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ORIGINAL ARTICLE

Implementation of laser ablation of fistula tract (LAFT) for perianal fistulas: do the results warrant continued application of this technique?

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Abstract

Background Laser Ablation of Fistula Tract (LAFT) is a novel technique for the treatment of perianal fistulas. Initial reports have shown moderate-to-good results. The aim of this study was to evaluate this implementation and the effectiveness of this technique. Patients were offered LAFT as a treatment option for their perianal fistulas at the outpatient clinic between November 2016 and April 2018. Inclusion criteria were intersphincteric and transsphincteric fistula of cryptoglandular origin [10]. Exclusion criteria were supra- or extrasphincteric fistula, Crohn's disease, presence of undrained collections or side tracts and malignancy-related fistula. The primary outcome was fistula healing rate, the main secondary outcome incidence of postoperative fecal incontinence. Healing and postoperative FISI were evaluated at our outpatient clinic during follow-up at 6 and 12 weeks. A questionnaire was sent to all patients to evaluate the long-term postoperative FISI and patient satisfaction after 3 months.

Results Between November 2016 and April 2018, 20 patients [m:f = 4:16, median age 45 (27–78) years] underwent LAFT. Median follow-up was 10 months (IQR 7.3 months). A draining seton was placed in 15 (75%) of all patients with a median time of 12 weeks (IQR 14 weeks) prior to LAFT. Five intersphincteric and 13 transsphincteric fistulas were treated. Overall healing rate was 20% (4/20). The median postoperative fecal incontinence severity index (FISI) score was 0 (range 0–38); however, we found a change in continence in 39% of the patients.

Conclusions LAFT has now been discontinued as a treatment of cryptoglandular perianal fistulas in our centre, because of its disappointing results. Further detailed research seems to be warranted to investigate its exact indication and limitations.

Keywords Perianal fistula · LAFT · Transsphincteric · Intersphincteric · FiLaC · Cryptoglandular

Introduction

Treating cryptoglandular perianal fistulas, while conserving anal sphincter integrity, remains a challenge. Despite the advent of a myriad of new techniques and technologies, perfect treatment that ensures acceptable healing rates while preserving continence has still not been discovered. Many of the techniques display a similar evolution: after promising initial results, it seems to be difficult to reproduce the outcomes [1]. Laser Ablation of Fistula Tract (LAFT) was introduced in 2011 as a new technique with high potential [2]. LAFT is based on ablation of the granulation tissue in the fistula tract by the use of a radial emitting laser probe (e.g. "FiLaC™", Biolitec, Germany). Removal of granulation tissue from the tract is believed to finally allow healing of the tissue. The technique was developed to preserve sphincter integrity and continence. Initial results showed high primary healing rates without impairment of continence [2–4], and these results appear to be sustained after long-term follow-up [5, 6].

Because of these promising outcomes, we implemented LAFT in our hospital in an effort to reproduce the already published results. The aim of this study was to evaluate the effectiveness of this new technique in our centre.

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Materials and methods

Implementation

LAFT was implemented in our hospital according to the Royal Dutch Medical Association (KNMG) guidelines [7]. A preliminary risk assessment was performed; no serious risks were expected, and the procedure was deemed as 'low risk'. One member of our surgical team (JS) was trained and certified in the use of this new technique. LAFT was also performed on porcine models before implementing this technique in our hospital. In concordance with Dutch guidelines, an assessment was planned 1 year after implementation. The present report was prepared in concordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [8].

Patient characteristics

Patients were offered LAFT as a treatment option for their perianal fistulas at the outpatient clinic between November 2016 and April 2018. All patients were fully informed about the novelty of the treatment; they were offered alternative options if possible [ligation of the intersphincteric fistula tract (LIFT), transanal advancement flap (TAF) or fistulotomy] and all patients gave informed consent. Digital rectal examination and preoperative assessment of fecal incontinence, measured using Fecal Incontinence Severity Index (FISI), were recorded at the outpatient clinic [9]. Inclusion criteria were intersphincteric and transsphincteric fistula of cryptoglandular origin [10]. Exclusion criteria were supra- or extrasphincteric fistula, Crohn's disease, presence of undrained collections or side tracts and malignancy-related fistula. These fistulas are more complex to treat and we therefore did not consider them as "ideal" to implement a new technique upon. Preoperative magnetic resonance imaging (MRI) was performed in all patients, for assessment of the fistula tract and visualisation of undrained collections or side tracts. As there is no convincing evidence to support prior seton placement [4–6], this was preferred but not deemed necessary before LAFT. When no excessive inflammation was noted on preoperative MRI and when no granulation tissue was detected, no seton was placed. The primary outcome was the healing rate after LAFT. A fistula was considered healed if the external opening was completely closed, without signs of septis or abscess. LAFT was considered unsuccessful if there was a recurrence of the external opening after initial healing, or recurrence of symptoms after 12 weeks. Secondary outcomes were postoperative fecal incontinence (POFI), change in continence status, and patient satisfaction.

