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Original Article

Comparative Study of Medical Management of Anal Fissure between Topical Application of Minoxidil and Diltiazem

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Abstract

Aims and Objectives: The aim of the study was to compare the outcome in the medical management of anal fissure with topical application of 2% minoxidil and 2% diltiazem for anal fissure.

Materials and Methods: Prospective study of 100 patients of anal fissure was done from October 2017 to August 2019 done at the Department of General Surgery NSCB Medical College Jabalpur. One subgroup of 49 patients treated with topical 2% minoxidil and other groups of 49 were treated with 2% diltiazem for 6 weeks and regularly followed every 2 weeks and assessed through pain visual analog scale from 0 to 10.

Results: Complete healing of fissure was seen in 34/49 patients used diltiazem and 42/49 who used minoxidil and use of minoxidil also associated with faster pain relief.

Conclusion: Minoxidil is a better alternative of diltiazem for medical management of anal fissure.

Key words: Fissure, Management, Topical application

INTRODUCTION

An anal fissure is linear, longitudinal tear, or split in the epithelial lining of the distal anal canal distal to the dentate line. Anal fissure is one of the most common anorectal problems. It is often associated with severe sharp pain upon defecation described as "tearing" or "passing broken glass" and sometimes bleeding followed by a less severe burning pain which may last for several hours afterward.[1-4]

Fissures can be classified as acute if they have been present for <6 weeks chronic if they persist for more than 6–8 weeks. Acute fissures are often superficial and well-demarcated edges. Chronic anal fissures on the other hand are wider and deeper and marked by ulcer with keratinous edges, presence of a sentinel tag at the external apex, and hypertrophy of the anal papillae.[5-7]

Minoxidil (2,4-diamino-6-piperidinopyrimidine-3-oxide) is a vasodilator which an effective vasodilator which acts directly on vascular smooth muscle cells, producing a decreasing in peripheral vascular resistance and reduces blood pressure. Minoxidil acts through opening the potassium channels. The potassium efflux leads to hyperpolarization of the smooth muscle and reduction in calcium influx through voltage-operated calcium channels. These pharmacological properties suggest potential benefits for minoxidil in the medical management of anal fissure. Diltiazem (calcium channel blocker) has a role in the treatment of anal fissure as they have shown to reduce resting anal pressure (RAP).[8-12]

Aims and Objective

In this study, we had compared the medical management of anal fissure with topical agent 2% minoxidil and 2% diltiazem.

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MATERIALS AND METHODS

After a detailed history clinically examination, the diagnosis of anal fissure was confirmed. Some of the cases of anal fissure had given ointment based topical minoxidil and some cases were given ointment based topical diltiazem to apply it circumferentially inside anal verge thrice a day for 6 weeks and ask to avoid laxative and stool softer and patient ask to visit the hospital every 2 weeks and assessed through pain visual analog scale (VAS). Pain score was recorded on a VAS from 0 to 10.0 being minimum pain and 10 being maximum (intolerable) pain which hampers routine activity.

This is a prospective, randomized controlled study for the duration of September 2017 to August 2019 and was conducted in Netaji Subhash Chandra Bose Medical College and Hospital Department of General Surgery Jabalpur (M.P.).

The ethics committee of our hospital approved the protocol and all patients provided written informed consent.

A total of 100 patients were enrolled for study, divided into two subgroups one subgroup (n-50) given treatment with 2% minoxidil, and another subgroup (*n*-50) received treatment with 2% diltiazem for medical management of anal fissure.

Patients were advised to apply ointment circumferentially inside the anal orifice every 8 hourly for 6 weeks and the patient was asked for follow-up on OPD basis every alternate week for a period of 6 weeks.

Anal pain was assessed before starting the treatment and at alternate week follow-up visit through using a linear visual analog pain score (0–10).

All the demographic and technical data related to patients included in the study were collected, entered in Pro forma, and master chart in excel sheet.

Statistical Analysis

All the data were entered in Microsoft Excel and then transferred to IBM SPSS version 21.0 for analysis. Data were analyzed and $P < 0.05$ was taken as the level of significance.

