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Authors
Brabender, DE
Moran, KL
Brady, M
et al.

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Assessing the effectiveness of laser fistulectomy for anal fistula: a retrospective cohort study

D. E. Brabender[1] · K. L. Moran[1] · M. Brady[1] · J. C. Carmichael[1] · S. Mills1 · A. Pigazzi[1] · M. J. Stamos[1] · M. D. Jafari[1]

Abstract

Background Laser fistulectomy is a minimally invasive, sphincter-sparing procedure for treatment of anal fistula. In several studies, this method has been shown to be safe and effective, with reported success rates ranging from 40 to 88%. We hypothesized that with longer follow-up, these rates would decrease.

Methods A retrospective case analysis assessing the effectiveness of laser fistulectomy in curing fistula-in-ano tracts within a cohort of patients at a single academic institution was conducted. All patients having laser ablation between March 2016 and July 2018 were analyzed. Cure of the fistula was determined by history and postoperative physical exam, and was defined as complete closure of fistula tract with resolution of symptoms. Secondary symptoms of fecal incontinence, infection, and pain were evaluated.

Results Eighteen patients (10 males, mean age 41 ± 13 years) were analyzed. Transphincteric fistula was the most common type (67%, N = 12). The mean number of previous fistula procedures was 1.33 ± 1.64. There was a 22% (N = 4) success rate at an average postoperative follow-up period of 29 ± 8 months (range 18–46 months). Of those who failed, 64% (N = 9) had a subsequent fistula procedure. There were no cases of fecal incontinence, but 3 cases (17%) of postoperative infection were reported and 8 patients (44%) had a subjective increase in pain at first follow-up appointment.

Conclusions Our data showed a much higher failure rate of laser fistulectomy compared to those reported in the literature. However, the small sample size, a large amount of heterogeneity in our patient population with a mixture of fistula types present, and various laser techniques applied decreased the power of this study.

Introduction

Complex anal fistulas pose a problem for colorectal surgeons since they are difficult to cure, and treatments often put the patient at risk of chronic complications including fecal incontinence. There is also increased risk of persistent cryptoglandular infections after repair due to acute-onchronic inflammatory response and the constant presence of stool at the surgical site [1]. Traditional procedures, such as fistulotomy, have been shown to be 95% effective. However, fistulotomy cannot be offered to patients with complex fistulas involving the sphincter complex which can cause significant reduction of sphincter function leading to

fecal incontinence [1]. Due to these observed complications, there has long been a push for minimally invasive and sphinctersparing procedures that would provide similarly effective treatment. However, few novel procedures have lived up to initial promise [2]. In 2011, Wilhelm published a minimally invasive technique [3], for primary closure of the fistula tract by using a diode laser probe (FiLaC™, Biolitec, Germany) that emitted energy through a radial fiber which caused coagulation of the surrounding tissue. This approach was designed to destroy both the crypt glands and the additional epithelial layer of the fistula tract via a photothermal effect with coincident obliteration of both the internal and external fistula orifices [4].

Since 2011, advances have been made in this technology, such as the development of the FiLaC method by Giamundo [5], and others have assessed the effectiveness of this technique. They found that laser fistulectomy had low complication rates and was successful at curing complex anal fistula tracts, with cure rates ranging from 40 to 88% [3–12]. Our aim was to add to this growing body of literature by conducting a retrospective case analysis assessing the effectiveness of laser fistulectomy in curing fistula-inano tracts within a cohort of patients at a single academic institution.

Materials and methods

Patients and methods

All patients with anal fistulas who were treated using laser ablation therapy from March 2016 until July 2018 at the University of California, Irvine were evaluated in this study. Assessment of the anal fistula was completed with an anorectal exam at the preoperative appointment for all patients, and prior to proceeding with surgery and was confirmed with an exam under anesthesia. Imaging such as magnetic resonance imaging (MRI) or ultrasound was not used routinely to assess the patient's anal fistula, pre- or postoperatively. The procedures were performed by one of three colorectal surgeons all using the same technique; however, the rate at which the laser was retracted was left to the discretion of the surgeon. All patients who had therapeutic treatment during the given time frame were analyzed, regardless of whether or not they had had prior treatments. Institutional review board approval was obtained for this study from the University of California, Irvine.

