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Comparison of Laser Ablation and Fistulectomy with Sphincteroplasty for the Management of Transsphincteric Fistulas Following Preliminary Seton Insertion

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Background: Cryptoglandular perianal fistulas are a frequent problem, and the traditional surgical procedure carries a risk of incontinence and recurrence. The ultimate goal of fistula management is to resolve and prevent sepsis, eradicate the fistula, prevent recurrence, and ensure continence. Laser Ablation of Fistula Tract (LAFT) offers a viable alternative sphincter-saving modality.

Patient and methods: In this study, we performed a randomized controlled trial to evaluate the safety and efficacy of laser ablation as a treatment for transsphincteric fistulas. This study was conducted at Ain Shams University hospitals from June 2019 to June 2022 and included eighty patients with cryptoglandular transsphincteric fistulas who had undergone previous drainage and seton, they were divided into two groups. The first group (Group A) underwent fistulectomy with subsequent sphincteroplasty while the second group (Group B) underwent laser ablation of the fistula tract. Follow-up was scheduled in the outpatient clinic at 1 and 2 weeks and 1, 3, and 6 months postoperatively. The Cleveland Clinic Florida Fecal Incontinence CCF-FI score and the visual analog scale (VAS) score were recorded at each visit.

Results: The results of the study showed that the laser ablation of the fistula track technique is a safe and effective sphincter-saving modality for transsphincteric fistula management with acceptable healing rates. The technique also carries the advantages of a short learning curve, reduced hospital stay, and minimal risk of incontinence.

Conclusion: Our study found that laser ablation is a safe and effective treatment option for transsphincteric fistulas. Preliminary seton insertion may have a positive impact on postoperative outcome. However, there is a need for further research to evaluate the long-term outcomes..

Key words: Anal fistulas, laser ablation, fistulectomy, transsphincteric fistulas, incontinence.

Introduction

Anal fistula disease (AF) is a condition with a long history, with evidence of its existence found in the ancient medical literature. The reported incidence of AF in the European Union ranges from 10.4 per 100,000 in Spain to 23.2 per 100,000 in Italy. Historically, the main treatment for AF was fistulotomy, fistulectomy, or the use of a seton. However, these treatments often resulted in defective continence, particularly in patients with high transsphincteric fistulas.[1]

The goal of surgical management for AF is to resolve and prevent sepsis, eradicate the fistula, prevent recurrence, and ensure continence. However, these goals can sometimes be in conflict, making it difficult to achieve an acceptable balance. This has led to the development of new strategies to improve current techniques.[2]

Historically, seton placement was the main method of surgical management for most perianal fistulas. Setons allow the drainage of associated abscesses while promoting the resolution of the tract through a local inflammatory process.[3] However, persistent fistulas occur in up to 30% of patients after definitive surgery, despite recent advancements in surgical techniques, such as the anal fistula plug and fibrin glue. The main reasons for recurrence include missing or untreated internal openings, incomplete drainage of the intersphincteric space, missed sidetracks, and persistence of the primary track.[4]

Complete excision of the fistula with sphincteroplasty has resulted in acceptable healing outcomes, but the main drawback of this technique is incontinence, which occurs in up to 20% of cases.[4] The challenge of treating cryptoglandular perianal fistulas while preserving anal sphincter function remains. Despite the development of various new techniques, a perfect treatment that leads to convenient healing rates while preserving sphincter function has not yet been discovered.

Laser Ablation of Fistula Tract (LAFT) was introduced in 2011 as a new technique with high potential. The LAFT involves the use of a radial emitting laser probe (E.g., "FiLaC™", Biolitec, Germany) to ablate the fistula tract. The removal of granulation tissue from the tract allows for the healing of the tissues and preservation of continence. Initial results have shown acceptable primary healing rates without

impairment of continence, with sustained results after long-term follow-up.[5]

Patients and methods

This study is a prospective randomized controlled trial that was conducted at Ain Shams University hospitals from June 2019 to June 2022. It included 80 patients with cryptoglandular transsphincteric fistula who had undergone previous drainage and seton placement.

