Does minimally invasive laser-assisted treatment of pilonidal sinus disease live up to its expectations : a multi-center study with 226 patients

DOES MINIMALLY INVASIVE LASER ASSISTED TREATMENT OF PILONIDAL SINUS DISEASE LIVE UP TO ITS EXPECTATIONS: A MULTICENTRE STUDY WITH 226 PATIENTS

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Statements and Declarations

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ABSTRACT

Purpose

The minimally invasive character, the possibility to perform under local anaesthesia and the ease to repeat has led to increasing popularity of laser assisted treatment of pilonidal sinus disease. Hereby potentially avoiding prolonged need for medical care at home, incapacity to work and high expenses for patients and society. This retrospective, multicentre study aims to evaluate the feasibility of laser assisted treatment for pilonidal sinus disease.

Methods

The patient population is comprised of all patients undergoing laser assisted treatment of pilonidal sinus disease at three Belgian hospitals between January 2017 and December 2021. Data were retrospectively collected. The primary endpoint was overall wound healing after one or more laser assisted procedures.

Results

A total of 226 patients were included with a mean follow-up time of 129 days [7-1120]. The healing rate after one laser procedure was 78.8%. Some of these patients were healed by a second or third procedure adding up to an overall healing rate of 85.4% after one or more laser procedures. Wound infections were the main postoperative complication (8.0%) of which 5 patients required drainage (2.2%). For 29 patients (12.8%) laser assisted treatment was insufficient, leading to a secondary operation (drainage, excision or flap).

Conclusion

This study shows that laser assisted treatment is feasible for pilonidal sinus disease. The minimally invasive character of this technique might make up for a higher non-healing rate compared to other techniques like flap repair. However, care must be taken that healing rate might be related to the presentation of the sinus and expectations should be lowered as presumed high healing rates are not always achieved.

Key words

Pilonidal sinus disease, minimally invasive, laser assisted treatment, healing

INTRODUCTION

Pilonidal sinus disease (PSD) is a common disease of the natal cleft with fistula and abscess formation. It is believed to be an acquired disease and has an incidence of 26 per 100,000 people.[1] The disease affects young patients, predominantly men in their early twenties, who are often working or studying. Risk factors include a sedentary lifestyle, obesity, and excessive body hair. PSD is a clinical diagnosis, characterized by pits in the midline with or without abscess formation. Treatment modalities vary from extensive surgery (such as flap repair) to limited excision or minimally invasive surgery (such as pit picking, phenol treatment and laser assisted treatment).[2] Laying open (deroofing) and curettage is less invasive than excision to the sacral fascia and has several advantages, like a low complication rate, short operative time and early return to normal routine and work.[3] Even excision to the sacral fascia with open healing or off-midline closure is associated with high recurrence rates after extensive follow-up and has the poorest quality of life.[4, 5] Off-midline closure techniques like flap repair have a lower recurrence rate and shorter wound healing.

Despite a variety in techniques, all surgical techniques are still associated with complications, such as wound infection, wound dehiscence, and recurrence, leading to re-operations. Surgical treatment of the disease leads to incapacity to work varying from several weeks to several months, which has a great impact on a socioeconomic level.[6] PSD is associated with a prolonged need for medical care at home and a high recurrence rate, varying from 5 to over 50%, depending on the technique.[2, 6] Due to the socioeconomic impact and decreased quality of life for patients recovering from PSD surgery, minimally invasive treatment for PSD is emerging, following the search for early recovery and shorter incapacity to work. One of these minimally invasive techniques is the laser assisted treatment, obliterating the pilonidal sinus tracts. Laser assisted treatment for hemorrhoids and anal fistula has proven to be a valuable treatment option, considered effective and safe. [7-9] Laser assisted treatment for PSD was first described by Georgiou in 2016 [10, 11]. Afterwards, several studies have been published, showing promising results with initial healing rates above 90%, setting high expectations of this rather new minimally invasive technique.[2, 12-14]

We setup a retrospective multicentre study that aims to investigate the feasibility of laser assisted treatment of PSD.

OBJECTIVE

This retrospective multicentre study aims to evaluate the feasibility of laser assisted tract ablation for the treatment of pilonidal sinus disease.

