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Original Research Article

Comparative study of topical diltiazem sphincterotomy and lateral internal sphincterotomy in the treatment of chronic fissure-in-ano: a prospective analytical study

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Abstract: Anal fissures are considered to be one of the commonest causes of proctalgia. Chronic fissure-in-ano is the condition when there is persistence of fissure for more than six weeks. Surgical techniques like manual anal dilatation or partial lateral internal sphincterotomy effectively heal most fissures, but may result in incontinence. Hence the search for alternative treatment options that includes pharmacological agents such as topical diltiazem, that doesn't result in disabling incontinence. The objective was to study the efficacy of topical diltiazem sphincterotomy for chronic fissure-in-ano. To study the efficacy of Lateral internal sphincterotomy for chronic fissure-in-ano. To compare the efficacy of Topical Diltiazem sphincterotomy with Lateral internal sphincterotomy in terms of relief of symptoms, healing of fissure, and complications. The study includes 70 symptomatic Patients, suffering from Chronic Fissure-in-ano attending the Dept. of Surgery R.L.J. Hospital & RC and attached hospitals, Kolar, during the period from October 2012 to May 2014. These seventy patients were divided into Group-P (Pharmacologic Group/ Topical Diltiazem group) and Group-S (Surgical Group/ Lateral Sphincterotomy group) of 35 patients each by odd & even method. Patients are followed up at 2^{nd}, 4^{th} and 6^{th} weeks for assessment of healing of fissure, pain relief and incontinence. Statistical analysis for P value is done by chi-square test. In Results In the present study, male/female ratio is 1.8:1; Peak incidence for development of fissure-in-ano was the fourth decade of life. Pain and bleeding during defecation were the commonest complaint. All patients complained of constipation. 98.6% of patients were consuming mixed diet. Relief of symptoms was 82.8% with group-p and 97.14% with group-s which was statistically significant with p value 0.04. Healing of fissure between the two group was statistically significant at 2 weeks, 4 weeks, and 6 weeks interval with p value <0.0001 at all three weeks. In Conclusion Lateral Internal Sphincterotomy is found to be better treatment modality for chronic Fissure-in-Ano than Topical Diltiazem ointment, in this study. It is associated with minimal post-op complications, like haemorrhage, impaired control of flatus and post op pain. However, Topical Diltiazem ointment can be used as the initial modality of treatment in patients unwilling or unfit for Lateral Internal Sphincterotomy.
Keywords: Chronic fissure-in-ano; Lateral Internal Sphincterotomy; Topical Diltiazem Sphincterotomy

INTRODUCTION:

Anal fissure or fissure-in-ano is a common condition in surgical practice. It can be a very troubling problem because the severity of the patient discomfort and extent of disability far exceeds that which would be expected from a seemingly trivial lesion. Fissure-in-ano is defined as a longitudinal split in the anoderm of the distal anal canal which extends from the anal verge proximally towards, but not beyond, the dentate line [1].

Anal fissures can be acute or chronic. It may occur at any age but is usually a condition of young adults and middle aged people. Both sexes are affected equally [2]. Its situation in the unmentionable site adds to the morbidity as the shy patients and females avoid surgical consultation. The pathogenesis of chronic anal fissure is poorly understood. Constipation and hard stools are often associated with fissure and they have been believed to initiate fissure formation [2].

Chronic anal fissure usually do not heal by simple conservative measures. They are most

commonly treated surgically by lateral internal sphincterotomy, which lowers the resting anal pressure and heals them. But, sphincterotomy carries a significant risk of incontinence [2]. This drawback of the surgical treatment has led to a search for alternative therapies.

Chemical sphincterotomy has been tried by using a variety of agents which include topical glyceryl trinitrate, calcium channel blockers such as nifedipine or diltiazem and botulinum toxin [3]. An attempt is made in this dissertation to study the comparison between surgical (Lateral Internal Sphincterotomy) and pharmacological (Topical Diltiazem Sphincterotomy) modalities of treatment of chronic fissure-in-ano.

OBJECTIVES:

1. To study the efficacy of Topical Diltiazem Sphincterotomy for chronic fissure-in-ano.
2. To study the efficacy of Lateral Internal Sphincterotomy for chronic fissure-in-ano.
3. To compare the efficacy of Topical Diltiazem Sphincterotomy with Lateral Internal Sphincterotomy in terms of relief of symptoms, healing of fissure and complications.

MATERIALS AND METHODS:

An analytical prospective study on 70 patients diagnosed with chronic fissure-in-ano was done from January 2013 and August 2014. 70 patients were included in the study that met inclusion criteria and were allotted into two groups of 35 each based on odd & even method. All odd number patients were allocated to surgical group (Lateral Internal Sphincterotomy) and all even number patients were allocated to pharmacological group (Topical Diltiazem Sphincterotomy), after a formal informed consent.

An evaluation of the two groups was done considering.

1. Relief symptoms
2. Healing of fissure
3. Post-operative complications

OBSERVATIONS:

Totally 70 cases were studied in the present series. All the cases seen at Surgery OPD or admitted and operated at R. L. Jalappa hospital & research centre and attached hospitals, kolar, during the study period with a final diagnosis of chronic fissure-in-ano were included in this study. The cases were compared keeping in mind the two modalities of treatment given.

In these prospective analytical study 70 cases of chronic fissure-in-ano are enrolled and by odd & even method divided into odd group of 35 cases-surgical group (Lateral Internal Sphincterotomy) and even group of 35 cases-pharmacological groups (Topical Diltiazem Sphincterotomy).

On comparing relief of symptoms in the 2 modalities of treatment for chronic fissure-in-ano, it was observed that symptom relief was 82.8% with topical application of Diltiazem ointment and 97.14% with Lateral Internal Sphincterotomy patients. This observation was statistically significant, i.e. Relief of symptoms was better in Lateral Internal Sphincterotomy group (Table 1).