Surgical technique

No prophylactic antibiotics or bowel preparation were given. Patients had spinal or general anesthesia (patient preference) and were all operated on in lithotomy position. A disposable plastic retractor (Beak®, Endomed) was used for exposure of the anal canal. The external opening was probed gently to identify the fistula tract and the internal opening. We used 2/0 Vicryl© as a guide wire placed through this tract. In patients with a draining seton was present, this was used as a guidewire to introduce the fistula probe. In fistulas without a seton, the guidewire was placed on a fistula probe and passed through the tract.

The CORONA™ fistula probe (neoLaser was used to perform the LAFT with a radial laser fibre with a wavelength of 1470 nm (neoV™ device). A laser energy of 10 W was used to seal the tract. The probe was withdrawn incrementally at a speed of about 1 mm/s to seal the tract, starting at the internal opening. We gently probed with the laser fibre to check if the internal opening was sealed properly. The total energy (in Joules) used to seal the tract was recorded. No additional treatment (flap or suture) was used to close the internal opening. We did not perform any dissection or curettage of the external part of the fistula tract. All procedures were performed as day care procedures. Postoperatively patients were prescribed paracetamol and psyllium fibres (Metamucil®) and were advised to clean the external wound in the shower 1–2 times daily and optionally after defecation.

Follow-up

Healing and postoperative fecal incontinence severity index (FISI) was evaluated at our outpatient clinic during follow-up at 6 and 12 weeks. Patients were instructed to visit the outpatient clinic when symptoms of recurrence like pain, discharge or signs of an abscess occurred. A questionnaire was sent to all patients to evaluate the long-term postoperative FISI after 3 months, we also asked whether they would choose LAFT again. Patients with healing after 3 months were instructed to plan a new visit at our outpatient clinic when symptoms occurred.

Statistical analysis

Statistical software SPSS version 22 was used to collect data, calculate median, means, and IQR. Student's *t* test was used to compare continued values when normal variation was assumed.

Results

A total of 20 patients [male:female = 4:16, mean age 45 years (range 27–78)] underwent 21 LAFT procedures for 6 intersphincteric and 15 transsphincteric fistulas. Patient characteristics are described in Table 1. One of these patients underwent 2 LAFT procedures in 2 separate sessions. Median fistula tract length was 40 mm (range 11–60 mm). Two patients (10%) were treated for a recurrent fistula, 1 patient had an intersphincteric recurrence after a failed LIFT procedure, and the previous procedure in the other patient was unknown (undocumented). Fifteen patients (75%) had a draining seton for a median time of 12 weeks (IQR 14 weeks) prior to LAFT. Total median energy used to seal the fistula tract was 315 J (range 180–870 J). The mean amount of energy used in the healed fistulas was 333 J, the median amount of energy used in the recurred fistulas was 418 J. This difference was not statistically significant ($p = 0.237$, Student's T test).

Primary outcome

The overall healing rate was 20% (4/20) at a median follow-up of 10 months (IQR 7.3 months). Healing rates at outpatient follow-up 6 weeks after LAFT was 30% (6/20). Two of those patients had a recurrence after 7 and 13 months of follow-up despite initial healing.

Of the 16 patients with a recurrence, 4 patients (25%) had only minimal suppurative drainage from the fistula tract and experienced minor to no discomfort. They did not wish for further surgical treatment at this time (Fig. 1). Three patients (19%) underwent a fistulotomy and all healed.

Four patients (25%) had LIFT: two fistulas healed, one patient had a recurrence as an intersphincteric fistula and healed after simple fistulotomy and the fourth one did not heal after LIFT.