METHODS

Patient population

The patient population was comprised of all patients, undergoing laser assisted treatment for PSD at three Belgian Hospitals (UZA, GZA and AZ Turnhout) between January 2017 and December 2021. Ethical approval was obtained from the Ethics committee of Antwerp University Hospital (UZA). Patients who received laser assisted treatment as primary intervention as for recurrent disease were included. Recurrent disease was defined as reoccurrence of pits after another treatment (e.g., excision or flap). Patients who received laser assisted treatment after abscess drainage were included as well. This was not considered a curative procedure for PSD. Patients were selected based on nomenclature reference according to the ICD-9 coding for "sinus pilonidalis". Data were retrospectively collected from the electronic patient records (ECR) of the included hospital groups and coded to guarantee patient's privacy. Pregnant patients, patients who were under the age of 14 (before puberty) and patients without any follow-up were excluded.

Data collection and statistical analysis

Patient's demographic information, extracted from their medical file, consists of patient characteristics (age, BMI, alcohol abuse, smoking and patient's medical history), information regarding PSD (first presentation, history of prior intervention, recurrent disease), treatment details (number of treatments, antibiotic administration, type of anaesthesia, type of hospital stay, product used for infiltration, number of Joules, surgeon), follow-up method and follow-up time, number and type of complications, and failure to heal. The collected data was analysed using descriptive statistics (chi-square test and T-test) in IBM-SPSS (v28.0). A P-value of less than 0.05 was considered statistically significant.

Primary and secondary endpoints

The primary endpoint of this study was overall wound healing after one or more laser assisted procedures. Wound healing after 30, 60 and 90 days, was defined as considered by the surgeon and noted like this in the patient's medical file. Failure to heal or non-healing was defined as reoccurrence of pits or abscess after closure of the skin, or persistent skin defect, as mentioned in the ECR, leading to a new surgical intervention or new follow up. A consultation with clinical examination of the patient was considered as follow-up.

The secondary endpoint was complication rate, which was defined as any treatment-related problem in the postoperative period, such as wound infection, abscess formation or bleeding. Complications were classified according to the Clavien-Dindo classification. The healing rate after repeated laser assisted treatment was registered. We also observed the overall healing rate at the end of the follow-up.

RESULTS

Patient population and demographics

A total of 409 patients underwent treatment for PSD in our hospitals of whom 236 patients matched the inclusion criteria. Ten patients were lost to follow-up, and 226 patients were included for analysis (fig. 1). A total of 173 patients did not receive laser treatment. The selection for laser treatment was based upon surgeon's and patient's preference. Patients were eligible for laser treatment when there were no signs of infection. There were no significant differences in patient demographics between hospitals. We observed a mean follow-up time of 129 days, ranging from 7 to 1120 days.

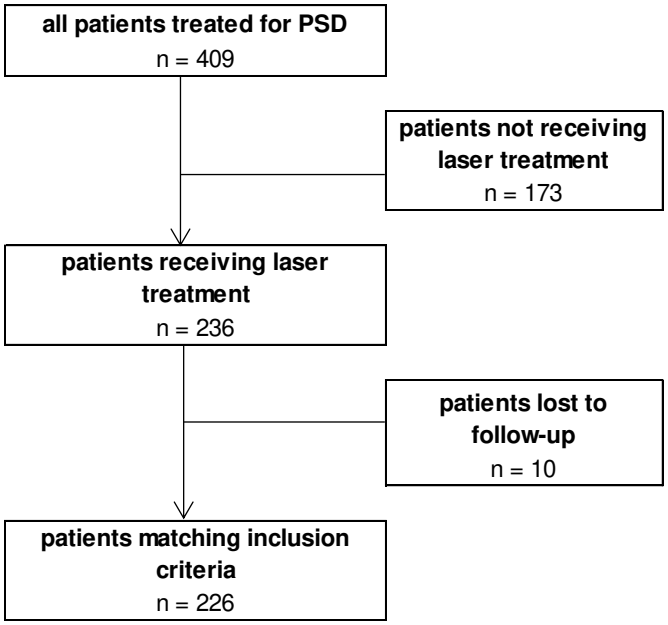

Fig. 1 Process of patient selection

The mean age of patients was 27.7 years [14-77]. Most patients were male (81%, 183 patients), 43 were female (19%). The procedures were performed by six abdominal surgeons (two surgeons per hospital).

