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Comparative Study of Lateral Anal Sphincterotomy Versus Botulinum Toxin Injection for Treatment of Chronic Anal Fissure

Asim Aslam, Muhammad Jalil Malik*, Madhia Sundas, Farukh Gulzar Khawaja, Ammad ud din Nasir***, Shahid Abbas******

Department of Surgery, Combined Military Hospital /National University of Medical Sciences (NUMS) Rawalpindi Pakistan,
*Department of Surgery, Combined Military Hospital, Lahore/National University of Medical Sciences (NUMS) Pakistan,
**Department of Dermatology, Pak Emirates Military Hospital/National University of Medical Sciences (NUMS) Pakistan,
***Department of Surgery, Combined Military Hospital, Pano Aqil/National University of Medical Sciences (NUMS) Pakistan,
****Department of Cardiology, Combined Military Hospital, Bahawalpur/National University of Medical Sciences (NUMS) Pakistan

ABSTRACT

Objective: To compare lateral internal sphincterotomy with injection Botulinum toxin for chronic anal fissure treatment in terms of improvement in mean postoperative pain, frequency of healing and fecal incontinence.
Study Design: Quasi-experimental study.
Place and Duration of Study: Combined Military Hospital, Rawalpindi, Pakistan, from Feb to Aug 2019.
Methodology: Among the patients reporting to Surgical Unit II of Combined Military Hospital Rawalpindi, Pakistan. 80 individuals with chronic anal fissure, 12- 60 years of age were included in the study. Patients who have recurrent disease, fistula in ano, hemorrhoids, cardiovascular disease, and coagulopathies were excluded. Group-A patients had lateral anal sphincterotomy as an elective case under spinal anesthesia. Whereas Botulinum Toxin A was administered under local anesthesia in internal anal sphincter in Group-B patients in the outpatient department (OPD). Patients were followed up at 1, 4, 8, and 12 weeks in the OPD.
Results: In Group-A, mean postoperative pain was found to be 3(4–2) in Group-A, and in Group-B was found to be 2(2–1) with a significant *p*-value <0.001. Healing of fissure was seen in 26(65.0%) in Group-A and 34(85.0%) in Group-B (*p*-value=0.039). Temporary fecal incontinence was seen in 16(40.0%) in Group-A and 05(12.50%) in Group-B (*p*-value =0.005)
Conclusion: This study determined that in chronic anal fissure treatment, injection Botulinum toxin is superior to lateral internal sphincterotomy in postoperative pain, healing, and fecal incontinence.

Keywords: Chronic Anal fissure (CAF), Injection Botulinum Toxin, Lateral internal sphincterotomy (LIS), Postoperative Pain.

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INTRODUCTION

Globally, fissure in ano is considered the most common among anorectal diseases, which is classified into acute and chronic. The disease is common in young adults with a male preponderance. Chronic anal fissures are linear breaks or ulcers in the anoderm that arise below the dentate line and are more than 6-8 weeks old. The prevalence of chronic anal fissure is between 15.62 to 30.7% among patients reporting with anorectal problems.[1,2]

The aim of treatment is to decrease the anal tone. Various treatment options available for chronic anal fissure include conservative options like use of Lignocaine, Nitroglycerine and Nifedipine ointments/ gels for local application and procedures like Botulinum toxin injection, anal dilatation, anal advancement flaps, fissurectomy and lateral internal sphincterotomy.[3,4] The main goal of sphincterotomy is to decrease the anal sphincter pressure up to 50% by increasing the blood flow to the anoderm. This is considered the best procedure for chronic anal fissure, because of high rate of healing. However, it is associated with postoperative pain and fecal incontinence.[5]

Botulinum toxin has been employed in chronic anal fissure management since 1993. It blocks acetylcholine, leading to a chemical sphincterotomy, resulting in healing. It is easy to administer, and the procedure can be performed in an outpatient setting with promising results.[6]

A meta-analysis by Chen *et al.*, in 2014 reported that lateral sphincterotomy was superior to injection Botulinum toxin for chronic anal fissure in terms of healing rate (p<0.00001).[7] However, Botulinum toxin was found to be superior to lateral sphincterotomy in terms of postoperative fecal incontinence (*p*<0.00001).[8,9]

Correspondence: Dr Muhammad Jalil Malik, Department of Surgery, Combined Military Hospital, Lahore Pakistan
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There is paucity of data in the local literature regarding management of chronic anal fissure with no local study comparing both procedures. The findings of this study will help in developing evidence-based practices for the management of patients presenting with long standing anal fissure. This will also aid in optimizing patient outcomes and reducing the need for unnecessary surgical interventions.