Two patients (12.5%) had an abscess at the same location and were treated with incision and drainage. Two patients (12.5%) had a transanal advancement flap repair and both healed. One patient (6%) underwent another LAFT and still had a fistula a last follow-up.

Table 1 Patients and fistula characteristics

Patient	Sex	Parks classification	Seton pre-LAFT	Pre-LAFT FISI	Post-LAFT FISI	Energy during LAFT (j)	Healed after LAFT	Other treatment after LAFT	Healed after other treatments after LAFT
1	F	Transsphincteric	Yes	0	28	297	No	LIFT	No
2	F	Transsphincteric	Yes	0	7	400	No	No treatment	No
3	F	Transsphincteric	Yes	0	0	299	No	I&D	No
4	F	Intersphincteric	No	0	12	180	No	No treatment	No
5	F	Transsphincteric	Yes	0	0	297	Yes	–	–
6	F	Intersphincteric	No	0	0	209	No	No treatment	No
7	F	Transsphincteric	Yes	0	4	330	No	LIFT	Yes
8	F	Intersphincteric	No	0	38	259	Yes	–	–
9	M	Intersphincteric	No	0	0	228	No	Fistulotomy	Yes
10	F	Transsphincteric	Yes	0	–*	500	No	Seton, LIFT, fistulotomy	Yes
11	F	Intersphincteric	Yes	0	19	350	No	No treatment	No
12	F	Transsphincteric	Yes	0	0	300	No	Fistulotomy	Yes
13	F	Transsphincteric	No	0	0	330	No	Fistulotomy	Yes
14	M	Transsphincteric	Yes	0	0	390	Yes	–	–
15	F	Transsphincteric	Yes	22	–*	480	No	LAFT	No
16	M	Transsphincteric	Yes	0	25	480	No	TAF	Yes
17	F	Transsphincteric	Yes	0	0	660	No	LIFT	Yes
18	F	Transsphincteric	Yes	0	0	870	No	TAF	Yes
19	F	Transsphincteric	Yes	0	0	219	Yes	–	–
20	M	Intersphincteric	Yes	0	0	312	No	I&D	No

LAFT laser ablation of fistula tract, *FISI* fecal incontinence score index, *LIFT* ligation of intersphincteric fistula tract, *TAF* transanal advancement flap

*Not eligible for fecal incontinence analysis

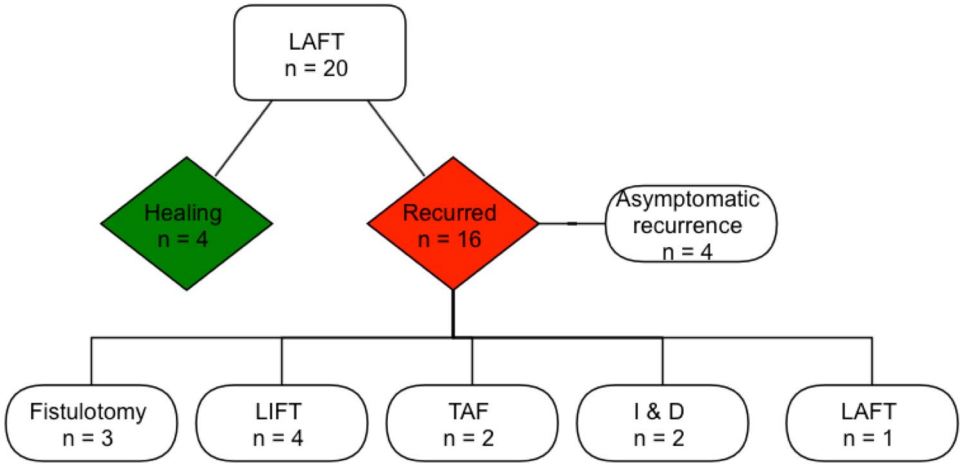

Fig. 1 Recurrence after LAFT

Secondary outcomes

Preoperatively, 1 patient had a FISI of 22. Postoperative FISI was recorded in a total of 18 patients. Two patients were not eligible for fecal incontinence analysis. One patient underwent a sigmoidectomy due to complicated diverticulitis which resulted in an end colostomy. The other patient had another surgical treatment before we could assess the FISI and was therefore excluded from the analysis. The median post-LAFT FISI was 0 (range 0–38). An alteration in FISI was noted in 7 patients (39%). To the question whether they would choose LAFT again, 6 patients (30%) gave a negative response.

