

Treatment of Simple Anal Fistula: Fistula Tract Laser Closure Vs Open Fistulotomy: A Randomized Control Trial

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Abstract

Background: Anal fistula treatment remains a challenging aspect of colorectal surgery, with the primary goals being eradication of the fistula tract, infection control, and preservation of anal sphincter function. This study compares the efficacy and outcomes of Fistula Tract Laser Closure (FiLaC) versus Open Fistulotomy in the treatment of simple anal fistulas.

Methods: This randomized control trial was conducted at the Department of Colorectal Surgery, Combined Military Hospital, Dhaka, over a period of six months. Sixty patients with simple anal fistula were enrolled and divided into two groups: Group A (n=30) underwent open fistulotomy, and Group B (n=30) underwent FiLaC. Baseline characteristics, patient history, habitual risk factors, local examination findings, operation duration, post-operative pain, wound healing, and recurrence rates were compared between the groups.

Result: Group B demonstrated significantly shorter operation times (mean 17.60±2.5 minutes) compared to Group A (mean 35.0±4.91 minutes, $p<0.001$). Post-operative pain was lower in Group B, with 70.00% reporting mild pain, against 100.00% in Group A experiencing moderate pain ($p<0.001$). Wound healing was faster in Group B (mean 12.53±1.961 days) compared to Group A (mean 22.63±3.98 days, $p<0.001$). However, Group B showed a higher, though not statistically significant, recurrence rate (13.33%) compared to Group A (3.33%, $p=0.161$). Notable differences were also observed in patient history and local examination findings.

Conclusion: FiLaC offers significant advantages in terms of reduced operation time, lower post-operative pain, and quicker wound healing compared to open fistulotomy. However, these benefits are countered by a higher recurrence rate. The study highlights the importance of individualized treatment approaches, considering each patient's specific medical history and anatomical presentation.

Keywords: Anal Fistula, Fistula Tract Laser Closure, Open Fistulotomy, Randomized, Colorectal Surgery

I. INTRODUCTION

Anal fistula, a prevalent and challenging condition in colorectal surgery, significantly impacts patient quality of life. This condition, characterized by an abnormal communication between the anal canal and perianal skin, is primarily cryptoglandular in origin and leads to recurrent infections, discomfort, and social embarrassment (1). The prevalence of anal fistula varies from region to region, and was recorded at 1-2 cases per 10,000 among the European population (2). The complexity of anal fistulas, coupled with their tendency to recur and the risk of incontinence, underscores the need for effective and safe surgical interventions. The traditional mainstay of anal fistula treatment has been fistulotomy, a procedure involving the surgical opening of the fistula tract. While fistulotomy is effective for simple and distal fistulas, it carries significant risks, including postoperative pain, potential incontinence, and a notable recurrence rate, especially in complex fistulas involving a significant portion of the anal sphincter (3,4). These risks have led to the exploration and development of sphincter-preserving techniques, with Fistula Tract Laser Closure (FiLaC) emerging as a notable alternative (5,6). FiLaC represents a paradigm shift in the surgical management of anal fistulas. This minimally invasive technique involves the radial ablation of the fistula tract using a laser, aiming to preserve