METHODOLOGY

This quasi-experimental study was conducted at Surgical Unit-II of Combined Military Hospital, Rawalpindi, Pakistan, from Feb to Aug 2019. Non-probability convenience sampling was used to select participants for the study. Sample size of 80 patients (40 patients in each group) was estimated by using 5% level of significance, 80% power of test with expected percentage of healing in both groups i.e., Group-A as 94.0% and Group-B as 65.0%.

Inclusion Criteria: The study included male patients aged 12 to 60 with chronic anal fissure symptoms lasting more than 2 months.

Exclusion Criteria: Patients having acute anal fissure, recurrent disease, hypersensitivity to Botulinum toxin A, concomitant fistula-in-ano, hemorrhoids or any other perianal pathology, cardiovascular disease and coagulopathies, immuno-compromised patients and females were not included in the study.

Among the patients reporting to Surgical Unit II of Combined Military Hospital, Rawalpindi for treatment of chronic anal fissure, 80 were registered in the research as per inclusion and exclusion standards after getting hospital ethical committee authorization vide serial number 247 / 2 / 22. A written informed consent was taken from all the patients. Patients were randomly distributed among two equal groups by lottery method in Groups A and B, each comprising 40 patients.

A thorough history, along with physical examination in detail was conducted in patients. Demographic data were documented. Before commencement of treatment, a visual analog scale was used to assess patients for painful defecation, fecal incontinence, bleeding per rectum, site of the fissure, and disease duration. Patients in Group-A underwent lateral anal sphincterotomy as an elective case under spinal anesthesia. After placing the patient in lithotomy and under direct vision, strands of internal sphincter muscle were cut partly at left lateral side with the help of electrocautery. Enlarged anal papillae and anal tags, if present, excised. Group-B patients underwent Botulinum toxin A injection in the outpatient department under local anesthesia. 5% lignocaine gel was used as a local anesthetic. The procedure was performed in the knee-elbow position. (Fig-1) After diluting the Botulinum toxin A in normal saline to a strength of 150 U/ml, 1 ml was administered in same doses on either side of the midline after palpation of fibers of internal sphincter. Patients were advised to take Sitz bath twice daily for 15 minutes, stool softeners in the form of syrup lactulose, and a rich fiber diet till complete healing was achieved. Patients were instructed to apply 5% lignocaine gel thrice daily for two weeks. Follow-up was done at 1, 4, 8, and 12 weeks in the OPD. Physical examination was performed to check for healing. Patients reporting fecal incontinence were documented. All patients were taught to express the severity of their postoperative pain according to the Visual Analog Scale (VAS) of pain on a 10 cm long linear strip. Severity of pain was recorded on the follow-up visits. Post-operative data in both groups were recorded on a pre-designed proforma. During examination, appropriate care and respect were given to every patient. The confounders and bias in the study were controlled by firm adherence to the exclusion standards.

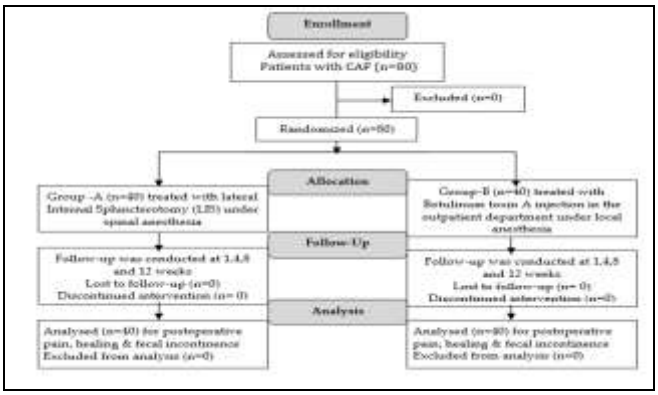

Figure-1: Patient flow Diagram Representing the Management of Chronic Anal Fissure (CAF) with Lateral Internal Sphincterotomy and Botulinum Toxin Injection (n= 80)

