CONSERVATIVE LATERAL INTERNAL ANAL SPHINCTEROTOMY VERSUS TOPICAL DILTIAZEM IN THE MANAGEMENT OF CHRONIC ANAL FISSURE

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ABSTRACT

Objectives: To compare and assess the efficacy of conservative lateral internal sphincterotomy with topical diltiazem in the management of chronic anal fissure.

Study design: Quasi experimental.

Place and Duration of Study: Surgical Unit IV, Liaquat University of medical and health sciences, Jamshoro from 1st March 07 to 31st August 08.

Patients and methods: In total, 70 patients were included in the study and were divided into two groups. Group A was prescribed topical diltiazem whereas group B underwent conservative lateral anal sphincterotomy. Patients were followed up at 2nd, 4th and 8th week. The markers of efficacy were pain relief, healing of fissure, incontinence and recurrence. Data was collected on a questionnaire and was analyzed statistically using SPSS version 10. The p values were calculated using chi-square test and were considered significant below 0.05.

Results: Conservative lateral internal anal sphincterotomy produced a statistically significant response in comparison with topical diltiazem in terms of pain relief at first follow up (p=<0.001). It was also associated with a better response rate of healing of fissure at the end of study and recurrence rates (p=0.002, 0.019). However, at the end, topical diltiazem was associated with symptomatic relief in study population that was statistically insignificant (p=0.033). Also patients who underwent conservative lateral internal sphincterotomy, 3 of them developed transient incontinence. None of the patients in diltiazem group experienced fecal incontinence.

Conclusion: Conservative lateral internal anal sphincterotomy remains the modality of choice in the management of chronic anal fissure as it provides early pain relief, better healing rates and minimum number of recurrence. However, topical diltiazem can be prescribed as first line of management since it is non-invasive and is free of complications associated with surgical division of internal anal sphincter.

Keywords: Anal Fissure, Internal and Sphincterotomy, Topical Diltiazem

INTRODUCTION

Chronic anal fissure is one of the common anoproctological conditions besides hemorrhoids. It is a painful tear situated in the lower part of anal canal below dentate line that was acknowledged as a disease in 1934[1]. The typical symptoms are severe pain during defecation and blood streaked stools. Clinically the presence of sentinel pile and exposed fibers of internal anal sphincter are characteristic of this disease. Majority of times, this is a primary condition without any underlying pathology and is being attributed to high sphincter tone[1], though epidermoid carcinoma of anal canal, tuberculosis, AIDS[2] and Crohn's disease can also present with fissure in ano[3]. The treatment options available are evolved after a detailed work pertinent to the possible mechanism behind its pathogenesis. The key insight into this problem came with the observation in the 1970's, that resting anal pressure is elevated in fissure patients[4]. Studies using ambulatory manometry, have confirmed the presence of sustained resting hypertonia, with abnormally few episodes of spontaneous IAS relaxation in chronic fissure patients[6].Gibbons and Read in (1986)[6] suggested an ischemic cause supported by postmortem angiographic studies of the inferior rectal artery. The association of anal fissure with sphincter hypertonia was not noted until the 1970s and its relationship to anodermal hypoperfusion till the 90s, the mainstays of surgical therapy for fissure, anal dilatation, and internal sphincterotomy, both

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Received: 24 April 2009; Accepted: 03 March 2010

resulted in decreased anal tone[7]. In contrast, the 90's witnessed the development of several specific pharmacological therapies for fissure, each of which is designed to correct sphincter hypertonia. The common pharmaceutical agents evolved during this period are nitrates calcium channel blockers botox and sildefanil[10]. These agents reduce the tone of internal anal sphincter and hence induce a state of reversible sphincterotomy. Because sphincter is relaxed but is not divided, hence they are free of risk of incontinence but side effects of drugs and recurrence remains an issue. Due to this, the lateral sphincterotomy is still considered as gold standard in the management of chronic anal fissure despite its suggested risks of incontinence reported variably by different authors. The classical sphincterotomy divides the sphincter up to dentate line but the different modifications like tailored sphincterotomy, conservative sphincterotomy and calibrated sphincterotomy aims to divide sphincter with a conservative approach and thereby minimizes the risks of incontinence.

This study was designed for the hypothesis that 2% topical Diltiazem is equally effective as conservative lateral sphincterotomy in the management of chronic anal fissure

PATIENS AND METHODS:

This experimental quasi study was carried out at SU IV of Liaquat University of Medical & Health Sciences, Jamshoro from March 07 to August 08. Seventy patients diagnosed with chronic anal fissure were included. Written informed consent was obtained and they were given the choice liberty to withdraw from study at any point without stating a reason. The protocol was considered violated, if a patient was either lost to follow up or they did not comply with the treatment as described. They were not included in the final statistical analysis. All patients with chronic anal fissure were included in the study. The criteria for chronicity were three of these four features; pain during defecation, bleeding per rectum, sentinel pile and exposed fibers of internal anal sphincter. Those with fissure secondary to some underlying pathology, with associated local or systemic co-morbid like hemorrhoids, fistula in ano, ischemic heart disease and postural hypertension were excluded from the study. Also patients with failed medical treatment were also not included.