Adverse events

There was 1 immediate (30 days) LAFT-related postoperative complication: the patient had a perianal abscess 2 weeks after LAFT. Incision and drainage were performed. Three patients developed a perianal abscess at a later stage and subsequent recurrence. One of them presented at the outpatient clinic at 6 weeks with swelling and pain at the external opening. Pus and blood were drained at an outpatient procedure. The other 2 patients presented at 7 and 13 months after LAFT treatment with a perianal abscess.

Two of our patients suffered serious adverse events (SAE). One patient developed obstructive ileus 41 days after the LAFT procedure, for which she underwent explorative surgery. The ileus was caused by a single adhesion, but she had no history of abdominal surgery. This SAE was considered not to be related to the LAFT procedure. One patient had a complication after her spinal anesthesia, resulting in bacterial meningitis from which she recovered after antibiotic treatment. This SAE was considered a complication of anesthesia, but not related to the LAFT technique.

Discussion

LAFT is a relatively new technique for the treatment of perianal fistula. Initial results were promising with high success rates [2–6]. The lack of pain, absence of large wounds, relatively easy surgical technique, and low impact on fecal continence are all aspects which made LAFT an attractive alternative to the already existing techniques in the treatment of perianal fistulas. The cost of the laser fibre, which is single use, in our centre is €200. This is an additional cost for the hospital and is covered by the patients' health insurance.

Our results seem to compare unfavourably to the ones initially published by other authors (Table 2). Notably, it is evident from this table that the reported healing rates of LAFT declined over time, after initial high rates of fistula healing. This evolution is similar to the decline in success rates of other treatments for perianal fistula like the use of fibrin glue or plugs. We are unsure of the exact reason for this phenomenon but recognize this trend in many different techniques [1].

At first glance, LAFT would seem to be the ideal treatment modality because of the reasons mentioned above, even if healing rates are not extremely high. The relatively low chance of success might be outweighed by the lack of impact on sphincter integrity. In our analysis 6 months after LAFT we found no difference in overall fecal continence. However, a minor change in continence was recorded in 7 (39%) of our patients ranging from incontinence for flatus to incontinence for liquid stool (FISI range 0–38). A limitation of the present study was that preoperative and postoperative fecal incontinence scores were recorded in different ways (outpatient clinic vs mailed questionnaire, respectively). This might be an explanation for the higher postoperative FISI. However, we do not believe that this would be the full explanation for the increase in the FISI score. Most likely, any operation performed on the anus in which retraction and application of thermal energy is utilised, may negatively

Table 2 LAFT in the literature

Study	No. of patients	Type of treatment	Type of laser fibre	Use of a seton	Median follow-up (months)	POFI scoring	Sponsoring received	Overall healing rate (%)
Wilhelm et al.	11	LAFT + closure of internal opening	FiLaC	Yes	7.4	No	No	81.8
Giamundo et al.	35	LAFT + dissection of external opening in 5 patients		Yes	20	Yes	Yes	72
Ozturk et al.	45	LAFT		No	12	No	No	82
Giamundo et al.	50	LAFT		53%	30	No	Yes	71
Wilhelm et al.	117	LAFT + closure of internal opening		Yes (110 of 117)	25	No	Yes	64
Terzi et al.	103	LAFT	FiLaC	No	28	No	No	41
Current study	18	LAFT	NeoV	Yes (13 of 18)	11	Yes	No	20

POFI postoperative fecal incontinence, *FiLaC* fistula laser closure, *LAFT* laser ablation of fistula tract

influence anorectal function. The negative impact of LAFT was very minor and for most patients, probably not clinically relevant. However, we cannot ignore individual patient outcomes when 7 out of 18 patients had minor impairment or deterioration of anorectal function after LAFT.

There is a selection bias in our study because we only selected fistula that are generally considered relatively "easy to treat". We do not know if this bias influences our results in a positive or a negative way, as we do not know which type of fistula is more likely to benefit from this procedure.