Data analysis was done by using version 23:00 of Statistician Package for Social Sciences (SPSS). Mean±SD were calculated for quantitative variables, i.e., age, duration of symptoms. Categorical variables like healing and fecal incontinence were expressed as frequency percentages. Median (IQR) was calculated for pain score. Mann-Whitney U test was applied to compare postoperative pain score as per VAS among

each group. To compare healing rate and fecal incontinence among each group, Chi-square test was applied. The *p*-value of ≤0.05 was taken as significant.

RESULTS

Eighty (n=80) patients were included in the study; the mean age of the patients was 36.93±7.97 years, ranging from 12 to 60 years. The majority of the patients, 50(62.50%), were between 36 and 60 years. Patients in the same age range of Group-A had a mean age of 28(70.0%), and in Group-B had mean age value 22(55.0%) as shown in Table-I.

Table-I: Age Distribution of Patients (n=80)

Age (years)	Group A n (%)	Group-B n (%)	Total n (%)
12-35	12(30.0%)	18(45.0%)	30 (37.5%)
36-60	28(70.0%)	22(55.0%)	50 (62.5%)

The mean duration of disease was 5.53±2.47 months. Patients' distribution according to disease duration is shown in Table-II. In the study, median postoperative pain in lateral anal sphincterotomy Group-A was found to be 3(4–2) and in Group-B Botulinum toxin injection was found to be 2(2–1) with significant *p*-value<0.001. Healing of fissure was seen in 26(65.0%) in Group-A and 34(85.0%) in Group-B(*p*-value=0.039). Fecal incontinence was seen in 16(40.0%) in Group-A and 05(12.50%) in Group-B(*p*-value=0.005) shown in Table-III.

Table-II: Patients Distribution According to Disease Duration (n=80).

Duration (months)	Group A n (%)	Group-B n (%)	Total n (%)
≤6	25(62.5%)	27(67.5%)	52(65.0%)
>6	15(37.5%)	13 (32.5%)	28(35.0%)
Mean±SD	5.95±2.47	5.28±2.48	5.53±2.47

Table-III: Comparison of Postoperative pain, Healing, and Fecal Incontinence Between the Groups (n=80)

Duration (months)	Group A Median (IQR)	Group-B Median (IQR)	*p*-value
Postoperative pain	3 (4 – 2)	2 (2 – 1)	< 0.001
Healing of Fissure	Group A n (%)	Group-B n (%)	*p*-value
Yes	26 (65.0%)	34 (85.0%)	0.039
No	14 (35.0%)	6 (15.0%)	
Fecal Incontinence	Group A n(%)	Group-B n(%)	*p*-value
Yes	24 (60.0%)	35 (87.5%)	0.005
No	16 (40.0%)	5 (12.55%)	

DISCUSSION

The study confirmed that patients who received Botulinum toxin injection presented with reduced post-operative pain with a value of 2(2–1), and faster fissure healing in 34(85.0%) patients was reported. But fecal incontinence was reported in 35(87.5%) patients which was higher than the patients treated with lateral anal sphincterotomy. However, literature has shown that high quiescent anal pressure is considered as a chief pathophysiologic factor in patients having chronic anal fissure (CAF). Healing of fissure in ano has been succeeded by using various remedies that lowers anal sphincter pressure. Lateral internal sphincterotomy (LIS) done under local or general anesthesia is considered the most common treatment for CAF, being effective in more than 90 percent of cases.[10,11] The potential shortcomings of LIS include permanent incontinence of stool, gas, and mucus, which is seen in up to 8 to 30 percent of patients. It may lead to deformity of anal canal and abscess formation.[12]