The patients were randomly allocated into two groups: Group A underwent fistulectomy with subsequent sphincteroplasty, while Group B underwent laser ablation of the fistula tract. Both groups had 40 patients each. Exclusion criteria included superficial fistulas that could be managed by fistulotomy without affecting anal sphincter function and any fistulas related to inflammatory bowel diseases or malignancy. Approval from the ethical committee was granted and informed consent to undergo the surgical intervention was signed out by all patients. Patients agreed to participate in regular follow-up visits.

The primary operation involved drainage of perianal abscesses (If present), clearance of sidetracks, and seton drainage of the main fistula track using a 2 mm silicone vessel loop.

Prior to the definitive procedure, all patients underwent routine preoperative clinical assessment and examination, including assessments of incontinence history. Magnetic resonance imaging (MRI) was done routinely for all patients, and if continence was questioned, anorectal manometry and endoanal ultrasound were performed.

All patients received antibiotics (Cephalosporins and metronidazole) prior to the procedure and were placed under general anesthesia in the lithotomy position. An anal examination was performed, and anal retractor was inserted. After adequate mobilization, the seton tie was cut and the distal part of the track and the external opening of the fistula were excised. Afterward, the remaining part of the track was cleaned, curetted, and irrigated with saline.

In Group A, end-to-end sphincter repair was performed, taking into consideration not to leave any dead space deep to the repaired sphincter muscle. To facilitate the repair, the sphincter muscle was mobilized from the skin and the external ischioanal fat. The sphincter muscle was identified and held by applying Vicryl® 2-0 stay sutures on each side **(Figure 1)**.

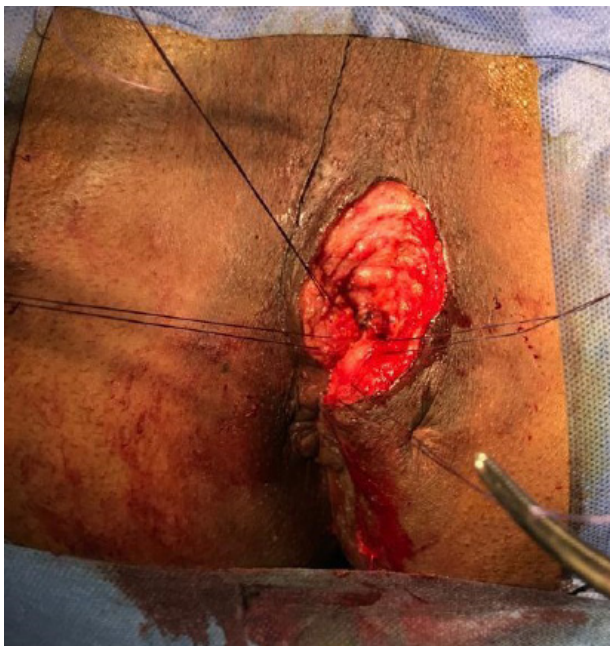

Fig 1: The sphincter is identified and held by Vicryl® 2-0 sutures.

Starting from the proximal part of the cut sphincter, the repair proceeds using polydioxanone 3-0 interrupted sutures starting from the outer to the inner side of the sphincter, then from the inner to the outer aspect in a U-shaped manner tying both ends in a firm secure knot placed at the outer aspect of the repaired sphincter. Through progressive deep bites the entire sphincter is progressively repaired. The remaining part of the wound is left open for good wound drainage **(Figure 2).**

Fig 2: Complete repair of the sphincter muscles after fistulectomy.

In Group B, laser ablation of the fistula tract was conducted using a 1470-nm diameter laser fiber and the Ceralas ® platform (Biolitec AG, Jena, Germany),

(Figures 3,4). The laser probe was inserted from the external opening emerging from the internal opening guided by the previously inserted seton, **(Figures 5-7).**

Fig 3: The (Biolitec AG, Jena, Germany) laser device.

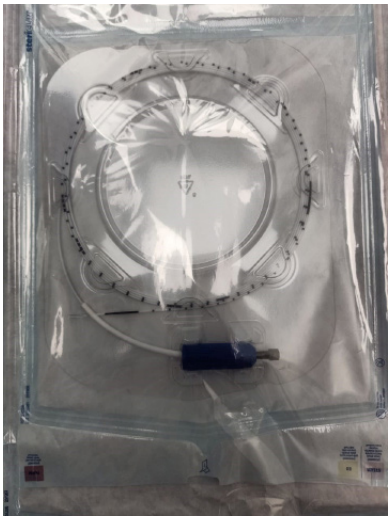

Fig 4: The disposable 1470-nm diameter laser fiber.

