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CHEMICAL SPHINCTEROTOMY VERSUS SURGICAL SPHINCTEROTOMY (LATERAL INTERNAL SPHINCTEROTOMY) FOR CHRONIC FISSURE-IN-ANO – OUTCOME

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ABSTRACT: BACKGROUND: Chronic fissure-in-ano is a common problem across the world treated largely by surgical methods. Previous studies have demonstrated the efficacy of topical agents like Glyceryl-trinitrate and Diltiazem in anal fissure. Hence, this study was taken up to assess, compare the efficacy and adverse effects of topical 2% Diltiazem gel with that of Lateral internal sphincterotomy (LIS). **METHODS:** 100 patients with chronic fissure were divided into Diltiazem and LIS groups. Patients were followed up at regular intervals for symptomatic relief and healing of fissure. **RESULTS:** Fissure healed completely in 42 (89.36%) patients by 8 weeks in the Diltiazem group as compared to 48 (100%) patients by 4 weeks in the LIS group. Of the 47 patients who applied Diltiazem, 13 (27.7%) were pain-free at the end of 4 weeks, 39 (83%) by 8 weeks and 42 (89.4%) by 14 weeks, while 5 (10.6%) patients remained symptomatic at the end of 14 weeks. In the LIS group, 32 (66.7%) patients were pain-free by 4 weeks and all by 8 weekstime. Mild headache (6.4%) and local irritation (4.3%) was noticed with Diltiazem. **CONCLUSION:** Our study showed results in favor of LIS with a healing rate of 100%, however, topical 2% diltiazem gel is also an effective agent in the treatment of chronic fissure. Topical diltiazem can be safely prescribed for patients having contraindications for surgical procedures. The healing rate of the fissure is much slower compared to surgery but the need for hospital stay is abolished, psychological and financial burden on the patient is reduced. With a healing rate close to 90%, topical 2% Diltiazem can be easily advised as the first line of treatment of chronic anal fissure.

KEYWORDS: Anal Fissure; Diltiazem; Lateral Internal Sphincterotomy.

INTRODUCTION: Proctologic diseases are a group of conditions affecting the mankind since time immemorial. They encompass a diverse set of disorders which cause significant discomfort to the patients. Majority of the population (30-40%) suffers from these conditions at least once in a lifetime.¹

Anal fissure, a common disease under this category was first described by Recamier² in 1829. It is a vertically oriented tear or ulceration in the squamous lining of the anal canal between the pectinate line and anal verge. This condition is associated with pain on defecation, bleeding per anum and anal sphincter spasm. It can affect all age groups particularly young and otherwise healthy adults but shows no sex preponderance. Most of the anal fissures are acute, resolving spontaneously or with increased dietary fiber intake and stool softeners. Those lesions which fail to heal despite simple lifestyle modifications and persist beyond six weeks are designated as chronic anal fissures.

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A chronic fissure is usually deeper and generally has exposed internal sphincter fibers at its base. It is frequently associated with a hypertrophic anal papilla at its upper aspect and with a sentinel pile at its distal aspect. Painful fissures are generally associated with spasm of the internal sphincter. The natural resting tone of the internal sphincter along with that of external sphincter complex, maintains continence. Like the involuntary muscle of colon and rectum, the internal sphincter possesses the ability to go into spasm involuntarily. It is this involuntary spasm, in response to trauma of the exposed subcutaneous tissue of the fissure, which creates the severe pain associated with anal fissure disease.

Chronic anal fissures are caused due to raised resting anal canal pressure, secondary to hyper tonicity of internal sphincter and hence treatment is targeted at eliminating this. Surgical techniques like manual anal dilatation or lateral internal sphincterotomy, effectively heal most fissures within a few weeks, but may result in permanently impaired anal continence. This has led to the research for alternative non-surgical treatment, and thus 'Chemical Sphincterotomy' is being investigated and used as the possible first line of treatment for chronic anal fissure.

Topical nitroglycerine ointment has been shown to be effective but has reduced compliance due to headache as side effect. Topical calcium channel blockers offer a suitable alternative for fissure treatment, healing 65-95 % cases with lesser side effects. Topical 2% diltiazem gel has been reported to cause healing of chronic anal fissures in 60-75%, with less than 80% patients having no adverse effects in previous studies.³

The present study comprises the comparison of 2% Diltiazem gel application and Lateral internal sphincterotomy in the treatment of chronic fissure in ano with respect to both efficacy and complications.

