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Diltiazem gel versus Lateral Sphincterotomy in the Treatment of Anal Fissures

Ahmed M. N. Alsarraf [(1)]; Mohammed H. M. AlALI [(2)]; Jasim M. J. AL-MOULA [(3)]

[(1)] CABMS,HDGS; [(2)] CABMS,FICMS,MRCS; [(3)] F.I.C.M.S.G.S

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ABSTRACT

Background: An anal fissure is defined as an ulcer in the anoderm usually in the posterior midline, less frequently in the anterior midline, and rarely in the lateral position of the anal canal.

Objective: The objective of this study was to compare the efficacy of outcome of lateral internal sphincterotomy with topical 2% Diltiazem gel in the treatment of chronic fissure in ano.

Methodology: 100 patients were randomly selected from the admitted patients with chronic fissure in ano. where this study was done from August 2018 to August 2019. were randomly divided into Group 1 (Diltiazem gel) and Group 2 (internal sphincterotomy) with 50 patients in each Group. The data obtained was analysed using SPSS software version 20.0.

Results: Dominant part of the fissure were back in area with sentinel pile present in 46 of cases. Cases were followed up at week by week intervals for 6 sequential weeks and every other week for consequent 3 months. 2 cases from Group 1developed fistula in ano and required medical procedure. 25 of patients in Group 1 and 50 of patients in Group 2 had completely healed fissures at the end of 4 weeks. 48 of patients in Group 1 who were totally healed with Diltiazem gel application and 49 of patients in Group 2 were free from pain toward the part of the arrangement. Three patients in Group 1, whose fissure did not recuperate following a month and a half of Diltiazem application and stayed symptomatic, in this manner experienced inner sphincterotomy and fissures healed in about a month after medical procedure. The mean length of healing was relatively longer in Group 1(5.04 weeks) than Group 2 (3.6 weeks). Confusion was accounted for in 1 case in Group1 which was return in signs and indications which required sebsequent medical procedure.

Conclusion:

Hence Subcutaneous fissurectomy with topical 2% Diltiazem gel is a better surgical option for chronic fissure in ano than conventional Lateral internal sphincterotomy.

Corresponding author E mail: ahmedalsarraf74@gmail.com

Introduction:

Anal fissure is a unique clinicopathological disorder affecting the lower anal canal.[1] An ulcer in the anoderm, generally in the posterior midline, but less commonly in the anterior midline and infrequently in the lateral location of the anal canal, can be identified. The fissure appears to be triangular in shape when traction is given on each side of the anus, with the apex at the dentate line and the base across the lower anal canal. [2] The primary and secondary types of fissures can be distinguished. [3] The main or idiopathic kind of fissure is the most prevalent, however the actual etiology is unknown. There is a fissure in the midline, either posteriorly or anteriorly. [4] If the primary fissure is not treated while it is still acute, permanent organic changes in tissues such as ulcer margin indurations, ulcer base fibrosis, development of sentinel pile, and anal papilla occur, leading to chronic stage. [5] Some pathological conditions of the anal canal, such as Crohn's disease, ulcerative colitis, trauma, previous anorectal operations, or infection, cause secondary types of fissures. [6,7] They will only heal if the underlying pathology is removed or treated. [8] Typically, fissures of this nature are seen eccentrically along the anal edge. [9] Before the 19th century, there is no evidence of anal fissure surgery in the literature. [10] Only cautious remedies like a high-fiber diet and stool softeners were advised at the time. Recamier proposed anal sphincter stretching in 1829, and it gained popularity in 1968 when Lord employed it on a significant number of patients. [11][12] Because of the high rate of problems, Eisenhammer coined the term "internal sphincterotomy," which involves separating the sphincter in the posterior midline. [1]. Parks described open LAS (lateral anal sphincterotomy) in 1967 because of the very extended healing period necessary in this type of treatment.[5] In 1969, Notaras reduced this to the

closed lateral anal sphincterotomy. [1] A trial of fiber supplements, sitz baths, and topical analgesics has long been the usual strategy for anal fissure therapy. [2] Surgery is a possibility if the pain is unbearable or if conservative treatment fails. [3] Many therapeutic alternatives have emerged since Lord's anal dilatation, including lateral internal sphincterotomy and sclerotherapy (using Sodium tetradecyl sulphate).[4] Topical glyceryl trinitrate, calcium channel blockers such as Nifedipine or Diltiazem, and Botulinum toxin are all examples of chemical sphincterotomy. [15]