Fig 5: Careful examination of the previously inserted seton in the fistulous track.

Fig 6: Adequate mobilization of the track.

Fig 7: The laser fiber is successively inserted into the fistulous track.

By applying a 13-watt energy output, the fistula track was obliterated using continuous retraction of the laser fiber at a rate of approximately 1 cm every 7 seconds, then it was advanced back towards the internal opening. Care was taken during the procedure to avoid excessive burns to the treated and surrounding tissue, as well as damage to adjacent tissues **(Figure 8).** The previously identified internal opening was closed using interrupted Vicryl® sutures (Polyglactin 910, 3-0 needle, 26 mm, 5/8 circle) to ensure proper healing.

Fig 8: The fistulous track after successful ablation.

Patients were discharged with a prescription for simple analgesia, oral cephalosporins, and metronidazole. Patients who underwent sphincter repair were advised to avoid straining and to limit physical activity for four to eight weeks. All patients were instructed on proper wound care, including adequate cleaning the wound and applying local antibiotic cream after defecation and before bedtime.

Follow-up visits were scheduled for the outpatient clinic at 1 and 2 weeks, as well as 1, 3, and 6 months post-surgery. However, patients were instructed to return to the clinic at any time if they experienced any symptoms. The Cleveland Clinic Florida Fecal Incontinence (CCF-FI) score and the Visual Analogue Scale (VAS) score (To measure pain) were evaluated during each visit. Any signs of recurrence were closely monitored through clinical examination and MRI. The patient was considered cured if the external and internal openings were closed, with no discharge, pain, or swelling present. Treatment was considered a failure if the external opening remained unclosed at the three-month follow-up.

Statistical analyses were conducted using SPSS, IBM. Corp, USA (Version 26.0), and MINITAB, USA (Version 19). The results were presented as mean and standard deviation, frequency, or proportion. To compare the results between the groups, the Student's t-test (For normally distributed data), the Chi-square test (for categorical variables), and the percentage comparison method were used. The hypotheses were either two-tailed or one-tailed, and statistical significance was set at $p < 0.05$.

Results

This prospective randomized controlled study includes eighty patients presented with transphincteric anal fistula who was primarily treated with drainage and seton placement which were randomly allocated into two groups, each group consists of forty patients. The first group (Group A) underwent fistulectomy followed by sphincteroplasty while the other group underwent laser ablation of the fistulous tract. No significant statistical differences were noted regarding patient's age, sex, and risk factors including smoking and diabetes mellitus. No significant statistical differences was found regarding the time interval between the definitive intervention and preliminary seton insertion. Patient's characteristics were shown in **(Table 1).**

There was a clear significancant statistical difference regarding mean operative time which was clearly shorter in laser ablation group (P value 0.000).The mean hospital stay was shorter in the laser ablation group with statistical significance (P value 0.000) **(Table 2).**

Postoperative pain was assessed using VAS score in the first day, first and second week. Statistical significance difference regarding the mean VAS scores was found in favor of the laser ablation group **(Table 3)**.

Analysis of the postoperative complications revealed no statistical significant difference between both groups. Recurrence was higher in laser ablation group with statistical significance (P value 0.002) while the median time for healing was shorter in laser ablation group with statistical significance (P value 0.000) **(Table 4).**

Postoperative continence was carefully assessed and recorded using CCF score. No significant statistical difference was found in both groups.

