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A COMPARATIVE STUDY OF TOPICAL NIFEDIPINE AND 2% DILTIAZEM GEL LOCAL APPLICATION IN THE TREATMENT OF FISSURE-IN-ANO

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Keywords:

Anal fissure, Nifedipine, Diltiazem, Calcium channel blockers, Conservative therapy, Topical treatment

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ABSTRACT: Background: Anal fissure is a common anorectal disorder characterised by severe pain during defaecation, bleeding, and internal anal sphincter spasm. Conservative treatment using topical calcium channel blockers offers an effective, non-invasive alternative to surgery. **Objectives:** To compare the efficacy and safety of 0.3% nifedipine versus 2% diltiazem gel in the non-surgical management of fissure-in-ano. **Methods:** This prospective observational study was conducted over 18 months at a tertiary care centre. A total of 100 adult patients with primary anal fissure were enrolled and randomly assigned into two groups via the SNOSE method. Group A received topical 0.3% nifedipine; Group B received 2% diltiazem gel. Pain severity (VAS), healing response, adverse effects, and quality of life (WHOQOL-BREF) were assessed at 1 and 4 weeks. Data were analysed using SPSS v26, with $p < 0.05$ considered statistically significant. **Results:** Both treatment groups showed statistically significant improvement in pain scores and bleeding ($p = 0.000$). Nifedipine demonstrated faster symptom relief, while diltiazem showed better tolerability. Minor adverse events included headache (3%) in the nifedipine group and dermatitis (2%) in the diltiazem group. Quality of life improved markedly in both groups. **Conclusion:** Both 0.3% nifedipine and 2% diltiazem gel are effective and safe for managing fissure-in-ano. Nifedipine may be preferred for faster relief, while diltiazem may be favoured in patients sensitive to side effects.

INTRODUCTION: Anal fissure is a common anorectal condition characterised by a longitudinal tear in the anoderm, typically located below the dentate line. It frequently presents with severe pain during defaecation, rectal bleeding, and internal anal sphincter spasm [1]. Most commonly affecting young to middle-aged adults, it significantly reduces quality of life. The condition is usually precipitated by trauma to the anal mucosa often from hard stools or diarrhoea which leads to increased sphincter tone, reduced local blood flow, and impaired healing [2].

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Fissures are broadly categorised as acute or chronic. Acute fissures are superficial and may heal spontaneously, whereas chronic fissures defined as persisting beyond 6 to 8 weeks typically present with features such as visible sphincter fibres and sentinel skin tags [3]. Although lateral internal sphincterotomy (LIS) remains the gold standard for treating chronic fissures, it is associated with complications such as faecal incontinence [4].

To avoid surgical risks, topical pharmacological agents have become the preferred initial management strategy. Glyceryl trinitrate has proven effective but is frequently limited by side effects such as headaches. Calcium channel blockers (CCBs), including diltiazem and nifedipine, offer comparable healing rates with fewer adverse effects [5]. However, direct comparative data between these agents are limited. Therefore, this study was undertaken to compare

the efficacy and safety of 0.3% nifedipine and 2% diltiazem gel in the conservative management of anal fissure, with the aim of guiding optimal, non-surgical treatment strategies.

MATERIALS AND METHODS: This prospective observational study was conducted in the Department of General Surgery, Shri Mahant Indresh Hospital, Dehradun, over 18 months (January 2022 to June 2023), following approval from the Institutional Ethics Committee (IEC Approval No. SGRR/IEC/20/23, dated 17 June 2023). Written informed consent was obtained from all participants. A total of 100 adult patients with clinically diagnosed primary anal fissure were enrolled.

Inclusion Criteria:

- Adults aged 18 years or older
- Clinically confirmed cases of primary anal fissure
- Both male and female patients

Exclusion Criteria:

- Fissures secondary to other aetiologies (e.g. inflammatory bowel disease, malignancy)
- Patients requiring surgery for coexisting anorectal conditions (e.g. haemorrhoids)
- Pregnant women

Participants were randomised using the SNOSE method into two groups: Group A received 0.3% nifedipine, and Group B received 2% diltiazem gel. Baseline data were collected, including age, sex, symptoms, and pain scores. Pain was assessed using a 10-point Visual Analogue Scale (VAS) and classified as mild (1–3), moderate (4–6), or severe (7–10). Follow-up was done at 1 and 4 weeks. Quality of life was assessed using WHOQOL-BREF and graded from "very poor" to "very good."

Data were analysed using SPSS v26. Means and standard deviations were used for continuous variables; proportions for categorical data. Student's *t*-test, Chi-square, and Fisher's exact test were applied. A *p*-value < 0.05 was considered statistically significant.

