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## Original Research

## Does the duration of symptoms of anal fissure impact its response to conservative treatment? A prospective cohort study



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## HIGHLIGHTS

- 60 patients with anal fissure were treated conservatively and were evaluated at 6 weeks.
- Mean pre-treatment VAS for acute fissure was significantly higher than chronic fissure.
- Post-treatment VAS for acute fissure was significantly lower at 6 weeks.
- Patients with acute fissure achieved significantly better healing than chronic fissure.
- Healing declined from 100% when symptoms were < one month to 33.3% when symptoms >6 months.

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## ABSTRACT

**Background:** Conservative treatment is the first line of treatment for anal fissure. The current study aimed to evaluate the impact of symptom duration on the response of anal fissure to conservative treatment.

**Patients and methods:** This prospective study was conducted on sixty patients with acute or chronic anal fissure who were treated conservatively with bulking agents, Sitz baths, and topical glyceryl trinitrate (GTN) 0.2%. Pain and constipation were assessed prior to treatment and at 6 weeks after therapy using visual analogue scale (VAS) and Wexner constipation score. Adverse effects as headache and postural hypotension were also queried.

**Results:** The mean pre-treatment VAS for acute fissure was significantly higher than chronic fissure ( $8.8 \pm 0.96$  Vs  $5.8 \pm 1.12$ ), also the post-treatment VAS for acute fissure was significantly lower at 6 weeks of treatment ( $0.47 \pm 0.8$  Vs  $2.5 \pm 1.3$ ). The baseline Wexner constipation score was comparable in both groups; however, at six weeks of treatment it declined more significantly in patients with acute fissure. Patients with acute fissure achieved significantly better healing than chronic fissure (80% Vs 40%). Healing rates decreased from 100% in patients with symptoms < one month to 33.3% in patients with symptoms >6 months.

**Conclusion:** Conservative treatment including topical GTN 0.2% significantly hastened healing and relieved pain and other symptoms of acute more than chronic anal fissure. Healing rates of anal fissure in response to conservative treatment showed remarkable decrease in proportion to the duration of complaint.

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## 1. Introduction

Anal fissure is a well-recognized cause of acute anal pain. It is defined as a superficial linear tear in the anoderm distal to the dentate line, most commonly caused by the passage of hard faecal matter [1] but also with acute diarrhoea, pregnancy and other medical conditions [2]. Typically, anal fissure causes cyclical pain that occurs during defecation and persists for one to 2 h afterwards.

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The classic finding on examination is the spasm of the internal anal sphincter (IAS), which is responsible for the exquisite pain during evacuation, this spasm was theoretically attributed to ischemia of the sphincter. In almost 90% of cases, the fissure is located in the posterior midline which Schouten et al. [3] explained that anodermal blood flow at the posterior midline is less than in the other segments of the anal canal. The remaining 10% are usually in the anterior midline position.

Permanent reduction of the anal pressure by lateral internal sphincterotomy (LIS) is the standard surgical procedure for the treatment of chronic anal fissure. This procedure results in permanent sphincter defect and occasionally minor faecal incontinence (FI). This may occur in around 10% of the patients [4]. Additionally, the recurrence rate of anal fissure after internal sphincterotomy has been reported up to 16% [5].

A literature review [6] of medical therapies for anal fissure include nitroglycerin (NTG) ointment, glyceryl trinitrate (GTN) or its analogues such as isosorbide dinitrate (ISDN), botulinum toxin injection, calcium channel inhibitors, bulk agents for treating underlying constipation and topical anesthetic ointments applied to the anus. Some of the reports included into that literature review [6] compared the medical therapy with LIS, the surgical gold standard for the treatment of chronic anal fissure. The authors concluded that local application of exogenous nitric oxide donors such as GTN and ISDN reduce anal pressure and improve anodermal blood flow resulting in healing rates of more than 80% - a reversible chemical sphincterotomy.

Nitric oxide donors are usually applied topically to the perianal region two to three times a day in the form of paste or ointment at a concentration of 0.2% or 0.4%. Adverse effects of GTN applications include postural hypotension and severe headache in around 20–30% of patients within approximately 30 min following application [7]. These side-effects often force the patients to abandon the treatment.

