

Treatment Option for Anal Fissure – Chemical or Surgical?

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ABSTRACT

Background: Anal fissure is treated surgically with lateral internal sphincterotomy (LIS) or by chemical denervation using Botulinum toxin (Botox). Due to fear of incontinence surgeons used Botox instead of LIS. In this study we evaluated the outcome of LIS & Botox treatment in patients with anal fissure. **Objective:** The aim of our study was compare the satisfaction rate of patients, recurrence and incontinence in Botox vs LIS. **Study Design:** prospective study. **Settings:** University of Lahore, Lahore Pakistan. **Duration:** From 2018 to 2019. **Methods:** Its prospective study from 2018 to 2019 to find out the outcome of LIS vs Botox in patients suffering from anal fissure in regard of patient satisfaction and incontinence. **Results:** Study included 71 patients who met the criteria, 52 patients underwent lateral sphincterotomy and 19 patients got Botulinum toxin injection with median age of 47 for LIS and 39 for Botox. Cleveland Clinic Fecal Incontinence (CCFI) score was higher in Botox than LIS patients (2.3 vs 0.6, P=0.006) and continence was about 52% in Botox vs 91% for LIS. Recurrence rate was quite high in Botox than LIS patients (40% vs 7%, P=0.04). **Conclusion:** The recurrence rate is quite low in LIS. However, regarding continence outcome, both procedures may need a safe approach.

Keywords: Lateral sphincterotomy, Botulinum toxin, anal fissure.

INTRODUCTION

Painful defecation is the characteristic of tear in the lower end of anal canal known as anal fissure. According to guidelines of European Society of colorectal surgeon, the initial management is nonsurgical lead to healing of anal fissure in majority of cases.¹ But majority of patients on nonsurgical management fail to respond and need further management.² Surgical management is the main stay of non-responding patient with nonsurgical treatment. Lateral sphincterotomy is a gold standard.¹ Surgical (LIS) approach is quite effective in anal fissure treatment but is not without risk. Different studies showed that incontinence for gas, liquid or solid stool after surgical (LIS) intervention is range from zero to forty-two percent.³

Botox (Botulinum Toxin) is another option for the treatment of anal fissure which has low risk for fecal incontinence compare to LIS. Intramuscular Injection of Botox causes temporary de-innervation of internal sphincter. The intramuscular effect of this chemical dissipate in a period of 3 months, causes relaxation of sphincter tone led to healing of fissure.³ As the effect of

this injection is transitory, so incontinence last only for few months if it occurs. This treatment option used widely in USA and European countries for anal fissure, however, in Pakistan there is limited use in colorectal disease.⁴

It has been seen that incontinence is low in case of chemical de-innervation as compare to LIS, however, recurrence rate is quite high.⁵ Goal of treatment is to heal the anal fissure, pain, bleeding and catering for low risk of incontinence. Many patients presented with fissure and incontinence together in our study and CCLS scoring was done before proceeding with treatment. Many factors influence the continence of patient like age, anorectal surgery, obstetric history and gender.⁶

The aim of our study was compare the satisfaction rate of patients, recurrence and incontinence in Botox vs LIS.

METHODS

After the approval from Ethical Committee on Research University of Lahore, a prospective study was performed from Jan. 2018 to July 2019 on the patients suffering with anal fissure undergoing lateral internal sphincterotomy

or Botox injection. All Patients with anal fissure included in the study except patients who were having BMI more than 35, previous anorectal surgery or patients presented with incontinence of stool with anal fissure were excluded from the study. Incontinence measured by using Cleveland Clinic Fecal Incontinence (CCFI) score ranging from zero, complete/perfect continent to 20, complete incontinent. Patients were subjected for LIS or Botox injection depending upon their randomize turn of management.

Patient underwent Botox injection about 60 to 100 Units in 15 ml of distal water. We used to infiltrate four quadrant of internal sphincter.

Lateral internal sphincterotomy was performed by making a stab incision with surgical blade No:15 at intersphincteric groove after infiltrating the groove with injection lignocaine 1% with adrenalin diluted with 5 ml distal water at 3, O clock position. Internal sphincter was isolated and divided with cautery. Wound kept open by packing with gauze soaked with polyfex ointment and pyodine lotion for next 6 to 8 hours to reduce any chance of bleeding.

The patients were asked to come fortnightly for follow up regarding their satisfaction of the procedure, any additional treatment they took from physician/surgeon or feeling of recurrence and incontinence score was calculated in each patient. More than 74% patient did not return to follow-up clinic and they were asked these questions on telephone. Student's t-test was used for comparing demographic data. Nonparametric data was compared by using Wilcoxon rank sum test.

