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Original Research Article

# Study to Evaluate the Effectiveness of Combination Therapy with Topical Nifedipine (0.3%) Plus Lignocaine (1.5%), Sitz Bath and Oral Lactulose on Acute Fissure-In-Ano

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**Conflict of interest: Nil**

**Abstract:**

**Objective:** The objective of present study was to evaluate the effectiveness of combination therapy with topical nifedipine (0.3%) plus lignocaine (1.5%), sitz bath and oral lactulose in the management of acute fissure-in-ano.

**Background:** The combination therapy with topical nifedipine (0.3%) plus lignocaine (1.5%), sitz bath and oral lactulose in the management of acute fissure-in-ano were presented and it's effectiveness evaluated.

**Material and Methods:** This prospective observational study was conducted during the period of July 2023 to June 2025 on 75 patients who attended the OPD with the history of acute Fissure-in-Ano. All patients were evaluated clinically and prescribed the combination therapy consists of topical nifedipine(0.3%) plus lignocaine (1.5%), Sitz bath and oral lactulose solution. All patients were evaluated for relief from pain, bleeding per anus, fissure healing and patient's satisfaction. Follow-up was done for the period of two weeks.

**Results:** Acute fissure-in-ano is common in young age group patients (53.33%). It is more common in females (73.33%) than males (26.66%). Midline posterior is the commonest site in both males(90%) and females (81.81%). Patients taking mixed diet (low fibre diet) are commonly affected (80%). Sedentary life style accounts for 60% of cases. Some type of addiction (like alcohol, smoking, tobacco) associated with 66.66% and no addiction in 33.33% of cases. Combination therapy with topical Nifedepine (0.3%) plus Lignocaine (1.5%), Sitz bath and oral Lactulose accounts for pain relief in 80% cases in first week and 97.33% cases in second week, whereas cessation of bleeding per rectum in 91% cases in first week and 100% cases in second week. Increased anal tone is relieved in 93.33% cases in first week and 98.66% cases in second week of combination therapy. Complete healing of fissure is found in 53.33% cases in first week and 98.66% cases in second week of combination therapy.

**Conclusion:** Among the different managements of acute fissure-in-ano, the present study found that the combination therapy with topical nifedipine (0.3%) plus lignocaine (1.5%), sitz bath and oral lactulose is the best option in the respect of duration to become symptoms free and fissure healing, non-invasive nature of treatment and excellent patient's acceptance and satisfaction.

**Keywords:** Fissure in Ano, Nifedipine, Lignocaine, Lactulose.

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## Introduction

An anal fissure is a longitudinal ulcer in the anoderm of distal anal canal, which extends from the anal verge proximally towards, but not beyond, the dentate line.[1] The pathophysiology of acute anal fissure is related to trauma either the passage of hard stool or prolonged diarrhea.[2]Mixed and predominantly non-vegetarian diet appears to be most commonly associated with fissure-in-ano.[4]

The location of fissure in the posterior midline may relate to the shearing forces acting at that site at defecation, combined with a less elastic anoderm endowed with an increased density of longitudinal muscle extension in that region of the anal circumference.

In men, 95% are close to posterior midline and 5% near anterior midline, whereas in women, about 80% are located posteriorly and 10% anteriorly. [1,3] A fissure that is not in midline or one with atypical feature should raise the suspicion of either Crohn's disease, tuberculosis, sexually transmitted or HIV related ulcers (Syphilis, Chlamydia, Chancroid, Lymphogranuloma Venerium, HSV, Cytomegalovirus, Kaposi's Sarcoma, B-cell lymphoma) and squamous cell carcinoma.[1,5]

Severe anal pain during defaecation ('passing glass' or 'knife cutting'), which usually resolves only to recure at the next evacuation, is the most prominent symptom amongst all the patients of acute anal fissure. Bleeding per rectum, usually a trace of blood is the next prominent symptom.[1,4] Most of the acute anal fissure heal spontaneously within three weeks with various conservative managements. Various invasive techniques like lateral internal sphicterotomy, manual anal dilatation are also the modality of treatment for acute fissure-in-ano.[1,6]

The purpose of this study was to evaluate the effectiveness of combination therapy with topical Nifedipine (0.3%) plus Lignocaine (1.5%), Sitz bath and oral Lactulose on acute Fissure-in-Ano in respect of duration to become symptom free and patient's acceptance and satisfaction.