Botulinum toxin (BT) administration in intrasphincteric space is a novel effective treatment option. Jost and Schmrigk,[13] first described this technique, and when compared with a placebo, it was found to be effective.[14] BT was a better treatment option when compared to topical nitrate,[15] with no persistent incontinence post-administration.[16] This study has been conducted to compare lateral internal sphincterotomy versus injection Botulinum toxin for chronic anal fissure treatment in terms of improvement in mean postoperative pain and frequency of healing and fecal incontinence. In this study, mean postoperative pain in Group-A was found to be 3.30±1.26, and in Group-B it was found to be 1.75±1.06, with significance of 0.0001. Healing of fissure was seen in 26(65.0%) in Group-A and 34(85.0%) in Group-B (*p*-value=0.039). Fecal incontinence was seen in 16(40.0%) in Group-A and in 05(12.50%) in Group-B (*p*-value=0.005).

A study by Gandomkar *et al*.[17] in 2015 from Iran reported that the overall healing rate in patients undergoing lateral internal sphincterotomy (LIS) was 94% versus 65% for patients undergoing Botulinum toxin A injection (BT), which was statistically significant (*p*<0.001). Median healing time was also shorter in LIS group in comparison to BT group, 4 weeks versus 8 weeks respectively with *p*=0.001). The rate of fecal incontinence between the two groups was statistically insignificant (*p*=0.13). The mean postoperative pain as per VAS was1.62±1.33 in the LIS group versus 2.96±2.44 in the BT, which was statistically significant (*p*=0.001). The findings of this

study is different from this study in which the patients treated with Botulinum toxin showed results that signify that this treatment is more effective in treating fissure in ano, as compared to LIS.

It has been seen in a recent prospective, randomized study by Rashid *et al*., that LIS has more robust and long-lasting effects in terms of healing of CAF when compared to BT, which requires longer follow-up.[18,19] After 12 months of follow-up, the success rate in LIS group was found to be constant (94%), whereas in BT group, it dropped to 75.4%. In conclusion, Nasr *et al*., proposed that LIS is superior to BT in the treatment of CAF. However, they reported anal incontinence in 16% of patients after surgery, whereas in the BT group, it was found to be 0% (p<0.001) within the same follow- up period. If anal incontinence is considered as a failure of LIS, the advantage of this treatment will disappear.[20]

CONCLUSION

This study concluded that the Botulinum toxin injection is better than lateral anal sphincterotomy for the chronic anal fissure treatment in terms of postoperative pain, frequency of healing and fecal incontinence. Additionally, the minimally invasive nature of the injection makes it a safer and more favorable option, particularly for patients with comorbidities. These findings support the consideration of botulinum toxin as a first-line treatment option in the management of chronic anal fissure.

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Authors' Contribution

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

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

MS & FGK: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

AN & SA: Conception, data acquisition, drafting the manuscript, 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.

