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RESEARCH ARTICLE

CHEMICAL SPHINCTEROTOMY WITH TOPICAL 2% DILTIAZEM *VS*. INTERNAL SPHINCTEROTOMY FOR CHRONIC ANAL FISSURE: A COMPARATIVE STUDY

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ABSTRACT

Chronic fissure in Ano is a common benign anal disease. The pain associated with it may affect the quality of life. Morbidity associated with surgical treatment of Chronic Anal Fissure has led to the increasing use of pharmacological agents. The present study was undertaken to test the efficacy of topical 2% Diltiazem and compare it with Internal Sphincterotomy in context with effectiveness, side effects and complications. 70 patients with chronic anal fissure were enrolled for the study and were divided into two groups. Group I and Group II patients were submitted to topical 2% diltiazem ointment and internal sphincterotomy respectively. All the patients were followed up for a period of 8 weeks. Early relief of pain and healing of fissure was observed in Group II compared to Group I. 60% patients in Group I and 100% patients in Group II showed healing of fissure. 2 patients (5.71%) of Group I reported headache. Our study demonstrates the superiority of Internal Sphincterotomy over topical 2% diltiazem in context of rapid relief of pain, early healing of fissure and better cure rates. However, in the responders topical 2% diltiazem can be used as a non invasive first line of management to avoid surgery.

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INTRODUCTION

An Anal Fissure (AF) is a longitudinal tear in the mucosa and skin of the distal anal canal usually extending from the level of dentate line to anal verge. It causes severe anal pain during and after defecation and rectal bleeding. Most common location is posterior midline (80%), followed by anterior midline (10%-13%) and rest lateral (Norman *et al.*, 2008). Current evidence supports the role of sphincter hypertony in the etiology of anal fissure. Sphincter hypertony by increasing the anal pressure causes poor irrigation of the anoderm, resulting in a painful ischemic ulcer. However the above theory fails to explain the cause of sphincter hypertony (Puche *et al*., 2010). In view of the above concept the treatment of anal fissure must focus at reducing the hypertony of the sphincter along with analgesia. The available treatment options include maintenance of hygiene and dietary modifications, conservative and surgical management. Surgical treatment includes manual dilatation (Lord's) under anesthesia and lateral internal sphincterotomy. The first of these two options is the treatment of choice. (Norman *et al*., 2008; Puche *et al*., 2010; Pernikoff *et al.*, 1994). Manual anal dilatation or partial lateral internal sphincterotomy, effectively heal most fissures within a few weeks, but may result in permanent impairment & incontinence. This has led to the search for alternative treatment. Various pharmacological agents are being used which reduce sphincter hypertony, lower resting anal pressure & heal fissures without a threat to anal continence. During the last few years, the medical treatment of chronic anal fissure ("Chemical Sphincterotomy") has gained popularity as a consequence of the morbidity associated with surgical sphincterotomy. A variety of novel drugs including topical Glyceryl trinitrate, Calcium channel blockers such as Nifedipine or Diltiazem, & Botulinum toxin are being used to achieve relaxation of internal anal sphincter (Garcia *et al.*, 2009; De Nardi *et al.*, 2006; Kassai *et al.*, 2001). Diltiazem is a Calcium channel blocker which acts by blocking L-type calcium channels in smooth muscle to bring about temporary and reversible relaxation of internal anal sphincter. Topical Diltiazem has recently been shown to be effective & may not have the same side-effect profile as the oral preparation (Knight *et al.*, 2001). Hence the present study was designed to study the efficacy of topical 2 % diltiazem ointment in the treatment of chronic anal fissure & comparison of topical 2% Diltiazem with the conventional surgical treatment i.e. Internal sphincterotomy in context with effectiveness, complications and side effects.

MATERIALS AND METHODS

This comparative prospective study was carried out in the department of general surgery of BLDEU's Shri B M Patil Medical College Hospital and Research Centre, Bijapur from 2009-2011. Patients between 20 to 60 years of both sex attending surgery OPD &/or admitted patients with chronic fissure in ano were enrolled for the study. History was noted and thorough clinical examination of patients was undertaken to confirm chronic fissure in ano. Institutional ethical clearance was obtained and written informed consent was taken from all patients.

Exclusion criteria

Fissures with hemorrhoids & fistula, Fissures associated with malignancies, Fissures secondary to specific diseases like tuberculosis, Crohn's disease, Fissures in patients with immunocompromised disease, Patients on oral calcium channel blockers, Pregnant women & patients with history of allergy to Diltiazem, Patients with cardiac diseases were excluded from the study. 70 patients were selected for the study & patients were divided on the lottery basis into two groups by simple random sampling technique.

Group I: Treated by topical 2% Diltiazem ointment. All patients were treated on domiciliary basis. Patients were advised to apply 1.5-2cm length of ointment as given in the ointment pack twice daily at least 1.5cm in to the anus for 8 weeks. Patients were instructed to wash hands before & after use of ointment. All patients were reviewed once a week for a minimum of 8 weeks. At follow up patients were evaluated for relief of pain, healing of the fissure and h/o side effects and complications were noted.

Group II: Treated by Internal Sphincterotomy. All patients were admitted and had post-operative hospital stay of around 3 -5 days. Patients who underwent Internal Sphincterotomy were followed up weekly for 8 weeks minimum. At follow up patients were evaluated for healing of fissure.

Statistical Analysis

Statistical analysis was carried out using SPSS version 9.0. Variables are analyzed by Descriptive statistics. Comparison of variables between Group I and Group II was done using Students t test. P value <0.05 is taken as statistically significant.

