

## Efficacy and Adverse Effects of Topical Application of 2% Diltiazem Gel With That of Lateral Internal Sphincterotomy: A Retrospective Study

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### Abstract

**Aim:** The aim of the present study was to assess and compare the efficacy and adverse effects of topical application of 2% Diltiazem gel with that of Lateral internal sphincterotomy.

**Material & Methods:** A retrospective study including cases of chronic anal fissure admitted/operated in the Department of General Surgery, Anugrah Narayan Magadh medical College and hospital Gaya, Bihar, India. This study includes 100 patients presenting with chronic anal fissure for the duration from January 2016 to December 2016

**Results:** Majority of the patients belonged to 21-40 years. Majority of the patients had pain followed by bleeding. In male and females, site of fissure was posterior. In diltiazem group, pain was relieved at the end of 8 weeks and in LIS group, pain was relieved at the end of 4 weeks. In diltiazem group, headache was the complication and in LIS group, post operative pain was the complication.

**Conclusion:** The current study shows results in favour of lateral internal sphincterotomy with a healing rate of 100% with a faster pain-relief and minimal complications if performed by the experienced surgeon. However topical 2% diltiazem gel is an effective agent can be safely prescribed for patients having contraindications for surgery.

**Keywords:** Chronic Fissure in Ano, Lateral Sphincterotomy, 2% Diltiazem gel

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### Introduction

Anal fissures are benign anorectal disorder that causes pain and bleeding during defecating. An anal fissure is a superficial rupture or ulcer within the distal anoderm that extends from the anal margin to the dentate line and is most typically observed within the posterior midline, less frequently in the anterior midline, and infrequently within the lateral side of the anal canal. Primary (idiopathic) and secondary (underlying pathological condition) fissures can be distinguished. [1] Chronic anal fissures are defined as anal fissures that last longer than 6 weeks. A chronic anal fissure is usually deeper and usually has exposed internal sphincter fibres at its base. It is associated with a hypertrophied papilla superiorly and a sentinel tag inferiorly. Internal sphincter spasm is present in painful fissures. [2]

The resting pressure of the internal sphincter and the external sphincter complex, maintains continence. Similar to involuntary muscles of the colon and rectum, the internal sphincter fibres spasm

involuntarily. This involuntary spasm in response to injury to the exposed subcutaneous tissue of the fissure causes the severe pain associated with anal fissure disease. Chronic anal fissures occur due to increased resting pressure in the anal canal due to hypertonicity of the internal sphincter, and treatment is therefore aimed at its elimination. Various treatment modalities like anal dilatation, sphincter lysis, flap procedures, fissurectomy, non-invasive pharmacological therapies like chemical sphincterotomy, sclerotherapy, and sclerotherapy had been developed and emphasised in fissure patients in the past, resulting in secondary complications. [3]

Surgical techniques like manual anal dilatation or lateral internal sphincterotomy, effectively heal most fissures within a few weeks, but may result in permanently impaired anal continence. [4] Lateral internal sphincterotomy is the preferred treatment for persistent anal January 2016 to December 2016

fissures, with healing rates exceeding 95%. However, the need for an alternative to alleviate postoperative stress and the possibility of incontinence has long existed. Diltiazem, a calcium channel blocker with a unique profile of outstanding healing rates and moderate side effects, is one such chemical approach that has been utilized in its locally relevant form [5,6] 'Chemical Sphincterotomy' (Topical nitro glycerine ointment, Topical calcium channel blockers and Topical 2% diltiazem gel) are being investigated and used as the first line of treatment for chronic anal fissure.

Hence the aim of study was to assess and compare the efficacy and adverse effects of topical application of 2% Diltiazem gel with that of Lateral internal sphincterotomy.

### Material & Methods

A retrospective study including cases of chronic anal fissure admitted/operated in the Department of General surgery, Anugrah Narayan Magadh medical College and hospital Gaya, Bihar, India. This study includes 100 patients presenting with chronic anal fissure for the duration from January 2016 to December 2016

### Inclusion Criteria:

All with complaints of painful passage of stool, with or without bleeding of more than 6 weeks duration, diagnosed to be having chronic anal fissure based on the history and on clinical examination.

### Exclusion Criteria

- Tuberculosis
- Haemorrhoids
- Ano rectal abscesses
- Anal malignancies
- Immunocompromised patients
- Previous history of faecal incontinence or anal stenosis
- Patients who have undergone previous anal surgeries

### Methodology

Informed/written consent will be taken from all the patients included in the study. All patients in study will undergo a detailed history taking including general examination and investigations. Patients are randomly selected and classified into two groups each consisting of 50 patients.

Group A: 50 patients who are subjected to chemical sphincterotomy using topical application of 2% Diltiazem gel.

Method of application of 2% Diltiazem gel: Informed consent from the patient was taken prior to the study. Patients were advised to apply 1.5 to 2cms length of gel thrice daily at least 1.5 cm into the anus.

Group B: 50 patients who are subjected to Lateral Internal Sphincterotomy.

Both the groups are advised plenty of oral fluids, high fibre diet, laxatives and Seitz bath. Follow-up of the patients is done by history and per-rectal examination to assess the efficacy of the treatment and the complications like pain, bleeding, sphincter spasm, discharge per Anum and incontinence.

Patients from the both the group were followed up for a period of 3 months on 1st week, 1st month and 3rd month respectively.

### Assessment tools

- NRS score/visual analogue pain scale;
- incontinence (faecal/flatul) number of work days lost;
- wound infection;
- recurrence;
- and (e) per rectal digital examination.