The response of chronic anal fissure to topical GTN is inconsistent and often unpredictable with healing rates ranging between 40 and 69% [8]. The varying response of chronic anal fissure to topical GTN therapy may suggest that the healing effect of GTN on anal fissure is influenced by certain factors such as the duration of the patients' complaint. Pitt et al. [9] have previously implied that patients with history of anal fissure exceeding 6 months are less likely to heal.

The aim of our study was to evaluate the impact of duration of initial symptoms on the response of acute and chronic anal fissures to conservative treatment, and to demonstrate how acute and chronic anal fissures respond to conservative treatment.

## 2. Patients and methods

### 2.1. Study design and setting

This prospective case-series study was conducted in a general surgery department in the period of January 2015 to November 2016. Ethical approval was obtained from the institutional review board. The study was registered on the Research Registry ([www.researchregistry.com](http://www.researchregistry.com)).

### 2.2. Patients

The study included adult patients with either acute or chronic anal fissure who were treated conservatively with bulking agents, Sitz baths, and topical GTN 0.2% ointment. Patients were subdivided according to the duration of their initial symptoms reported at the first visit to the outpatient clinic into acute (<6 weeks) or chronic (>6 weeks) anal fissure [10]. We excluded patients with associated

anorectal pathology such as hemorrhoids, fistula or abscess, patients with Crohn's disease or malignancy, pregnant females, patients with recurrent anal fissure after previous surgery, and patients taking corticosteroid or other immunosuppressive therapy.

### 2.3. Assessments

A detailed history was taken and thorough physical examination was conducted for all patients before the start of conservative treatment. Patients were interviewed about the relevant present history including the type, onset, and duration of complaint, degree of pain, presence of constipation, rectal bleeding, previous treatments received, and associated medical conditions. We subdivided the patients according to their clinical history and duration of complaint into two groups; group I (acute anal fissure) and group II (chronic anal fissure).

In order to have objective assessment we used standardized methods for evaluation as visual analogue scale (VAS) from 0 to 10 for assessment of pain during and after defecation where zero means absence of pain and 10 represents the worst possible pain. Wexner constipation Score [11] was employed for evaluation of constipation. Patients were examined in the left lateral position to inspect the type and position of the anal fissure and to exclude the presence of associated anal pathology as hemorrhoids or anal fistula. The presence of sentinel skin tag confirmed the chronicity of anal fissure.

### 2.4. Details of conservative treatment

Conservative treatment consisted of three main components: bulk laxatives, Sitz baths and topical GTN 0.2% ointment. Patients were instructed to apply a pea-sized dot of GTN 0.2% ointment using the tip on the index finger three times per day for six consecutive weeks which is the standard initial treatment duration of topical GTN therapy [12]. Patients were instructed not to use other topical therapies concomitantly with GTN ointment during the period of treatment.

### 2.5. Follow-up and outcomes assessed

Patients visited the outpatient clinic every week for six consecutive weeks (the endpoint of the study) after the start of treatment. At every visit patients were interviewed by an independent specialist nurse to eliminate the risk of investigator bias. Compliance with treatment was recorded alongside the degree of anal pain according to VAS, constipation symptoms as evaluated by Wexner constipation score. The presence or absence of rectal bleeding or discharge, and any adverse effects of GTN therapy including postural hypotension and headache were also recorded. Patients were examined by two of the authors (S.E & H.E) in the left lateral position to assess and record the extent of healing of anal fissure.

The primary outcome of the study was the degree of healing of anal fissure at six weeks of conservative treatment as observed by clinical examination. Healing was defined as complete epithelisation of the site of anal fissure with no residual cracks or ulcers. Secondary outcomes included reduction in pain score, improvement in constipation and other symptoms, and the incidence of treatment-related complications.

### 2.6. Sample size calculation and statistical analysis

The sample size calculation was based on the analysis of the primary endpoint (percentage of patients who achieved complete

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