RESULTS

Table 1. Clinical Data of Group I and Group II patients:

	Group I	Group II
n	39	31
Age (years)	32.40±10.22	36.11±10.98
Sex (Male/Female)	23/12	16/19
Position of Anal Fissure Anterior (A) Posterior (P) Both A & P	 2 32 01	 1 34 0

Group I and Group II were matched with respect to age (p=0.14, >0.05). A higher prevalence of fissure in ano was observed in men compared to women with male female ratio being 1.2:1 Posterior midline fissures were more common. Out of 70 patients, 66 patients (94.30%) had posterior midline fissure, 3 patients (4.30%) had anterior midline fissure and 1 patient (1.40%) had both anterior and posterior fissure. Fig 1 Age of Incidence of Chronic Anal Fissure in Group I and Group II

Average duration for the relief of symptoms in Group I (Topical 2% Diltiazem) and Group II (Internal Sphincterotomy) were 18 days and 7 days respectively. The average duration for complete healing of fissure in Group I and Group II were 49 days and 20 days respectively.

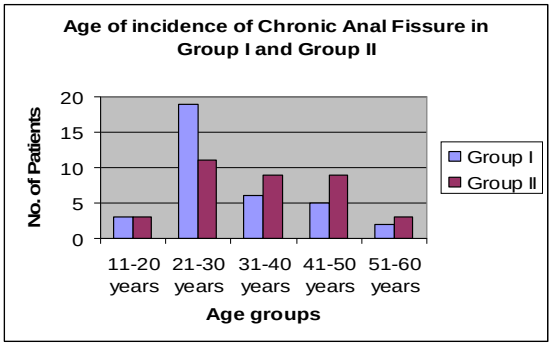

Table 2: Duration for relief of symptoms & healing of fissure

Groups	Relief of symptoms	Healing of fissure
Group I	18.2 days	49 days
Group II	7days	20 days
P- value	0.000	0.000

Table 3: Response to Treatment in Group I and Group II.

	Group I	Group II
Healed	21 (60%)	35 (100%)
Not healed	14 (40%)	0 (0%)

All patients treated by internal sphincterotomy (Group II) showed complete healing. In patients treated by 2% topical Diltiazem ointment (group I) 21 patients (60%) showed complete healing and 14 patients (40%) were not healed. Almost no complications were observed with Group II patients. Among Group I patients 2 (5.74%) presented with headache which was relieved by mild analgesics.

DISCUSSION

In the present study majority of patients belonged to 21-30 years group followed by 31-40 years with a male predominance (Male: Female= 1.2:1). However there are studies indicating that men and women are equally affected (Norman *et al*., 2008; Hannel and Gordon *et al*., 1997). In the group of patients studied, majority of them had posterior midline fissure (66 patients, 94.30%) which is comparable with other studies (Jahan and Muhammad *et al*., 2011). It has been observed that posterior midline fissure is more common in both sexes, although anterior midline fissure is comparatively common in females.

Topical 2% Diltiazem versus Internal Sphincterotomy

***Group I* (Topical 2% Diltiazem ointment)**

Out of 35 patients undergoing treatment with topical 2% Diltiazem application complete relief of symptoms was present in 21 (60%) patients with a mean duration for the relief of pain being 18 days and mean duration for the healing of fissure being approx 49 days (7 weeks).

Table 4. Comparison of Healing rates with topical 2% Diltiazem in different studies

Series	Healing Rates
Present study	60%
Jonas *et al*., 2001	65%
Griffin *et al*., 2002	70%
Kocher HM *et al*., 2002	83%
Bielecki K and Kolodziejczak, 2003	86%
Knight *et al*., 2001	88%
C a r a p e t i EA *et al*., 2000	75%

Das Gupta *et al.,* studied the effect of Topical 2% Diltiazem (8mg) in patients with chronic anal fissure and observed no recurrence at 3 months and no adverse effects (Dasgupta *et al*., 2002).

***Group II* (Internal sphincterotomy)**

Out of 35 patients undergoing internal sphincterotomy all the patients had complete pain relief in 7 days. Fissure healed in all the 35 patients (100%), in a period of 3 weeks (20 days). Ho and Ho reported relief of pain in 92% of patients after 2 weeks (Ho and Ho, 2005). Tocchi *et al.,* observed 100% healing rate to Lateral subcutaneous internal sphincterotomy within a period of 6 weeks in non-responders to 0.2% GTN (Tocchi *et al*., 2004). Liratzopoulos *et al.,* observed a healing rate of 97.5% on lateral subcutaneous sphincterotomy at the end of 3 months (Liratzopoulos *et al.,* 2006)

Complications and side effects

***Group I* (2% Topical Diltiazem group)**

Various side effects have been reported with 2% topical Diltiazem which include headache, hypotension, rashes, nausea, vomiting, perianal dermatitis and itching, reduced smell and taste (Knight *et al.,*2001; Liratzopoulos *et al.,* 2006; Jonas *et al.,* 2001). Headache which is the most frequently reported side effect was noticed in 2 patients (5.71%) in our study

***Group II* (Internal sphincterotomy group)**

In the patients treated surgically, the fissure had healed completely without any complications. Comparable results were obtained by Brown *et al.,* 2007; Richard *et al.,* 2000. The results of our study confirms the superiority of internal sphincterotomy over topical 2% Diltiazem in regards to rapid relief of pain and early fissure healing, minimal side effects and complications and efficacy of treatment. However topical 2% Diltiazem is non-invasive, has minimal side effects, well tolerated and can be administered on a domiciliary basis. Can be used as a first line of management so as to avoid surgery in responders of 2% topical Diltiazem.

Conclusion

Internal Sphincterotomy has stood the test of time and till today is an effective treatment option for chronic anal fissure in regards to efficacy, rapid relief of pain, minimal side effects. However topical 2% Diltiazem can be administered as a first line of management to avoid surgery in those who are not fit for surgery and those who are at risk for incontinence.

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