RESULTS:

TABLE 1: DISTRIBUTION OF AGE AND GENDER AMONG PATIENTS RECEIVING 0.3% NIFEDIPINE AND 2% DILTIAZEM

Variable		0.3% Nifedipine	2% Diltiazem	Total	P value
Age Group	< 25	7	11	18	
	25 – 35	15	15	30	
	36 – 45	17	8	25	
	46 – 55	9	5	14	0.538
	56 – 65	2	3	5	
	> 65	4	4	8	
	Total	54	46	100	
Gender	Female	25	23	48	
	Male	29	23	52	0.712
	Total	54	46	100	

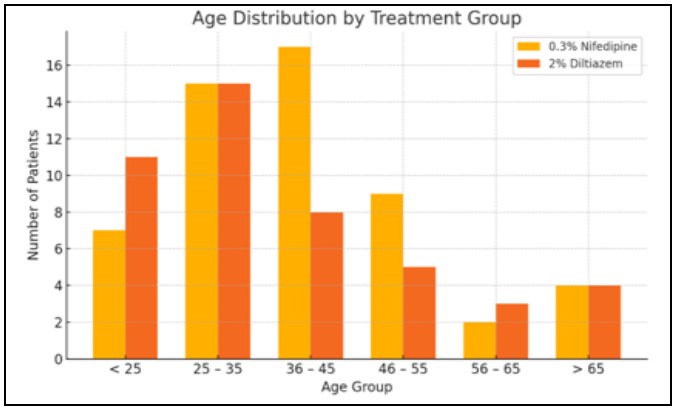

FIG. 1: AGE DISTRIBUTION

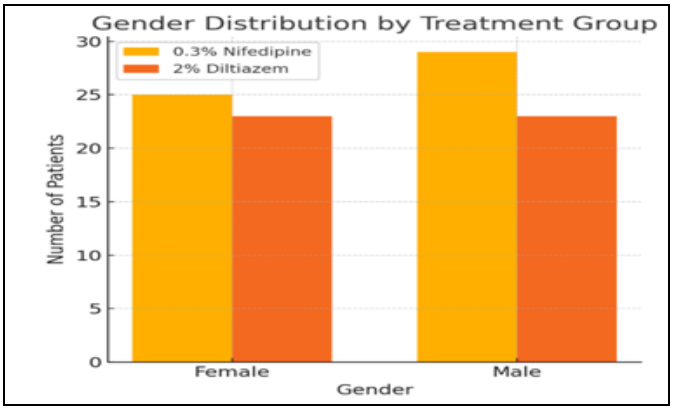

FIG. 2: GENDER DISTRIBUTION

TABLE 2: IMPACT OF 0.3% NIFEDIPINE AND 2% DILTIAZEM TREATMENT ON PATIENT SYMPTOMS

Symptom	0.3% Nifedipine			2% Diltiazem		
	1st follow-up	2nd follow-up	P value	1st follow-up	2nd follow-up	P value
Constipation	2	0		1	1	
Headache	0	3		0	0	
Dermatitis	0	0		0	2	
Patient better	0	49		0	41	
Persistent pain	1	1	0.001	0	1	
No fresh complaints	49	0		44	0	
Tachycardia	0	1		0	1	
Painful defecation	2	0		1	0	0.001
Total	54	54		46	46	

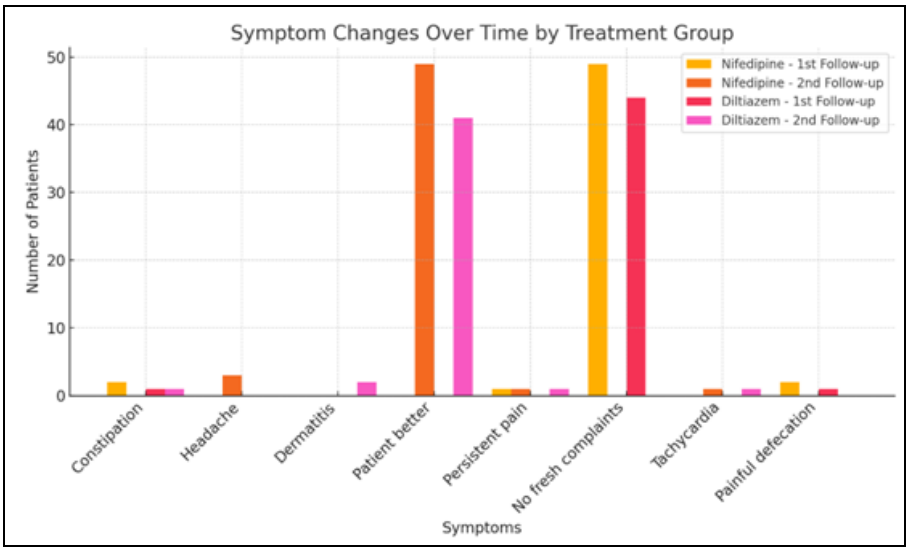

FIG. 3: SYMPTOMS CHANGES OVER TIME BY TREATMENT GROUP

TABLE 3: PAIN SCORE AND THE EFFECT ON BLEEDING PER RECTUM BEFORE AND AFTER TREATMENT WITH 0.3% NIFEDIPINE AND 2% DILTIAZEM

