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Original Research Article

Efficacy of chemical sphincterotomy with 2% diltiazem cream vs. surgical sphincterotomy in the management of chronic fissure in ano: a clinical study

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ABSTRACT

Background: Surgical intervention like lateral internal sphincterotomy is very effective and in a time of few weeks, healing can occur but there is danger of the anal incontinence. Hence alternative methods were sought like 2% diltiazem and other agents and they have been shown to lead to proper healing without anal incontinence. The objective was to study efficacy of chemical sphincterotomy with 2% diltiazem cream vs. surgical sphincterotomy in the management of chronic fissure in ano.
Methods: A hospital based follow up study was carried out among 60 patients with chronic fissure in ano. They were randomly assigned in two groups. Group I consisted 30 patients who were treated with 2% diltiazem cream on outpatient basis. Group II patients i.e. 30 patients were operated for sphincterotomy. Both the group patients were followed for six weeks at two weeks interval. Outcome like complete healing, fecal incontinence, flatus incontinence was seen at follow up. Chi square test and t test were used to determine the significant difference between the groups.
Results: Both the groups were comparable to each other in terms of age, sex, presenting symptoms, mean duration of symptoms and internal findings. Diltiazem group patients had significantly much better healing rate i.e. 96.7% compared to only 80% from patients with surgery group. Incidence of complications like fecal/flatus incontinence was zero in diltiazem group compared to 13.3%/20% in surgery group.
Conclusions: Authors conclude that diltiazem 2% topical application is better than surgical sphincterotomy and should be used instead of surgery.

Keywords: Chemical sphincterotomy, Chronic fissure in ano, Outcome, 2% topical diltiazem

INTRODUCTION

The most common cause of pain in the anus of severe nature is the fissure in ano. In Anal fissure or fissure in ano, there is a vertical tear in the distal part of the anal canal or presence of ulcer in the distal part of the anal canal. The usual location of anal fissure is in the midline of the anal canal either posterior or anterior. It usually starts from dentate line and extends up to the anal verge. If the patient presents within 3-6 weeks of formation of the anal fissure or from the occurrence of the symptoms of the anal fissure, then it is called as acute anal fissure. On examination, in the anoderm, it looks like a clean vertical tear with areas of inflammation surrounding it. There are chances of spontaneous healing in case of acute anal fissure and this usually takes place in the first six weeks. If the patient presents after six weeks of appearance of the symptoms, then it is called as chronic

anal fissure. By this time, it becomes deeper. At the base of the anal fissure, the internal fiber gets exposed. It can be idiopathic or may be due to some other causes which are called as secondary. Tuberculosis, Crohn's diseases etc. can lead to the formation of secondary anal fissures. Pain while passing stools, and bleeding per rectum are the common presentations of anal fissure. The exact cause is not known but trauma due to hard stools can cause team in the anal canal which leads to the formation of the anal fissure. Frequent acute diarrhea can also cause anal fissure. Due to pain, there is spasm in the anal canal which leads to resistance to pass the stools and this aggravates the anal fissure. Thus, over activity of the internal sphincter can also lead to the formation of the anal fissure. If the spasm can be reduced, then the blood supply improves, and the healing takes place. Surgical intervention like lateral internal sphincterotomy is very effective and in a time of few weeks, healing can occur.[1,2] but there is danger of the anal incontinence. Hence alternative methods were sought like 2% diltiazem and other agents and they have been shown to lead to proper healing without anal incontinence.[3]

Pain in the anus is the most common feature that causes lot of discomfort for patients with anal fissure. After one or two hours of passing stools, pain occurs. Anal fissure for more than six weeks is usually called as chronic anal fissures. The exact mechanism that leads to the formation of the anal fissure is not yet very clear. Chronic constipation, passing hard stools due to less water intake or less fibres in the diet are implicated as the risk factors for chronic anal fissure. Reduced blood supply to the posterior side of the anal canal in its midline is a risk factor which adversely affects the healing of the fissure in ano.[4]

"The American Society of Colon and Rectal Surgeons (ASCRS)" had recommended non-surgical management of chronic fissure in ano. They recommended use of high fibre diet, use of stool softeners and sitz bath in the early part of the management of the anal fissure.[5]

Topical therapies or injected therapies were found to be only slightly effective compared to the placebo in the treatment of the fissure in ano in the Cochrane review. Hence, they recommended that lateral internal sphincterotomy is the only gold standard for treatment of the chronic fissure in ano.[6]

But the danger with surgical intervention is that it can lead to flatus incontinence or fecal incontinence. Hence chemical sphincterotomy should be tried. NICE, UK has issued an evidence-based summary on the role of diltiazem in the management of the chronic anal fissures.[7]

Hence present study was undertaken to study the efficacy of chemical sphincterotomy with 2% diltiazem cream vs. surgical sphincterotomy in the management of chronic fissure in ano.