MATERIALS AND METHODS:

Method of collection of data: The cases attending the OPD of all the units of the Department of General Surgery, KVG Medical College & Hospital, Sullia, Karnataka who came with the complaints of painful defecation with or without bleeding per rectum of more than 6 weeks duration, between July 2010 and June 2012 were considered for this study after taking due clearance from the ethical committee. With informed consent of the patient, detailed history was taken and per-rectal examination done to diagnose chronic anal fissure. Patients with hemorrhoids, anorectal abscess, anal malignancies and tuberculosis of anorectal region were excluded from this study. Patients with previous history of fecal incontinence or anal stenosis and those who had undergone previous anal surgeries were not included. Immunocompromised patients and those with history of bleeding diathesis were also not taken up.

Systemic examination and routine investigations (complete blood count, bleeding and clotting time, urine routine, random blood glucose, HIV & HBsAg) were done. Baseline clinical photographs were taken. Patients were randomly divided into 2 groups (Group A: 50 patients who were subjected to chemical sphincterotomy using topical application of 2% Diltiazem gel and Group B: 50 patients who were subjected to Lateral Internal Sphincterotomy). Chemical sphincterotomy involved local application of 2% Diltiazem gel thrice a day, for a period of 8 weeks. Surgical mode of management involved Lateral Internal Sphincterotomy. Both the groups were advised plenty of oral fluids, high fiber diet, laxatives and sitz bath. Follow-up of the patients was done by history and per-rectal examination to assess the efficacy of the treatment and complications like pain, bleeding, sphincter spasm, discharge per anum and incontinence for stools/flatatus.

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Method of application of 2% Diltiazem gel: Patients were advised to apply 1.5 to 2cms length of gel thrice daily at least 1.5cms into the anus. Patients were instructed to wash their hands before and after use of gel.

Lateral Internal Sphincterotomy: Lateral Internal sphincterotomy was carried out under spinal anesthesia. Post operatively patients were kept nil orally till evening. Adequate fluids were administered. Appropriate antibiotic coverage was given to all patients post-operatively. Patients were advised liquid diet on the day of operation and changed to soft diet on first post-operative day. All patients were given mild laxatives three tea spoons, at bed time from first post-operative day onwards and sitz bath started. Post-operative assessment for bleeding and hematoma formation was done. Patients were discharged between 3rd and 4th post-operative days.

Follow-up: Patients were followed up at 2, 4, 6, 8, 14 weeks and 6 months. During each visit enquiries were made regarding the expected complications using a simple questionnaire. Patients were also examined to look for healing of the fissure. Digital examination was done to assess the relaxation of sphincter. Signs of infection, if present were looked for. Results were tabulated and analyzed using SPSS software (19th version).

RESULTS: In our study of 100 patients, there were 54 males and 46 females with a male to female ratio of 1.2:1. The study showed that most (36%) of the patients were in the age group of 21-30 years which included 37% males and 34.8% females. 31% of patients were in the 31-40 years age group, 15% in 41-50 years age group and 9% each in 11-20 years and 51-60 years age groups.

The mean age of occurrence of fissure in males was 32.43 years and in females, 36.63 years with a standard deviation of 10.85 and 11.4 respectively.

All the patients included in the study group had painful defecation which was the most common symptom. This was followed by constipation and bleeding per anum in 82% and 76% of the patients respectively. Local pruritis was present in 12% of the patients and discharge per anum noted in 9% (Chart 1).

CHART 1: Percentage distribution of symptoms

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The occurrence of posterior anal fissure (CHART 2) was noted to be 96.2% (52 out of 54 patients) in males and 86.9% (40 out of 46 patients) in females. The overall occurrence of posterior anal fissure was found to be 92%. Anterior anal fissure was noted in 1.9% of male and 10.9% of female patients. The presence of both anterior and posterior fissure-in-ano was seen in 1.9% and 2.2% of males and females respectively. Sentinel pile was present in 78% of the patients.

CHART 2: Site of chronic fissure-in-ano

Out of the 50 patients who underwent treatment with 2% Diltiazem gel (Group A), fissures in 42 patients (89.36%) healed completely between 4-8 weeks. Of the 50 patients who underwent LIS (Group B), 48 patients (100%) had complete resolution at the end of 4 weeks.