The other variables analyzed by using chi-squared test. Statistical analysis was performed by using Stata/SE 14.1. Less than 0.05 P-values were considered as significant.

RESULTS

Total of 107 cases presented with symptoms of anal fissure, 36 patients did not meet the criteria and excluded from the study as they have fistulae or anorectal procedures or having incontinence of various degree. There were total 71 cases selected for this study, 52 patients underwent LIS and 19 Botox injection. The median age on IQR (interquartile range) was 47 for LIS and 39 for Botox as shown in table-1

Statistically there was no difference in both group regarding demographic aspect. The median age was 47 for LIS and 39 for Botox group (p=1.0). The median duration of symptoms was about 3 months in Botox patients and 5 months for LIS group (p=0.3). More than 75% patients had medical management like stool softener, local analgesic ointment, GTN cream topically before coming to our hospital. More female patient opt for

Botox 68% rather than LIS i.e. 56% with P=0.07, statistically it is insignificant. More than half of female patient 68% had vaginal deliveries.

Table 1: Patient demographics aspects and history

	Botox (n=19)	LIS (n=52)	p-value
Median, age (IQR)	39 (29-53)	47 (31-51)	1.0
Female (n, %)	13 (68%)	25 (48%)	0.07
Vaginal Delivery (n, %)	08 (61%)	14 (56%)	0.4
Median (IQR) duration of symptoms	3 (2-09)	5 (2-11)	0.3
Use of stool Softener	13 (68)	37 (71)	0.5
Laxative	10 (48)	42 (58)	0.4
GTN topical cream	15 (69)	38 (73)	0.7

LIS=Lateral Internal Sphincterotomy, Botox=Botulinum toxin, IQR=Interquartile Range, GTN=Glyceril Trinitrate

50% of patients underwent Botox injection treatment were found to have perfect continence with CCFI score=0. On other hand CCFI score was zero in 82% of patient but 49% cases in both groups end up with secondary procedure which varies as shown in Table-2

Figure 1: Cleveland Clinic Fecal Incontinence Score. The CCFI score is determined by adding up the scores from each of the categories in the above table. Scores ranges from zero, representing perfect continence to 20, representing complete incontinence

	Incontinence frequency				
	Never	Rarely	sometimes	Usually	Always
Solid stool					
Liquid stool					
Gas					

Never = 0; Rarely = 1, less than once/month; Sometimes = 2, less than once a week but at least once a month; Usually = 3, less than once per day but at least once per week; Always = 4, at least once a day.

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Table 2: Operative data

Procedure Performed	Botox (n, %)	LIS (n, %)	p-value
Total	19 (27%)	52 (73%)	-
Other procedure apart from Botox or LIS	10 (51%)	26 (50%)	1.0
Other Procedure Details:			
Fissurectomy	2 (10%)	11 (21%)	0.06
Skin tag removal, anal papilla	4 (21%)	10 (19%)	0.
Band ligation of Hemorrhoids	2 (10%)	09 (17%)	1.0
Fissurotomy	1 (5%)	1 (1%)	0.4

LIS = Lateral Internal Sphincterotomy, BT = Botulinum toxin.

Patient presented with bleeding per rectum underwent colonoscopy to rule out any inflammatory bowel disease or to evaluate additional source of bleeding. About 21% patients having LIS underwent fissurectomy, on other hand only 10% (5) in case of Botox treated patients.

21% of Botox and 19% of LIS had skin tag/sentinel removed as part of their operation (p=0.4)

Only 25% patients visited clinic for follow up, the rest were consulted through telephone to collect their data as shown in table-3

Table 3: Result of survey (n = 71, Botox = 19, LIS = 52)

	Botox	LIS	Total	P-value
Post op follow up in clinic, 25% (n (%))	05 (27)	13 (72)	18 (25)	NA
Follow up through telephone 75% (n, %)	14 (26)	39 (73)	53 (75)	NA
Mean (SD) time of follow up in months	28 (±21)	34 (±23)	34 (±20)	0.7
Satisfaction with procedure, n (%)				
Totally satisfied	13 (68)	34 (65)	47 (66)	-
Satisfied	2 (10)	14 (26)	16 (22)	-
Not satisfied	3(15)	2(3)	5 (7)	0.1
totally unsatisfied	2(10)	0(0)	2 (3)	
patient presented with recurrence	7 (36)	3 (5)	10 (14)	0.03
patient went other Physician for Recurrence	01(05)	2 (3)	3 (4)	0.7
Treatment for Recurrence	3 (15)	3 (5)	06 (8)	0.4
Postoperative Medication Use	7 (36)	09 (17)	16 (22)	0.007