METHODS

This was a hospital based follow up study. The study was carried out at Department of General Surgery, Government Medical College, Mahabubnagar. The study was carried out over a period of one and half years from April 2017 to October 2018. During the study period, it was possible to include 60 patients as per inclusion and exclusion criteria set out for the present study.

Inclusion criteria

- Patients with confirmed diagnosis of anal fissure
- Patients age ranging from 18years to 60years of both the sexes
- Patients willing to be part of the present study

Exclusion criteria

- Patients with co-morbidities of severe nature
- Age <18years and >60years
- Patients not willing to be part of the present study
- Patients who were bed ridden and were not able to participate in the present study.

Institutional Ethics Committee permission was sought before the present study was started. Patients in the present study were included only after they gave written informed consent.

All patients presenting to outpatient department of General Surgery, Government Medical College, Mahabubnagar with symptoms of anal fissure were examined thoroughly and a detailed history was taken as per the proforma.

The patients were finalized for the present study as per the inclusion and exclusion criteria. If they were willing, they were included in the present study. After history and general examination, local examination was carried out which included the digital rectal examination to assess the extent and the degree of the anal fissure. Proctoscopic examination was also carried out in all patients and the findings were noted down.

Whenever authors felt the need, colonoscopy and sigmoidoscopy was carried out if required.

Out of 60 patients thus selected for the present study, 30 patients were randomly assigned in group I and the remaining 30 patients in group II.

Group I patients were treated for anal fissure on outpatient basis and they were given 2% topical diltiazem which was applied around the anal skin. They were asked to apply it twice a day. The duration of this treatment was for six weeks.

Group II patients were treated on in-patient basis. They were operated using lateral internal sphincterotomy method.

Follow up

All patients were followed for six weeks and outcome like flatus incontinence and fecal incontinence was noted in both the group patients.

Statistical analysis

The data was expressed as proportions and means. Chi square test and students t test was used to determine the efficacy of the treatment groups.

RESULTS

Both the groups were comparable in terms of distribution of males and females in the present study. The p value was more than 0.05. The number of males and females in both the groups were also not much different from each other. So, fissure in ano can affect both sexes equally.

Table 1: Distribution as per sex.

Sex	Group I		Group II		Chi square	P value
	N	%	N	%		
Male	16	53.3	13	43.3	0.267	0.3027
Female	14	46.7	17	56.7		
Total	30	50	30	50		

Both the groups were comparable in terms of average age in the present study. The mean age in the group I patients was 39.32years and the mean age of patients from group II was 41.35years. The difference was statistically not significant.

Table 2: Comparison of mean age between the two groups.

Age (years) Mean±SD	Group I	Group II	T value	P value
	39.32± 12.45	41.35± 14.32	0.5860	0.5602

Bleeding per rectum was the most common presenting symptom in both the groups affecting about 90% of the patients. But in group II patients, pain was the presenting symptom in all the patients. Hence pain, bleeding, constipation were the main presenting symptoms in the present study for patients from both the groups. Both groups were comparable in terms of symptoms. Mean duration of symptoms were also comparable for both the groups.

Only co-morbidities were diabetes and hypertension. Four patients from group I and six patients from group II were found to have diabetes. Three patients from group I and two patients from group II were found to have hypertension. Thus, both the groups were comparable in terms of presence of co-morbidities.

Posterior midline anal fissure was seen in 80% of the patients as compared to 73.3% of the cases from group II, but the difference was not significant. Anterior midline anal fissure was seen in 13.3% of the patients as compared to 16.7% of the cases from group II, but the difference was not significant. Anterior as well as Posterior midline anal fissure was seen in 3.3% of the patients as compared to 6.7% of the cases from group II, but the difference was not significant.

At the end of second week, no patient from either group has healing of the fissure. But at the end of four weeks, 63.3% of the patients from group I had healing compared to only 40% of the cases from group II and this difference was found to be statistically significant. At the end of six weeks, 96.7% of the patients from group I had healing compared to only 80% of the cases from group II and this difference was found to be statistically significant.

Table 3: Comparison of symptoms between the two groups.

Symptoms	Group I		Group II		Chi square value	P value
	N	%	N	%		
Pain	20	66.7	30	100	0.979	0.6129
Bleeding	26	86.7	27	90		
Constipation	22	73.3	24	80		
Mean duration of symptoms	7.27±2.6		7.85±2.9		T value 0.8156	0.4180

Total 20% of the patients from group II had flatus incontinence compared to zero percent of the cases from group I and this difference was found to be statistically significant. 13.3% of the patients from group II had fecal incontinence compared to zero percent of the cases from group I and this difference was found to be statistically significant.