OBSERVATION AND RESULTS

We did this study in 98 patients which were divided into two groups consisting of 49 patients in each group. One group of 49 patients received 2% diltiazem, while other groups received 2% minoxidil for local application on perianal and anal orifice for 6 weeks for medical management of anal fissure.

Pre-treatment chief complaints like pain which was the main chief complaint were assessed with VAS and score was given from 0 to 10, another complaint was bleeding per rectum was assessed subjectively. After receiving treatment, the patient was reassessed every alternate week in a follow-up visit on OPD basis and after examination pain and healing of anal fissure was assessed. For 6 weeks, complete healing was defined as the presence of scar or disappearance of fissure after maximum 6 weeks of treatment, while partial healing was defined as persistence of fissure but improvement in symptoms (pain relief and/or control of bleeding).

Majority of patient participated in our study were mainly young male presented with complains of pain on defecation (70.4%) and pain on defecation with bleeding per rectum (26.5%) mainly.

Mean age of patients participated in our study was 31.63 years in one group (D) and 33.31 years in another group (M), while pre-intervention grade of pain in one group (D) is 4.69 while in another group (M) it was 4.76. The mean time complete healing was found 3.5 weeks in one group (D), while the meantime of complete healing in another group (M) was found to be 2.7 weeks. Complete healing was seen in 34 out of 49 patients (69.4%) in one group (D) and seen in 42 out of 49 patients (85.5%) in other groups (M). The main side effect seen within the group using diltiazem for anal fissure locally were perianal excoriation seen in two patients (4.1%), itching seen in eight patients (16.3%), and itching with excoriation seen in one patient (2%) while main complications seen with the group using minoxidil were excoriation in two patients (4.1%), haring in perianal and anal region in three patients (6.1%), and perianal itching in two patients (4%) [Figure 1, Graphs 1 and 2, Tables 1 and 2].

DISCUSSION

In Awan *et al*. prospective study, randomized, double-blind study, a total of 100 patients with anal fissure were recruited (50 patients in each group). The patient in Group A received local ointments containing 0.5% minoxidil while the patient in Group B received topical 2% diltiazem. Healing of anal fissure and symptomatic relief were observed and analyzed. The rate of healing was similar in two groups, meantime taken for healing was significantly shorter with minoxidil with no systemic or local side effect.[13]

Table 1: Distribution of complaints according to treatment option selected

Complaints	Treatment option selected		Total
	Diltiazem	Minoxidil	
Pain on defecation			
Count	38	31	69
% Within treatment option selected	77.6%	63.3%	70.4%
Pain on defecation with bleeding			
Count	11	15	26
% Within treatment option selected	22.4%	30.6%	26.5%
Pain on defecation with itching			
Count	0	3	3
% Within treatment option selected	0.0%	6.1%	3.1%

Chi-square=4.326; *P*=0.115

Table 2: Distribution of healing according to treatment option selected

Healing	Treatment option selected		Total
	Diltiazem	minoxidil	
Complete			
Count	34	42	76
% Within treatment option selected	69.4%	85.7%	77.6%
Partial			
Count	15	7	20
% Within treatment option selected	30.6%	14.3%	22.4%

Chi-square=4.64; *P*=0.098

In Alvandipour *et al.*, in a double-blind, randomized clinical trial, including 88 patients of anal fissure were randomly assigned to either 0.5% minoxidil ointment or 2% diltiazem cream for local application. In the study, diltiazem and minoxidil reduced the pain, bleeding and improved fissure healing with no significant difference with slight higher local complication, that is, itching was slightly higher with minoxidil.[14]

In Muthukumarassamy *et al.* in a prospective, randomized, double-blind study in 90 patients with anal fissure were recruited. The patient received a local application of an ointment containing 5% lignocaine (28), 0.5% minoxidil (36), or both (26). In this study, rate of healing was similar in three groups, while meantime taken for healing was significantly shorter in mix and minoxidil alone group compare to lignocaine alone group. The rate of pain relief was similar in the three groups. Stoppage of bleeding occurred more often with combination treatment than with lignocaine alone.[15]

Our study is in agreement with that of previous similar studies. The minoxidil group had a slightly higher rate of pain relief compare to diltiazem and more cases of complete healing of anal fissure compare to diltiazem.

