

ORIGINAL RESEARCH

Comparison of Surgical Outcome of the Laser Ablation of the Fistula Tract and Fistulectomy: A Prospective Study

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ABSTRACT

Introduction: Fistula-in-ano is a common medical condition affecting about 8.6 people per 100,000 people, resulting from untreated or inadequately drained cryptoglandular abscesses, Crohn's disease, radiation or carcinoma of the rectum or anal canal. It causes perianal pain, discharge and significant distress and embarrassment to the patient. Although treatment for anal fistulae has many approaches, surgeons have a challenging task dealing with postoperative complications like recurrence and incontinence as they are highly likely with conventional methods of approach. Hence, new sphincter-saving approaches are proposed and analyzed for the treatment of fistulae, amongst which one such method is the laser ablation of the fistula tract, which shows promising results in terms of patient satisfaction and surgical outcome. **Methods and Materials:** This randomized, controlled study included 68 patients, equally allocated into two groups by random allocation software. All patients were evaluated preoperatively with an MRI fistulogram and mechanical bowel preparation. Group A patients underwent Laser Ablation of Fistula Tract, and Group B patients underwent Fistulectomy. Postoperative patients were analyzed and compared between the two groups in terms of postoperative pain, discharge, duration of hospital stay, recurrence and anal incontinence for six months. **Results:** The study's results were analyzed using SPSS, and it was found that the median age was 40 years, with a male preponderance. A statistical significance was noted in the duration of hospital stay, postoperative pain, and wound discharge. The postoperative pain score in Group A was 3, whereas in Group B was 5. 47% of the patients in Group B had wound discharge, whereas no cases in Group A had this complaint. The mean operative time is 25 mins in Group A patients and 33 mins in Group B patients. When analyzed in both groups, recurrence showed a similar rate of 17.6%. No major forms of incontinence were reported in the groups. **Conclusion:** Laser Ablation of the Fistula Tract is a safe, effective and minimally invasive option for the treatment of anal fistulae. The procedure has the added advantage of reduced postoperative pain, wound discharge, and duration of hospitalization with reduced operative time, hence increasing patient satisfaction. Laser Ablation of the Fistula Tract has a short learning curve and can be easily practiced. Furthermore, this procedure can be done multiple times in a patient with minimal risk of sphincter injury.

Keywords: Fistula-in-ano, Anal fistula, Fistula Tract Laser Closure, Fistulectomy, Laser Ablation of Fistula Tract.

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INTRODUCTION

A fistula-in-ano is a tract lined by epithelium, connecting the perianal skin to the anal canal. Fistulae in the anal region are common sequelae of inadequately drained or untreated cryptoglandular abscesses that account for 40-60% of cases. Trauma, tuberculosis, Crohn's disease, radiation and tumors are some of the other etiological factors predisposing to the formation of a fistula [1]. The incidence of the fistula is analyzed to be 8.6 per 100,000, with a male preponderance [2]. The condition is known to cause perianal pain and discharge, which leads to significant

distress and embarrassment for the patient. Treatment of anal fistulas is challenging for surgeons as there is a high possibility of recurrence, incontinence in high anal fistula, and complex fistulas. The primary goal of fistula treatment is eradicating sepsis and maintaining fecal continence [3].

The conventional methods, like fistulectomy and fistulotomy, result in increased postoperative morbidity with compromised quality of life due to the increased duration of pain, infection of the wound with delayed healing time and high risk of incontinence of up to 20%, particularly in high and

recurrent fistulas [4]. Hence, novel sphincter-saving procedures are steadily proposed and analyzed for the treatment of cryptogenic anal fistula. Some of them are the use of plugs [5], collagen paste [6], fibrin glue [7], anorectal advancement flap [8], ligation of the inter-sphincteric fistula tract (LIFT) [9], video-assisted anal fistula treatment (VAAFT) [10], and laser ablation procedures to minimize the concerns about functional outcome in surgical treatment of fistula [11,12]. Laser ablation of the fistula tract is a sphincter-saving procedure that uses a radial emitting laser probe with a diode laser source to seal the fistula tract throughout its length from within and to seal the internal opening without damaging the sphincters. This photothermal effect eradicates the anal gland and the epithelial tissue while simultaneously closing the internal and external openings [11,12]. There are promising reports of success regarding patient satisfaction and surgical outcome, and it can be performed multiple times with minimal impact on continence [12].

