

ORIGINAL ARTICLE

Treatment of Acute Fissure in Ano using Topical Glycerine Trinitrate and Manual Anal Dilatation at the University Teaching Hospital, Lusaka

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ABSTRACT

Objective: To compare the effectiveness of topical glycerine trinitrate (GTN) cream to manual dilatation of the anus (MDA) method in the treatment of acute fissure in ano.

Method: Two cohorts each consisting of 34 participants with acute fissure in ano were selected. One cohort was treated with the manual dilatation of anus (MDA) while the other with 0.25% topical glycerine trinitrate (GTN) cream. Participants were followed for a period of 6 (six) weeks during which they were assessed for fissure healing at two weekly intervals. Fissure healing was defined as absence of fissure pain. Pain was quantified using numerical rating scale.

Results: Cure rate for the MDA group was 28 (82.4%) while that for GTN group was 31 (91.2%) giving a RR of 1.11 at the end of six (6) weeks follow up. Seven Participants (10.3%) all from the GTN cohort developed headache during the course of treatment. The observed side effect was effectively treated using paracetamol. There were however no other adverse events that were observed.

Conclusion: Both treatment methods showed effectiveness in the treatment of acute fissure in ano. However response to treatment was noted to be better with the MDA cohort compared to the GTN one as fissure healing was faster. Therefore MDA should be maintained as the first line treatment method for acute fissure in ano treatment at UTH and other hospitals in Zambia. Treatment with 0.25% GTN cream should be reserved for participants who decline MDA, health institutions where

theatre facilities are not available or conditions where there are contraindications to surgery.

INTRODUCTION

Fissure in ano is a well-recognized health problem not only in Zambia but the world over. At The University Teaching Hospital (UTH), many patients with this diagnosis are seen each year. These patients are largely managed by surgeons. The national prevalence rate is unknown but in 2010 alone 79 manual dilatations for acute fissure in ano were performed at UTH.

By definition a fissure in ano or ano fissure is a longitudinal tear of the lower anal canal. It is one of the painful anal conditions resulting in a lot of discomfort and embarrassment to the patient [1, 2,]. The pain is sharp, agonizing during defecation and may last for an hour or more. The patient is comfortable until the next defecation. A period of remission may occur, usually for days or weeks. Severe pain during defecation usually makes the patient avoid defecating and this result in constipation, doing so with a fresh tear more likely during next defecation.

The aetiology varies from precipitous diarrhoea, constipation, tight anal sphincter, trauma as in anal intercourse and child birth. Contrary to traditional teaching a precipitating history of constipation is found in 20% of patients [2]. Many a time, aetiology cannot be identified.

Cases of fissure in ano are classified into acute and chronic. In some cases patients present with acute on chronic fissure in anal.

In acute cases the history is usually short lasting less than 6 weeks. There is inflammation of the anal mucosa, slight induration and there are always spasms of the internal anal sphincter [2].

On the other hand, chronic cases presents with a long history lasting more than 6 weeks [1,2], characterized by oedematous skin tag known as sentinel pile, inflammation and marked induration of the margin and the base and spasm of internal anal sphincter. In chronic fissure differential diagnosis of other conditions particularly carcinoma should be considered. Acute on chronic anal fissures are very common.

Diagnosis is clinical by way of digital and proctoscopy examination, though painful and needs patient cooperation. Treatment is either conservative or surgical.

Conservative management includes topical GTN (glycerine trinitrate) cream and anaesthetic cream application, MDA (manual dilatation of anus= Lord's procedure), high fibre diet, sitz baths and antibiotics. GTN increases NO (nitric oxide) which is a very potent muscle relaxant. It acts on vascular smooth muscle there by causing vasodilatation. This increases blood flow to the fissure hence facilitating the healing process [3, 4, 5, 6].

At UTH, treatment is mainly by MDA in combination with sitz baths and high fibre diet. Topical GTN cream has an excellent effect to heal the fissure. Though it is an approved drug by the Pharmaceutical Regulation Authority (PRA), it is not on the market in Zambia [3]. Local anesthetics have been used to relieve pain but seem to be of little help [3].

The recommended concentration of GTN cream is 0.2 – 0.3%. Since it is not readily available locally, it can be made easily by crushing 210 tablets of glycerine trinitrate, 500micg each, which is then added to 20ml of KY jelly. [3].

The patient is instructed to take sitz baths for 10 minutes then apply this jelly with a gloved finger as far in the anus as possible at the same time massage gently. This can be repeated 2- 3 times per day. This breaks the vicious cycle of spasmodic pain and difficult in passing stool thus encouraging the fissure to heal. The only disadvantage with GTN cream is that it causes headache in some

patients [5]. If headache cannot be relieved by a pain killer, then treatment should be discontinued.

The study seeks to compare the effectiveness of MDA and GTN cream in the management of acute fissure in ano, and further develop a protocol for the management of this condition at UTH the rest of the country. This study has never been done elsewhere and is therefore scientifically relevant.

METHODS

Ethical clearance from the University of Zambia Research and Ethical Committee (UNZAREC) was sort prior to the start of this study.