As noted in Table I, in Group A, 13 (27.7%) patients were pain-free at the end of 4 weeks. An additional of 26 (55.3%) patients were free of pain by 8 weeks and 3 (6.4%) more patients by 14 weeks. 5 patients (10.6%) were not relieved of pain even at the end of 14 weeks. 3 patients were lost to follow up in this group. In Group B, 32 patients were relieved of pain by 4 weeks and all the patients were asymptomatic by 8 weeks time. 2 patients were lost to follow -up.

Pain relief	Diltiazem group		LIS group	
	No.	%	No.	%
At the end of 4 weeks	13	27.7	32	66.7
At the end of 8 weeks	26	55.3	16	33.3
At the end of 14 weeks	03	6.4	-	-
No relief	05	10.6	-	-

Table 1: Pain relief

Of the 47 patients that were followed up in the Diltiazem group, 3(6.4%) patients experienced mild headache and local irritation was present in 2(4.3%) patients (Table II). Out of the 48 patients that were followed up in the LIS group, 21(43.8%) patients experienced post-operative pain and transient incontinence for flatus was present in 1 (2.1%) patient.

Recurrence was seen in 1(2.1%) patient in the Diltiazem group and none in the LIS group.

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GROUP A - Diltiazem gel (n=47)	GROUP B - LIS (n=48)
Headache (n=3, 6.4%)	Post-operative pain (n=21, 43.8%)
Local irritation (n=2, 4.3%)	Incontinence for flatus (n=1, 2.1%)
Vertigo (n=0)	Bleeding (n=0)
	Infection (n=0)
Table 2: Complications in individual study groups	

DISCUSSION: Fissure-in-ano is a very common problem across the world which causes considerable morbidity and affects the patient's quality of life to a great extent. This warrants prompt treatment of the condition with appropriate methods.

The rationale of treating this condition lies in reducing the internal anal sphincter tone, relieving the spasm and thereby improving the circulation. Of the surgical modalities available, the gold standard procedure is lateral internal sphincterotomy (LIS) wherein there is partial division of the internal anal sphincter away from the fissure site. Chemical sphincterotomy, which is a medical line of treatment, has now been accepted as the first line of treatment of chronic anal fissures at various centers. As per various previous studies, diltiazem has been found efficacious in the treatment of chronic anal fissure. Studies showed that oral intake and topical applications of diltiazem reduced the anal pressure significantly.⁴

In the present study, a comparative analysis of topical application of 2% diltiazem gel and LIS was done with regards to efficacy, adverse effects and complications in patients with chronic anal fissure. The current study included a total of 100 patients of chronic anal fissure who presented to the surgery OPD at KVG Medical College & Hospital, Sullia between July 2010 and June 2012. The patients were randomly allocated into two groups of chemical (Group A) and surgical (Group B) sphincterotomy, comprising 50 patients each.

Patients with complaints of painful defecation with or without bleeding per rectum of more than 6 weeks duration were labeled as chronic fissure-in-ano and considered for this study. Patients were advised local application of 2% diltiazem gel thrice a day, for a period of 8 weeks in group A and taken up for lateral internal sphincterotomy in group B. They were adequately followed up at regular intervals and the final data was analyzed according to the proforma sheets.

In the present study, the age group most affected was 21-30 years (36%) and least affected was 11-20 and 51-60 years (9%). According to J.C. Goligher⁵ the disease is usually encountered in middle aged adults. In Udwardia T.E⁶ series maximum incidence was seen in 31-40 years age group.

There was only a slight male preponderance (54%) compared to females (46%) in our study. It is similar to the study from Bennett and Goligher⁵ which says anal fissure is equally common in the two sexes.

In our analysis, painful defecation was a universal and the most common symptom (100%). This was followed by constipation and bleeding per anum in 82% and 76% of the patients respectively. Local pruritis was present in 12% of the patients and discharge per anum noted in 9% of the study group.

The presence of posterior anal fissure was noted to be 96.2% (52 out of 54 patients) in males and 86.9% (40 out of 46 patients) in females. The overall incidence of posterior anal fissure was found to be 92% making it the most common site involved. Anterior anal fissure was noted in 1.9% of

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male and 10.9% of female patients. The incidence of concomitant anterior and posterior fissure-in-ano was seen in 1.9% and 2.2% of males and females respectively. This is in conjunction with the study from Boulos⁷ which says posterior fissure (85.7%) is more common than anterior fissure (14.2%).