Data retrospectively entered into the database included patient demographics (age, sex, and presence of Crohn's disease), status of fistula (recurrent or primary), fistula type, previous surgical treatments (i.e. ligation of intersphincteric fistula tract [LIFT], fistulotomy, partial fistulotomy with seton, advancement flap, fibrin glue, collagen plugs, and laser fistulectomy), previous seton placement, type of laser, and laser power used. Data collected from postoperative visits included length of follow-up period, success of the procedure in closing the fistula tract, secondary complications, and if any additional procedures were required for treatment of fistula after initial laser fistulotomy.

Closure of the fistula tract was determined by history and physical exam at subsequent postoperative appointments for all patients. Cure was defined as primary healing of the fistula tract being present with no sign of leakage and complete resolution of symptoms. Complications of the laser ablation therapy analyzed included subjective report of any pain at first post-procedure appointment (pain scales were not recorded in all patients and so were not included), infection (purulent drainage or abscess), and fecal incontinence. The primary end-point analyzed was the overall cure rate of fistulas after laser ablation, while the secondary end-points were the occurence of unexpected complications of the procedure.

Laser fistulectomy technique

An anorectal exam was performed and the fistula tract was identified. The tract was irrigated with normal saline. The laser probe was then placed within the fistula tract via the external opening. The laser was then fired in bursts as the fiber was slowly withdrawn through the fistula tract from the internal opening to the external opening. For the procedure, a laser fiber (Table 1) with an average of 10.63 + 1.3 W (range 10–14 W) at a wavelength of 1,470 nm was used. The internal opening was also suture ligated with 2–0 Vicryl suture and the external opening enlarged.

Results

There were 18 patients (mean age of the patients was 41 ± 13.2, 56% male). The fistula was recurrent in 15 patients (83.3%) and a first fistula in only three. Patients had an average of 1.33 ± 1.64 fistula procedures prior to laser ablation. Patient demographics are presented in Table 2. The most common type of fistula in the cohort was a transphincteric fistula (67%, N = 12). The devices used during the laser ablation were either a Ceralas or Corona diode laser fiber at 1470 nm. The mean power of the laser was 11 ± 1 W (range 10–14 W). Sixteen of the 18 patients had draining setons placed prior to surgery.

The laser fistulectomy procedure failed to close the fistula tract in 14 of the 18 patients with a failure rate of 77.8%, with the mean follow-up period was 29 ± 8 months (range 18–46 months). Failure was determined by lack of fistula tract closure on physical exam during follow-up appointments. Only 2 patients had postoperative imaging (i.e., MRI) to determine if the fistula tract had been successfully closed. In addition, 64% (N = 9) of patients who failed treatment needed to have at least one subsequent fistula procedure (Table 3), with 4 of those patients requiring 2 subsequent procedures. Of the subsequent procedures, fistulotomy had 100% success. There were 3 cases of postoperative infection, consisting of purulent drainage (n = 2) and newly formed abscess found on physical exam (n = 1). Eight patients reported subjective pain at the procedure site at the first follow-up appointment, which occurred at an average of 3 weeks after the procedure. There were no observed or reported cases of fecal incontinence after treatment. The 4 patients whose fistulas were successfully closed were last seen in clinic with complete resolution of symptoms, and on physical exam were found to have primary healing of the fistula site with no evidence of leakage.

