of random numbers. Each group consisted of 30 patients.

Interventions

- **Group A (Topical Therapy):** Patients were instructed to apply a 1.5 cm ribbon of Nifedipine 0.3% with Lignocaine ointment into the anal canal three times daily for eight weeks.
- **Group B (Surgical Therapy):** Patients underwent partial lateral internal sphincterotomy under spinal anesthesia.

Both groups received standard supportive care, which included:

- Sitz baths twice daily
- A high-fiber diet
- Stool softeners (3 teaspoons of Cremaffin Plus at bedtime)

Follow-Up and Outcome Assessment

Patients were reviewed at 2, 4, 6, and 8 weeks in the surgical OPD. The following parameters were recorded at each visit:

- Pain intensity using a visual analog scale (VAS)
- Bleeding per rectum
- Healing of the fissure (assessed clinically)

Data Collection and Analysis

Research personnel recorded the data in pre-designed pro forma which was analyzed through statistical tests recommended by the statistician. The researchers presented information about categorical variables gender and sentinel pile detection through percentages and absolute frequencies. Statistical summary of age data contained either mean values or median values based on their distribution type. The statistical analysis used Chi-square tests together with Fisher's exact tests for categorical variable comparisons with a significance level of $p < 0.05$.

Permission for ethical approval came from the institutional ethics committee before beginning the study.

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RESULTS

Overall Findings

In total, 60 patients (23 males, 37 females) with chronic anal fissure were studied. The majority presented between 20 and 50 years of age. Pain during defecation was the most common symptom, often accompanied by bleeding and constipation. About half of the patients had a sentinel pile, with anterior fissures more commonly observed in females.

Initial analysis revealed that partial lateral internal sphincterotomy provided rapid relief of symptoms, particularly pain, sometimes as early as the first postoperative day. Patients on topical therapy also experienced significant improvement, although their pain relief and healing were more gradual over the eight-week follow-up. Overall fissure healing rates were high in both groups, with minimal complications.

Below is a summary of the key findings in tabular and graphical formats

Table 1. Gender Distribution (n = 60)

Gender	Frequency	Percentage
Male	23	38.3%
Female	37	61.7%

Table 2. Age Distribution

Age Group (years)	Males (n=23)	Females (n=37)
< 20	1	2
20–30	8	19
30–40	8	12
40–50	6	6
> 50	0	0

Table 3. Comparison of Healing Rates

Time Point	Partial LIS (n=30)	Topical Nifedipine+Lignocaine (n=30)	p-Value
2 weeks	80.0%	10.0%	0.000
4 weeks	16.0%	30.0%	0.2501
6 weeks	0.0%	46.0%	0.000
8 weeks	96.0% (cumulative)	86.0% (cumulative)	

Observation: By the end of the follow-up, 96% of patients in the partial LIS group achieved complete healing compared to 86% in the topical therapy group. However, the topical group demonstrated a more gradual healing profile.

