

Outcome of Botulinum Toxin with Lateral Internal Sphincterotomy for Treatment of Chronic Anal Fissure

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ABSTRACT

Background: Therapies that reduce anal sphincter pressures have been used to achieve fissure healing. Lateral internal sphincterotomy (LIS) is the most common treatment for CAF and can be effective in more than 90 percent of cases but needs general or local anesthesia.

Aim: To compare the outcome of Botulinum toxin with lateral internal sphincterotomy for treatment of chronic anal fissure.

Methods: This Randomized control trials was conducted at Department of Surgery, Jinah Hospital Lahore. Using non-probability purposive sampling study was completed in six months. Patients were divided into two groups. Informed and written consent was taken. Fifty patients in Group A received treatment with Botulinum toxin (0.5cc of Injection Neuronox injected in the sphincters under direct vision and digital examination) and fifty patients in group B with internal sphincterotomy (distal internal sphincters was incised surgically with electrocoagulation). Patients were discharged next day from hospital and follow up was done after two weeks. At follow up, patients were evaluated for fecal incontinence (yes or no), healing (yes or no) and recurrence (yes or no).

Results: In our study, age and gender were insignificantly different while comparison of recurrence of anal fissure in both groups show 10(20%) in Group-A and 2(4%) were in Group-B while 40(80%) in Group-A and 48(96%) in Group-B had no recurrence, p value was computed as 0.02, 19(38%) in Group-A and 43(86%) were in Group-B while 31(62%) in Group-A and 7(14%) in Group-B could not heal, p value was 0.000, while fecal incontinence of anal fissure in both groups was compared and it shows 3(6%) in Group-A and 5(10%) in Group-B had fecal incontinence while 47(94%) in Group-A and 45(90%) in Group-B had no fecal incontinence, p value=0.71.

Conclusion: Comparison of the outcome of Botulinum toxin with lateral internal sphincterotomy for treatment of chronic anal fissure concludes that lateral internal sphincterotomy is significantly better and may be offered in our patients in future.

Keywords: Chronic anal fissure, Botulinum toxin Injection, lateral internal sphincterotomy

INTRODUCTION

Anal fissure is a common peri-anal condition presenting with bleeding, itching and pain of varying severity¹. It usually results from poor anodermal perfusion due to an elevated resting anal pressure.² The internal sphincter spasm is the main factor in the pathogenesis of chronic anal fissure. Therefore the treatment of this condition is aimed to reduce the internal sphincter hypertonia.³ Lateral internal sphincterotomy is the most frequently performed surgical procedure for treatment of chronic anal fissure. It acts by sphincter hypertonia which is the main etiological factor in the development of chronic anal fissure. However sphincterotomy also carries a

significant risk of incontinence³. In comparison to lateral internal sphincterotomy, less invasive strategies have been advocated for sphincter relaxation, including local application of nitroglycerin or diltiazem hydrochloride and injection of botulinum toxin into the internal sphincter, resulting in a temporary chemical or medical sphincterotomy until the fissure heals. These methods are increasing in popularity^{4,5}.

In a study by Arroyo A, et al, compared the both treatment options were compared among 80 patients with anal fissure. Overall healing was 92.5% in the open sphincterotomy group and 45% in the toxin botulinum group (P<0.001). It was observed that at 2 months follow up, incontinence was present among 7.5% patients who were treated with lateral sphincterotomy and was present among 5% patients who were treated with botulinum toxin (P>0.05). However, recurrence rate at 2 months follow up was 2.5% in patients treated with open sphincterotomy

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and 15% in patients treated with Botulinum toxin group ($p < 0.05$)⁶.

In another study by Algaithy ZK, et al, this was observed that anal incontinence was more among patients treated with botulin toxin (20%) as compared to those receiving surgery (2%)⁷. In another study by Giral A et al, no significant difference in healing rate was found i.e., the fissures were healed in 70 percent of patients in the botulinum group and 82 percent in the surgery group ($p > 0.05$). And the no difference in recurrence rate was observed i.e., 0% in both groups⁸.

Lateral internal sphincterotomy is routinely practiced. Recently, some authors have suggested the use of botulinum toxin. Botulinum toxin is considered a safer option for sphincters saving, however, the results of previous studies are controversial. Some have shown no difference in between the two techniques, while the others have shown better outcome with botulinum toxin while others are in favor of open sphincterotomy^{6,7,8}. The objective of this study was to compare the outcome of Botulinum toxin with lateral internal sphincterotomy for treatment of chronic anal fissure. Moreover, we hypothesized that there is a difference in frequency of healing, incontinence and recurrence in patients treated with lateral internal sphincterotomy as compared to Botulinum Toxin injection in chronic anal fissure.