**Material and Methods**

This prospective observational study was conducted during the period of July 2023 to June 2025 on 75 patients who attended the OPD with the history of acute Fissure-in-Ano. All patients were evaluated clinically and prescribed the combination therapy consists of topical nifedipine (0.3%) plus lignocaine (1.5%), Sitz bath and oral lactulose solution.

All patients were evaluated for relief from pain, bleeding per anus, fissure healing and patient's satisfaction. Follow-up was done for the period of two weeks.

**Result**

**Demographic Data:** Acute Fissure-in-Ano is common in young age group patients (53.33%) and least common in old age group patients (6.66%).It is more common in females (73.33%) than males (26.66%).

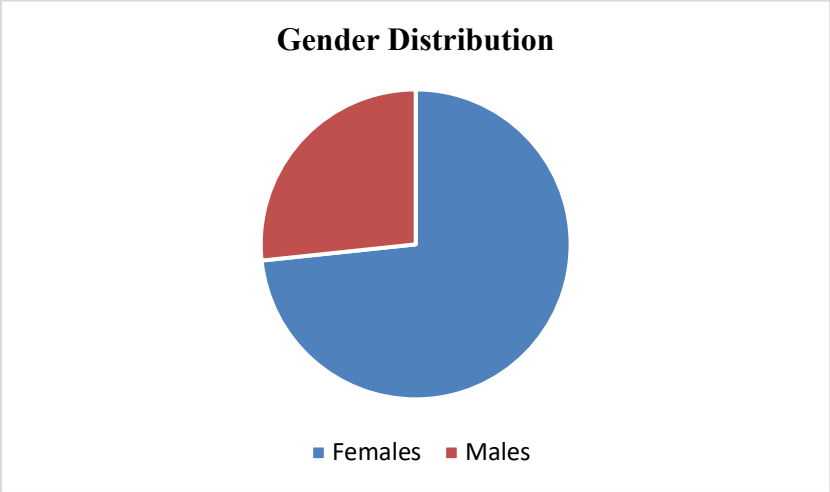


**Figure 1: Gender distribution**

**Patient evaluation:** Midline posterior is the commonest site in both males (90%) and females (81.81%). Patients taking mixed diet (low fibre diet) are commonly affected (80%). Sedentary lifestyle accounts for 60% of cases.

**Table 1: Site of fissure**

| Site | Males(20 patients) | Females(55 patients) |
|---|---|---|
| Midline anterior | 2 (10%) | 10(18.18%) |
| Midline posterior | 18 (90%) | 45(81.81%) |

**Table 2: Age incidence**

| Age group(in years) | Number of patients | Percentage (%) |
|---|---|---|
| 15-25 | 10 | 13.33% |
| 26-35 | 30 | 40% |
| 36-45 | 20 | 26.66% |
| 46-55 | 10 | 13.33% |
| 56-65 | 05 | 06.66% |

**Table 3: Diet as risk factor**

| Diet | Number of patients | Percentage |
|---|---|---|
| Vegetarian | 15 | 20% |
| Mixed | 60 | 80% |

**Table 4: Effect of life style**

| Life style | Number of patients | Percentage |
|---|---|---|
| Active | 30 | 40% |
| Sedentary | 45 | 60% |

Some type of addiction (like alcohol, smoking, tobacco) associated with 66.66% and no addiction in 33.33% of cases.

**Table 5: Role of addiction**

| Addiction | Number of patients | Percentage (%) |
|---|---|---|
| Alcohol | 20 | 26.66% |
| Smoking | 10 | 13.33% |
| Tobacco | 20 | 26.66% |
| No addiction | 25 | 33.33% |

Some type of addiction (like alcohol, smoking, tobacco) accounts for 66.66% and no addiction for 33.33% of cases. Combination therapy with topical Nifedepine(0.3%) plus Lignocaine(1.5%),Sitz bath and oral Lactulose accounts for pain relief in 80% cases in first week and 97.33% cases in second week, whereas cessation of bleeding per rectum in 91% cases in first week and 100% cases in second week. Increased anal tone is relieved in 93.33% cases in first week and 98.66% cases in second week of combination therapy. Complete healing of fissure is found in 53.33% cases in first week and 98.66% cases in second week of combination therapy.