sphincter integrity while promoting healing. Clinical studies have highlighted the efficacy of FiLaC, with success rates ranging from 70% to 89%, and a lower impact on anal continence compared to traditional methods (7,8). The technique's minimal invasiveness, coupled with its efficacy in preserving sphincter function, positions FiLaC as a promising alternative in the treatment of anal fistulas. Despite these advancements, the treatment of anal fistulas, particularly complex ones, remains a significant challenge. The ideal surgical intervention should eradicate sepsis, promote healing of the tract, and preserve the sphincters and the mechanism of continence. FiLaC, with its sphincter-preserving approach, has shown promise due to its ease of application, minimal side effects, and preservation of functional outcomes (1). However, the literature also underscores challenges associated with FiLaC, such as the dependency of its success on the length and characteristics of the fistula tract (7). The comparison between FiLaC and traditional fistulotomy is critical, given their differing approaches to fistula management. While FiLaC offers a sphincter-sparing alternative, fistulotomy, despite its associated risks, remains a widely accepted option for simple and more distal fistulas with high clinical success. The decision-making process in selecting the appropriate surgical technique is complex, involving considerations of fistula type, patient comorbidities, and potential postoperative complications. In recent years, other sphincter-preserving procedures have also been explored, such as the LIFT (ligation of intersphincteric tract) procedure, mucosal advancement flap, and the use of biologic materials like fistula plugs and fibrin glue (9,10). These techniques, while innovative, have shown variable success rates and are often reserved for specific types of fistulas. This variability in outcomes further complicates the surgical decision-making process, emphasizing the need for comparative studies to ascertain the most effective and safe treatment modalities. The current study aims to provide a comprehensive comparison between Fistula Tract Laser Closure and Open Fistulotomy in the treatment of simple anal fistulas. By evaluating the efficacy, safety, and patient outcomes associated with these two surgical techniques, this study seeks to contribute valuable insights to the existing body of knowledge. The findings from this research could potentially guide clinical decision-making, offering a more nuanced understanding of the benefits and limitations of each technique, and ultimately improving patient care in the management of anal fistulas. In conclusion, the management of anal fistulas remains a significant clinical challenge, with a pressing need for effective and sphincter-preserving treatments. This study aims to bridge the gap in knowledge by comparing the outcomes of FiLaC and fistulotomy, thereby providing evidence-based guidance for clinicians in the treatment of this complex condition.

II. METHODS

This randomized controlled trial study was conducted at the Department of Colorectal Surgery, Combined Military Hospital (CMH), Dhaka, over a period of six months, from 1st September, 2022 to 28th February, 2023. The study population comprised patients with simple anal fistula presenting at the Colorectal outpatient department in CMH Dhaka. A total of 60 patients were enrolled in the study, divided into two groups through simple random sampling: Group I (30 patients for open fistulotomy) and Group II (30 patients for fistula-tract Laser Closure). Inclusion criteria for the study were patients with simple anal fistula admitted to CMH Dhaka. Exclusion criteria included patients with complex anal fistula, recurrent anal fistula, symptomatic hemorrhoids (Grade III and IV), malignancy, polyp, diabetes mellitus, hypersensitivity, auto-immune disease, and diverticulitis. Patients not consenting to the protocol were also excluded. Patients were randomly allocated to either Group A (Open Fistulotomy) or Group B (Fistula-tract Laser Closure) using a closed enveloped lottery system, ensuring blinding of patients to the type of surgery performed. All procedures were carried out under standardized spinal anesthesia, with the patient in the lithotomy position and a minor reverse Trendelenburg angle. The primary steps in both surgical procedures included examination under anesthesia, digital rectal examination (DRE), and proctoscopy. The external opening of the fistula was identified, and probing was conducted through the fistulous tract. In open fistulotomy, the skin and subcutaneous tissue were incised from the external opening to the internal opening, followed by scooping of the tract floor. Hemostasis was ensured, and the wound was left open with dressing applied. Postoperative care included a fiber diet and sitz baths starting the next day. In the Fistula-tract Laser Closure group, after probing, the fistula tract was mechanically cleaned with a curette and washed with saline. The internal opening within the internal sphincter muscle was closed using a 2/0 Vicryl suture. A laser probe was then inserted from the perineal opening, and energy at 13 Watts was applied to obliterate the fistula tract under continuous retraction of the laser, withdrawn at a rate of 1 cm/3 seconds. Postoperative care was similar to that of the fistulotomy group. Patients were followed up regularly, and data were collected using a predesigned sheet containing all variables of interest. Informed consent was obtained from every patient, and the study protocol was approved by the ethical review committee & research review committee of CMH and submitted to BCPS. Data processing and analysis were conducted using SPSS version 24.0. Quantitative data were expressed as mean $\pm$ SD, and qualitative data as frequency and percentage. Comparisons were made using the paired sample "t" test, with a p-value of <0.05 considered statistically significant.