Patients were divided equally in two groups comprising of 35 patients each. The first group (Group A, DTZ group) was prescribed 2% topical Diltiazem ointment, about a size of pea taken at fingertip to be applied at anal verge, three times a day for eight consecutive weeks. The second group (Group B, cLIAS group) underwent conservative lateral internal anal sphincterotomy. This procedure was carried out under spinal anesthesia in all the patients. Once in lithotomy position, 5 ml of 2% lignocaine+adrenaline was injected at the proposed site of incision at either 3 or 9 O' clock position in the intersphinteric plane. This facilitated bloodless dissection. A transverse incision was made at 9 O' clock or 3 O' clock position and blunt dissection was carried in the plane between internal and external anal sphincters. The internal sphincter was also dissected away from anal mucosa. Once free in both planes, the sphincter was grasped between two hemostats and was brought on to the surface of wound. The hemostats were kept for 30 seconds and lower half of sphincter (approximately 1 cm) was divided with the help of scissors. Sentinel tags, if any were also excised. The wound was left open and a small wick was placed to control oozing. The dressing was removed on first post-operative day after sitz bath. Patients were discharged on second postoperative day with advice to have sitz bath for next two weeks. They were reported to attend the outpatient clinic for follow up at first, second, fourth and eight week.

The relief in symptoms was defined as complete absence of pain on defecation. Healing was defined as absence of ulcer on examination. Disease was termed recurrent if either the symptoms or the ulcer reappears. A patient was defined as completely continent had there been control on passage of flatus.

Statistical analysis was done and p values were calculated with level of significance below 0.05% using chi square test.

RESULTS

In total 70 patients entered the trial at the beginning of study. Amongst them four were excluded from final analysis due to violation of protocol as described above. Three of them were in group A and one from group B.

The mean age of the patients in group A was 30 years, (16-52 years), whereas in group B it was 32 years (18-54 years).

The gender distribution in both groups is illustrated in figure. Table 1 depicts the clinical presentation of the patients.

Symptomatic relief was noted in a large number of patients in group A, at first follow-up. In that group 32 (91%) of them were symptom free during first week whereas those in group B, only 10 (28.5%) had improvement in their symptoms. This was statistically highly significant (p=<0.001). Table 2 depicts the relief in symptoms at subsequent follow-ups.

At first visit, no patient in group A, showed healing of fissure, whereas in group B, only 3 (8.5%) patients had fissure healing. This is elaborated in detail in Table3.

Though there was a discrepancy in number of patients who had improvement in their symptoms as compared to those who had healing on clinical examination. But patients were, deemed successful to the treatment on the basis of improvement in their symptomatology.

Amongst patients in group A, 3 (8.5%) developed transient incontinence to flatus during first fifteen days of surgery. But none reported such problem in group B (p=0.085).

Patients who applied topical DTZ were informed about the side effects, since being a chemical it is associated with certain undesirable effects. Commonest was headache reported by 2(5%) patients, peri-anal itching and postural hypotension, each by 1 (2.8%) patient.

At the end of the study, 7 (22%) of patients in group A, returned with recurrence of symptoms, minimum period in which symptoms returned back was four months. While only 1 (3%) reported back with recurrence of symptoms in group B (p=0.02).

Table 1: Clinical Presentation of Patients

Variable	No of Patients (n)	%
Symptomatology;		
Pain during defecation	31	44%
Bleeding per rectum	18	26%
Pain during defecation with constipation	21	30%
Examination Findings;		
Ulcer with Sentinel Pile	31	47%
Ulcer	10	15%
Sentinel pile & exposed fibers of IAS	15	23%
Ulcer, sentinel pile and exposed fibers of IAS	10	15%

Table 2: Symptom Relief Profile of the Patients:

Follow-up In weeks	Group A *n*=31	Group B *n*=34	*p*-value
First	10(31)	30(88)	< 0.001
Second	16(50)	30(88)	<0.001
Fourth	19(59)	31(91)	0.003
Eight	28(87.5)	34(100)	0.033

Values in parenthesis are percentages.

Table 3: Healing Profile of Patients

Follow-up in Weeks	Group A n= 31	Group B *n*= 34	*p*-value
First	0(0)	3(9)	0.085
Second	2(6)	8(24)	0.050
Fourth	9(28)	24(70)	<0.001
Eight	22(69)	34(100)	<0.001

Values in parenthesis are percentages.