Table 1 Summary of laser types

Type of laser	Number of patients
600 micron Corona 360 degree laser fiber, Neolaser (diode)	7
FiLaC laser fiber, Neofiber	1
400 micron corona, 360 degree optical laser (diode)	2
Neolaser diode	4
400 micron Ceralas E15 diode laser. A cerampetc ELVeS radial slim fiber 400 um, 4F fiber	4

Table 2 Summary of demographics and characteristics of patients with fistulectomy

Characteristic	Results
Mean age in years (range)	41 (19–57)
Sex	
Male	10
Female	8
Types of fistulas	
Transphincteric	14 (Two patients had a second concurrent fistula)
Intersphincteric	5 (Three patients had a second concurrent fistula)
Suprasphincteric	1 (Patient had a second concurrent fistula)
Superficial	1
Recurrent fistula	15 (83.33)
Primary fistula	3 (16.67)
Crohn's disease patients	4 (22.22)
Previous fistula procedures, mean (SD)	1.33 ± 1.64
Ligation of intersphincteric fistula tract	4 (16.67)
Advancement flap	8 (33.33)
Fibrin glue	2 (8.33)
Fistulotomy	4 (16.67)
Partial fistulotomy	2 (8.33)
Collagen plug	3 (12.5)
Laser fistulectomy	1 (4.17)

Data are reported as n (% l) unless otherwise indicated

Table 3 Laser fistulectomy postoperative assessment

Characteristic	Results
Successful closure (% total)	4 (22.2)
Failed closure (% total)	14 (77.8)
Mean length of follow-up period in months, SD, range	29 ± 8
Procedure complications (% total)	
Subjective pain	8 (44.4)
Infection	Purulent drainage = 2 (11.1), abscess = 1 (5.6)
Fecal incontinence	0 (0)
Subsequent fistula procedures (success rate) (% total)	
Fibrin glue	2 (0)
Fistulotomy	3 (100)
Collagen plug	1 (0)
Anal advancement flap	1 (0)
Ligation of intersphincteric fistula tract	5 (20)
Partial fistulotomy with seton	1 (0)

Discussion

We report the clinical outcomes of a cohort of 18 patients who presented with anal fistula and had laser fistulectomy. The primary success rate over a mean follow-up time of 29 months was 22%. Patient demographics, features of the fistula, and number of prior operations had no effect on outcome. There were limited complications in this cohort with only 3 cases of postoperative infection, and no cases of fecal incontinence. Postoperative pain was the most common complaint and was reported by 8 patients (44%). These data suggest that laser fistulectomy has a significantly higher failure rate compared to what has so far been reported in the literature (18–60%) [3–5, 9–12].

The repair of anal fistulas can be challenging, largely due to the persistence of fistulas after attempts at repair. Up to 30% of fistulas persist after surgery despite advancements in treatment [1, 5]. More invasive procedures such as fistulotomy can be extremely effective with success rates of 95%. However, fistulotomy is not recommended for more complicated fistulas as these procedures place the
patient at risk for postoperative fecal incontinence [1]. For this reason, various types of minimally invasive sphincter-sparing methods have been developed such as collagen plugs, fibrin glue, LIFT, closure of primary opening using endorectal or dermal flaps, video-assisted anal fistula treatment (VAAFT), and over-the-scope clip (OTSC®) proctology system [6, 8, 13, 14]. The failure rate for these procedures varies in the literature but continues to be high at approximately 30–50% [1]. Thus, laser fistulectomy as a new minimally invasive procedure has increased in popularity due to its minimal safety issues, limited side effect profile, and short learning curve.

Previous studies reported higher success rates for the laser fistulectomy procedure compared to our study. Wilhelm et al. initially followed 11 patients who had a laser fistulectomy and found that 81% of the patient showed primary healing at a median follow-up of 7.4 months, with only 1 case of fecal incontinence [3]. In a subsequent study assessing long-term outcomes in 117 patients, the same authors found that the primary success rate for laser

fistulectomy was 64.1%; however, after patients had a second laser fistulectomy of the success rate was 88% [4]. In our study, 1 patient had a repeat laser fistulectomy but was not cured.