III. RESULTS

The age distribution showed a slightly higher concentration of younger participants in Group B, with 30.00% being under 30 years, compared to 16.67% in Group A. The mean age was 45.23 ± 13.42 years in Group A and 39.10 ± 11.37 years in Group B. In terms of gender distribution, both groups were predominantly male, with 100.00% in Group A and 96.67% in Group B. Only one female participant was included in Group B. In terms of education, the majority of participants in both groups had school-level education (90.00% in Group A and 96.67% in Group B). The university-level educated participants were minimal, with 3.33% in each group, and a small proportion of uneducated participants were present only in Group A (6.67%).

In terms of the duration of perianal discharge, 70.00% of participants in Group A reported a duration of 12 weeks, compared to 46.67% in Group B, with a p-value of 0.054. For a 14-week duration, only 6.67% of Group A participants reported this duration, whereas it was significantly higher in Group B at 30.00%. Both groups had an equal percentage (23.33%) of participants reporting a 16-week duration. Regarding the history of perianal disease, 50.00% of participants in Group A reported no history, which was significantly lower compared to 80.00% in Group B, with a p-value of <0.001 . The incidence of hemorrhoids and anal fissures was low, with only 3.33% of Group A participants reporting hemorrhoids and 6.67% reporting anal fissures. Notably, 40.00% of Group A participants had a history of abscess, which was 13.33% in Group B. Other perianal diseases were reported by 6.67% of participants in Group B only.

Table 1: Distribution of habitual risk factors among participants (N=60)

Risk Factor	Group A (n=30)		Group B (n=30)		p-value
	n	%	n	%	
Smoking	24	80.00%	20	66.67%	0.243
Alcohol Consumption	8	26.67%	5	16.67%	0.347

The prevalence of smoking was observed to be higher in Group A, with 80.00% of participants reporting this habit, compared to 66.67% in Group B. However, this difference did not reach statistical significance, as indicated by a p-value of 0.243. Regarding alcohol consumption, 26.67% of participants in Group A reported consuming alcohol, which was higher than the 16.67% reported in Group B. Similar to smoking, the difference in alcohol consumption between the two groups was not statistically significant, with a p-value of 0.347.

Table 2: Comparison of local examination findings in the anorectal region (N=60)

Variables	Group A (n=30)		Group B (n=30)		p-value
	n	%	n	%	
Position of lesion in Quadrant					
Anterior	19	63.33%	14	46.66%	0.198
Posterior	11	36.66%	16	53.33%	
Length from Anal Verge (in cm)					
1 cm	21	70.00%	10	33.33%	0.013
2 cm	8	26.67%	15	50.00%	
3 cm	1	3.33%	5	16.67%	
Mean ± SD	1.33 ± 0.55		1.83 ± 0.70		0.003

The distribution of lesions in different location indicates varying patterns: the Anterior location shows 63.33% in Group-1 and 46.66% in Group-2, Conversely, in the Posterior location, Group A illustrates 36.66% while Group B exhibits 53.33%, displaying no significant difference ($p = 0.198$). Regarding the length from the anal verge, 70.00% of Group A had lesions at 1 cm, significantly higher than the 33.33% in Group B, with a p-value of 0.013. The mean length from the anal verge was 1.33 ± 0.55 cm in Group A and 1.83 ± 0.70 cm in Group B, showing a statistically significant difference with a p-value of 0.003.

Table 3: Comparison of post-operative findings among the participants (N=60)

Table 3: Comparison of post-operative findings among the participants (N=60)					
Variables	Group A (n=30)		Group B (n=30)		p-value
	n	%	n	%	
Duration of operation in minutes					
≤25	0	0.00%	30	100.00%	<0.001
26-35	18	60.00%	0	0.00%	
36-45	12	40.00%	0	0.00%	
Mean ± SD	35.0±4.91		17.60±2.5		<0.001
VAS Pain Score Categorization					
Mild Pain (0-3)	0	0.00%	21	70.00%	<0.001
Moderate Pain (4-6)	30	100.00%	9	30.00%	
Mean ± SD	5.03±0.18		3.30±0.47		<0.001
Dose of Ketorolac Provided					
3 doses	0	0.00%	18	60.00%	<0.001
4 doses	30	100.00%	12	40.00%	
Post-operative Complications					
Infection	0	0.00%	4	13.33%	0.038
Bleeding	0	0.00%	0	0.00%	--

