

**A COMPARATIVE STUDY ON USE OF TOPICAL METRONIDAZOLE ALONG WITH
TOPICAL DILTIAZEM VERSUS ONLY TOPICAL DILTIAZEM IN THE TREATMENT
OF ACUTE ANAL FISSURE**Md. Shakeel^{1*} and Raghavendra Reddy AV²¹Professor, Department of General Surgery, Navodaya Medical College, Raichur, Karnataka.²Postgraduate, Department of General Surgery, Navodaya Medical College, Raichur, Karnataka.***Corresponding Author: Dr. Md. Shakeel**

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ABSTRACT

Background: Acute anal fissure, a disease characterized by severe pain in the anorectal area, reduces quality of life and becomes chronic absent appropriate treatment. More recently, anaerobic infections have been noted as a contribute to etiopathogenesis. This study investigates topical metronidazole's effect in the treatment of acute anal fissure. **Methods:** Our prospective randomized controlled double-blind study included 2 groups of 90 patients older than 18 years from our General Surgery out patient department with anal fissure complaints for less than 8 weeks. Topical diltiazem & metronidazole treatment was started in group 1, and topical diltiazem in group 2. Pain levels were evaluated by the visual analogue scale (VAS) score, and recovery status was evaluated by physical examination findings initially and at the 1st, 4th, and 6th weeks. VAS score levels, demographic, clinical, and recovery status were then compared. **Results:** There was no difference between the groups as to age, sex, pain on defecation, bleeding, constipation, and duration of pain, bleeding and constipation. From week 1, fissure epithelialization and healing rates were higher in group 2; group 2 VAS score levels were lower than in group 1 and achieved by group 1 only in week 4. **Conclusion:** Adding topical metronidazole to treatment reduces the duration and severity of pain, shortens healing time, and increases the healing rate.

KEYWORDS: Acute anal fissure; Anti-bacterial agents; Diltiazem; Metronidazole; Topical therapy.**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; but also with acute diarrhoea, pregnancy and other medical conditions. Typically, anal fissure causes cyclical pain that occurs during defecation and persists for one to two hours afterwards.^[1] The disease can be acute or chronic.^[5] In an acute anal fissure, only the epithelial tissue is ruptured, with pain in the anal region, with symptoms of defecation and bleeding lasting less than 2 months. In a chronic anal fissure, symptoms last longer than 6 to 8 weeks; in addition to the symptoms noted above, it is characterized by exposed fibers of the internal anal sphincter at the base of the fissure, hypertrophied anal papillae at the proximal end, and skin tags at the distal.^[2] Although its etiology is not known exactly, it is thought to be multifactorial and can be the result of spontaneous internal anal sphincter spasm, ischemia, infection, and local trauma. In recent studies, it has been reported that there can be subclinical infection mostly due to the presence of anaerobic bacteria in the anal fissure region, and the use of topical or oral

antibiotics in addition to conventional medical treatment increases wound healing and reduces pain.^[5]

In this study, our aim is to investigate whether the use of topical metronidazole, which is effective against anaerobic bacteria, which are claimed to cause subclinical infection in the anal fissure, in addition to diltiazem, a calcium channel blocker that has been used for years in the treatment of acute anal fissure, are superior to the use of diltiazem alone.

MATERIALS AND METHODS

The studies involve 90 patients with acute anal fissure, having typical symptoms of painful defaecation, bleeding PR and constipation. Patients older than 18 years are considered. Upto 90% of acute anal fissures are located posteriorly and 10% located anteriorly. In medically treated groups, two groups of 45 patients each were divided; In group 1 patients topical metronidazole(1%) along with (2%)topical diltiazem was applied twice daily for a given period. In group 2 patients topical agent (2% diltiazem) were applied twice daily for a given period. Supportive treatment with high fiber diet, fiber supplements, sitz baths, stool softeners and plenty of

fluid intake was provided to all the patients. Results were observed on regular follow-ups: 1st, 4th, and 6th weeks of treatment.

Pain relief is compared by using visual analog scale (VAS) score and fissure healing is noted by complete epithelialization of fissure. The scale is divided into 10 equal parts; 0 indicated no pain and 10 indicated unbearable pain. Clinical improvement was considered as complete reepithelialization of the anal canal mucosa and closure of the fissure without erythema or inflammation and relief of patient complaints.

RESULT

Out of 90 patients, In this study patients are divided into two groups of 45 patients each. Group A was treated medically with 2% topical diltiazem cream and group B was treated medically with 1% topical metronidazole + 2% topical diltiazem.

The median age of the patients in group 1 was 30 years and in group 2, it was 33 years. 28 patients in group 1 and 32 in group 2 were female. Pain symptoms were present in defecation in all patients in both groups. Constipation and bleeding during defecation were detected in 44 patients in group 1 and 42 patients in group 2.

The medians of the duration of pain, bleeding time, and constipation duration of the patients were detected to be

and 3 weeks, 3 weeks, and 4 weeks in group 1 & 4 weeks, 4 weeks, and 4 weeks in group 2, respectively.