A total of 252 procedures were performed. The patient was placed in prone position. Tumescence was given in all patients: in 29 patients with NaCl 0.9% with chirocaine (1:1) and in 197 patients with NaCl 0.9% alone. The type of infiltration product was hospital dependent. All pits were dilated, and hair and debris were removed from the sinus using a mosquito clamp. The pits were lasered but not excised or curetted. The cavity and all tracts were ablated with a laser device: Biolitec® laser device (SiLaC®) with a continuous pulse at 10.0 Watt and a wavelength of 1470 nm. The mean administered energy was 867 Joules. Antibiotics were administered in 14 patients. All cases were done in day clinic. Most procedures were done under general anaesthesia (215 patients), 3 cases under spinal anaesthesia and 8 cases under local anaesthesia. Almost 90% of patients underwent only one procedure, 20 patients (8.8%) underwent 2 and 3 patients underwent 3 (1.3%) procedures. These factors showed not to be significant for the outcome (non-healing), except for the type of infiltration product (Table 1). The non-healing rate in UZA was not significantly higher than in AZ Turnhout or GZA. However, AZ Turnhout had a lower non-healing (17.7%) rate compared to UZA (29.7%) and GZA (32.0%). They also performed more

procedures: 164 procedures vs 37 (UZA) and 25 (GZA) procedures. A total of 164 patients (72.6%) received laser treatment as primary intervention (no invasive procedure for PSD in patient's history), 28 patients (12.4%) presented after abscess drainage (stab incision) and 34 patients (15.0%) presented with recurrent disease after an alternative intervention (flap, excision). Non-healing rates did not significantly differ between these groups.

	Total	**Healing**		**P-value**
		Yes	**No**	
Gender n (%)				**.235**
Male	183	147 (80.3)	36 (19.7)	
Female	43	31 (72.1)	12 (27.9)	
BMI n (%)				**.813[a]**
18-25	24	16 (66.7)	8 (33.3)	
>25	20	14 (70.0)	6 (30.0)	
Smoking n (%)				**.662**
No	196	156 (79.6)	40 (20.4)	
Yes	13	11 (84.6)	2 (15.4)	
Ethyl n (%)				**.299**
No	211	166 (78.7)	45 (21.3)	
Yes	4	4 (100)	0 (0)	
Antibiotic administration n (%)				**.172**
No	212	169 (79.7)	43 (20.3)	
Yes	14	9 (64.3)	5 (35.7)	
Type of anesthesia n (%)				**.448**
General	215	171 (79.5)	44 (20.5)	
Spinal	3	2 (66.7)	1 (33.3)	
Local	8	5 (62.5)	3 (37.5)	
Infiltration product n (%)				**.019**
NaCl 0.9%	197	160 (81.2)	37 (18.8)	
NaCl 0.9% chirocaine (1:1)	29	18 (62.1)	11 (37.9)	
Patient presentation n (%)				**.945**
first presentation	164	129 (78.7)	35 (21.3)	
recurrent disease	34	27 (79.4)	7 (20.6)	
after abscess drainage	27	22 (81.5)	5 (18.5)	
Hospital n (%)				**.102**
GZA	25	17 (68.0)	8 (32.0)	
UZA	37	26 (70.3)	11 (29.7)	
AZT	164	135 (82.3)	29 (17.7)	
Mean number of Joules (J)	867	800	900	**.265**

[a] Insufficient data

Table 1. Risk factors for recurrence or non-healing after one laser assisted treatment

Overall healing rate and failure to heal (non-healing or recurrence)

Of the 226 patients, 178 patients (78.8%) were healed by one laser procedure, while 48 patients (21.2%) failed to heal after one laser procedure (Fig. 2). Almost half of these patients received a second laser assisted treatment. The remaining patients were treated alternatively (drainage, excision, flap). Of these 23 patients receiving a second laser treatment, 13 patients (56.6%) were healed and 8 failed to heal (34.8%). Three patients received a third laser treatment, being successful in 2 of them. This adds up to a cumulative healing rate of 85.4% after one or more laser procedures. For 29 patients (12.8%) laser assisted treatment was insufficient and they were treated with an alternative technique (excision in most of the cases, drainage, or flap). At the end of the inclusion period, four patients were planned for excision and 1 patient was planned for another laser assisted treatment. The mean time interval to return to the doctor's office with new complaints or non-healing was 263 days (8.7 months).