In general, anal problems are grossly underappreciated. According to studies, people conceal anal symptoms, resulting in late identification and treatment. [1] General practitioners' management is inadequately characterized. Anal fissure is a frequent and painful condition for which conservative therapy should be reserved. [2] The cornerstones of therapy include hygiene guidelines, stool softeners, and topical local anesthetic drugs. Healing takes a lengthy period in most cases. [15] Recurrences can be avoided by using stool softeners on a regular basis. Chronic fissures, acute fissures unresponsive to two months of conservative therapy, and persistent painful forms are all candidates for surgery. [5] Diltiazem and nifedipine, both oral and topical calcium channel blockers, have been demonstrated to be effective treatments for anal fissures. Calcium channel blockers cause blood vessels to dilate. They can aid in the healing of anal fissures. [3] Headaches are one of the possible side effects. Anal fissures can also be treated with calcium channel blockers taken orally. However, this may take longer and have more noticeable negative effects. Anal fissures that have been present for a long time are generally repaired surgically.[4]

The objective of this study was to compare the efficacy of outcome of lateral internal sphincterotomy with

topical 2% Diltiazem gel in the treatment of chronic fissure in ano.

Methodology:

The study was a prospective, parallel group, randomised, comparative study. 100 patients were randomly selected from the admitted patients with chronic fissure in ano. The study was approved by the Institutional Ethics Committee. Informed written consent was taken from all patients prior to enrolling into the study. Study was done from August 2018 to August 2019

Inclusion criteria

Patients between 20 to 60 years of age of male

Admitted patients of chronic fissure in ano not

responding to conservative management for more than 2 months

Exclusion criteria

Children and mentally challenged patients

Recurrent fissures

Fissures with haemorrhoids and fistula

Fissure associated with malignancies

Fissure secondary to specific diseases like tuberculosis, Crohn's disease etc.

Pregnant women

Patients who have undergone previous anal surgeries

In this prospective trial, 100 surgical out patients and/or admitted patients with chronic fissure in ano were randomly divided into Group 1 (Diltiazem gel) and Group 2 (internal sphincterotomy) with 50 patients in each Group.

Patients were followed up on weekly for six weeks and then biweekly for the next three months. The ethics committee in the area gave its clearance.

For 6 weeks, patients in Group 1 were instructed to apply 1.5 to 2 cms of gel twice daily, at least 1.5 cm into the anus. Before and after using the gel,

patients were encouraged to wash their hands. Group 2 patients had a left lateral internal sphincterotomy performed under spinal or general anaesthesia. Cases in both groups were instructed to take three teaspoons of cremaffin (milk of magnesia 11.25 ml, liquid paraffin 3.75 ml, per 15 ml of emulsion) before bedtime, eat a high-fiber diet, and take warm sitz baths. For the first six weeks, cases were examined weekly in the Outpatient Department, then biweekly for the next three months. At each appointment, questions about pain alleviation, flatus/feces leaking, and other adverse effects were asked. Visually, healing was defined as the total elimination of the fissure. Pain was measured using a pain scale ranging from 0 (almost pain-free) to 4 (very painful) (severe pain). The data was collected and evaluated, and the Chi Square test was used to get the p-values. The majority of the fissures were posterior, with a sentinel pile in 80 of the cases. For the first six weeks, cases were followed up on weekly, then biweekly for the next three months. Two of the individuals in Group 1 developed a fistula in the ano, necessitating surgery. After four weeks, 25 patients in Group 1 and 50 patients in Group 2 had totally healed fissures. At the end of three months, 48 patients in Group 1 were entirely healed with Diltiazem gel application while 49 patients in Group 2 were pain-free. Three patients in Group 1 had internal sphincterotomie after their fissures did not heal after 6 weeks of Diltiazem administration and remained symptomatic. The fissures closed in 4 weeks following surgery. The average healing time in Group 1 (5.04 weeks) was significantly longer than in Group 2. (3.6 weeks). One instance in Group 1 had a complication, which was a recurrence of signs and symptoms that necessitated further surgery. There was no difference in pain alleviation or fissure healing when Group 1 and Group 2 were compared.