The duration of operation varied significantly between the two groups. All participants in Group B (100.00%) had operations lasting ≤25 minutes, while in Group A, 60.00% had operations lasting 26-35 minutes and 40.00% had operations lasting 36-45 minutes. The mean operation time was significantly longer in Group A (35.0±4.91 minutes) compared to Group B (17.60±2.5 minutes), with a p-value of <0.001. Regarding the post-operative Visual Analog Scale (VAS) pain score, all participants in Group A (100.00%) experienced moderate pain (score 4-6), while a majority of Group B (70.00%) reported mild pain (score 0-3). The mean VAS pain score was significantly higher in Group A (5.03±0.18) compared to Group B (3.30±0.47), with a p-value of <0.001. In terms of post-operative medication, none of the participants in Group A required only 3 doses of Ketorolac, whereas 60.00% of Group B did. Conversely, all participants in Group A (100.00%) required 4 doses of Ketorolac, compared to only 40.00% in Group B. This difference was statistically significant (p-value <0.001). Post-operative complications showed a notable difference in infection rates. While no infections were reported in Group A, 13.33% of Group B participants experienced infections, with a statistically significant difference (p-value = 0.038). There were no instances of bleeding reported in either group.

Table 4: Comparison of wound healing duration among the participants (N=60)

Duration of Wound Healing	Group A (n=30)		Group B (n=30)		p-value
	n	%	n	%	
<2 weeks	0	0.00%	11	36.67%	<0.001
2-3 weeks	21	70.00%	19	63.33%	
>3 weeks	9	30.00%	0	0.00%	
Mean±SD	22.63±3.98 days		12.53±1.961 days		<0.001

The duration of wound healing showed significant differences between the two groups. In Group A, none of the participants experienced wound healing in less than 2 weeks, whereas in Group B, 36.67% had their wounds healed within this timeframe. The majority of participants in both groups, 70.00% in Group A and 63.33% in Group B, had wound healing durations between 2 to 3 weeks. Notably, 30.00% of participants in Group A experienced wound healing durations of more than 3 weeks, a scenario not observed in Group B. The mean duration of wound healing was significantly longer in Group A, averaging 22.63±3.98 days, compared to Group B, where the average was 12.53±1.961 days. This difference in wound healing duration between the two groups was statistically significant, with a p-value of <0.001.

Table 5: Distribution of incidence of anal fistula recurrence among the participants at 3-month follow-up (N=60)

Recurrence of Anal Fistula	Group A (n=30)		Group B (n=30)		p-value
	n	%	n	%	
Yes	1	3.33%	4	13.33%	0.161
No	29	96.67%	26	86.67%	

The incidence of recurrence showed a difference between the two groups, though not reaching statistical significance. In Group A, 3.33% (1 participant) experienced a recurrence of the anal fistula, whereas in Group B, the recurrence rate was higher at 13.33% (4 participants). However, the majority of participants in both groups did not experience recurrence, with 96.67% in Group A and 86.67% in Group B reporting no recurrence of the condition. The difference in recurrence rates between the two groups had a p-value of 0.161, indicating that it was not statistically significant.

