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EFFECTIVENESS OF TOPICAL DILITIAZEM VS TOPICAL LIGNOCAINE IN TREATMENT OF ANAL FISSURE

General Surgery

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ABSTRACT

Background: Anal fissure (AF) is a common anorectal disorder characterized by a linear tear in the anal canal, leading to pain, bleeding, and discomfort. While surgical sphincterotomy is effective, it carries the risk of permanent anal incontinence, necessitating the exploration of pharmacological alternatives. This study compares the efficacy and safety of topical 2% diltiazem ointment versus topical 2% lignocaine in the treatment of chronic AF. **Methods:** This prospective clinical study was conducted at Mahatma Gandhi Medical College, Jaipur, from October 2022 to December 2023. A total of 60 patients diagnosed with chronic AF were randomly assigned to two groups: Group A (diltiazem ointment) and Group B (lignocaine ointment). Both groups applied their respective treatments twice daily for six weeks while maintaining a high-fiber diet and using warm sitz baths. Patients were assessed at regular intervals over one year for fissure healing, pain relief (measured via Visual Analogue Scale), bleeding control, itching, side effects, and recurrence rates. **Results:** Fissure healing was significantly higher in the diltiazem group (72%) compared to the lignocaine group (23%) (P<0.0001). Pain scores in the diltiazem group decreased from 80 to 5 over six weeks, demonstrating superior pain relief. Bleeding control was also more effective in the diltiazem group (80% vs. 42%, P<0.001). Side effects were mild, with 3% of diltiazem patients reporting headaches and 10% experiencing perianal itching. Recurrence rates were significantly lower in the diltiazem group (4.61%) compared to the lignocaine group (38%). **Conclusion:** Topical 2% diltiazem ointment demonstrated superior efficacy in fissure healing, pain relief, and recurrence prevention compared to topical lignocaine. Although mild side effects were reported, diltiazem was well tolerated. Given its effectiveness and safety profile, topical diltiazem may be considered a first-line pharmacological treatment for chronic anal fissure, potentially reducing the need for surgical intervention. Further research is warranted to optimize treatment protocols and enhance patient compliance.

KEYWORDS

Anal fissure, diltiazem ointment, lignocaine, chemical sphincterotomy, pain relief, recurrence rates.

INTRODUCTION

Anal fissure (AF) is characterized by a linear tear in the anal canal, typically distal to the dentate line, and represents a common source of morbidity, particularly among young adults. While acute anal fissure often resolves with conservative measures such as stool softeners and dietary modifications, chronic AF frequently necessitates intervention due to its resistance to such measures.

Traditionally, surgical sphincterotomy has been the primary treatment for chronic anal fissure. However, concerns regarding the risk of permanent anal incontinence have prompted exploration into pharmacological alternatives. One such alternative is chemical sphincterotomy, initially pursued with topical glyceryl trinitrate.

However, enthusiasm for this approach has diminished due to side effects, notably headaches. In response to the limitations of glyceryl trinitrate, this study investigates the potential of topical 2% diltiazem ointment as an effective and safe alternative for chemical sphincterotomy.

Diltiazem, a calcium channel blocker, targets the main pathology of anal fissure by reducing persistent hypertonia and spasm of the internal anal sphincter, thus alleviating mucosal ischemia. By evaluating the efficacy and safety profile of topical diltiazem ointment in the treatment of chronic AF, this study aims to provide valuable insights into its potential as a therapeutic option.

If proven effective, diltiazem ointment could offer patients a non-invasive and well-tolerated treatment option, mitigating the risks associated with surgical interventions and enhancing the management of this debilitating condition.

MATERIAL AND METHODS

- This prospective clinical study, conducted at Mahatma Gandhi Medical College in Jaipur from October 2022 to December 2023, aimed to compare the efficacy and safety of topical 2% diltiazem ointment versus topical 2% lignocaine in the treatment of chronic AF.
- A total of 60 patients meeting specified inclusion criteria were enrolled and randomized into two groups: Group A receiving diltiazem ointment and the Group B receiving lignocaine. The treatment protocol involved applying the respective ointments twice daily for six consecutive weeks, with patients instructed on application techniques and encouraged to maintain a high-fiber diet and use warm sitz baths.
- Follow-up assessments were conducted at regular intervals over a one-year period to evaluate parameters including fissure healing, pain relief, bleeding control, itching control, presence of side effects, and recurrence.
- They were randomized into the test group and the control group, with 100 patients in each group. They were subjected to the treatment with 2% topical diltiazem ointment for group A and topical 2% lignocaine for group B, twice daily for 6 consecutive weeks. The subjects were instructed to apply the medicine to just inside the anal canal and 1cm around the anus circumferentially by using the tip of their index fingers. The patients were encouraged to eat a high fibre diet and to use warm sitz baths.
- Fissure healing was assessed visually, while pain intensity was measured using a visual analogue score ranging from 0 (no pain) to 100 (worst pain). Recurrence was defined as the reappearance of symptoms or fissure one month after completion of the six-week treatment course..
- By systematically evaluating the outcomes of topical diltiazem versus lignocaine in chronic anal fissure management, this study aims to contribute valuable insights into the efficacy and safety profile of these treatments, informing evidence-based therapeutic decisions and optimizing patient care.