LIS = Lateral Internal Sphincterotomy, Botox = Botulinum toxin, SD = Standard Deviation

There was not much difference regarding age, CCFI score, symptom's duration or other previous treatment of anal fissure. The mean follows up time for Botox group was 28 months while it was 34 months in LIS group p=0.7. CCFI score higher in Botox group (2.1-2.9) as compared to LIS group (0.8-1.8, p=0.03). CCFI score value was higher in Botox (0.3) as compare to LIS group (0.5) but not significant in regard of statistical value. 32% patients Botox group got various level of incontinence ranging from 4-15 as shown in talbe-4 while only 19% become incontinent of various level in LIS group.

Table 4: Postoperative CCFI Score

	LIS (n=06)	BT (n =9)	p-value
Postoperative, mean (SD)	0.9 (±1.9)	1.2 (±3=2.1)	0.04

CCFI =Cleveland Clinic Fecal Incontinence. LIS = Lateral Internal Sphincterotomy

Regarding patient's satisfaction, more than 80% were satisfied in each group. However, 15% in Botox and 3% in LIS were not satisfied regarding treatment. While 2

patients in Botox group not satisfied at all about the treatment. If compare statistically, it is significant.

Recurrence rate was quite high in Botox group (n=7,36%) as compared to LIS group, having only 3%. Patient in Botox group were taking stool softener more than LIS group 40% vs 8% respectively. Patients in each group with recurrence were treated conservatively except one patient in LIS group underwent surgical treatment.

DISCUSSION

In this study we would like to determine whether the outcome of Botox and LIS treatment in anal fissure, is same.

Our data support that recurrence rate is high in Botox than LIS group treated for anal fissure as shown by Nasr *et al* study.^{7,8} However, Valizadeh *et al*⁹ reported 52% non-healing rate of Botox patients while in our study only 22% in Botox and 11% in LIS group showed non-healing of fissure. In a follow up of more than 3 years it has been seen that recurrence is high among Botox group. About more than 75% patient in each group were satisfied with their treatment and is comparable with Garcia-Aguilar *et al*,³ however, data regarding Botox satisfaction is sparse.^{10,11} But rate of incontinence regarding gas and liquid stool were quite high in Gausia Agulier *et al*³ than in our study.

Which procedure is better for anal fissure, is an enigma. Female choice is more for Botox than LIS due to inherent problem with surgical procedure of incontinence for life time. Female having different anatomy as compare to male and stress of deliveries and mostly subjected for endoscopy, have more chance to have incontinence rather than the procedure itself.^{12,13,14} Risk of incontinence is not only after LIS procedure but from child birth and minor surgical procedure in perineal area have an inherent injury lead to incontinence in female.^{3,10} May be this is the reason that surgeon usually reluctant to provide LIS treatment for female. Female patients are more prone to have Botox injection rather than LIS procedure. This needs further evaluation and study to know that its choice of female or its surgeon choice regarding anal fissure treatment options.

Definitely patients undergoing Botox injection for anal fissure do suffer with incontinence but it improves gradually to near normal, but after LIS approach, if the incontinence do happen, it's for long time. However, data suggest in our study that change is long lasting in both procedures. About 32% in Botox and 21% in LIS group patients showed some type of incontinence on CCFI score but without any statistically significance.

Valizadeh N *et al* and Jan Y *et al*^{9,10} showed that there is no change of continence in Botox treated patient while LIS has chances of incontinence but low rate.¹³ Healing is quite high in LIS (86%) than Botox (71.2%). 11% become incontinent but only one patient got CCFI score of >5.

So, it's evident from the study that patients with anal fissure must be thoroughly counseled about continence problem in LIS procedure and Botox is also not without risk, rather more chances of recurrence.

CONCLUSION

Patients who are not responding to conservative treatment can safely be offered Botox or LIS for anal fissure. On the basis of previous operation, perineal area diseases, gender and presence of incontinence, surgeon can choose treatment options, Botox or LIS. However, Botox treatment viewed as better, but in either procedure the continence is declined. Rate of recurrence is high in Botox patients however, satisfaction level was equal in both procedures. Which method is more beneficial, need to be evaluated by further study.

LIMITATIONS

Financial hurdles are the main issue.

SUGGESTIONS / RECOMMENDATIONS

We may not recommend definitely treatment option.

CONFLICT OF INTEREST / DISCLOSURE

None.

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