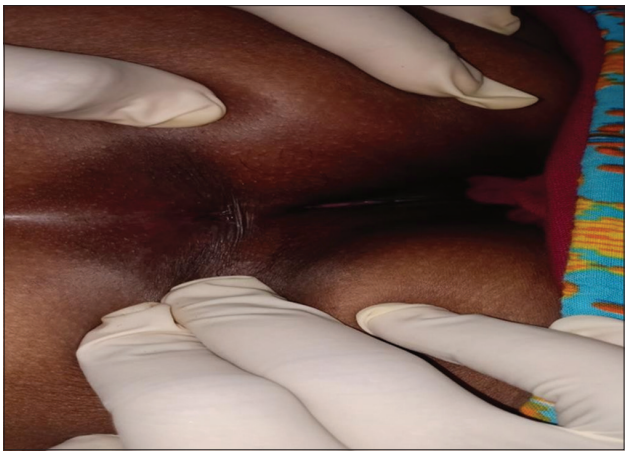
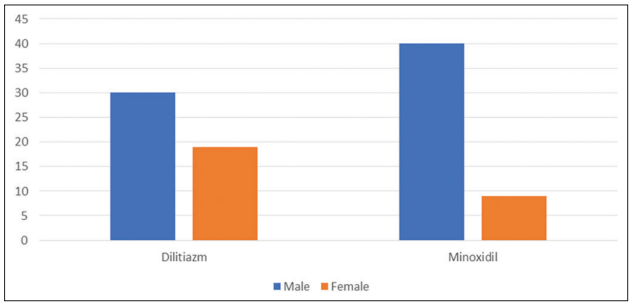
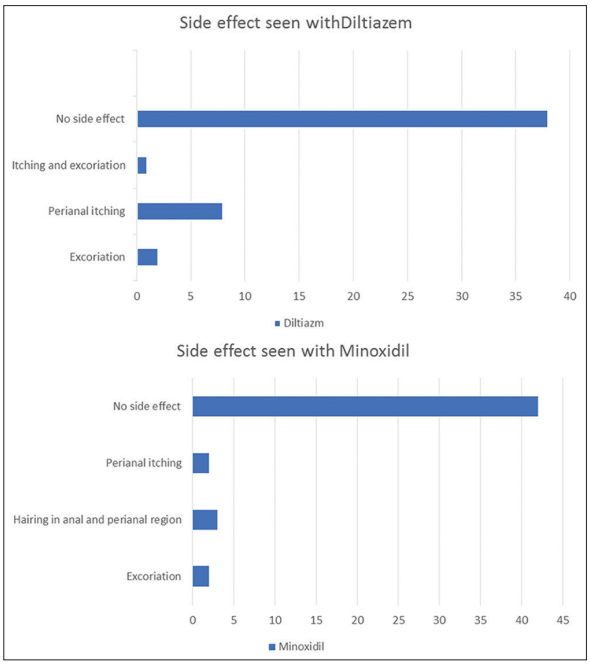


Figure 1: Pre-treatment anal fissure clinical pic



Graph 1: Distribution of gender according to treatment option selected



Graph 2: Distribution of side effects according to treatment option selected

The small sample size was the main limiting factor of our study.

CONCLUSION

Complete healing anal fissure was seen in 34/49 patients used diltiazem while complete healing seen in 42/49 patients used minoxidil. The rate of pain relief was found to be faster in a group using minoxidil compare to a group using diltiazem. This difference between rate of pain relief and fissure healing between diltiazem and minoxidil local application for anal fissure was found statistically significant. Hence, we conclude that the use of 2% minoxidil local application for medical management of anal fissure has advantages of a faster rate of pain relief and complete healing and hence may be considered as an alternative treatment modality for medical management of anal fissure.

Hence, in view of faster pain relief and complete healing and less side effect, we conclude that minoxidil is a better alternative for medical management of anal fissure compare to diltiazem.

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