MATERIALS AND METHODS

This study aims to assess the efficacy of the laser ablation of the fistula tract over the conventional fistulectomy approach regarding postoperative pain, wound discharge, and morbidity in terms of maintenance of continence, duration of hospitalization, and recurrence of fistulae.

This prospective comparative study was conducted after approval from the institutional ethics committee and informed consent from all patients included in the study. This study analyses 68 patients treated for anal fistulae at a single tertiary care center from 2021 to 2024. Amongst a total of 68 cases of anal fistula of varying types, the patients were allocated by random allocation software as group A, who underwent laser ablation of the fistula tract (34 cases), and group B, who underwent fistulectomy (34 cases). All high and low anal fistulas, irrespective of their previous history of perianal surgeries, were included in the study. Cases with ongoing abscesses, proven cases of tuberculosis, actinomycosis, inflammatory bowel diseases and carcinoma of the rectum or anal canal were excluded from the study.

All the patients were evaluated preoperatively, which included patient demographics like age, sex, body mass index, co-morbidities, duration of fistula, history of previous perianal abscess and intervention, thorough clinical examination with assessment of incontinence, digital examination, and proctoscopy. Additionally, an MRI fistulogram was done preoperatively in all patients to detect abscesses, identify internal openings, and evaluate the type of tract and its relation to the sphincters. Mechanical bowel preparation was done for all the patients, and they received 1g of cefuroxime and 500mg of metronidazole intravenously before surgery.

All patients underwent surgery under spinal anesthesia.

Group A (Laser Ablation of Fistula Tract): The external opening was identified, and the fistula probe was passed until the internal opening. Mechanical debridement of the tract using a curette was done, and the tract was flushed with hydrogen peroxide and normal saline. The internal opening was identified and was sealed using a laser probe with a diode laser source if the opening is narrow and either with a mucosal advancement flap or figure of 8 suturing with absorbable suture material if the opening is wide. The machine used was a Lasotronix 1470nm diode laser, as shown in Figure 1. The fistula tract was then ablated through the external opening with a diode laser and a radial emitting laser probe (Figure 2) at 100-120 joules/cm of energy and a wavelength of 1470 nm with slow continuous fiber retraction at the rate of 1mm/sec. Lastly, the external opening is excised for proper drainage of the wound.



Figure 1: Lasotronix 1470nm diode laser machine, set at 12J with energy of 100-120 J/cm.



Figure 2: Laser ablation of the fistula tract through the external opening using a radial emitting laser probe with a retraction rate of 1mm/sec.

Alternatively, in Group B (Fistulectomy), The cases selected for fistulectomy underwent the standard procedure, where we identified the fistula tract and internal opening by injecting a dye such as methylene blue into the external opening, followed by probing the tract with a fistula probe. The external opening was circumscribed and dissected along with the fistulous tract using electric cautery or Metzenbaum scissors. The dissection was carried down as far as possible through the sphincters' planes. The internal opening of the fistula was circumferentially excised at the mucosal surface and closed by either Figure 8 sutures or a mucosal advancement flap with absorbable sutures. A complete excision of the tract was done. 3-0 PDS sutures (polydioxanone) were used to perform end-to-end sphincteroplasty. The external part of the wound was left open to permit drainage.

The duration of hospital stay was analyzed from the day of admission until the day of discharge. The surgery was conducted on the third day of admission. On postoperative day 1, and subsequently, at regular follow-ups, the patient was analyzed for post-operative pain and wound discharge. Post-operative follow-up at 1st, 3rd, and 6th months was scheduled at the outpatient clinic. A simple questionnaire was used to assess the postoperative pain score, the type of

discharge from the external opening and its duration, recurrence and incontinence. Clinical examination and proctoscopy were also done during the patient review. Data were entered and analyzed using SPSS (Version 20). For normally distributed continuous variables, comparisons between two groups were made using the independent sample t-test, while non-normally distributed variables were compared using the Mann-Whitney U test. Categorical variables were compared using the Chi-square test or Fisher's exact test. A p-value <0.05 was considered statistically significant with all two-tailed statistical tests.

RESULTS

A total of 68 patients were included in the study, of which 34 were divided into Group A: The laser ablation of the fistula tract and 34 were divided into Group B: fistulectomy. The male-to-female ratio was 54:14, with a median age of 40 years and a range of 9-76 years. According to Park's classification, 62% of cases (42) were inter-sphincteric, and 38% (26) were trans-sphincteric fistulas, of which cases were equally divided into both groups. Out of 64, 57% (39) had a history of previous intervention, and 13% (9) had secondary tracts. The patient characteristics are depicted in Table 1.