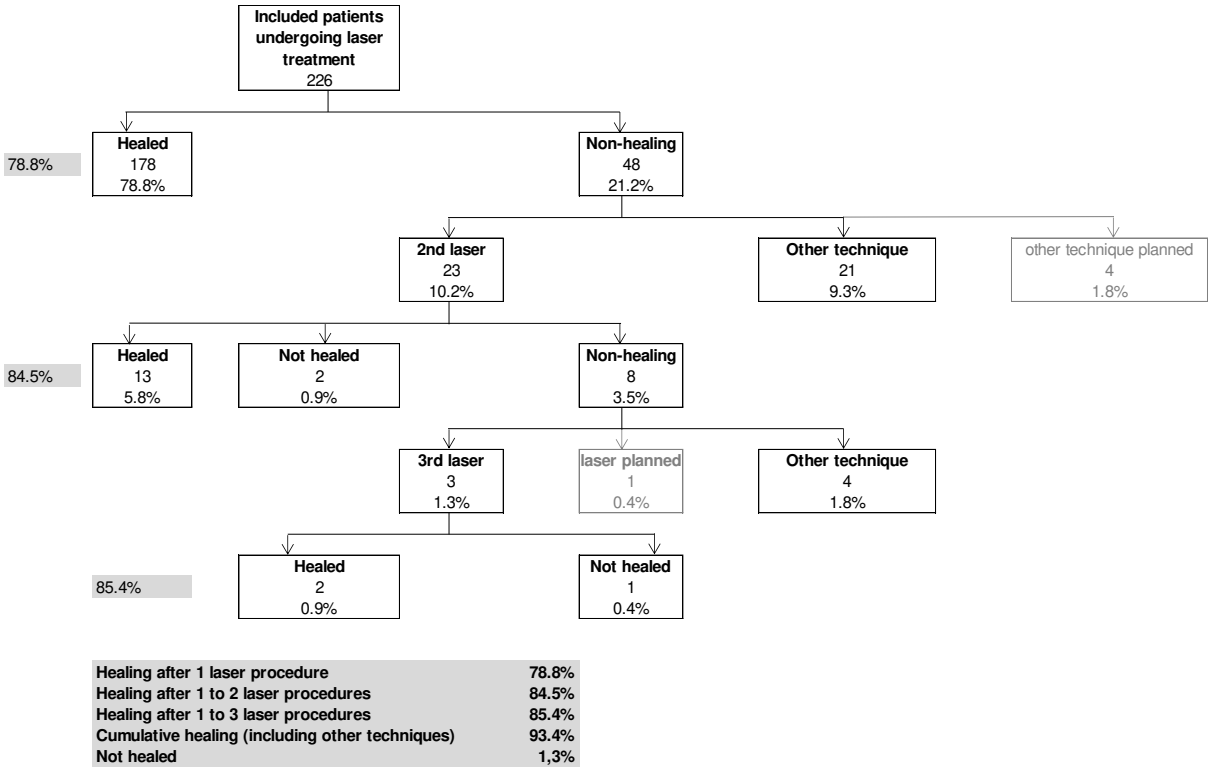

Fig. 2 Overall healing and non-healing rates at the end of the follow-up after one or more laser assisted procedures

Healing over time

The initial healing rate after one laser procedure, defined as complete healing, was 60.9% after 30 days. The healing rate increased without additional treatment to 78.8% and 84% after 60 and 90 days respectively. The mean time to heal was 41 days. One patient was lost to follow-up between 2 laser assisted treatments. He showed up with a recurrence for which a second laser assisted procedure was performed. When patients were not healed after 30 days, 35.2% of them needed another procedure. When they were not healed after 60 and 90 days, 55.1% and 66.7% needed another procedure respectively (Table 2). Prolonged wound healing influenced the outcome as it was associated with a higher recurrence or non-healing rate ($p<0.001$). Delayed wound healing seems to be a predictor for the need for another surgical procedure (repeated laser or other technique).

	Time	**Number of patients (%)**	**Number of patients needing another procedure (%)**
Not healed after	**30 days**	88 (39.1)	31 (35.2)
	60 days	49 (21.3)	27 (55.1)
	90 days	36 (16.0)	24 (66.7)

Table 2. Failure to heal over time and risk for re-operation

Complications

Registered complications of the procedure were mainly wound infection, affecting 18 patients (7.9%), from which 5 patients required drainage (2.2%) (CDC grade IIIa). Thirteen of these patients (5.8%) were treated conservatively with local wound care and antibiotics (CDC grade II). The appearance of wound infection was significantly associated to non-healing ($p <0.05$) (Table 3). The mean number of Joules was 792 in patients with a wound infection and 821 in patients without.

		Total	**Healing**		**P-value**
			Yes	**No**	
Wound infection n (%)	**No**	208	168 (80.8)	40 (19.2)	
	Yes	18	10 (55.6)	8 (44.4)	0.012

Table 3. Wound infections and non-healing

DISCUSSION

The laser technique for PSD was implemented in our hospitals due to the high expectations set. Early recovery and avoiding an extensive wound were the main reasons to consider this technique for our patients. This retrospective cohort study has a reasonable number of patients. Despite the high number of surgeons, the technique was relatively constant. With healing rates of 78.8% after one procedure, rising to 85.4% after more procedures, laser assisted treatment of PSD is feasible. It has an acceptable non-healing rate, taking the minimally invasive character and the possibility to perform under local anaesthesia into account.