Table 4: Comparison of Side-Effects and Recurrence Rates in Different Studies

Series	Side Effects*	Recurrence Rate
Knight et al[28]	7%	34%
Kocher et al[26]	42%	None
Bielecki et al[27]	None	Not reported
Jonas et al[29]	11%	None
This Study	12%	21%

*Headache, postural hypotension and peri-anal itching

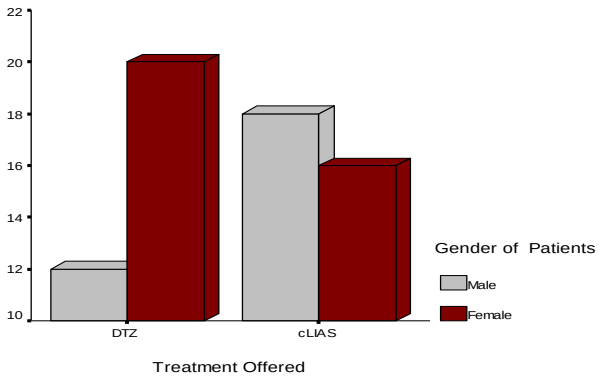

Figure: Gender Distribution Profile.

DISCUSSION

Lateral anal sphincterotomy is been considered gold standard in the management of chronic anal fissure. This option worries many surgeons because of the significant risk of incontinence as reported in work done at different centers[10]. Hence the enthusiasm to treat anal fissure conservatively. With the advent of topical agents like DTZ, GTN and Botox, the current trend is shifted towards managing this condition with an initial trial of pharmacological therapy before embarking on surgery. As these drugs reduce the sphincter tone without actually dividing it, the tone can return to pre-treatment level resulting in recurrence of disease. The conservative lateral internal anal sphincterotomy divides the sphincter to a limited extent and theoretically minimizes the risk of incontinence with complete relief in symptoms. This approach though, may prove ineffective in young tall individual with long sphincters, causing either the persistence of symptoms or recurrence. In the literature there are many comparisons between the pharmacological agents vs placebo and between two pharmacological agents[11]. Also there have been published trials comparing different pharmacological agents with surgical sphincterotomy[12]. Most of the work is been done on nitrates and botox and their efficacy being compared with surgery. The calcium channel blockers on the other hand have been proven quite effective in managing chronic anal fissure with nominal side effects mainly the headaches but relatively few studies are so far done to compare the efficacy of calcium channel blockers with surgical sphincterotomy. This study presents the experience with topical DTZ and conservative lateral internal sphincterotomy in the management of chronic anal fissure.

In the present study symptomatic relief was marked within the first two weeks in majority of patients who underwent cLIAS. This is consistent with other studies that claim surgical sphincterotomy brings rapid relief in pain associated with anal fissure[12]. At eight week follow up, all of our patients were completely healed. This is comparable with the healing rates presented by the Parellada et al[13], Algaithy Z[14] and Iswariah et al[15]. Varying degree of incontinence is been reported by different authors, more commonly observed in women. In the present study three patients, two females and a male developed transient incontinence to flatus. This minimal morbidity can be attributed to the conservative division of internal anal sphincter. Siddique et al[16] and Jaleel et al[17].

As the sphincter was divided with a conservative approach, we assumed that some patients may come back with either recurrence or persistence of symptoms. None of the patient had persistence of symptoms but one patient reported with recurrence within six months. This is comparable with 2% of Jaleel et al[17] and Rosa et al[18] but is more than what is reported by Algaithy et al[14].

At the end of the study, we came to know that healing was statistically significant in patients who underwent sphincterotomy as compared to those, who applied topical DTZ. Also, to have relief in symptoms mainly pain during defecation occurred at a slower rate in DTZ group. Fissure healing in this group was 65%, which is comparatively less than of Kocher et al[19] and Bielecki et al[20] which reported a healing rate of 77% and 86% respectively and was more in comparison to Jonas et al of 49%[21]. Table 4 elaborates the side effects and recurrence rates reported by different studies in comparison with the present study.

Chemical sphincterotomy using topical DTZ remains an effective modality in managing chronic anal fissure without the risk of incontinence. This is especially true for females for social and ethical reasons and those in their postpartum period, elderly and patients who deny surgery. Though this relief in symptoms may occur at slower pace and there is always a chance of recurrence. On the other hand, conservative lateral sphincterotomy is associated with prompt relief in symptoms, better healing and low rate of incontinence. This approach also deals with removal of sentinel skin tag, which is not possible with

topical DTZ. As the sphincter is cut conservatively, the recurrence may evolve as a problem but is much less than what is being observed with topical formulations.

CONCLUSION

We conclude that topical DTZ is an effective management for patients with chronic anal fissure and in majority it is a safe and sole treatment option. The conservative lateral internal anal sphincterotomy offers excellent results in term of rapid pain relief and better cure rates with minimal complication.

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