Table 1: Demographic characteristics with previous history of surgery and characteristics of fistula on the basis of preoperative MRI

Characteristic	Fistula Tract Laser Closure (n= 34) Group A	Fistulectomy (n=34) Group B	p-value
Age			0.012 ²
21 to 30	3 (21%)	11 (79%)	
31 to 40	15 (71%)	6 (29%)	
41 to 50	8 (67%)	4 (33%)	
Above 50	6 (33%)	12 (67%)	
Less than 20	2 (67%)	1 (33%)	
Sex			0.016 ³
Female	3 (21%)	11 (79%)	
Male	31 (57%)	23 (43%)	
Body Mass Index			0.006 ²
Normal	22 (41%)	32 (59%)	
Obese	2 (100%)	0 (0%)	
Overweight	10 (83%)	2 (17%)	
Previous surgery			0.06 ²
Positive history	20 (51%)	19 (49%)	
No history	14 (48%)	15 (52%)	
External openings			0.5 ²
Multiple	6 (67%)	3 (33%)	
Single	28 (47%)	31 (53%)	
Type of fistula			>0.9 ³
Inter-sphincteric	21 (50%)	21 (50%)	
Trans-sphincteric	13 (50%)	13 (50%)	
Low lying fistula	33 (51%)	32 (49%)	
High anal fistula	1 (33%)	2 (67%)	
Length of the tract (cm)			0.4 ²
2	1 (16%)	5 (84%)	
3	5 (26%)	14 (74%)	

4	3 (19%)	13 (81%)	
5	4 (100%)	0 (0%)	
6	8 (89%)	1 (11%)	
7	7 (88%)	1 (12%)	
8	6 (100%)	0 (0%)	

¹Wilcoxonrank sumtest

²Fisher's exact test

³Pearson's Chi-squared test

The mean operative time for group A was 25 mins (range is 10-42 minutes), and with group B was 33 mins (range is 25-60 minutes). No intraoperative complications were reported in group A. Whereas, in group B, intraoperative bleeding was noted in 5 cases, which was managed through compression and cautery. Amongst the cases of group A, the internal opening was closed by means of the figure of eight sutures with absorbable suture material in 14% of cases (5) and by mucosal flap advancement in 73% of cases

(25); in the rest 12% of the cases (4), the internal opening was ablated directly by the laser fibre. Meanwhile, in group B, 85% of cases (29) underwent mucosal flap advancement, and the rest, 15% of cases (5), underwent suturing in figure eight. Excision of the external opening was done in 88% of cases (30) of group A so as to facilitate adequate drainage of the wound. The parameters mentioned above are shown in Table 2.

Table 2: Operative time and intraoperative findings with its management.

	Fistula Tract Laser Closure (n= 34) Group A	Fistulectomy (n=34) Group B
Operative time		
10 – 20 mins	4 (100%)	0 (0%)
20 – 30 mins	18 (60%)	12 (40%)
30 – 40 mins	10 (37%)	17 (63%)
40 – 50 mins	2 (40%)	3 (60%)
50 – 60 mins	0 (0%)	2 (100%)
mean	25 mins	33 mins
Site of the internal opening		
Proximal to dentate line	18 (47%)	20 (53%)
On the dentate line	7 (58%)	5 (42%)
Distal to the dentate line	9 (50%)	9 (50%)
Intra-operative bleeding		
Yes	0 (0%)	5 (100%)
No	34 (54%)	29 (56%)
Method of closing the internal opening		
The figure of 8 suture	5 (50%)	5 (50%)
Mucosal-Advancement Flap	25 (46%)	29 (54%)
Direct ablation by the laser probe	4 (100%)	0 (0%)
Excision of the external orifice		
Yes	30	
No	4	

There was a statistical difference in the duration of hospital stay, which was noted from the day of admission. Laser ablation of fistula tract cases showed a mean of 5 days (range 3-6 days), and fistulectomy cases showed a mean of 6 days (range 5-8 days). Mean post-operative hospitalisation for laser ablation was two days, whereas, for fistulectomy, it was three days. Analysis of postoperative complications showed a significant difference in postoperative pain score on day 1, with the mean postoperative pain score in group A being 3 (range 2-5) and in group B being 5 (range 4-7). A statistically significant postoperative wound discharge was found in 16 cases from the

fistulectomy group, whereas none from the laser group had this complication. All the cases were followed up for six months, at the intervals of 1st month, 3rd month and 6th month. The laser group showed a recurrence in 3 cases until the 3rd-month visit and a total of 6 instances until the 6th-month visit. The fistulectomy showed a recurrence in 6 cases at the 6th-month visit. The cases of recurrence were taken up for repeat surgery, and a fistulectomy was done. No major forms of incontinence for solid stool, liquid stool or gas were reported in both groups. The postoperative complications are listed in Table 3.