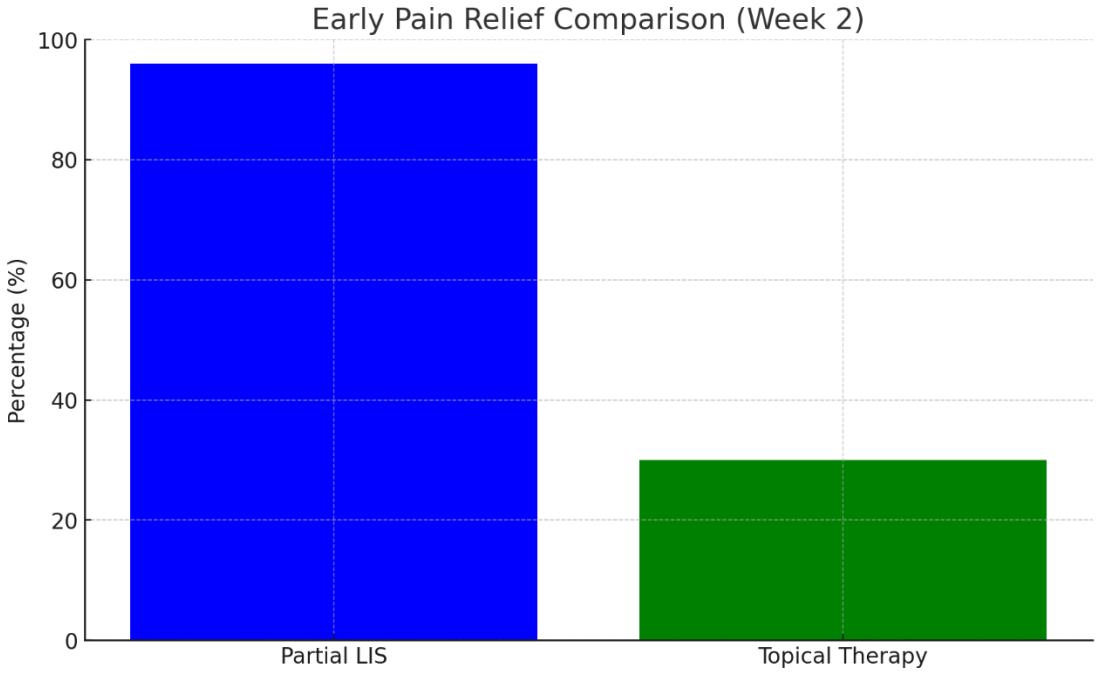

Figure 1. Early Pain Relief Comparison

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Figure 1: This bar graph illustrates the early pain relief comparison, showing that 96% of patients in the surgical group (Partial LIS) reported significant pain relief by week 2, whereas only about 30% of the topical group experienced similar relief by that time.

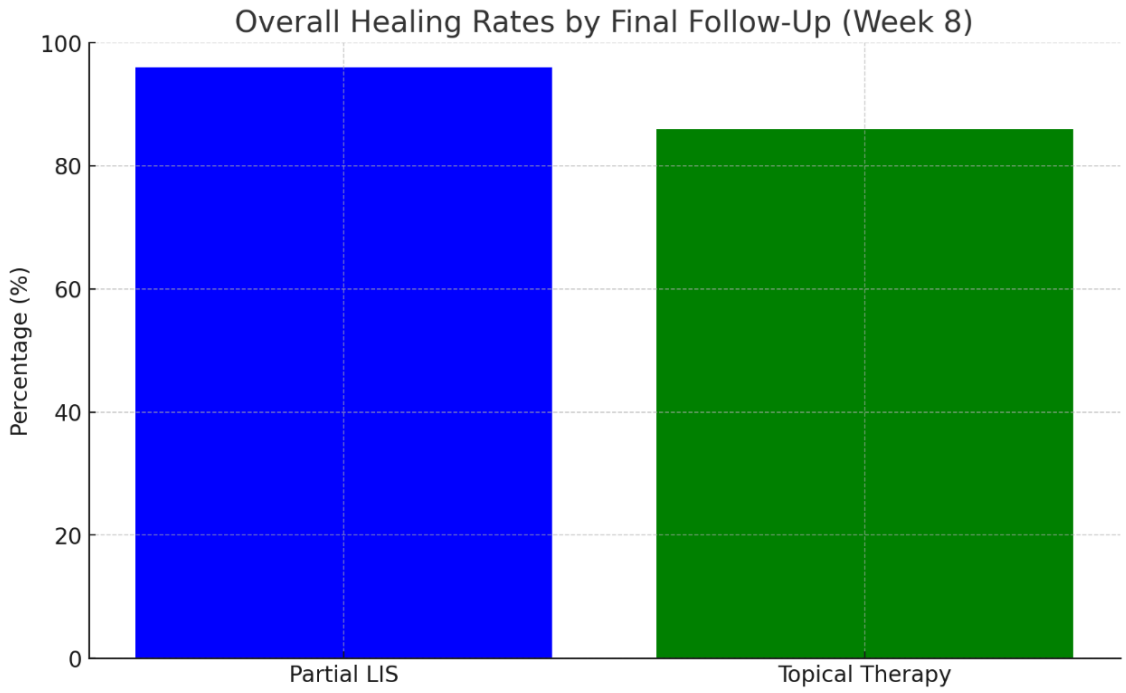

Figure 2. Overall Healing Rates by Final Follow-Up

Figure 2: This bar chart compares the percentage of fully healed patients at the end of 8 weeks in both groups, highlighting the higher healing rate in the Partial LIS group compared to the topical therapy group

Detailed Observations

1. **Symptom Relief (Pain):** Almost all patients in the surgical group (96%) reported marked pain relief as early as postoperative day 1 or 2. Patients in the topical group exhibited progressive improvement, with significant pain reduction noted by 4–6 weeks.
2. **Bleeding Per Rectum:** Minimal residual bleeding was observed in both groups at 2 and 4 weeks, which largely resolved by 6 weeks.
3. **Constipation:** High-fiber diet and stool softeners led to improvement of bowel habits in both groups, reducing defecation-related trauma.
4. **Adverse Effects:** One patient in the partial LIS group experienced transient incontinence, which improved over time. No significant side effects were documented in the topical group.

