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Original Article

Comparison of The Postoperative Outcomes of Surgical Lateral Internal Sphincterotomy and Botulinum Toxin Injection in Patients Presenting With Chronic Anal Fissure At CMH, Rawalpindi

Saadan Saleem, Syeda Rifaat Qamar Naqvi, Mansoor Tariq Azim*, Malik Muhammad Jalil,Khurram Sarfraz, Aimen Luqman*****

Department of Surgery, Combined Military Hospital /National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Department of Surgery, Pak Emirates Military Hospital Rawalpindi /National University of Medical Sciences (NUMS) Rawalpindi Pakistan, **Department of Surgery, Combined Military Hospital Lahore /National University of Medical Sciences (NUMS) Pakistan, ***Ganga Ram Hospital, Lahore

ABSTRACT

Objective: To compare the postoperative outcomes in Lateral Internal Sphincterotomy Group and in Botulinum toxin injection Group in patients managed for chronic anal fissure.

Study Design: Quasi-experimental study.

Place and Duration of Study: Department of Surgery, Combined Military Hospital, Rawalpindi Pakistan, from Aug 2021 to Feb 2022.

Methodology: All patients of either gender, aged 30 to 70 years, who had presented to CMH, were included in this study. Block randomization was done to allocate half of them to Lateral Internal Sphincterotomy and half to Botulinum toxin injection. Patients in both Groups were followed for four weeks to assess and compare various short and long term post-surgical outcomes.

Results: There were 82 patients in total with 41 in each treatment arm. In the Lateral Internal Sphincterotomy Group, 35 85(37%) of the patients reported postoperative pain relief at 24 hours, 39(95.12%) patients healed, only 2(4.88%) patients had a recurrence. In the Botulinum toxin Group, 29(70.73%) reported postoperative pain relief at 24 hours, 35(85.37%) patients healed, whereas 6(4.63%) had a recurrence. There was no statistical difference in any parameter between either Group.

Conclusion: Both methods did not show any statistically significant difference in post-operative outcomes thus other parameters like patient's choice, cost and expertise may be considered in treatment of chronic anal fissure.

Keywords: Botulinum Toxin Injection; Chronic Anal Fissure; Lateral Internal Sphincterotomy

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INTRODUCTION

Chronic anal fissures are commonly found in adults, resulting from the passage of hard feces within the bowel.[1] Patients experience extreme pain during defecation, along with bleeding per rectum.[2] Numerous treatment options have been explored that employ enhancing internal sphincter muscle's vascularity as a cure for the anal fissure.[3] Common methods of treatment include dilatation of anal sphincter, excision of fissure with or without sphincterotomy.[4,5] Usually Lateral Internal Sphincterotomy is performed for controlling chronic anal fissure.[6] however, sphincterotomy has an increased probability of causing incontinence.[7] Researchers have noted that Botulinum toxin (BT) results in transient paralysis of internal sphincter muscle.[8] for a period of approximately 90 days, within which the fissure may heal.[9] but patients tend to experience adverse outcomes like incontinence of flatus, which may improve with time, and typically there has not been any documentation of any enduring harm.[10] As limited local data is available on this commonly encountered condition in our set up, our primary aim was to compare the postoperative outcomes of surgical Lateral Internal Sphincterotomy and Botulinum toxin injection among patients who presented with chronic anal fissure.

Correspondence: Dr Saadan Saleem, Department of Surgery, Combined Military Hospital Rawalpindi Pakistan

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METHODOLOGY

The quasi-experimental study was conducted at Department of Surgery, Combined Military Hospital (CMH), Rawalpindi, Pakistan. This research was carried out after gaining approval from institutional ethics committee approval via letter no 209/8/21. The sample size was calculated using the World Health Organization (WHO) calculator taking prevalence of recurrence of anal fissure as 20% versus 04% in Lateral Internal Sphincterotomy Group and Botulinum toxin injection Group. 11 Non-probability consecutive sampling was used to enroll the calculated sample.

Inclusion Criteria: Patients of either gender, aged of 30 to 70 years, with chronic anal fissure undergoing Lateral Internal Sphincterotomy and Botulinum toxin

injection and who were American Society of Anesthesiologists (ASA) ≤ 2, were included.

Exclusion Criteria: Patients with history of Hepatitis C, B or HIV infection, inflammatory bowel disease, abscess, hypo or hyperthyroidism, malignancy, pregnant women, and patients with history of congestive cardiac failure, chronic liver disease, chronic obstructive pulmonary disease (COPD), asthma, myocardial infarction, chronic kidney disease and stroke, were excluded.