Sixty eight males and females patients were enrolled in a randomized controlled trial which was conducted in a period of 8 months (August 2011 to April 2012). The study was conducted at UTH, Lusaka, Zambia. The minimum age for enrolment was 18 years and only patient with acute ano pain duration of up to 6 weeks and without history of previous treatment for a similar condition or with another anal condition were considered for entry. Two cohorts were created; MDA (control) and GTN (intervention), each with 34 participants. The patients were recruited as they presented.

Allocation was done by using a randomized computer number generator using groups of four, and labeled papers either for MDA or GTN were placed in opaque envelopes. Participants were asked to pick an envelope from the top of the pack for their allocation to either to MDA or GTN cohort depending on its content. About 0.25% GTN was supplied by UTH pharmacy. The participants in the MDA cohort were treated by manually dilating the anus under general anaesthesia whereas those in the GTN cohort were treated with topical 0.25% glycerine trinitrate cream which was applied to the fissure twice daily. Participants were followed up for 6 weeks after initiation of treatment. They were reviewed at 2, 4 and 6 weeks intervals and during each visit, fissure healing was assessed. Data was collected using a standard questionnaire during the initial and subsequent visits. At the end of 6 weeks, the patients were assessed for fissure healing. The primary outcome was fissure healing defined as total absence of pain at 6 weeks. Pain was assessed using numerical rating scale [7].

All the patients reached the end point of the study and were included in the analysis. However 7(10.3%) of the clients all in the GTN cohort developed mild headache at some point during the course of the study. This side effect was successfully treated with paracetamol. The Data collected was entered in the open epi infor software and processed.

RESULTS

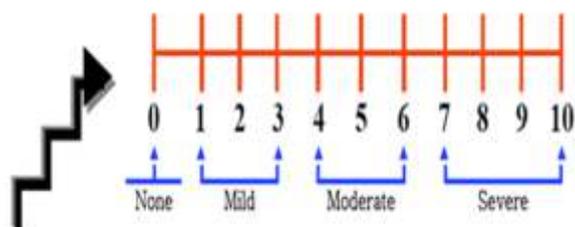


Fig 1. Patients pain was graded using the Numerical rating scale (NRS)

Table 1: Outcome for 68 participants with acute fissure in ano after treatment with MDA and 0.25% GTN cream.

#VARIABLE	MDA(n=34)	GTN(n=34)	RR (95% CL)
Fissure healing at			
2 weeks	9(26.5)	2(5.9)	0.22 (0.05-0.95)
4 weeks	22(64.7)	9(26.5)	0.41 (0.22-0.75)
6 weeks	28(82.4)	31(91.2)	1.11 (0.91-1.33)
Improvement of symptoms at			
2 weeks	33(97.1)	27(79.4)	0.8 (0.68-0.98)
4 weeks	33(97.1)	34(100.0)	-
6 weeks	34(100.0)	34(100.0)	-

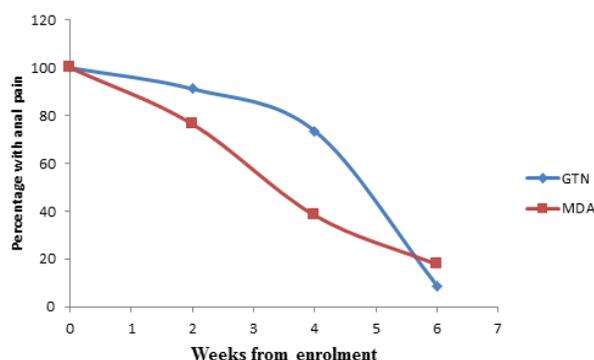


Fig 2. Pain reduction rates (MDA vs 0.25% GTN cream)

DISCUSSION AND CONCLUSION

This study was conducted within the stipulated time and progressed to completion incident free.

The relative risk (RR) of 1.11 (0.91-1.33) indicates that anal stretch (MDA) and application of 0.25% topical GTN cream are both effective in the treatment of acute fissure in ano

However the study has shown that healing of acute fissure in ano is faster with the MDA method compared with the GTN method.

There were no adverse effects reported with the manual dilatation method such as fecal incontinence as reported in other studies [8,9] which focused on determination of effectiveness of this method in the treatment of acute fissure in ano.

10.3% (7) of participants all from the GTN cohort had experienced mild headache at some point during the study which was effectively treated with paracetamol. Headache is a well known complication associated with use of GTN cream in the treatment of this condition. Studies [10,11,12] focusing on determination of effectiveness of GTN cream in treating this condition reported mild headache in some participants and recommended that the participant be treated with analgesia. They recommended discontinuation of treatment only if headache is severe or persistent.

It is desirable that acute fissure in ano heals as quick as possible as was observed with the MDA cohort so as to alleviate patient suffering .

In conclusion, anal stretch method (MDA) should be maintained as the first line treatment of choice for acute fissure in ano while use of topical 0.25% GTN cream should only be considered for use in treating this condition only where theatre facilities are not available, patient choice or where there are contraindications to surgery.

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