Variables	Treatment Group	Pretreatment	Post-treatment	P value
Pain Score	0.3% Nifedipine	5.18 ± 1.55	2.07 ± 1.27	0.000
	2% Diltiazem	5.26 ± 1.45	2.17 ± 1.14	
Bleeding per Rectum	0.3% Nifedipine	44	4	0.000
	2% Diltiazem	35	4	

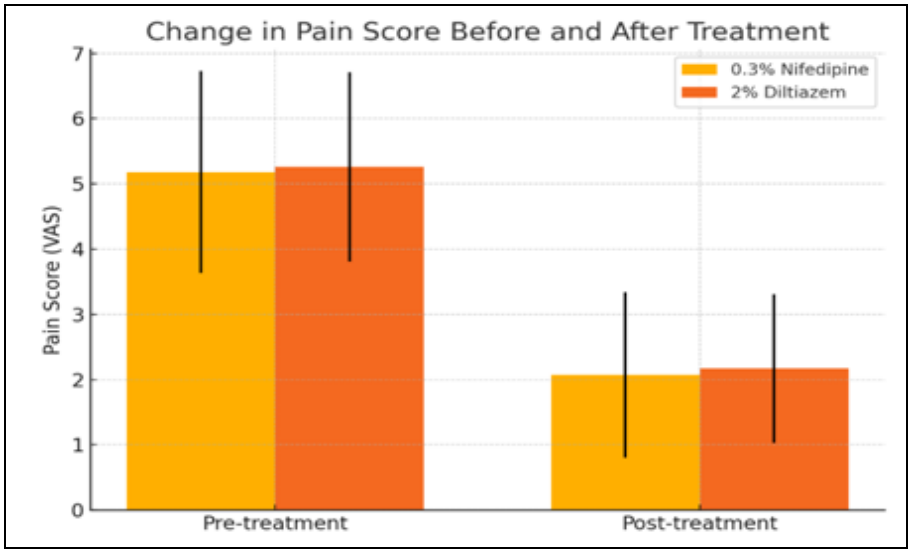

FIG. 4: PAIN SCORE

TABLE 4: IMPACT OF 0.3% NIFEDIPINE AND 2% DILTIAZEM ON QUALITY OF LIFE (QOL) BEFORE AND AFTER TREATMENT

QoL Grade	0.3% Nifedipine on QoL			2% Diltiazem on QoL		
	1st follow-up	2nd follow-up	P value	1st follow-up	2nd follow-up	P value
Fair	11	3		9	4	
Good	0	28		0	28	
Very Good	0	18	0.001	0	11	
Poor	35	5		31	3	0.001
Very Poor	8	0		6	0	
Total	54	54		46	46	

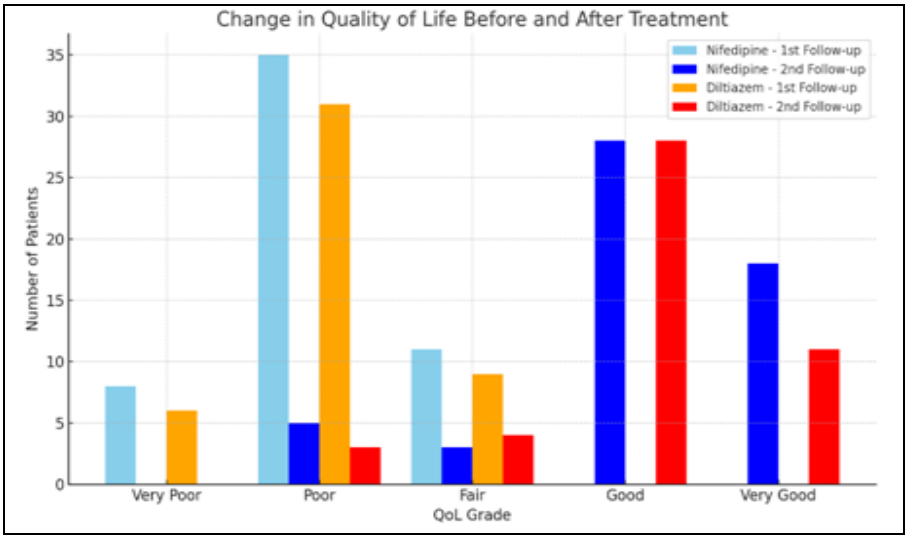

FIG. 5: CHANGE IN QUALITY OF LIFE BEFORE AND AFTER TREATMENT

TABLE 5: POST-TREATMENT COMPLICATIONS IN PATIENTS TREATED WITH 0.3% NIFEDIPINE AND 2% DILTIAZEM

Complications	0.3% Nifedipine	2% Diltiazem	Total	P value
Dermatitis	0	2	2	
Headache	3	0	3	
None	50	43	93	0.178
Tachycardia	1	1	2	
Total	54	46	100	