Demographic information was collected after obtaining written informed consent in local language (Urdu) from every subject. Patients were randomly allocated to an arm of this study, by utilizing sealed opaque envelop bearing "B" which was for the Botulinum toxin injection Group and "L" which was for the Lateral Internal Sphincterotomy Group (Figure-1). Patients were operated on by a surgeon who had over ten years of practice. Patients were discharged on the subsequent postoperative day and guidance was given about analgesics, high residue diet, and warm, sitz baths. The researcher followed the subjects postoperatively for four weeks and every subject in both study Groups was assessed for postoperative outcomes. Pain relief was defined as Visual Analog Scale (VAS) ≤ 3 at 24 hours post-surgery, patients were asked to mark a point on the line that matches the intensity of pain felt. Postoperative infection was defined by the presence of any one or more of the following occurring within 4 weeks postoperatively as documented by the physician examination: temperature ≥ 37.5oC, erythema labeled by the red coloration of skin at port insertion site, and any discharge from the wound.

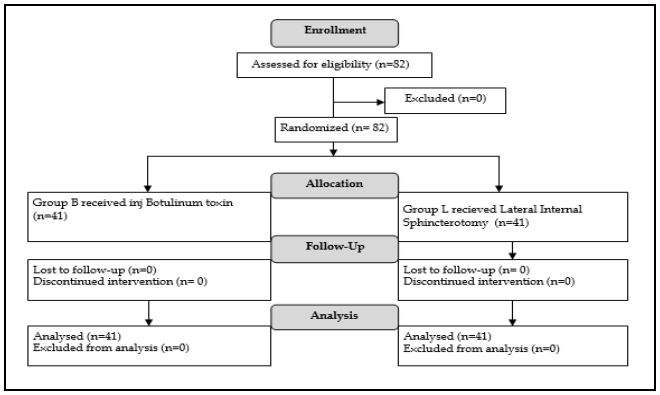

Figure-1: Patient Flow Diagram (n= 82)

Data was analyzed using Statistical Package for the Social Sciences (SPSS) version 23.0. Mean and standard deviations were noted for the quantitative variables. Frequencies and percentages were calculated for the qualitative variables. Chi-square was applied to compare outcomes postoperatively between both study Groups with *p*-value of ≤ 0.05 considered significant.

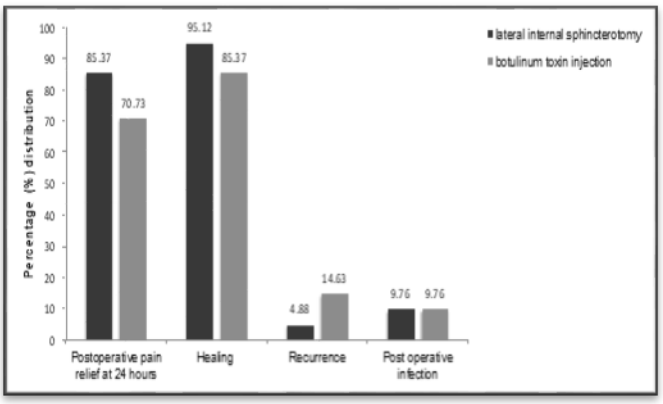

Figure-2: Distribution Of Outcomes In Lateral Internal Sphincterotomy And Botulinum Toxin Injection, (n=82)

RESULTS

A total of 82 patients were included in the analysis. The general characteristics of study participants can be seen in Table-I. In the LIS Group, 23(56.10%) patients belonged to the age Group of 30 to 50 years, whereas 18(43.90%) patients were older with 23(56.10%) males, and 18(43.90%) females. In the Botulinum toxin Group, 21(51.22%) belonged to the age Group of 30 to 50 years, whereas 20(48.78%) of the patients were older with 24(58.54%) males, and 17(41.46%) females.

In LIS Group, 35(85.37%) patients reported postoperative pain relief at 24 hours, and 6(14.63%) still had pain at 24 hours post operatively. There were 39(95.12%) patients who had reported healing, whereas 2(4.88%) patients did not heal. In Botulinum toxin Group, 29(70.73%) patients reported postoperative pain relief at 24 hours, and 12(29.27%) still had pain at 24 hours post operatively. There were 35(85.37%) patients who had reported healing, whereas 6(14.63%) patients did not heal. All post-operative parameters are listed in Table-II.

There was no significant statistical difference in any of the post-operative parameters included in the study between either Group.