When assessing whether or not LAFT would be suitable as a treatment modality for perianal fistulas, we need to take several things into account. First, incontinence status, as described previously. Also, several of the treated fistulas could have been treated in a safe and effective way using established techniques such as fistulotomy. A procedure that has been well described with healing rates over 95% in published data [11]. This would make the indication for LAFT somewhat difficult to defend, especially when compared with our healing rates. It could be advocated that it is unnecessary to expose a patient to a treatment modality that would result in multiple interventions, whilst a safe and effective treatment is available. In female patients with a low anterior fistula, a LAFT might be considered as an option instead of a fistulotomy, to save as much sphincter muscle as possible.

There is considerable debate about outcome measures for fistula surgery. Some surgeons advocate that persistent fistula with no, or few symptoms can also be considered a successful outcome of LAFT [12]. Some say that even if the fistula does not heal, the reduction of the burden of the disease should also be considered a successful outcome. Terzi et al. [12] report an overall healing rate of 40%. However, 19% still had slight drainage and declined further treatment but were considered as cured. In the present series this was the case in 4 (20%) patients. We did not consider these patients to be cured of their fistula. Even though we recognize the importance of the decrease of symptoms, especially in everyday clinical practice, we strongly feel that outcome should be evaluated objectively if only to openly and honestly inform patients concerning this technique. Furthermore, we need to remember that it is highly unlikely that the improvement in quality of life in asymptomatic (or mildly symptomatic) patients is a result of LAFT. If these patients would have undergone seton implantation for example, it is likely that they would also have had adequate improvement of their symptoms. In our opinion these patients should not be considered cases of partial or completely successful treatment. We strongly recommend that actual closure of the fistula be defined as closure of the internal and external opening, without drainage. Preferably, MRI data should be added, even though no clear definition of "healing" exists. We are therefore ordering more MRI scans postoperatively.

Part of the reason for our low healing rates might be the use of a different laser fibre or other technique than that used in the original FiLaC™ studies. Even though technical specifications of our radial laser fibre (CORONA™ fistula probe) are identical to the fibres used in initial reports (FiLaC™), it is impossible for us to compare the true differences in the effects of the fibres. Currently, several manufacturers offer similar laser fibres. It would be an interesting avenue of research to compare the output of the different laser fibres.

We used an energy of 10 W and withdrawn at 1 mm/s as done by Giamundo et al. in their first series [3]. However, they later changed the setting to 12 W [5], although the reason for this was not mentioned. Wilhelm and colleagues

used a laser energy of 13 W and withdrawal at 1 cm per 3 s [6]. It is unknown which setting leads to an optimal balance between destruction of granulation tissue and collateral damage of the healthy perifistular tissue. This is the reason why total energy (J) applied to treat the entire fistula tract was reported. The mean energy used in the fistulas that healed was 333 J, and 418 J in those that recurred. In our series this difference was not statistically significant.

Interestingly, prior reports of this technique are basically describing two completely different techniques. Wilhelm's group describes a technique where all internal openings are closed, either by flap repair or by direct closure, whereas Giamundo's group proposes ablation of the tract without closure of the internal opening. These two techniques seem to rely on two different theories. The first technique uses ablation as an additive (or augmentative) procedure to closure techniques. As we described in a letter to the editor [13], we question the additional beneficial effect of LAFT, when combined with a procedure to close the internal opening. Closure of the internal opening might not be the only reason for the success of the LAFT technique, since Giamundo et al. have high rates of fistula healing after only laser treatment without additional closure of the internal opening. In his reply to our letter [14] Wilhelm states that fistulas with large internal openings cannot be closed by LAFT alone. We consider this a possible explanation for our low healing rates and one of the reasons that we do not consider LAFT as a successful treatment for perianal fistulas.

Conclusions

The high failure rates in our study have resulted in the discontinuation of LAFT as a treatment for perianal fistula in our centre. We feel that the LAFT procedure must be subjected to further research to sort out its indication (when to use in what type of fistula), the differences of the types of laser fibres used and the added effect of closing the internal opening versus only LAFT. We believe that there is no 'one size fits all' principle in fistula surgery and further work should be done on identifying the right procedure for each type of fistula.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Approval of the institutional review board or ethics committee was not required because of the observational character of this study.

Informed consent All patients were fully informed about the novelty of the treatment and gave their consent.

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