MATERIALS AND METHODS

This randomized control trials was carried out in the Department of Surgery, Jinnah Hospital Lahore during 6 months after approval of Synopsis. Sample size of 100 cases (50 in each group) was calculated with 80% power of test, 5% of level of significance and taking expected percentage of recurrence in both groups i.e., 0% in lateral sphincterotomy group versus 15% in Botulinum toxin group for the management of chronic anal fissure. The sampling technique was Non probability purposive sampling. Patients having age 20-45 years with either gender having chronic anal fissure were taken in this study.

Exclusion criteria

- Chronic anal fissure with associated pathologies like abscess (measured by tenderness and swelling in perianal region), fistula (history of persistent discharge in perianal region)
- Patients with known cases of intestinal tuberculosis (diagnosed on endoscopy), crohn's disease (diagnosed on endoscopy)

Data Collection: 100 cases fulfilling inclusion criteria were registered through outpatient department of Surgery, Jinnah Hospital Lahore. Patients were divided into two groups. Informed and written consent

was taken. Fifty patients in Group A received treatment with Botulinum toxin (0.5 cc of Injection Neuronox injected in the sphincters under direct vision and digital examination) and fifty patients in group B with internal sphincterotomy (distal internal sphincters was incised surgically with electrocoagulation). Patients were discharged next day from hospital and follow up was done after two weeks. At follow up, patients were evaluated for fecal incontinence (yes or no), healing (yes or no) and recurrence (yes or no). The data was collected on a specially designed Performa. Procedure was performed by consultants with minimum 2 years of post graduation experience.

Data analysis: All the collected data was entered into SPSS version 10 and analyzed. The qualitative data like (sex; male or female), recurrence (yes or no), fecal incontinence (yes or no) and healing (yes or no) was described as frequency distribution and percentages. Mean and S.D was calculated for age (years). The two groups were compared for outcome in both groups for statistical significance. Chi-square test was applied. P-value ≤ 0.05 was considered significant.

RESULTS

In our study a total of 100 patients fulfilling the inclusion/exclusion criteria were enrolled to compare the outcome of Botulinum toxin with lateral internal sphincterotomy for treatment of chronic anal fissure. Age distribution of the patients was done which shows that 18(36%) in Group-A and 21(42%) in Group-B were between 20-30 years, 22(44%) in Group-A and 20(40%) in Group-B were between 31-40 years and 10(20%) in Group-A and 9(18%) were between 41-45 years of age, the mean age was 34.76 ± 3.12 in Group-A and 32.92 ± 4.64 years in Group-B.

Gender distribution of the patients shows that majority of the patients in both groups were male i.e., 37(74%) in Group-A and 41(82%) in Group-B while remaining 13(26%) in Group-A and 9(18%) in Group-B were females.

Comparison of recurrence of anal fissure in both groups was done, it shows 10(20%) in Group-A and 2(4%) were in Group-B while 40(80%) in Group-A and 48(96%) in Group-B had no recurrence, p value was computed as 0.02.

Comparison of healing of anal fissure in both groups reveals 19(38%) in Group-A and 43(86%) were in Group-B while 31(62%) in Group-A and 7(14%) in Group-B could not heal, p value was 0.000. Another outcome i.e., fecal incontinence of anal fissure in both groups was compared and it shows 3(6%) in Group-A and 5(10%) in Group-B had fecal

incontinence while 47(94%) in Group-A and 45(90%) in Group-B had no fecal incontinence, p value=0.71.

Table 1: Comparison of demographic and clinical outcome in both study groups

	Group A	Group B	P value
20-30 yrs	18(36%)	21(42%)	0.828
31-40 yrs	22 (44%)	20(40%)	
41-45 yrs	10(20%)	9 (18%)	
Gender			
Male	37 (74%)	41(82%)	0.235
Female	13 (26%)	9 (18%)	
Recurrence			
Yes	10(20%)	2 (4%)	0.02
No	40 (80%)	8(96%)	
Healing			
Yes	19 (38%)	43 (86%)	<0.001
No	31 (62%)	7 (14%)	
Fecal incontinence			
Yes	3 (6%)	5(10%)	0.71
No	47(94%)	45(90%)	

P-values were calculated using Chi-square test.