Application of diltiazem gel :

Patients in Group 1 were instructed to administer a 2 cm length of 2 percent Diltiazem gel at least 1.5 cm into the anus twice daily. Before and after using the gel, patients were encouraged to wash their hands. 13 SPSS software version 20.0 was used to analyze the data. The chi square test and the student's t test were used to compare Group 1 with Group 2. The mean and standard deviation of various parameters are used to express descriptive results. The degree of significance was determined using the probability value (p value). A p value of 0.05 was deemed significant, and a p value of 0.01 was regarded extremely significant.

RESULTS:

In the present study we found majority of the subjects were in the age group of 30-50 years (Table 1) and (figure1). This study showed bulk of the patients were males.

Table 1: Age distribution

Age in years	No. of patients	Percentage (%)
21-30	26	26
31-40	40	40
41-50	30	30
51-60	4	4

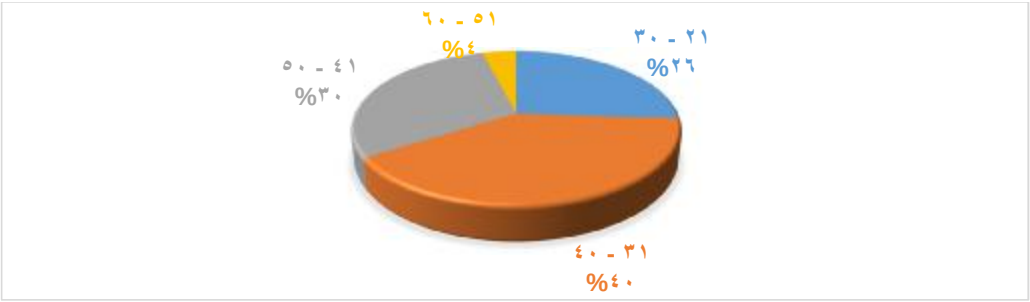

Figure 1: showed percentage of age for patient

Posterior fissure in ano was more common (80%) in this study (Table 2) and (figure 2) showed it.

Table 2: Fissure location.

Site	No. of patients	Percentage (%)
Anterior	20	20
Posterior	80	80

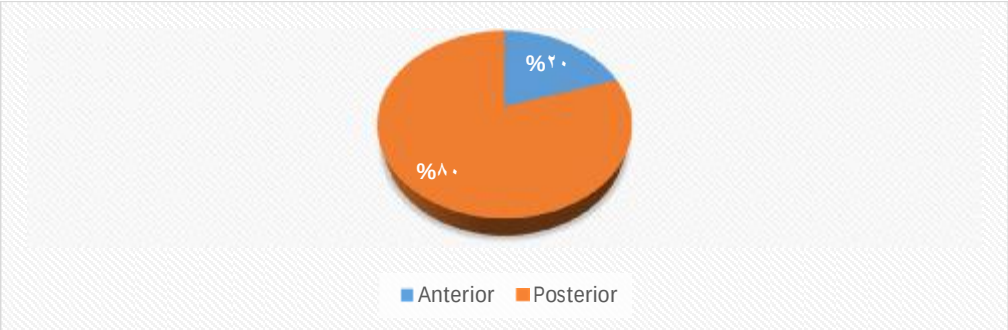

Figure 2: showed percentage of fissure location in patients.

According to this study, 46 (46%) of patients had a preoperative sentinel pile, and all of them had sphincter spasm (100 percent). After 3 weeks, all of the patients were followed up on, and the mean NRS pain score in Group 2 was considerably greater than Group 1 (p=0.0004) (Table 3).

Table 3: Comparison of pain score in patients after 3 weeks follow up.

NRS score for pain	Group 2		Group 1	
	Mean	SD	Mean	
Pain	6.84	1.46	Pain	6.84
t- value	3.8112			

After three months of follow-up, it was shown that the mean pain score in Group 2 was 1.84, compared to 0.6 in Group 1. This reduction in average pain was statistically significant (p0.0001) (table4).