Table 1: Comparison of relief of symptoms in both treatment modalities

Relief of Symptoms	**Lateral Internal Sphincterotomy**		**Topical Diltiazem Sphincterotomy**	
	n=35		**n=35**	
	No. of Patients	**Percentage**	**No. of Patients**	**Percentage**
Present	34	97.14	29	82.8
Absent	1	2.85	6	17.1
Total	**35**	**100.00**	**35**	**100.00**

X^2=3.968, df=1, p=0.04**

On comparing healing of fissure in the 2 modalities of treatment for chronic fissure-in-ano, it was observed that healing of fissure was complete in 24 (68.7%) patients of Topical Diltiazem group and 33 (94.28%) patients of Lateral Internal Sphincterotomy group. Time taken for fissure healing in Topical Diltiazem group is long in comparison to Lateral Internal Sphincterotomy group. 22 (62.8%) patient out of 35 in Lateral Internal Sphincterotomy group had fissure healing within 2 weeks, whereas none of the patient in Topical Diltiazem group had fissure healing during first 2 weeks. This observation of difference in healing between the two procedures was statistically significant at 2 weeks, 4 weeks, and 6 weeks interval, i.e. Healing was better in Lateral Internal Sphincterotomy group at all the intervals compared to Topical Diltiazem group (Table 2).

The results of the present study were evaluated tabulated for with the results of previous studies done (Table 3 and Table 4).

Table 2: Comparison of healing of fissure in both treatment modalities

	2 weeks		**4 weeks**		**6 weeks**		**Total**
	Healed	**No Healing**	**Healed**	**No Healing**	**Healed**	**No Healing**	
Group P	0 (0%)	35 (100%)	10 (28.57%)	25 (71.42%)	24 (68.57%)	11 (31.42%)	35
Group S	22 (62.8%)	13 (37.14%)	31 (88.57%)	4 (11.42%)	33 (94.28%)	2 (5.71%)	35
X^2,df P value	**$X^{2=}$32.08, df=1 p<0.0001****		**$X^{2=}$25.96, df=1 P<0.0001****		**$X^{2=}$19.21, df=1 P<0.0001****		

Table 3: Topical Diltiazem Sphincterotomy for Chronic Fissure-in-ano in comparison with previous studies (In percentage)

Results		**Present study**	**Knight** *et al.;* [4]	**Jonas** *et al.;* [5]	**Carapeti** *et al.,*[6]
Number of patients (n)		35	71	39	30
Healing of fissure	Complete	68.7	89.4	49	67
	Persistent	31.4	11.8	51	33
Headache		11.42	1.40	0	2.82
Perianal itching		14.28	1.40	10	4.7

Table 4: Lateral Internal Sphincterotomy for Chronic Fissure-in-ano in comparison with Previous studies (in percentage)

Results		**Present study**	**Liratezepoulos N** [7]	**Sanchez Romero A** [8]	**Syed SA** [9]
Number of patients (n)		35	246	120	112
Relief of pain	Immediate	88.57	98	100	100
	Delayed	11.43	2	0	0
Healing of fissure	Complete	94.28	97.50	100	99
	Persistent	5.71	2.50	0	1
Haemorrhage		2.85	0.80	2.50	1.70
Disturbances of anal continence	Soiling of undergarments	0	0	5	1.70
	Incontinence to flatus	8.57	7.02	7.50	2.60
	Incontinence to faeces	0	0	0	0

DISCUSSION

Fissure-in-ano, a common disease of the anal canal, basically consists of a crack in the squamous lined part of the anal canal and is remarkably constant in its situation, posterior midline, with a few exceptions. It starts as an acute tear in the anoderm probably due to over stretching from passage of a large or hard stool.

The angulation of the anal canal and the elliptical shape of the superficial portion of the external sphincter leave the posterior midline segment of the internal sphincter relatively unsupported and this leaves the posterior midline more prone for fissure formation. Recent studies have indicated that the posterior midline region of the anal canal has a relatively reduced blood supply. With reduced or minimal nutrition, healing of any injury is delayed, which explains the development of chronic fissures.

Constant hyper tonicity in the sphincter muscles will compress the blood vessels supplying the anoderm and leads to the development of ischemic ulcers. These ischemic ulcers refuse to heal with adequate conservative treatment unless the sphincter muscle is relaxed.

In the present study, male/female ratio is 1.8:1, consisting of 45 male and 25 female patients. Peak incidence for development of fissure-in-ano was the fourth decade of life. Pain and bleeding during defecation were the commonest complaint in patients with chronic fissure-in-ano (100%). The presenting complaints documented in the study by Khubchandani and Reed were pain (23.5%), bleeding (76.2%), pruritis ani (34.9%) and an anal lump (24.3%) and burning sensation in the anal region (33%) [10].

In the present study, all 70 patients (100%) complained of constipation. In the study by Jensen *et al.;* in 1967, 67% of patients complained of constipation [11]. 98.6% of patients were consuming mixed diet consisting of both vegetarian and non-vegetarian food and 1.4% was purely vegetarian.

The symptoms relief, fissure healing was significantly better in Lateral Internal Sphincterotomy

group when compared to the Topical Diltiazem group of patients with low post operative complications. These findings are statistically significant.

CONCLUSION:

Lateral Internal Sphincterotomy is found to be better treatment modality for chronic Fissure-in-Ano than Topical Diltiazem ointment, in this study. It is associated with minimal post-op complications, like haemorrhage, impaired control of flatus and post op pain. However, Topical Diltiazem ointment can be used as the initial modality of treatment in patients unwilling or unfit for Lateral Internal Sphincterotomy.

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