Table 3: Statistical analysis of post-operative complications.

Post-operative complications	Fistula Tract Laser Closure (n= 34)Group A	Fistulectomy (n=34) Group B	p-value
Duration of hospital stay	Five days (Range 3-6)	Six days (Range 5-8)	<0.001 ¹
Post-operative pain score:			<0.001 ²
Mean pain score	3 (Range 2-5)	5 (Range 4-7)	
2	3 (100%)	0 (0%)	
3	22 (100%)	0 (0%)	
4	8 (73%)	3 (27%)	
5	1(4.3%)	22 (96%)	
6	0 (0%)	8 (100%)	
7	0 (0%)	1 (100%)	
Post-operative wound discharge			<0.001 ³
Present	0 (0%)	16 (100%)	
Absent	34 (65%)	18 (35%)	
Recurrence in 3rd month	3 (100%)	0 (0%)	0.2 ^{2,3}
Recurrence at 6th month	6 (50%)	6 (50%)	>0.9 ^{2,3}
Incontinence for solid, liquid stool or gas	0	0	

¹Wilcoxonrank sumtest²Fisher'ssexacttest³Pearson'sChi-squaredtest

DISCUSSION

During the last decade, interest in minimally invasive procedures to treat fistula in ano has exponentially increased due to the reduced incidence of incontinence, recurrence and high patient satisfaction [11]. However, many have not resulted in long-term success, such as fistula plugs, collagen paste, and fibrin glue [13]. The goal of any fistula surgery is to eliminate sepsis and maintain continence.

Fistulectomy is considered a gold standard treatment strategy for all types of fistula, reporting a primary healing rate of 88.2% and a mean post-operative hospitalisation of 3 days in a study done on 424 patients [14]. However, it can result in anal incontinence in 20% of cases as an undesirable outcome leading to a high rate of patient dissatisfaction [15]. This has led the surgeon to turn to other treatments. Vial et al. conducted a study in which they systematically reviewed seton procedures and found an incontinence rate of 5.6% - 25.2% and a recurrence rate of 5% in 448 patients [16]. Additionally, A retrospective study of 56 patients with trans-sphincteric and complex anal fistulas, initially managed by seton placement and followed by fistulectomy and sphincteroplasty, reported an average healing time of 3.7 weeks (2-8 weeks), with an incontinence rate of 3.6% and a recurrence rate of 3.6% [17]. In our study, out of 34 patients of group B who underwent fistulectomy, there was a success rate of 82.3%, with a mean post-operative hospitalisation of 3 days and a mean post-operative VAS score for pain of 5 on the first postoperative day. 17.6% of patients (6) had recurrence at the end of 6 months of follow-up with no cases of incontinence. Meanwhile, group A patients who underwent laser ablation had a significantly lower mean post-operative

hospitalisation of 2 days and a mean post-operative VAS score on the first postoperative day of 3.

Ligation of the inter-sphincteric fistulous tract (LIFT) was first described in 2007 as a sphincter-saving procedure for treating the fistula [9]. In subsequent studies, LIFT has been recommended for treating recurrent and low trans-sphincteric fistula with a low success rate in high trans-sphincteric and horseshoe fistula [18]. In advancement flaps, a pooled success rate of approximately 75% has been reported in a study on 800 patients [19].

Laser ablation of the fistula tract is a novel sphincter-saving procedure, which is done for all types of fistula with promising results in high anal fistulae and trans-sphincteric fistulae [20].

The laser energy emitted into the lumen of the tract encourages postoperative shrinking and subsequent closing of the tract while destroying the epithelium, sparing the surrounding sphincters [11,21,22]. Wolicki et al. conducted a retrospective study of 83 patients of trans-sphincteric and inter-sphincteric anal fistulae, of which 78.3% had prior abscess drainage and seton insertion followed by laser ablation, showed a recurrence rate of 15.7%, primary healing rate in 74.7% with no major incontinence post-operatively [23].