Giamundo et al. developed the fistula laser closure (FiLaC™) based on the work of Wilhelm. They observed primary healing in 25 (71.4%) patients, with 8 (23%) failures and 2 recurrences at 3 and 6 months [5]. They reported long-term outcomes in 45 patients with a median follow-up time of 30 months. Primary healing was observed in 32 patients (71.1%), and the best healing rate was observed in patients who had been previously treated with a loose seton [9]. Giamundo et al. hypothesized that the use of a seton stimulates the growth of a new epithelial lining of the fistula tract [5]. However, 88.9% of ourpatients had prior draining setons which did not prove to be a factor linked with success of the procedure. Ozurk et al. also demonstrated a similar success rate of 82% in 50 patients [10] with a median follow-up of 12 months. Other studies have also recommended a longer time interval before a subsequent follow-up procedure, with the idea that this would allow more time for primary healing of the tract [4]. However Giamundo et al. observed healing within 5 weeks with a majority of their patients [9]. In clinical application, our surgeons waited an average of 17 ± 14 weeks before offering a subsequent procedure, and still did not see improvement in results; thus, this practice was not enforced.

This study has limitations. As a retrospective study, inherent biases exist. The small sample size is a limitation that decreases the power of this study. In conjunction with this we had a large amount of heterogeneity in our patient population with a mixture of fistula types present. A large majority of the cases were extremely complicated: 4 patients had Crohn's disease and 61% had a diverse range of prior procedures that failed. Lauretta et al. in 2018 showed that patients with more simple fistulas, with a length under 30 mm, were more likely to have primary closure of the tract with laser fistulectomy [11]. Thus, the more complicated nature of the fistulas in our study population may have limited the success rate of laser fistulectomy. Furthermore, during the study period it was noted by the surgeons that the power of 10 W appeared insufficient to seal the tracts due to the early low success rates. Thus, the power was increased to 12 W and subsequently 14 W in later patients; however, the lack of successful healing persisted and did not appear to correlate with the wattage used. Also of note, there were 5 different devices used in our study (see Table 1) which included different probe sizes (400 micron, 600 micron), and the velocity of retraction of the fiber was left to the discretion of the 3 surgeons. In prior studies, Wilhelm withdrew the fiber at a rate of 1 cm per 3 s, while Giamundo retracted the fiber inside the fistula at the speed of 1 mm/s, which shows that there is currently no universally accepted speed at which to retract the fiber and this is often left to the surgeon's discretion [3, 5]. Unfortunately, a limitation of our study was that the rate at which the fiber was withdrawn and total operating time was not included in the operative notes, and thus we were unable to determine if the rate of retraction was consistent and if this variable had an effect upon outcomes. It is difficult to determine if it was because of this variation between procedures that our results were worse than those of other studies

which used consistent parameters. Future studies should assess the effect of using different products, wattage, and rate of retraction on outcomes.

Conclusions

Our data showed a much higher failure rate (78%) of laser fistulectomy for complicated fistulas than the rates so far reported in the literature. Therefore, despite the low side effect profile, this method should not being considered as first-line treatment for patients with complicated fistulas. Although one cannot eliminate patient factors that influenced rate of fistula representation, the high failure rate observed has led to a change in clinical practice at our institution. However, the small sample size, a large amount of heterogeneity in our patient population with a mixture of fistula types present, and various laser techniques applied decreased the power of this study. Larger prospective studies with a more homogenous patient population is need to be conducted to further validate our findings.

Compliance with ethical standards

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

Ethical approval The study was approved by internal review board at the University of California, Irvine and conformed to the ethical guidelines of the Helsinki Declaration (as revised in Tokyo 2004). No study advertising was made and no remuneration was offered.

Informed consent No informed consent was required.

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Corresponding author: M. D. Jafari jafarim@uci.edu

[1] Irvine Department of General Surgery, University of California, Irvine Medical Center, 333