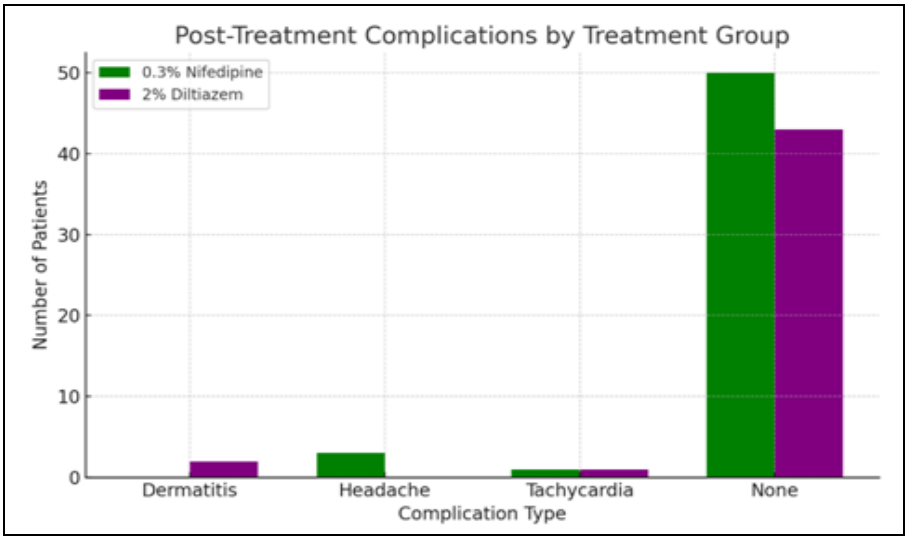

FIG. 6: POST-TREATMENT COMPLICATIONS BY TREATMENT GROUP

DISCUSSION: In our study, the majority of patients belonged to the 25–45 age group, consistent with the findings of Wang C *et al.* and Sharma E *et al.*, who reported a higher incidence of

anal fissure in young adults due to dietary irregularities, sedentary lifestyles, and constipation [6, 7]. The gender distribution revealed a slight male predominance (M:F = 1.08:1), in line with observations by Wang C *et al.*, who attributed this trend to male-specific dietary patterns and occupational stressors [6].

Among presenting symptoms, constipation (72%) and rectal bleeding (71%) were most prevalent, findings strongly supported by Li P *et al.* and Ray R *et al.*, who emphasised the role of hard stools and anorectal trauma in the pathogenesis of fissures [8, 9]. Notably, 60% of patients sought medical attention within 15 days of symptom onset, suggesting acute presentations. This early intervention facilitated favourable outcomes, comparable to those reported by Nakrani P. and Wasfy *et al.*, who highlighted improved healing rates with prompt pharmacological therapy [10, 11]. Most patients had a solitary fissure, aligning with the data from Ali MO, Sadiq M., and Sharma E *et al.*, who observed similar uncomplicated cases [12, 13].

Both nifedipine and diltiazem resulted in marked symptom improvement, with pain scores decreasing from 5.18 to 2.07 in the nifedipine group and from 5.26 to 2.17 in the diltiazem group (p = 0.000). This reflects findings by Ray *et al.*, who observed faster pain relief with nifedipine owing to superior local absorption [9]. Comparable outcomes were noted by Ali MO, Sadiq M., who reported rapid symptom resolution with nifedipine, although the final efficacy was similar across both treatments [12].

Quality of life improved significantly in both groups, with most patients transitioning from poor to good or very good categories. These findings are supported by Ray *et al.*, who underscored the direct association between symptomatic relief and enhanced quality of life [9]. Adverse effects were minor: headache (3%) in the nifedipine group and dermatitis (2%) in the diltiazem group also documented by Li P *et al*, and Ali MO, Sadiq M., thereby confirming the overall safety of both agents [8,12]. The limitations of the study include a relatively small sample size, short follow-up duration, lack of long-term recurrence data, and being conducted at a single center, which may limit generalizability of findings. The study's strengths include a prospective design, balanced group allocation, use of standardised outcome measures such as pain scores and WHOQOL-BREF, and a direct comparison of two commonly used topical agents.

CONCLUSION: Both 0.3% nifedipine and 2% diltiazem gels are effective, safe, and well-tolerated treatments for fissure-in-ano. Nifedipine offers slightly faster symptom relief, while diltiazem shows better tolerability in sensitive patients.

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