DISCUSSION

Both procedures had no statistically significant difference in postoperative outcomes in either Group.

Table-I: Distribution of General Characteristics of the Patients (n=82)

Variables		Lateral Internal Sphincterotomy n (%)	Botulinum Toxin Injection n (%)
Age	30 to 50 years	23(56.10)	21(51.22)
	51 to 70 years	18(43.90)	20(48.78)
Gender	Male	23(56.10)	24(58.54)
	Female	18(43.90)	17(41.46)
Duration of Surgery	≤ 2 hours	24(58.54)	23(56.10)
	> 2 hours	17(41.46)	18(43.90)
Diabetes Mellitus	Yes	27(65.85)	21(51.22)
	No	14(34.15)	20(48.78)
Hypertension	Yes	21(51.22)	25(60.98)
	No	20(48.78)	16(39.02)
Smoking status	Yes	13(31.71)	14(34.15)
	No	28(68.29)	27(65.85)
Obesity	Yes	14(34.15)	10(24.39)
	No	27(65.85)	31(75.61)
History of constipation	Yes	7(17.07)	10(24.39)
	No	34(82.93)	31(75.61)

Table-II: Distribution of Patient Outcomes Between Both Groups (n=82)

Outcomes		Lateral Internal Sphincterotomy n (%)	Botulinum Toxin Injection n (%)	*p*-value
Postoperative pain relief at 24 hours	Yes	35(85.37)	29(70.73)	0.109
	No	6(14.63)	12(29.27)	
Healing	Yes	39(95.12)	35(85.37)	0.137
	No	2(4.88)	6(14.63)	
Recurrence	Yes	2(4.88)	6(14.63)	0.137
	No	39(95.12)	35(85.37)	
No fecal incontinence	Yes	19(46.34)	32(78.05)	0.530
	No	22(53.66)	9(21.95)	
Post operative infection	Yes	4(9.76)	4(9.76)	0.990
	No	37(90.24)	37(90.24)	

While an injection of Botulinum toxin when given in the anal sphincter has proven to be a beneficial therapy.[11-13] it has been noted to be quite useful for alleviating the symptoms of chronic anal fissure and preventing the hazard of long-term damage to the anal sphincter, but this denervation is not temporary, lasting for a period of 2 - 3 months, which allows for healing of the anal fissure and eliminating the requirement for surgery.[14] Contemporary literature has shown benefit of using Botulinum toxin as a therapy for anal fissure as there is evidence to suggest that Botulinum toxin is a comparatively safer method for protecting the sphincters, however, the literature is somewhat divided on this topic with some studies that support sphincterotomy as a more efficacious treatment, whereas other studies demonstrate that botulunim toxin is the more suitable treatment.[15] One study.[16] investigated the outcome of Botulinum toxin injection treatments and Lateral Internal Sphincterotomy (LIS) among subjects with uncomplicated chronic anal fissure and reported a statistically significantly higher healing proportion among those who were in the LIS Group than those who were in the Botulinum Group (p value =0.0086).[17] Our study results are in opposition to one a study.[18] as their results showed that overall healing was about 92.5% in the Group who had open sphincterotomy and almost half, that is, 45% in the Botulinum toxin Group (p value ≤ 0.0001), this difference being statistically significant, and the authors noted that when follow-up was conducted at two months, incontinence was reported in 7.5% of the subjects who were treated with lateral sphincterotomy, and it was present among 5% of the subjects who were treated with Botulinum toxin (p value ≥ 0.05). Another randomized trial compared Botulinum toxin with lateral internal anal sphincterotomy.[19] and established that though the curative proportion of chronic anal fissure cases is substantially high with Botulinum toxin injection with earlier recovery and less complications associated with

sphincterotomy, it seldom necessitates a repeated injection. These results are comparable to our study, as LIS demonstrated a clear superiority over botulin toxin Group.

LIMITATION OF STUDY

Multi centre trials could be planned with a larger sample size in future to make results generalizable to the rest of the population. In future, RCTs could be planned to formulate local guidelines for this procedure.

CONCLUSION

While both methods did not show any statistically significant difference in post operative outcomes, other parameters like patient's choice, cost and expertise may be considered in choosing an appropriate procedure.

Conflict of Interest: None.

Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

SS & SRQN: Conception, study design, drafting the manuscript, approval of the final version to be published.

MTA & MMJ: Data acquisition, data analysis, drafting the manuscript, critical review, approval of the final version to be published.

KS & AL: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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