Table 4: Comparison of co-morbidity between the two groups.

Co-morbidity	Group I		Group II		Chi square value	P value
	N	%	N	%		
Diabetes	4	13.3	6	20	0.03348	0.4274
Hypertension	3	10	2	6.7		
Total	7	23.3	8	26.7		

DISCUSSION

A hospital based follow up study was carried out among 60 patients with chronic anal fissure. They were randomly assigned into two groups of 30 each. Both the groups were comparable in terms of age, sex, symptoms,

duration of symptoms, presence of co-morbidities and local findings per rectum or on sigmoidoscopy. Diltiazem group i.e. group I was found to be more effective than surgical intervention in terms of healing rate and occurrence of complications.

Table 5: Comparison of local findings between the two groups.

Local findings	Group I		Group II		Chi square	P value
	Number	%	Number	%		
Posterior midline anal fissure	24	80	22	73.3	0.542	0.9692
Anterior midline anal fissure	4	13.3	5	16.7		
Anterior + posterior anal fissure	1	3.3	2	6.7		
Multiple/lateral fissure	1	3.3	1	3.3		
Sentinel pile	25	83.3	26	86.7		
Sphincter spasm	27	90	26	86.7		

Table 6: Comparison of outcome between the groups.

Healing of fissure	Group I		Group II		Chi square	P value
	Number	%	Number	%		
At the end of second week	0	0	0	0	-	-
At the end of fourth week	19	63.3	12	40	3.27	0.0358
At the end of six weeks	29	96.7	24	80	4.043	0.02218

Table 7: Comparison of complications between the groups.

Side effects	Group I		Group II		Chi square	P value
	Number	%	Number	%		
Flatus incontinence	0	0	6	20	4.63	0.0157
Fecal incontinence	0	0	4	13.3	4.286	0.01922

Giridhar CM et al, carried out a study and found that the healing rate was 88.46% in surgical group compared to 100% in the diltiazem group.[8] Authors also found that the healing rate was 80% in the surgical group compared to 96.7% in the diltiazem group. The authors also reported that the mean duration of healing was much less in the diltiazem group compared to surgical group. Pain was relieved in 78.3% of the cases in surgical group compared to 85.2% in the diltiazem group. The authors did not find any side effects in either group. Thus, the authors concluded that topical diltiazem is superior to surgery. They mentioned that surgery should be second option in case the diltiazem therapy fails.[8]

Vaithiananthan R et al, explored the role of diltiazem as an alternative to surgical intervention in patients with fissure in ano.[9] They found that in diltiazem group the healing rate was 71% compared to 96% in the surgery group. But in the present study we found that the healing rate at the end of six weeks was more in the diltiazem group compared to the surgery group. The authors found that the VAS score was higher i.e. 3.38 in the diltiazem group compared to only 1.87 in the surgery group. Two patients in the diltiazem group had flushing and headache. Thus, the authors concluded that surgery is better than topical diltiazem but also suggested to try diltiazem as an initial option before going for surgery.[9]

Abhivardan D et al, carried out a prospective study in 80 patients and assigned 40 patients each randomly in two groups; one group with diltiazem and the other group patients underwent surgery.[10] They noted that in the diltiazem group 37 out of 40 patients had complete healing. In this diltiazem group only three patients had recurrence. They concluded that 2% diltiazem should be preferred only for acute fissure in ano and for the management of the chronic fissure in ano, surgery is better than topical diltiazem.[10]

Chauhan A et al, carried out a study over 18 months and studied 108 patients having hemorrhoids with grade three and four.[11] They divided the patients in two groups randomly. One group underwent surgery and the other group patients received 2% topical application of diltiazem. They found that the VAS was much less in surgery group patients compared to diltiazem group patients and the difference was statistically significant. The requirement of pain killers was much significantly lesser in the surgery group compared to the diltiazem group. The authors concluded that in cases of hemorrhoidectomy, surgical internal sphincterotomy is

better than diltiazem in terms of post-operative pain relief.[11]

Gandomkar H et al, noted that healing rate was better in the surgery group and this finding was in contrast to the finding of the present study.[12] But the authors also observed that the fecal incontinence was significantly higher in the surgery group compared to the diltiazem group. This finding is in accordance with the finding of the present study. The authors also found that healing rate was better in surgery group if the duration of fissure was longer but was similar if the duration of the fissure was lesser. The authors concluded that if the duration of the fissure is less than twelve weeks, then diltiazem should be used instead of surgery.[12]

CONCLUSION

Authors found that the healing rate was better in the diltiazem group compared to the surgery group. Also, the incidence of fecal incontinence and the flatus incontinence is zero in the diltiazem group whereas few patients from surgery group had this complication.

Hence 2% topical application of diltiazem should be the first treatment of choice.

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