Table 4: Comparison of pain score in patients after 3 months follow up

NRS score for pain	Group 1		Group 2	
	Mean	SD	Mean	
Pain	1.84	1.1789	0.6	0.707
t- value	4.5102	P <0.0001		

In this study, the comparison of complications in patients after 3 months showed that none of the patients in Group 1 had complications, but 16 percent of the patients in Group 2 had complications, including one case of wound infection, two cases of flatus incontinence, and one case of recurrence of symptoms. Complications occurred at a considerably greater rate (p=0.03) in Group 1 (Table 5) and (Figure 3).

Table 5: Comparison of complications in patients after 3 months follow up.

Complications	**Group 2**		**Group 1**	
	No	%	No	%
Present	8	16	0	0
Absent	42	84	50	100
Chi square	4.34		p 0.03	

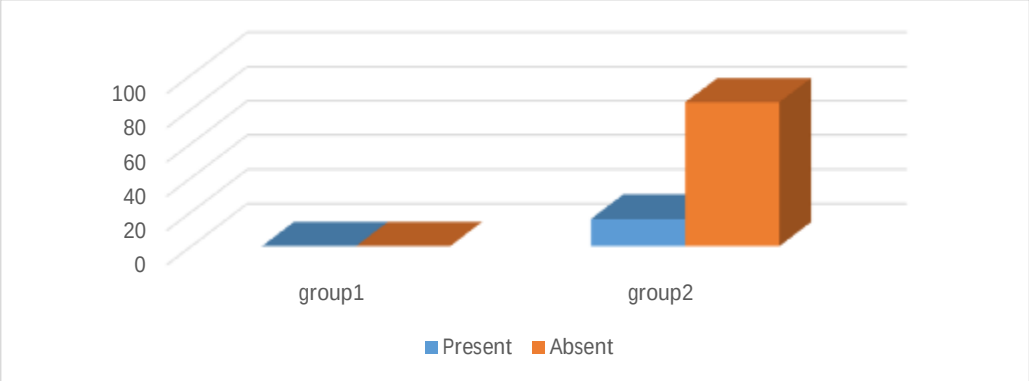

Figure3: Comparison of complications in patients after 3 months follow up

In the current study, we discovered that patients in Group 2 required a sitz bath following surgery for an average of 6.12 weeks, compared to 3.44 weeks for patients in Group 1. In group 1, the length of the sitz bath was substantially longer (p0.0001) (table6).

Table 6: Comparison of mean duration of Sitz bath in patients after surgery.

Sitz bath (weeks)	Group 2		Group 1	
	Mean	SD	Mean	SD
Sitz bath	6.12	1.4525	3.44	1.5567
t value	6.2937		P<0.0001	

When the mean duration of absenteeism in patients following surgery was compared, patients in Group 2 had a longer mean duration of absenteeism, 4.56 weeks, whereas patients in Group 1 had a shorter mean duration of absenteeism, 2.88 weeks. In group 2, the period of absence was substantially longer (p0.0001) (table 7).

Table 7: Comparison of mean duration of absenteeism in patients after surgery.

Absenteeism (weeks)	Group 2		Group 1	
	Mean	SD	Mean	SD
Absenteeism	4.56	0.961	2.88	1.364
t value	5.0343		p <0.0001	