Table 1: Patients characteristics

	Fistulectomy and sphincterolplasty	Group B Laser ablation of fistulous tract	P value	Statistical significance
Number of patients	40	40		
Median age	34.5	34.00	0.958	No significance difference
Gender (M:F)	(28:12)	(26:14)	0.633	No significance difference
Smoking	12 (30%)	14 (35%)	0.633	No significance difference
Diabetes Mellitus	8 (20%)	9 (22.5%)	0.785	No significance difference
Median time between seton placement and definitive intervention	14.50	14.00	0.194	No significance difference

Table 2: Mean operative time and mean hospital stay in both groups

	Group A Fistulectomy and sphincterolplasty	Group B Laser ablation of fistulous tracr	P value	Statistical significance
Mean operative time	47.025	37.750	0.000	Significance difference
Mean hospital stay	2.00	1.08	0.000	Significance difference

Table 3: Vas scores in the first, first and second week in both groups

Mean VAS score	Group A Fistulectomy and sphincterolplasty	Group B Laser ablation of fistulous tract	P value	Statistical significance
First day	5.18	3.88	0.000	Significance difference
First week	3.85	2.4	0.000	Significance difference
Second Week	2.02	1.5	0.001	Significance difference

Table 4: Post-operative outcomes in both groups

Post-operative complications And outcome	Group A Fistulectomy and sphincterolplasty	Group B Laser ablation of fistulous tract	P value	Statistical significance
Bleeding	2 (5%)	1 (2.5%)	0.555	No significance difference
Urinary retention	4 (10%)	2 (5%)	0.394	No significance difference
Infection	1 (2.5%)	0	0.311	No significance difference
Recurrence	2 (5%)	12 (30%)	0.002	significance difference
Median time for healing	8	6	0.000	Significance difference

Table 5: Postoperative CCF score assessment

	Group A Fistulectomy and sphincterolplasty	Group B Laser ablation of fistulous tract	P value	Statistical significance
First Month	(0) 92.5% (1) 5% (2) 2.5%	(0) 95% (1) 5%	0.630	No significance difference
Second month	(0) 97.5% (1) 2.5%	(0) 100%	0.317	No significance difference

Discussion

Complex perianal fistulas can be a challenging condition to treat, as the goal is to achieve successful fistula closure while also maintaining continence and patient satisfaction. There have been various surgical techniques proposed for sphincter-preserving fistula repair, but many of these techniques have not resulted in sustained long-term success.[6,7] Reasons for recurrence may include persistent or recurrent disease from the internal opening, inadequate drainage of the intersphincteric space, and sidetracks that are frequently missed. As a result, when patients present with perianal abscesses or persistent fistulas, appropriate primary surgery must be performed. Evacuation of abscesses, excision of secondary tracks, and drainage of the intersphincteric space are crucial.[4]

The seton placement promotes continuous drainage of the fistula track to minimize infection but can lead to recurrence from epithelial remnants or granulation tissue. Fistula laser closure (FiLaC™) is a promising technique that uses diode laser energy, via a flexible radial fiber, to shrink the fistula tract and achieve primary closure. But it has the drawback of not being able to visualize the tract and the potential to damage the sphincter if high powers were used.[4] The use of a draining seton with laser treatment may help to achieve complete shrinkage of the fistula tract.[8]

Seyfried et al. conducted a study on 424 patients who underwent fistulectomy and primary sphincter repair, reporting a primary healing rate of 88.2% and a median postoperative hospitalization of three days. However, it should be noted that this patient population only consisted of less than 4.2% of individuals with high transsphincteric fistulas.[9] On the other hand, Arroyo et al. reported on a series of patients with transsphincteric fistulas who underwent fistulotomy and sphincter reconstruction. They reported an incontinence rate of 16.6% and recurrent incontinence in 8.5%.[10]

In Ratto et al.'s study, 40.3% of the patients had a seton drainage, followed by a fistulotomy and end-to-end primary sphincteroplasty. There was no statistically significant change in fecal incontinence, and three out of 72 patients (4.3%) experienced a recurrence. Similarly, Pearl et al. reported that a staged fistulotomy using a seton is a safe and effective procedure for treating high or complicated anal fistulas, with an incontinence rate of 5% and a recurrence rate of 3%.[11]

Al-Ozaibi et al. conducted a retrospective study of 56 patients with transsphincteric and complex anal fistulas, managed preliminarily with a loose seton followed by fistulectomy and sphincteroplasty. The average healing time was 3.7 weeks (2-8 weeks), with an incontinence rate of 3.6% and a recurrence rate of 3.6%.[11]

The laser emitted by the radial-tip fiber into the fistula track is capable of eliminating the endoluminal granulation tissue and the epithelium of the fistula tract due to its shrinkage effect, which is similar to that observed in the treatment of varicose veins. This is in contrast to simple diathermy, which cannot achieve the same effect, and is less easily controlled, particularly with regard to thermal damage on the sphincter muscle.[8]