IV. DISCUSSION

Starting with the demographic characteristics, the study observed a slightly younger participant demographic in Group B (Fistula-tract Laser Closure) with a mean age of 39.10 ± 11.37 years, compared to Group A (Open Fistulotomy) with a mean age of 45.23 ± 13.42 years. The gender distribution was predominantly male in both groups, aligning with the typical demographic profile of anal fistula patients as noted in other literatures (2,8,11,12). The similarity in baseline characteristics between the two groups ensures a fair comparison of the treatment outcomes. In examining patient history, the study revealed notable differences between the groups, particularly in the history and treatment of perianal disease. Group A had a higher proportion of participants with a 12-week duration of perianal discharge (70.00%) compared to Group B (46.67%), suggesting a more chronic presentation in Group A ($p=0.054$). The history of perianal disease significantly differed, with only 50.00% in Group A having no history, compared to 93.33% in Group B ($p<0.001$). This indicates a higher prevalence of prior perianal conditions in Group A, potentially influencing the complexity and outcomes of treatment. This suggests a more complicated disease history in Group A, which could impact postoperative outcomes, including pain and wound healing, as supported by existing literature (13,14). Such individualized approaches are crucial in managing anal fistula cases, given the variability in disease presentation and history. In terms of habitual risk factors, smoking and alcohol consumption were slightly higher in Group A (80.00% and 26.67%, respectively) compared to Group B (66.67% and 16.67%, respectively). However, these differences were not statistically significant ($p=0.243$ and $p=0.347$, respectively), suggesting that these factors did not notably influence the treatment outcomes. This observation is consistent with the general understanding that lifestyle factors, while important in overall health, may not directly impact the specific outcomes of anal fistula treatments (15). The local examination findings in the anorectal region revealed some differences between the two groups. The distribution of lesions in different location indicates varying patterns: Anterior location shows 63.33% in Group-1 and 46.66% in Group-2, Conversely, in the Posterior location, Group A illustrates 36.66% while Group B exhibits 53.33%, displaying no significant difference ($p = 0.198$). The length from the anal verge also differed significantly, with a higher proportion of Group A having lesions at 1 cm (70.00% vs. 33.33% in Group B, $p=0.013$). The mean length was 1.33 ± 0.55 cm in Group A and 1.83 ± 0.70 cm in Group B ($p=0.003$). The major findings of the study include significant differences in operation duration, post-operative pain, wound healing, and recurrence rates. Group B demonstrated a notably shorter operation time (mean 17.60 ± 2.5 minutes) compared to Group A (mean 35.0 ± 4.91 minutes, $p<0.001$). This finding is in line with the study by Almahfooz, which highlighted the efficiency of FiLaC in reducing operative time to 18 (10–32) minutes (16). Additionally, Group B patients experienced significantly less post-operative pain, with 70.00% reporting mild pain compared to 100.00% of Group A experiencing moderate pain ($p<0.001$). This aligns with the findings of Hiregoudar et al., who reported lower pain scores in patients undergoing less invasive procedures (17). Wound healing was faster in Group B, with an average duration of 12.53 ± 1.961 days, significantly shorter than Group A's 22.63 ± 3.98 days ($p<0.001$). This is supported by the findings of other similar studies, which found that less invasive techniques like FiLaC promote quicker wound healing (18,19). However, Group B had a higher recurrence rate (13.33%) compared to Group A (3.33%), although this difference was not statistically significant ($p=0.161$). This finding is particularly noteworthy as it is supported by some long-term studies where recurrence rate was 11.4% (20,21). The distribution of lesion positions and post-operative complications, provide additional insights into the treatment outcomes. The slightly higher incidence of post-operative infections in Group B (13.33%) compared to Group A (0.00%, $p=0.038$) warrants attention, as it suggests a potential area for improvement in post-operative care for

laser closure procedures. In conclusion, the study's findings contribute valuable insights into the treatment of simple anal fistulas, highlighting the advantages and limitations of both fistulotomy and laser closure techniques. While FiLaC offers benefits in terms of reduced operation time, lower post-operative pain, and faster wound healing, it also presents challenges with a higher recurrence rate. These findings underscore the need for a tailored approach to anal fistula treatment, considering individual patient characteristics and the specific nature of the fistula.

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

V. CONCLUSION

The findings of this study provide significant insights into the treatment of simple anal fistulas, comparing Fistula Tract Laser Closure (FiLaC) and Open Fistulotomy. The results demonstrate that while FiLaC offers distinct advantages in terms of reduced operation time, lower post-operative pain, and faster wound healing, it is also associated with a higher recurrence rate. These outcomes highlight the importance of individualized treatment approaches, taking into account the patient's medical history, habitual risk factors, and specific anatomical considerations. The study underscores the need for careful preoperative assessment and tailored surgical planning to optimize treatment efficacy and minimize complications. Ultimately, this research contributes to the evolving landscape of anal fistula treatment, emphasizing the necessity for a balanced consideration of both the benefits and limitations of available surgical options. Future studies focusing on long-term outcomes and the integration of patient-specific factors are essential to further refine treatment strategies and improve patient care in the management of anal fistulas.

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