Inclusion And Exclusion Criteria

- The inclusion criteria were: patients who were aged between ≥18 years and ≤65 years; the presence of chronic anal fissure for more than 6 weeks that had failed to resolve with simple measures (stool softeners, a high fibre diet and a warm sitz bath); the physical examination had revealed fibrotic anal fissure with induration at the edges, an external skin tag.
- The exclusion criteria were any history of reaction to topical agents and associated co-morbidity such as ischaemic heart disease, hypertension, diabetes mellitus, anal fistula, haemorrhoides, perianal abscess, inflammatory bowel disease, HIV-related fissure, tuberculosis ulcer, leukaemic ulcer, pregnancy and lactation

RESULTS

- The study found that the ages of patients were comparable across both the test and control groups, Pain was identified as the primary presenting symptom in both groups, followed by bleeding per-rectum, anal discharge, and pruritis. Approximately 54%-58% of cases exhibited associated constipation, a common predisposing factor for fissure development. The posterior midline fissure was the most prevalent location, often accompanied by external skin tags.
- At the 2nd, 4th, and 6th-week evaluations, the Group A and Group B were compared regarding fissure healing, pain response, bleeding response, , peri-anal itching, and side effects. Notable findings included:
- **Fissure Healing:** Complete healing occurred in 72% in group patients versus 23% in the control group by the end of 6 weeks, demonstrating a statistically highly significant difference (P<0.0001, see Table/Figure 3 and 4).
- **Pain Response:** The mean pain score in the test group decreased from 80 to 5 over 6 weeks, with maximal improvement observed within the first 4 weeks (see Table/Figure 5).
- **Bleeding Response:** The test group exhibited a significantly better bleeding response, with 80% experiencing a significant reduction compared to 42% in the control group (P<0.001, statistically significant)

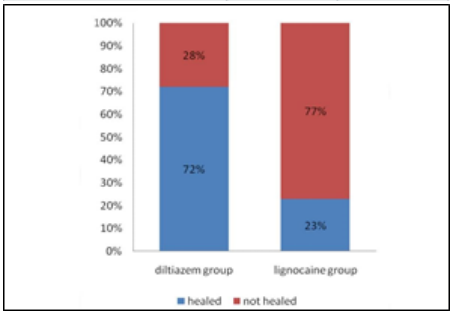
Adverse Effects Of The Medicines: Mild headache was reported by 3% of patients in the (diltiazem) group A, whereas none in the (lignocaine) group B experienced it (P<0.0001). All cases of headache responded satisfactorily to paracetamol.

- Perianal itching was another side effect, reported by 10% of patients in group A compared to 4% in the group B (P<0.0001). However, the itching was mild in nature and did not necessitate any treatment (see Table/Figure 6). All patients in both the groups completed the full 6-week treatment course.

Features/characteristic	Group A (N=30)	Group B (N=30)
Male	14	17
Female	16	13
Age in years (Range)	18-65	18-63
Duration of symptoms (range)	6-9 months	6-8 months
Above 60		
Symptoms:		
Pain	25	23
Bleeding	22	20
Discharge/Itching	17	19
Constipation	14	13
Local findings:		
Posterior midline AF	19	17
Anterior midline AF	5	3
Sentinel pile	22	21
Sphincter spasm	24	19

Clinical details of the 60 cases have been shown

Fissure healing	Group A	Group B
At 2nd week end	0	0
At 4th week end	11	7
At 6th week end	18	15



Recurrences

- Recurrence rates differed between both the groups, with 4.61% of cases in group A experiencing recurrence compared to 38% in the group B. This significant difference underscores the efficacy of diltiazem in reducing recurrence rates compared to lignocaine

DISCUSSION

- Anal fissure represents a significant source of morbidity, characterized by severe anal pain, with the posterior midline being the most common site, particularly in females. Constipation often serves as a precipitating factor, while occurrences during pregnancy and childbirth are frequent due to associated sphincter muscle spasm, hindering fissure healing.
- While acute fissures may resolve with conservative measures, chronic fissures often necessitate intervention. Non-operative therapies, including botulin toxin injection, oral nifedipine, topical glyceryl trinitrate (GTN), and topical diltiazem ointment, have been explored. Among these, topical GTN has been extensively utilized but is limited by common side effects such as headache and dizziness, along with a high recurrence rate.
- In contrast, calcium channel blockers like nifedipine and diltiazem offer an alternative mechanism of action by inducing smooth muscle relaxation.
- Studies have reported favorable fissure healing rates with topical diltiazem, with fewer side effects and lower recurrence rates compared to GTN. Additionally, diltiazem has shown efficacy in treating chronic anal fissure refractory to GTN therapy.
- Our discussion corroborates previous findings indicating that topical diltiazem may offer a more tolerable and effective alternative to GTN in the treatment of chronic anal fissure. The reduced incidence of side effects and lower recurrence rates associated with diltiazem highlight its potential as a preferred therapeutic option. Further research and clinical trials are warranted to validate these findings and refine treatment protocols for chronic anal fissure management.

CONCLUSION

- In our study, we observed successful fissure healing in 72% of patients treated with topical diltiazem. Additionally, satisfactory pain relief was achieved in a majority of cases. Although mild headache and perianal itching were reported as common side effects, they were generally well-tolerated.
- One limitation identified was patient compliance, as the duration of treatment lasted for 6 weeks. Despite this drawback, our findings support the effectiveness of 2% topical diltiazem in treating chronic fissure in ano.
- Considering its favorable efficacy profile, diltiazem may be considered as a first-line treatment option for chronic anal fissure. Further research focusing on optimizing treatment duration and enhancing patient compliance could help refine its clinical utility in managing this debilitating condition

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