Wilhelm conducted a pilot study of eleven patients presented with cryptoglandular type (1-4) fistulas who had undergone previous surgery for perianal abscess and fistula with seton insertions. After the closure of the internal opening with either a mucosal or anodermic flap, a laser probe with a wavelength of 1,470 nm and 13-Watt energy was used to obliterate the track. Primary healing occurred in 81.8% of patients after a median follow-up of 7.4 months, with no major or minor complications reported. Wilhelm continued to use the technique in the management of high anal fistulae in an unselected patient population over the next five years.[4,12]

A study was conducted involving 117 patients with a median follow-up period of 25.4 months. Two types of diode laser devices, "Ceralas®" and "Leonardo DUAL 4®" were used. The majority of patients, 113 (96.6%), had previously undergone surgery such as abscess drainage and fistula operations. In 99 patients (84.6%), a seton was placed with an average period of 16.1 (±29.2) weeks between seton insertion and fistula treatment.[12]

In the study by Wilhelm et al., it was found that the use of laser energy at a wavelength of 1470 nm resulted in more efficient local tissue shrinkage and protein denaturation. This was achieved by the absorption of the laser energy in water, which caused the destruction of the granulation and epithelial tissue in a controlled manner. The damage was limited to a 2-3 mm zone and required less power 13-Watt while minimizing collateral thermal damage to the surrounding tissues.[12]

It was reported that the FiLaC™ procedure had a primary success rate of 64.1% (75/117) with similar outcomes for both cryptoglandular (63.5%; 66/104) and Crohn's-related (69.2%; 9/13) cases. The secondary success rate was 88.0% (103/117), with no differences observed between cryptoglandular and Crohn's-related cases. Additionally, the study reported no major forms of incontinence in their patients, with minor soiling being observed in only 5.9% of patients (Three after the primary FiLaC™ procedure and four after a repeated second fistula surgery).[12]

Giamundo and colleagues performed the FiLaC™ fistula laser closure technique on 35 patients. The procedure involved sealing the fistula tracks without any additional steps and no complications occurred during surgery. Some patients experienced urinary retention (5.8%), bleeding (2.8%), and anismus (17.1%) but the overall success rate was 71.4%. Additionally, none of the patients reported any significant changes in their continence.[8]

According to Giamundo et al., the cost of the fistula laser closure technique is higher than other sphincter-saving procedures because of the equipment needed. However, the laser device is portable and has multiple surgical uses, such as treating varicose veins. This allows for multiple specialists to use the equipment in one hospital, which can lower costs. Additionally, although the cost of laser fibers is moderate, it is still less expensive than most fistula plugs.[8]

They found that the fistula laser closure technique (FiLaC™) is a safe option for treating anal fistulas, as it does not require additional surgical procedures to close the internal orifice. The technique has an acceptable success rate and low complications, making it a desirable choice for patients with weak sphincters. They recommend using a loose seton to prepare the fistula track before the procedure, as this may improve healing outcomes. Overall, they suggest that this technique should be considered as part of the treatment plan for complex fistulas, as it preserves continence.[8]

Wolicki conducted a retrospective study of 83 patients who were treated with Fistula-tract Laser Closure (FiLaC®), Ceralas® or Leonardo® DUAL 45 diode laser for transsphincteric and intersphincteric anal fistulas. The procedure included the closure of the internal orifice using a simple 3-0 Z-stitch and had a mean follow-up period of 41.99 (± 21.59) months. The results showed that 15.7% of patients had a recurrence, 78.3% had prior abscess drainage and seton insertion, and 74.7% experienced primary healing. 9.6% of patients reported changes in continence, but no major incontinence was reported postoperatively.[14]

Lauretta and colleagues conducted a retrospective study on 30 patients with a median age of 52 years who were treated with a laser for transsphincteric anal fistulas. They used a diode laser emitting 12 watts of energy at a wavelength of 1470 nm. The study found that a cure was achieved in 10 patients (33.3%) and an overall healing rate of 40% (12 out of 30). Only 4 minor complications occurred, which is a rate of 13.3%. No changes in anal continence were reported.[14]