DISCUSSION

Chronic anal fissure poses a significant therapeutic challenge owing to the interplay of sphincter hypertonicity, local ischemia, and repetitive mucosal trauma [1,9]. The mainstay of treatment involves lowering the resting anal pressure to break the vicious cycle of pain and poor perfusion [2]. While numerous nonoperative methods—such as topical nitrates, calcium channel blockers (including nifedipine and diltiazem), and botulinum toxin injection—have been introduced, partial lateral internal sphincterotomy (LIS) remains a definitive option for resistant cases [3,10].In this study, partial LIS was shown to offer earlier symptomatic relief compared to topical nifedipine-lignocaine therapy. The immediate decrease in internal sphincter tone following sphincterotomy could explain this rapid resolution of pain [4,7]. This finding is congruent with prior literature, where surgical management consistently yields superior short-term pain control and faster healing [5]. However, one of the primary concerns with surgical treatment has been the risk of incontinence, which can range from minor soiling to more debilitating fecal incontinence [6]. In our series, only one patient reported transient incontinence, suggesting that careful surgical technique and a tailored approach to the patient's sphincter anatomy may mitigate this risk [8].On the other hand, topical treatment with nifedipine 0.3% and lignocaine provides a noninvasive approach to chemical sphincterotomy. It spares patients the risks associated with anesthesia and surgery, offering a viable first-line therapy [9]. Healing, while eventually comparable, generally lags behind that achieved with partial LIS. Our findings reflect an 86% cure rate at eight weeks in the topical arm, which is consistent with existing literature reporting success rates between 65% and 95% for various chemical sphincterotomy agents

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[2,10]. Furthermore, no patient in the topical therapy group reported serious adverse events, underscoring its safety profile.A notable consideration is patient compliance. In many cases, repeated or prolonged application of topical agents is required to maintain the fissure site in a state conducive to healing [9]. Nonadherence to the regimen or inconsistent use can lead to suboptimal results and prolong symptom duration. For individuals who cannot tolerate or do not respond to topical agents, partial LIS remains a valuable alternative [10].These findings highlight the importance of individualized treatment strategies for chronic anal fissures. In patients presenting with severe pain and a desire for rapid relief, partial LIS may be favored. Conversely, in those who prefer to avoid surgery or carry a high operative risk, topical nifedipine-lignocaine therapy offers an effective, conservative solution. Further studies with larger sample sizes and extended follow-up could elucidate the long-term recurrence rates and inform optimal management guidelines.

CONCLUSION

Partial lateral internal sphincterotomy provides faster symptom relief and a high healing rate in chronic fissure in ano, making it a preferred choice for those with severe symptoms or those unresponsive to medical therapy. Topical application of Nifedipine 0.3% with Lignocaine remains a safe, less invasive alternative, achieving respectable healing rates with minimal side effects. Both interventions demonstrate efficacy in managing this challenging condition. Ultimately, patient preference, severity of symptoms, and risk factors for surgical complications should guide treatment selection. Long-term follow-up is essential to monitor for recurrence and ensure sustained symptom control.

REFERENCES

1. Laurence Russel Sands, “0.4% nitro glycerin ointment in the treatment of chronic anal fissure Pain: a viewpoint by Laurence R. Sands.”. university of Miami, school of Medicine, Miami, Florida, USA. Drugs 2006; 66(3):350-2.
2. Haq Z, Rahman M, Chowdhary RA, “Chemical sphincterotomy-first line of treatment for Chronic anal fissure”. English abstract from Mymensingh Med J. 2005 Jan;14(1):88-90.
3. García-Granero E and others, “Treatment of chronic anal fissure”. An article in spanish, Cir Esp. 2005 Dec; 78 Suppl 3:24-7.
4. Bharadwaj R, Parker MC, “Modern Perspectives in the Treatment of Chronic Anal Fissures”. An English abstract from The US nation library of Medicine. Ann R CollSurg Engl. 2007 July; 89(5):472-478.
5. Sanju Dhawan, Ph.D. and Sunny Chopra, “Nonsurgical Approaches for the Treatment of Anal Fissures”. An English abstract from the American journal of Gastroenterology.
6. Aaron Poh, Kok-Yang Tan, Francis sew- Cheon, “Innovations in chronic anal fissure treatment: A systematic review”. An English abstract from the US National library of medicine. World J Gastrointestinal Surg. 2010 July;2(7):231-241.
7. Afsheenzafar, Ahmed Rehman, “Chronic anal fissures-association with sentinel skin tag”. An English abstract from Rawal Medical Journal. RMJ,2010; 35(2):177-179.
8. Gouda m, ellabban, Galal H. El-Gazzaz, and emad N. hok Kam Dr, “Is Topical Nitro glycerin Superior to Internal Sphincterotomy in the management of Chronic Anal Fissure”. An English abstract from, “World Journal of Colorectal Surgery: Vol.2: Iss.1, Article 9.
9. R Farouk MCh FRCSGI as Senior Registrar in Surgery Changing patterns of treatment for chronic anal fissure Ann R CollSurg Engl 1998; 80: 194-196.
10. A Carapeti, M A Kamm, P J McDonald, S J D Chadwick, D Melville, R K S Phillips Randomised controlled trial shows that glyceryl trinitrate heals anal fissures, higher doses are not more effective, and there is a high recurrence rate, Gut 1999;44:727–730.