However, this study has several limitations. The retrospective character of this study entails insufficient data, varying follow-up times and loss to follow-up. Return to work time and patient satisfaction could not be retracted from our data. The high variability of follow-up time can be explained by some patients only coming once to the appointment after surgery. They were then instructed to contact the surgeon or to come back when the wound would not heal after 30 days or when the disease came back. Several patients were lost to follow-up afterwards. Even with this short follow-up failure rate is up to 21.2%. These results do not compare to the expected healing rate above 90%. Care should also be taken that failure to heal might even be higher with longer follow-up. This could make the healing rate of laser treatment rather disappointing.

We defined recurrence as the reoccurrence of pits after complete wound healing and after closure of the skin was obtained. Due to the retrospective character of this study, a clear distinction between recurrence and persisting disease could not be made, as this was not clearly noted in the medical file as such. A part of these patients was probably never completely healed and presented with a persisting sinus. To avoid this in the future, prospective research is obligatory. Ideally, a classification system existed so a well-found decision could be made regarding the best technique for each patient. There is still no consensus on how to classify the disease. Variables such as the number of pits or the size of the sinus could alter the outcome. Selection of patients based on these variables might be interesting to improve the outcome of this technique. Unfortunately, these variables could not be extracted from the available patient's medical data. Not all patients who did not heal were treated by laser again. This decision could not be extracted from the available data but was probably made due to a combination of factors, such as patient's choice, surgeon's decision, size of the sinus, or presentation of the sinus (abscess). Most patients in this study were treated under general anaesthesia although it should be possible under local anaesthesia. Due to the surgeon's preference only 8 patients were treated under local anaesthesia.

The first study regarding laser treatment for PSD was published by Georgiou in 2016. Several authors published comparable results and reported healing rates above 90%. A recent meta-analysis of these international studies shows very promising results, with healing rates over 90% and recurrence rates as low as 3.8%.[15] When comparing our results to this meta-analysis, they might seem inferior. However, not all available studies were included. The study of Alferinck (2019, 50 patients) showed a 10% recurrence rate.[14] The study of Algazar (2021, 24 patients) showed an 8% recurrence rate and a 20.8% complication rate.[16] When looking at the individual studies, we can occasionally see higher recurrence rates, higher complication rates or a very short follow-up time. Seven out of the ten included studies have a patient total of less than 90. When looking at the biggest 3 studies, recurrence rates were between 2.6 and 11% with a mean follow-up time of 525 days (±266) [12] , a median follow-up time of 354 days (range 240-390) [13], and 12 months [17]. Recently a large multicentre study with 311 patients was conducted in the Netherlands.[18] A healing rate of 66% was observed

after one laser assisted procedure and rising above 90% after repeated procedures. A recurrence rate of 26% was noted. Their results are more in line with this study.

Pit picking, which should always be done in advance, combined with laser tract ablation, seems to be a good alternative among other minimally invasive techniques.[19] It shows to be a safe and effective procedure for the treatment of PSD, with good recovery rates. The non-healing rate seems acceptable, but it implies a threat that it might be higher with a longer follow-up time.[13, 20] Pit picking alone seems not to be sufficient for the treatment of PSD with recurrence rates above 60% at 5-years follow-up. [21] However, there is a lack of high-quality data. The additional value of the laser in comparison to pit picking alone should be investigated further. Although the cost of the laser material can be a threat to its further application, other techniques also result in high expenses for patients and society like medical care at home and prolonged incapacity to work.

Two comparative prospective studies have been conducted which show the laser procedure is comparable to the Limberg or Karydakis flap technique in terms of healing rate and recurrence rate. It is associated with shorter hospital stay and less postoperative pain.[19, 22]. The technique, however, appears to be less effective for overweight patients or those with one or more secondary openings.[23]

CONCLUSION

To conclude we report an overall healing rate of 85.4% after one or more laser procedures. This study shows that laser assisted treatment is feasible for PSD, for patients at first presentation as for patients with recurrent disease. The minimally invasive character of this technique might make up for a higher non-healing rate compared to other techniques, such as laying open or flap repair. However, care must be taken that healing rate might be related to presentation of the sinus and expectations should be lowered as extremely high healing rates are not always achieved.

CONFLICT OF INTEREST

None

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