NON-INFERIORITY STUDY BETWEEN TOPICAL NIFEDIPINE 0.2% AND TOPICAL NIFEDIPINE 0.5% IN TREATMENT OF ANAL FISSURE

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Introduction

Chronic anal fissure is a common and painful anorectal condition characterized by a longitudinal tear in the anoderm, most frequently located at the posterior midline. Its pathophysiology is closely linked to internal anal sphincter hypertonia and reduced anodermal blood flow, which impair healing. Topical calcium channel blockers, such as nifedipine, have gained popularity due to their ability to reduce sphincter tone and promote fissure healing without the risks associated with surgical intervention. However, the optimal concentration of nifedipine for efficacy and tolerability remains unclear.

Aim of the Work

This study aimed to determine whether 0.2% topical nifedipine is non-inferior to the standard 0.5% concentration in terms of fissure healing, pain relief, side effect profile, recurrence rate, continence, and quality of life in patients with chronic anal fissure.

Patients and Methods

A randomized, double-blind controlled trial was conducted at Alexandria Main University Hospital involving 142 adult patients with chronic anal fissure. Participants were randomly assigned to receive either 0.2% (Group A) or 0.5% (Group B) topical nifedipine ointment, applied twice daily for 4 weeks. Patients were followed for six months. Primary outcome was complete fissure healing by six weeks. Secondary outcomes included pain assessment using the Visual Analogue Scale (VAS), side effects, recurrence of symptoms, Wexner continence score, and quality of life using the SF-36 questionnaire.

Results

Both groups showed significant clinical improvement. Healing rates were 84.5% in the 0.2% group and 90.1% in the 0.5% group (p = 0.449), indicating no statistically significant difference. Pain scores decreased substantially in both arms from baseline, with final VAS scores of 2.3 and 1.8, respectively (p = 0.3304). Side effects such as headache and burning were more frequent in the 0.5% group but were generally mild and transient. Recurrence occurred in 34.17% of the overall sample, with a higher but non-significant rate in the 0.2% group (41% vs. 27.1%, p = 0.159). Continence remained unaffected in both groups (Wexner score ~0.1), and quality of life improved similarly in both arms across all SF-36 domains.

Table: Healing Progression at Different Time Points

Time Point	Nifedipine 0.2% (n=71)	Nifedipine 0.5% (n=71)	p-value
Healing at 2 weeks	0 (0%)	0 (0%)	0.99
Healing at 4 weeks	3 (4.2%)	6 (8.5%)	0.491
Healing at 6 weeks	60 (84.5%)	64 (90.1%)	0.449

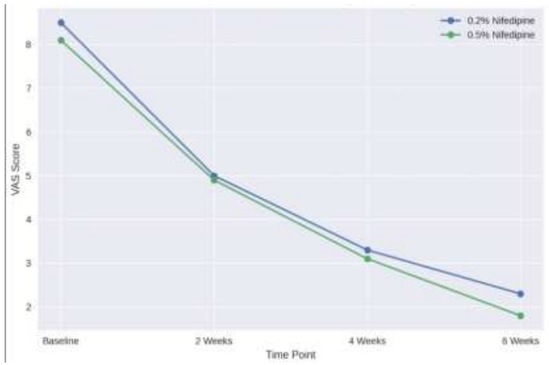

Figure 1: Pain reduction over time

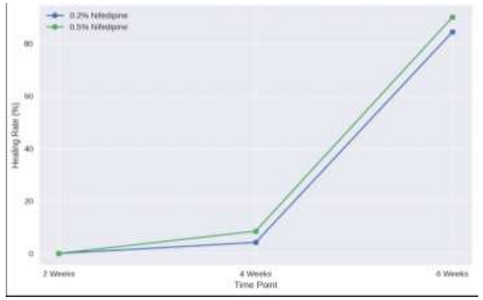

Figure 2 : Healing progression over time

Conclusion

Topical nifedipine 0.2% is non-inferior to 0.5% in managing chronic anal fissure. It offers similar healing and pain relief outcomes with a lower incidence of adverse effects.
Given its efficacy and better tolerability. 0.2% nifedipine can be considered a safe, effective, and preferable first-line conservative treatment for chronic anal fissure, especially in patients sensitive to side effects.