**Table 6: Symptoms of acute fissure-in-ano**

| Symptoms | No.of patients before therapy | No. of patients 7 days after therapy | % of patients with symptomatic relief 7 days after therapy | No. of patients 14 days after therapy | % of patients with symptomatic relief 14 days after therapy |
|---|---|---|---|---|---|
| Painful defaecation | 75 (100%) | 15 | 80% | 01 | 98.66% |
| Bleeding per rectum | 60 (80%) | 05 | 91.66% | 00 | 100% |
| Constipation | 70 (93.33%) | 25 | 64.28% | 02 | 97.14% |
| Hard stool | 68(90.66%) | 10 | 85.29% | 02 | 97.05% |

**Table 7: Clinical signs of acute fissure-in ano**

| Clinical signs | No. of patients before therapy | No. of patients 7 days after therapy | % of patients having relief 7 days after therapy | No. of patients 14 days after therapy | % of patients having relief 14 days after therapy |
|---|---|---|---|---|---|
| Increased anal tone | 75 (100%) | 05 | 93.33% | 01 | 98.66% |
| Fissure | 75 (100%) | 35 | 53.33% | 01 | 98.66% |
| Bleeding per rectum | 60 (80%) | 05 | 91.66% | 00 | 100% |

## Discussion

An anal fissure is a longitudinal ulcer in the anoderm of distal anal canal, which extends from the anal verge proximally towards, but not beyond, the dentate line.[1] The cause of acute anal fissure is related to trauma either the passage of hard stool or prolonged diarrhea.[2] It is disease of young and reproductive age group females owing to child bearing and hormonal effect on gut resulting in constipation.[7] In our study 53.33% patients are of young age group,73.33% are females, history of passage of hard stool in 90.66% and constipation in 93.33% patients. Mixed and predominantly non-vegetarian diet appears to be most commonly associated with fissure-in-ano.[4] In our study, it was associated with 80% patients having history of taking mixed diet. It is usually located close to the midline of anal canal. In males,95% and in females about 80% of fissures are located close to posterior midline, probably because of relatively unsupported nature and poor perfusion of anal wall in that location.[3,8,9] In our study, midline posterior location of acute anal fissure was found in 90% male and 81.81% female patients. Severe anal pain during defaecation is the most prominent symptom among all the patients of acute anal fissure. Bleeding per rectum, usually trace of blood is the next prominent symptom.[1,4] In our study, painful defaecation was found in all patients (100%), whereas bleeding per rectum in 60% of patients. No patients with history of atypical anal fissure were taken in this study.[1,5] Most of the acute anal fissures heal spontaneously within three weeks with various conservative management.[1,6] Surgical techniques like manual anal dilatation or lateral internal sphincterotomy effectively heal most of the fissures within few weeks.[7,10] In our study, 80% patients

became pain free and 91% having no bleeding per rectum in first week, whereas 100% patients have no bleeding per rectum, 98.66% became pain free, 97.14% have no constipation and 97.05% have no passage of hard stool after two weeks of combination therapy.

The main aim of our study was to evaluate the effectiveness of combination therapy with topical nifedipine (0.3%) plus lignocaine (1.5%), sitz bath and oral lactulose on acute fissure-in-ano. This study shows that within two weeks of combination therapy there was no any patient complaining of bleeding per rectum and only one patient having mild painful defaecation.

## Conclusion

Among the different managements of acute fissure-in-ano, the present study found that the combination therapy with topical nifedipine (0.3%) plus lignocaine (1.5%), sitz bath and oral lactulose is the best option in the respect of duration to become symptoms free and fissure healing, non-invasive nature of treatment and excellent patient's acceptance and satisfaction.

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