Another observation made in the study was regarding the sentinel pile which was present in 78% of the patients.

Out of 50 patients who underwent treatment with 2% Diltiazem gel, 42(89.36%) fissures healed completely between 4-8 weeks, while 3 patients were lost to follow-up.

In group B, out of 50 patients who underwent internal sphincterotomy, 48(100%) patients healed completely at the end of 4 weeks and 2 patients were lost to follow-up

In the diltiazem group, 13(27.7%) patients were pain-free at the end of 4 weeks, 26(55.3%) by 8 weeks and 3(6.4%) were pain free by 14 weeks. 5 patients (10.6%) were not relieved of pain even at the end of 14 weeks. Fissure was completely healed in 42 (89.36%) out of 47 patients by 8 weeks. Study (Table III) conducted by J. S. Knight⁸ et al (2001) reported a healing rate of 75% after 8-12 weeks treatment with Diltiazem gel. U. K. Srivastava⁹ (2007) reported a healing rate of 80% with Diltiazem gel in 12 weeks.

Studies	Number of patients	Healing rate (%)
Knight et al ⁸ (2001)	66	89.4
Bharadwaj et al ¹⁰ (2000)	27	73
Kocher et al ¹¹ (2002)	31	67
Srivastava et al ⁹ (2007)	90	80
Present study	47	89.3

Table 3: Comparison of results with Diltiazem

In the LIS group, 32 patients were pain-free by 4 weeks and all the patients were free of pain by 8 weeks time while 2 patients were lost to follow-up. Fissure was completely healed in 48 (100%) out of 48 patients by 4 weeks. Scouten W.R. et al¹² reported pain relief in 98% of cases after undergoing internal sphincterotomy. Adriano Tocchhi et al¹³ (2004) reported a healing rate of 100% with internal sphincterotomy at the end of 6 weeks post-sphincterotomy review.

In our study, out of the 47 patients that were followed up in the Diltiazem group, 3(6.2%) patients experienced mild headache and local irritation was present in 2(4.3%) patients. Study conducted by U. K. Srivastava reports no side effects in patients treated with Diltiazem gel.⁹

In a study conducted by G. F. Nash et al¹⁴ 112 patients were treated with 2% Diltiazem gel for 6 weeks and were followed up over 2 years. The success rate and satisfaction of topical Diltiazem were each over two thirds. Nearly 80% of patients reported no adverse effects.

Of the 48 patients that were followed up in the LIS group 21(43.8%) patients experienced post-operative pain and transient incontinence for flatus was present in 1(2.1%) patient. Adriano Tocchhi et al. report no long-term complication after internal sphincterotomy and patient satisfaction was 96%.¹³

Recurrence was seen in 1(2.1%) patient in the Diltiazem group and none in the LIS group.

Comparison between Diltiazem gel therapy and internal sphincterotomy showed a difference in pain relief ($P < 0.001$) and fissure healing ($P = 0.02$) which is statistically significant.

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The follow up period available after successful treatment with Diltiazem gel was short and therefore no long term conclusions could be drawn. Long term follow up is needed to assess the risk of recurrence after initial healing with Diltiazem gel therapy.

Studies	Number of patients	Healing rate
Jensen et al ¹⁵ (1984)	--	100
Evans et al ¹⁶ (2001)	65	97
Wiley et al ¹⁷ (2004)	79	97
Present study	48	100

Table 4: Comparison of results with LIS

CONCLUSION: The current study shows results in favor of LIS with a healing rate of 100% and a faster pain-relief with minimal or no complications, if performed by the hands of an experienced surgeon. However, topical 2% diltiazem gel is also effective in the treatment of chronic fissure-in-ano. Though there is latency in the clearance of symptoms and lesions when compared to surgical sphincterotomy, this has shown minimal and insignificant adverse effect profile. Topical diltiazem can be safely prescribed for patients having contraindications for surgical procedures. The healing rate of the fissure is much slower compared to surgery but the need for hospital stay is abolished and it also reduces the psychological as well as financial burden on the patient. With a healing rate close to 90%, topical 2% Diltiazem therapy can be easily advised as the first line of treatment for chronic anal fissure.

Fig. 1: Chronic anal fissure

Fig.2: Healed anal fissure

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