REFERENCES

1. Varadarajan MS, Sony PS, Anandan H. Prevalence and clinical presentation of fissure-in-ano in a tertiary care Centre. Int. J. Sci. Study 2018; 5 (12): 70-72. https://doi.org/10.17354/ijss/2018/86
2. Khan RM, Itrat M, Ansari AH, Zulkifle AS. Prevalence of fissure-in-ano among the patients of anorectal complaints visiting NIUM hospital. J Community Med Health Educ 2015; 5: 708-711. https://doi.org/10.4172/2161-0711.1000344
3. Latif A, Ansar A, Butt MQ. Morbidity associated with treatment of chronic anal fissure. Pak J Med Sci 2013; 29 (5) :1230-1235. https://doi.org/10.12669/pjms.295.3623
4. Zubair M, Saaiq M, Shah SA. Efficacy and safety of subcutaneous lateral internal sphincterotomy for chronic anal fissure. J Ayub Med Coll Abbottabad 2014; 26(2): 141-144. https://www.jamc.ayubmed.edu.pk/index.php/jamc/article/view/1537
5. Salih AM. Chronic anal fissures: Open lateral internal sphincterotomy result; A case series study. Ann Med Surg (Lond) 2017; 15: 56-57. https://doi.org/10.1016/j.amsu.2017.02.005
6. Dat A, Chin M, Skinner S, Farmer C, Wale R, Carne P, et al. Botulinum toxin therapy for chronic anal fissures: where are we at currently? ANZ J Surg 2017; 87(9): 70-73. https://doi.org/10.1111/ans.13329
7. Robles MS, Christopher JY. Real world of outcome of lateral internal sphincterotomy vs Botulinum toxin for management of chronic anal fissure. Asian J Surg 2022; 45(1): 184-188. https://doi.org/10.1016/j.asjsur.2021.04.027
8. Nevins EJ, Knanakala V. Topical diltiazem and GTN for chronic anal fissure: A meta-analysis of randomized control trials. Turk J Surg 2020; 36(4): 347-352. https://doi.org/10.47717/turkjsurg.2020.4895
9. Alyanak A, Gulen M, Edge B. Comparison of Botulinum toxin injection and lateral internal sphincterotomy for the treatment of chronic anal fissure. Dis Colon Rectum 2003; 46(2): 232-237. https://doi.org/10.1097/01.DCR.0000044712.58674.09
10. Zngana A. M., Hiwa B. Comparative study of lateral internal sphincterotomy and Botulinum toxin injection for the treatment of chronic anal fissure. Zanco J Med Sci 2021; 25(2): 513-519. https://doi.org/10.15218/zjms.2021.014
11. Herreros B, Espi A, Monton C, Granero EG, Ferriols FL, Almela P, et al. Botulinum toxin injection plus topical diltiazem for chronic anal fissure. Dis Colon Rectum 2021; 64(12): 1521-1530. https://doi.org/10.1097/DCR.0000000000001983
12. SekmenU, Paksoy M. The efficacy of Botulinum toxin injection site in chronic anal fissure healing. Niger J Clin Pract 2020; 23(12): 1639-1642. https://doi.org/10.4103/njcp.njcp_14_20
13. Jost WH, Schimrigk K. Use of Botulinum toxin in anal fissure. Dis Colon Rectum 1993; 36(10): 974. https://doi.org/10.1007/BF02050639
14. Maria G, Cassetta E, Gui D, Brisinda G, Bentivoglio AR, Albanese A et al. A comparison of Botulinum toxin and saline for the treatment of chronic anal fissure. N Engl J Med 1998; 338(4): 217-220. https://doi.org/10.1056/NEJM199801223380402

15. Brisinda G, Chiarello MM, Crocco A. Botulinum toxin injection for the treatment of chronic anal fissure uni - and multivariate analysis of the factors that promote healing. Int J Colorectal Dis 2022; 37(3): 693-700. https://doi.org/10.1007/s00384-022-04110-0
16. Gui D, Cassetta E, Asastasio G, Bentivoglio AR, Maria G, Albanese A et al. A comparison of Botulinum toxin and saline for the treatment of chronic anal fissure. N Engl J Med 1998; 338: 217-220. https://doi.org/10.1056/NEJM199801223380402
17. Hossein G, Atefeh Z, Reza H, Hadi AA, Partial lateral internal sphincterotomy versus combined botulinum toxin A injection and topical diltiazem in the treatment of chronic anal fissure: a randomized clinical trial. Dis Colon Rectum 2015; 58(2): 228-234. https://doi.org/10.1097/dcr.0000000000000307
18. Rashid Ibrahim, Ahmed Abdel Rahim. Incidence of anal incontinence among patients with chronic anal fissure treated with Botulinum toxin injection versus lateral internal sphincterotomy. Ann Med Surg (Lond) 2021; 68: 102636. https://doi.org/10.1016/j.amsu.2021.102636
19. Fatima Al-thoubaity. Safety and efficacy of the treatment of chronic anal fissure by lateral internal sphincterotomy. Ann Med Surg (Lond) 2020; 57: 291-294. https://doi.org/10.1016/j.amsu.2020.08.010
20. Nasr M, Ezzat H, Elsebae M. Botulinum toxin injection versus lateral internal sphincterotomy in the treatment of chronic anal fissure. A randomized controlled trial. World J Surg 2010; 34(11): 2730-2734. https://doi.org/10.1007/s00268-010-0736-5