Wilhelm et al., in their pilot study of 11 patients conducted in 2011, reported a success rate of 81.8%. He then conducted another study with 117 patients with a median follow-up period of 25.4 months who underwent laser ablation of the fistula tract, and the study reported a primary success rate of 64.1% with no major forms of incontinence [11,21]. Two other studies confirmed the high success rate, reporting 71.4% and 82% healing rates with no significant changes in incontinence, respectively, in 35 and 50 patients [22,24]. A recent clinical review and meta-

analysis of 296 patients by Elfeki et al. reported an overall healing rate after primary and secondary laser procedures of 65.2% and 69.7%, respectively [25]. In our study, out of 34 cases operated by laser ablation, we report a recurrence rate of 17.6% in 6 months of the follow-up period. The primary healing rate in our study accounts to be 82.3% with nil anal incontinence, which is comparable to other reports.

The closure of the internal opening by either suture or by mucosal advancement flaps in addition to laser ablation procedure has variable outcomes. Bonnechose et al., in their study of 100 patients with anal fistulae and a narrow internal opening, were treated with laser ablation of the fistula tract (LAFT) with low energy administration of 400 J for closure of the internal opening, they reported fistula healing in 44.6 % of patients after a median follow-up of 13.6 months [26]. Additionally, a retrospective study of 83 patients treated with laser ablation for trans-sphincteric and intra-sphincteric fistula with simple 3-0 Z-stitch for closure of internal orifice and a mean follow-up period of 41.99 months reported a primary healing rate of 74.7%, the recurrence rate of 15.7% and no cases of major incontinence [23]. In our study, out of the 17.6% of cases with recurrence in the laser group, 66.7% of patients(4) had undergone probe shrinkage of internal opening, and 33.3% of patients(2) had undergone a figure of 8 suturing for closure of internal opening.

In 2022, Abd El-Wahab et al. conducted a study with 80 patients of trans-sphincteric fistula who underwent preliminary seton insertion and were randomly divided into two groups. The first group underwent fistulectomy with subsequent sphincter repair, and the second group underwent laser ablation; they reported a statistically significant reduced operative time, postoperative pain assessed by VAS score, mean hospital stay, mean healing time and rate of recurrence in the laser ablation group [15]. This was in accordance with our study. The mean pain score on post-operative day one was found to be significantly lower in the laser group (VAS Score 3) than in the fistulectomy group (VAS Score 5). Post-operative wound discharge was a significant finding in patients who underwent fistulectomy (47% of patients), which was not found in any patients undergoing laser treatment. Additionally, intra-operative bleeding was noted in 14.7% of the fistulectomy group (5 cases), which was controlled by compression or by cautery before completing the procedure; this complication was not experienced with laser ablation.

Nordholm-Carstensen and colleagues reported that the mean surgical time for laser ablation in 66 patients with various types of fistulas was 22 minutes [27]. The mean surgery time for laser ablation in our study was 25 mins, and for fistulectomy, it was 33 mins.

Postoperative magnetic resonance imaging or endorectal ultrasound has not shown efficacy in detecting early recurrence or a persistent fistula tract

due to the high percentage of false positives. Scar tissue or a prolonged sealing process observed in some cases after laser treatment may be misleading [24]. For this reason, routine postoperative MRI or ERUS have been discontinued in our practice.

Analysis of our results clearly demonstrates a statistical significance in favour of laser ablation of the fistula tract in terms of operative time, postoperative VAS scores, postoperative wound discharge, and hospital stay. Although the advantages exist, the recurrence rates in both groups were found to be similar. Hence, the determination of the superiority of one procedure over the other was inconclusive regarding recurrence. Postoperative complications like incontinence were nil in both groups.

The results of this study cannot be generalised as it is a single-centred study with a small sample size and a short follow-up period of six months to assess the recurrence rate. Hence, further study is required with a larger sample size and longer follow-up period.

CONCLUSION

Laser ablation of the fistula tract is a safe, effective and minimally invasive option for the treatment of anal fistulas of all types with the added advantage of a relatively short learning curve, reduced hospital stay, decreased post-operative pain, recurrence and no risk of incontinence, thus producing a significant impact on quality of life of patients. Additionally, the closure of internal openings, either by simple suturing or with mucosal advancement flaps, allows the tract to heal completely without contamination. Further studies are needed to evaluate the effect of the combination of various techniques on patient outcomes and compare it to the established methods.

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