### Statistical analysis

Statistical software SPSS was used to calculate the p value. Pearson chi-square and unpaired t test was applied for comparing the data of both the groups and a p value of <0.05 was considered statistically significant.

### Results

**Table 1: Age and Sex distribution**

| Age group (years) | Males |     | Females |     | Total |     |
|-------------------|-------|-----|---------|-----|-------|-----|
|                   | No.   | %   | No.     | %   | No.   | %   |
| 11-20             | 6     | 12  | 3       | 6   | 9     | 9   |
| 21-30             | 18    | 36  | 17      | 34  | 35    | 35  |
| 31-40             | 17    | 34  | 13      | 26  | 30    | 30  |
| 41-50             | 5     | 10  | 11      | 22  | 16    | 16  |
| 51-60             | 4     | 8   | 6       | 12  | 10    | 10  |
| Total             | 50    | 100 | 50      | 100 | 100   | 100 |

Majority of the patients belonged to 21-40 years.

**Table 2: Symptomatology of Chronic anal fissure**

| Symptoms     | Males |     | Females |     | Total |     |
|--------------|-------|-----|---------|-----|-------|-----|
|              | No.   | %   | No.     | %   | No.   | %   |
| Pain         | 50    | 100 | 50      | 100 | 100   | 100 |
| Bleeding     | 42    | 84  | 36      | 72  | 78    | 78  |
| Discharge    | 06    | 12  | 03      | 06  | 09    | 09  |
| Constipation | 39    | 78  | 43      | 86  | 82    | 82  |
| Pruritus     | 04    | 08  | 08      | 16  | 12    | 12  |

Majority of the patients had pain followed by bleeding.

**Table 3: Site of Fissure-in-ano**

| Sex     | Site      | Number of patients | Percentage |
|---------|-----------|--------------------|------------|
| Males   | Anterior  | 1                  | 2          |
|         | Posterior | 48                 | 96         |
|         | Both      | 1                  | 2          |
| Females | Anterior  | 5                  | 10         |
|         | Posterior | 43                 | 86         |
|         | Both      | 2                  | 4          |

In male and females, site of fissure was posterior.

**Table 4: Duration for healing and postoperative findings in Diltiazem and LIS Group**

| Pain relief            | Diltiazem group |    | LIS group |    |
|------------------------|-----------------|----|-----------|----|
|                        | No.             | %  | No.       | %  |
| At the end of 4 Weeks  | 14              | 28 | 34        | 68 |
| At the end of 8 Weeks  | 28              | 56 | 16        | 32 |
| At the end of 14 Weeks | 3               | 6  | -         | -  |
| No relief              | 5               | 10 | -         | -  |

In diltiazem group, pain was relieved at the end of 8 weeks and in LIS group, pain was relieved at the end of 4 weeks.

**Table 5: Complications in Diltiazem group and LIS group**

| Complications          | Number of patients | Percentage |
|------------------------|--------------------|------------|
| <b>Diltiazem group</b> |                    |            |
| Headache               | 3                  | 6          |
| Vertigo                | --                 | --         |
| Local irritation       | 2                  | 4          |
| <b>LIS group</b>       |                    |            |
| Post-operative pain    | 21                 | 42         |
| Bleeding               | --                 | --         |
| Infection              | --                 | --         |
| Incontinence           | 1                  | 2          |

In diltiazem group, headache was the complication and in LIS group, post operative pain was the complication.

**Discussion**

Proctological disorders are problems that have affected mankind since history. They contain different conditions which make considerable discomfort for patients. Most of the people (30-40%) suffers with these problems in their life. [8]

Anal fissures are most commonly found on the posterior aspect of the anal canal; however they can also occur in other locations due to underlying secondary diseases. Raised anal sphincter pressure combined with hypoperfusion is thought to be the key underlying pathogenesis. Various therapeutic approaches, both pharmaceutical and surgical, have been used to reduce sphincter pressure. The gold standard treatment for the management of anal fissures is lateral internal sphincterotomy, in which the internal sphincter is separated in its distal third away from the fissure itself - either in the right or left

lateral position, although with the risk of incontinence. Majority of the patients belonged to 21-40 years. Majority of the patients had pain followed by bleeding. This evidence supports the findings of Varadarajan et al, Saiyad et al, and Khan et al. [8-10]

Even though there was no significant difference between the two groups, it was determined to be consistent with earlier research by Bara et al who found that patients who underwent LIS had a lower incontinence rate. In male and females, site of fissure was posterior. In diltiazem group, pain was relieved at the end of 8 weeks and in LIS group, pain was relieved at the end of 4 weeks. In diltiazem group, headache was the complication and in LIS group, post operative pain was the complication.

### Conclusion

The current study shows results in favour of lateral internal sphincterotomy with a healing rate of 100% with faster pain-relief and minimal or no complications. Topical 2% diltiazem gel is an effective agent in the treatment of chronic fissure-in-Ano. Though there is latency in the clearance of symptoms and lesions when compared to surgical sphincterotomy, this has shown minimal and insignificant adverse effect. Topical diltiazem can be safely prescribed for patients who are unfit or unwilling for surgery. Healing rate is slower compared to surgery but the need for hospital stay is abolished and it reduces the psychological and financial burden on the patient. By comparing the above two modalities of treatment for chronic anal fissure, we conclude that Lateral internal sphincterotomy appears to be the better line of treatment as there is 100% healing rate.

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