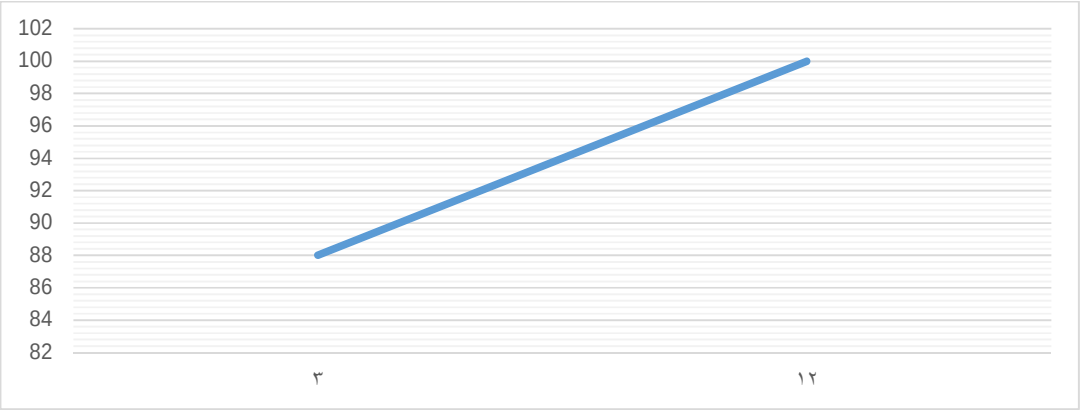

Figure 4: showed percentage healed of patient

DISCUSSION:

Anal fissure is associated with a high rate of morbidity and has a negative impact on one's quality of life. Surgery is the simplest and most successful approach to reduce internal anal sphincter tone. In the treatment of persistent anal fissures, lateral internal sphincterotomy is the gold standard RATHER et al 2010. [1] The internal anal sphincter is partially divided away from the fissure. Calcium channel blockers have been demonstrated to improve fissure healing and reduce resting anal pressure MAGDY et al 2012. [2] Diltiazem was shown to be effective in the treatment of chronic fissure in ano in a research by STEWART et al 2017. [3] Diltiazem, when taken orally and applied topically, dramatically decreased anal pressure and improved healing rates, according to a study. ASLAM et al 2014 found that Diltiazem was a viable option to glyceryl trinitrate, with better healing rates and reduced recurrence rates. [4]

In this study, the most common age group impacted was 31- 40 years (40 percent), which matches the findings of KARABULUT et al 2012, who found that the most common age group affected was 31- 40 years. [5] Though the frequency of chronic fissure was identical in both sexes in the same research, we only looked at guys in ours. According to BOBKIEWICZ et al 2016, roughly 90% of anal fissures in both men and women are placed posteriorly in the midline, while anterior fissures occur in 10% of patients; however, we observed the frequency of anterior fissure to be around 20% and posterior fissure to be around 80%. By the end of the third week, the average pain score in Group 1 was 5.36, and by the end of three months, it was 0.6. By 3 weeks, 44 (88%) of 50 patients had recovered entirely, and 50 (100%) had healed fully by the end of 3 months.[3] As indicated in the diagram (figure 4).

Subcutaneous fissurectomy is a relatively new treatment, and there are few data on it. According to

NELSON et al 2010, 100 percent of 118 patients who had subcutaneous fissurectomy sustained undisturbed wound healing, with just 2% experiencing flatus incontinence. [28] In this study there was no incontinence in Group 1 KARABULUT et al 2012 reported no long-term complication after internal sphincterotomy and patient satisfaction was 96%. [29] According to MADALINSKI et al 2011 with LIS, 140 out of 146 patients had completed healing of fissure by 3 months out of which 124 patients healed by 6 weeks, 12 patients healed by 7 weeks and 4 patients by 3 months. [21] Overall, 97.5 percent of patients were cured. However, 4.1 percent of individuals had temporary gas incontinence. There were no long-term problems in this trial, and patient satisfaction was 100%, however 2 (4%) of patients in group A experienced transitory flatus incontinence. There was no recurrence in group 1 in this trial, while there was one (2%) recurrence in group 2. Patients in group 1 required a sits bath for 3.44 weeks on average, whereas patients in group 2 required a sits bath for 6.12 weeks on average. The average duration of Group 1 patients was 3.44 weeks. Group 2 patients had a substantially shorter absence of 2.88 weeks compared to 4.56 weeks for group 1. Pain alleviation (p 0.001), complications (p = 0.03), mean sits bath length (p 0.0001), and absenteeism (p 0.0001) were all statistically significant differences between groups 1 and 1, which is in agreement with the results reached by RATHER et al 2010in their study. [25]

CONCLUSION:

As a result, for persistent fissure in ano, subcutaneous fissurectomy with topical 2 percent Diltiazem gel local is a superior surgical choice than lateral internal sphincterotomy. However, considerable work has to be done in terms of long-term outcomes, which will require more detailed and bigger clinical trials.