At the end of the 4th week, in group 1, 15 patients (33.3%) had complete recovery; while in group 2 only 5 patients (11.1%) had complete recovery

At the end of the 6th week, 39 patients (86.6%) in group 1 & 19 patients (42.2%) in group 2 had fully recovered. When the groups were compared in terms of physical examination findings and recovery rates, it was found that both epithelialization and the healing rates of the patients in group 1 were statistically significantly higher than those in group 2 from the 1st week.

The median (IQR) VAS score levels were found to be 8 in group 1 and 8 in group 2, respectively, on the day of enrolment. At the end of the 1st week of treatment, the median (IQR) VAS score decreased from 8 to 2 in group 1 while it decreased from 8 to 5 in group 2. When the groups were compared in terms of VAS scores detected on the day of enrolment and follow-up, it was found that the VAS scores of the patients in group 1 decreased much more rapidly after the 1st week, in line with the physical examination findings. In group, the VAS score started to decrease rapidly from the 1st week and there were almost no patients with pain in the 4th week. The VAS scores of the patients in group 2 decreased at a slower rate compared to group 1.

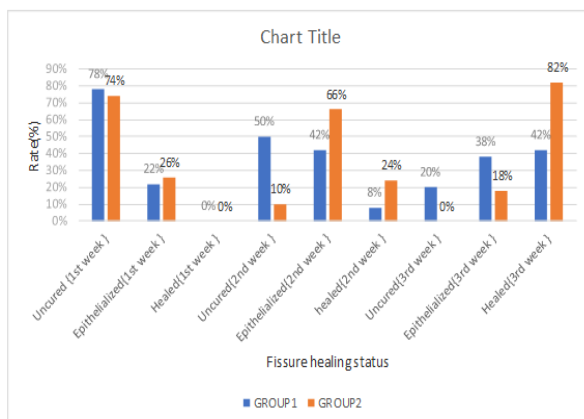


Fig. 1: Both the rate of epithelialization in the anal fissure and the rate of healing were found to be statistically higher in patients in group 1, in which topical metronidazole was added to conventional treatment from the 1st week of treatment, compared to the rates for patients in group 2, who received only conventional treatment.

DISCUSSION

In our study, it was shown that the use of diltiazem and topical metronidazole for the treatment of acute anal fissure compared to the use of topical diltiazem alone, reduced the severity of pain in a very short period of time and both shortened the healing time of the fissure and increased the healing rate.

Acute anal fissure affects both men and women equally.^[5] Typical presenting symptoms in acute anal fissure are pain on defecation and bleeding. Pain is

usually sharp and aggravated during defecation, sometimes painful defecation may be accompanied by bleeding.^[9] In addition, defecation was accompanied by bleeding in 81.0% of the patients. Spasm is known to occur in the internal anal sphincter in acute anal fissure.^[10] Warm sitz baths contribute to the relaxation of the internal anal sphincter and the healing of the anal fissure through the somatoanal reflex.^[11] Approximately half of acute anal fissures have been reported in studies to heal with only warm sitz baths and fiber diet intake.^[12] In studies on etiology, due to the inadequate response of

some patients to treatment, it has been shown that the bacteria found in the anal fissure area in 90% of patients with chronic anal fissure do not match the bacteria found in the stool flora of the same patients, *Escherichia coli* was reported to be one of the main causes.^[14] In light of these data, in a study involving the topical application of povidone-iodine solution in chronic anal fissure, it was revealed that it contributed positively to the treatment. In the following years, in another study by the same authors, it was reported that chronic anal fissure could be treated with topical or systemic antibiotic treatment by preventing constipation.^[8] In a study of Grekova et al. Unlike previous studies, Karapolat^[7] reported that a 44% improvement was found in the control group with 4 weeks of topical lidocaine treatment in acute anal fissure, while an improvement of 86% was achieved in the group that added topical metronidazole to topical lidocaine treatment. In our study, similar to the literature, complete recovery was achieved in 42.0% of patients in the 6th week of treatment, using only topical diltiazem, while complete recovery was achieved in 82.0% of patients using topical diltiazem and metronidazole. In addition, it was shown that the increase in the rate of complete recovery started from the 1st week of treatment compared to that in the control group.

Grekova et al.^[7] reported that the VAS score level decreased in a shorter period of time from the day the treatment was started in the patient group using topical metronidazole compared to the period required for a similar decrease in the non-user group.

In our study, similar to the literature, it was found that the VAS score level had decreased further in the patient group using topical metronidazole from the 1st week of treatment compared to the level of decrease in the group using diltiazem alone. In addition, in our study, it was shown that the VAS score level attained by the patient group using topical metronidazole in the 1st week of treatment was only achieved in the 4th week by the group using diltiazem alone.

In conclusion, with the addition of topical metronidazole to conventional treatment, the reduction of acute anal fissure-related pain in a short period of time, the shortening of the healing time of the fissure, and the high rate of healing indicate that infection plays an important role in the etiology of anal fissure. The use of topical metronidazole as an adjunct to conventional treatment may result in lower chronicity of acute anal fissures and avoidance of surgical interventions with high complication rates. We think that there is a need for new studies in which different topical antibiotic therapy options are employed.

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