Nordholm-Carstensen and colleagues examined the effectiveness of the FiLaC™ technique in a study of 66 patients with various types of anal fistulas, including high intersphincteric, low and high transsphincteric, and suprasphincteric fistulas. The median surgery time was 22 minutes and the healing rates at six-month and one-year follow-ups were 64.7% and 50%, respectively. There were no cases of postoperative bleeding or changes in continence reported and no additional pain medication was needed beyond the standard post-operative regimen.[6]

Terzi and colleagues studied 103 patients with fistula disease in a study that evaluated the effectiveness of the laser closure procedure. The average age of the patients was 43 years. Out of the 103 patients, 53 (52%) had undergone previous surgery for perianal fistula repair and 29 (28%) had transsphincteric fistulas. The results of the study showed that 41 patients (40%) experienced complete healing, 38 (37%) still had persistent drainage with symptoms, 20 (19%) had minor drainage with minor symptoms, and 4 (4%) had painful symptoms with drainage.[15]

Suhardja et al., from their center in Australia, evaluated the effectiveness of the fistula laser closure technique FiLaC™ on transsphincteric fistulas. They determined that FiLaC is a viable option for complex fistulas with benefits such as not impacting sphincter function, having a short learning curve, reducing post-operative hospital stay, and having success rates comparable to other surgical procedures for the management of complex fistulas.[16]

They proposed that the use of laser ablation to preserve the sphincter is a viable initial treatment option for complex fistulas, but further evaluation of its cost-effectiveness is necessary, particularly in cases where multiple surgeries may be required due to higher recurrence rates.[16]

In our study, 80 patients with transsphincteric fistulas who had undergone preliminary seton insertion were randomly divided into two groups. The first group underwent fistulectomy with subsequent sphincter repair, while the second group underwent laser ablation of the fistula tract.

Analysis of our results clearly demonstrates a statistical significance in favor of laser ablation procedure in terms of operative time, hospital stay, postoperative VAS scores, time for complete healing, thus may justify the recorded differences of recurrence rates which were statistically significant in favor of fistulectomy and sphicteroplasty. No significant statistical difference regarding post-operative complication and recorded CCF score. Laser ablation has a clearly positive impact on patient's quality of life which may attract more attention in further studies. We believe that progressive improvement in this relatively new technique will positively affect the recurrence rate especially in the management of this difficult type

of anal fistulas.

Our results regarding staged fistulectomy and sphincteroplasty were compatible with Ratto et al, Al-Ozaibi et al in terms of recurrence and incontinence. Preliminary seton insertion has positive impact in improving postoperative outcome which was quiet obvious comparing our recurrence results with Seyfrid et al and Roig et al series. Similarly comparing our incontinence results with Arroyo et al series.

In the same manner, our results regarding staged laser ablation were compatible with Wilhelm et al and Giamundo et al regarding recurrence and incontinence. We suggest that Preliminary seton improves postoperative recurrence which was obvious comparing our results with Lauretta et al.

The results of this study indicate that laser ablation is a promising option for the management of complex fistulas. It is less invasive than other procedures and has a lower risk of adverse effects, particularly incontinence, which can have a significant impact on the quality of life for patients with transsphincteric fistulas. However, there are still some technical considerations that need to be evaluated in further studies. For example, there is no consensus on the need to close the internal opening of the fistula. Different studies have used different methods, such as the flap technique,[4] a Z-stitch,[13] and simple sutures,[6] for the closure of the internal opening. However, others suggested no additional procedure.[8]

Conclusion

Our study suggests that laser ablation of the fistula tract technique is a safe and effective option for the management of transsphincteric fistulas. It is a sphincter-saving modality that has acceptable healing rates and several advantages, such as a relatively short learning curve, reduced hospital stay, and minimal risk of incontinence. Additionally, the use of a preliminary seton in our study was found to have several benefits, such as allowing adequate drainage, alleviating sepsis, and potentially closing secondary tracks. Furthermore, the seton may positively affect the results of fistulectomy and subsequent sphincteroplasty. While further studies are needed to evaluate the technique and compare it to other well-established procedures, the findings of this study support the use of laser ablation as a treatment option for transsphincteric fistulas.

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