DISCUSSION

Anal fissure is one of the most common anal diseases. It is characterized by anal pain on or after defecation and often by bright blood on the toilet paper. The pathogenesis of chronic anal fissure is not completely understood. For many years it was thought that passage of a hard large stool during a period of constipation tore the anoderm causing a fissure. Autopsy studies have found that the blood supply to the anoderm at the posterior midline is significantly lower than the other sides of the anal canal⁹.

Therapies that reduce anal sphincter pressures have been used to achieve fissure healing. Lateral internal sphincterotomy (LIS) is the most common treatment for CAF¹⁰ and can be effective in more than 90 percent of cases but needs general or local anesthesia¹⁰. The fundamental drawback of this surgery is its potential to cause gas, mucus or occasionally stool incontinence which is permanent in 8 to 30% of patients and may be associated with abscess and anal deformity¹⁰⁻¹⁴.

Recently, some authors have suggested the use of botulinum toxin. Botulinum toxin is considered a safer option for sphincters saving, however, the results of previous studies are controversial. Some have shown no difference in between the two techniques, while the others have shown better outcome with botulinum toxin while others are in favor of open sphincterotomy⁶⁻⁸. However, we planned to compare both of these treatment modalities in order to know which one is more effective.

In our study, age and gender were insignificantly different while comparison of recurrence of anal fissure in both groups show 10(20%) in Group-A and 2(4%) were in Group-B while 40(80%) in Group-A and 48(96%) in Group-B had no recurrence, p value was computed as 0.02, 19(38%) in Group-A and 43(86%) were in Group-B while 31(62%) in Group-A and 7(14%) in Group-B could not heal, p value was 0.000, while fecal incontinence of anal fissure in both groups was compared and it shows 3(6%) in Group-A and 5(10%) in Group-B had fecal incontinence while 47(94%) in Group-A and 45(90%) in Group-B had no fecal incontinence, p value=0.71.

The results of the current study are in agreement with Arroyo A et al⁶ who compared the both treatment options were compared among 80 patients with anal fissure. Overall healing was 92.5% in the open sphincterotomy group and 45% in the toxin botulinum group (P <0.001). It was observed that at 2 months follow up, incontinence was present among 7.5% patients who were treated with lateral sphincterotomy and was present among 5% patients who were treated with botulinum toxin (P >0.05). However, recurrence rate at 2 months follow up was 2.5% in patients treated with open sphincterotomy and 15% in patients treated with Botulinum toxin group (p<0.05)⁶.

Menteş BB and colleagues in a randomized, prospective trial compared botulinum toxin with lateral internal anal sphincterotomy as definitive management for chronic anal fissure and concluded that although the healing rate of chronic anal fissure is considerably high with botulinum toxin injection with earlier recovery and less complications compared with sphincterotomy, it occasionally requires a repeat injection, and the healing is slower¹⁵. The early (two months) and late (one year) healing rates are significantly higher in the sphincterotomy group, the two groups reaching similar healing rates only at six months, the results show insignificant difference in both groups but with repeat injection while in their study sphincterotomy was not repeated which is an additional effect of sphincterotomy.

Another study by Nasr M and co-workers¹⁶ compared the outcome of lateral internal sphincterotomy and botulinum toxin injection treatments in patients with uncomplicated chronic anal fissure and recorded a statistically significantly higher healing in the LIS group than the BT group (p=0.0086 and 95% CI=7.38-45.69%). In addition, LIS was associated with a high rate of anal incontinence as compared to BT (p=0.0338 and 95% CI=-1.64-27.53%). The recurrence rate in the BT group was significantly higher statistically than that in the LIS group (p=0.0111 and 95% CI=6.68-46.13%).

However, our results justify the hypothesis of our study that “there is a difference in frequency of healing, incontinence and recurrence in patients treated with lateral internal sphincterotomy as compared to Botulinum Toxin injection in chronic anal fissure.”

On the basis of results of the current study in accordance with other international studies, in future, sphincterotomy may be offered to the patients. This may help our patients by decreasing the morbidity by avoiding sphincter damage and recurrence and achieving healing.

CONCLUSION

Comparison of the outcome of Botulinum toxin with lateral internal sphincterotomy for treatment of chronic anal fissure concludes that lateral internal sphincterotomy is significantly better and may be offered in our patients in future.

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