RESEARCH ARTICLE / *Araştırma Makalesi*

Phenolization vs SILaC Laser: Which is More Successful in the Treatment of Pilonidal Sinus Disease?

Fenolizasyon ve SILaC Lazer: Pilonidal Sinüs Hastalığının Tedavisinde Hangisi Daha Başarılı?

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Geliş Tarihi / Received : **11.04.2022** Kabul Tarihi / Accepte: **07.09.2022**

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(Sakarya Tıp Dergisi / *Sakarya Med J* 2022, 12(3):518-526) DOI: 10.31832/smj.1101780

Abstract

Objective	In this study we aimed to compare phenol application and sinus laser-assisted closure (SiLaC) methods for the treatment of pilonidal sinus disease (PSD).
Materials and Methods	A total of 141 patients were divided into two groups with 73 patients being in the phenol group and 68 patients in the laser group. Patients' demographic characteristics, smoking status, presence of co-morbidities, history of abscess drainage, previous PSD surgery, recurrence status, need for re-operation, postoperative complications, distance of orifice from the midline and number of sinus tract were retrospectively recorded and compared between the groups.
Results	No statistically significant difference was observed between the two groups in terms of demographic features and disease free survival (DFS). DFS was statistically significantly shorter in the patients with previous pilonidal sinus surgery, in smoker patients and in the patients with complications. Recurrence rate was similar between both groups. Previous pilonidal sinus surgery, smoking and complications are the factors affecting disease free survival. Number of sinus tracts and distance of the orifice to the midline are the factors affecting recurrence. According to the ROC curve analysis, a cut-off value for orifice distance >1.4 cm predicted the development of recurrence sensitivity 100%, specificity 92.91%.
Conclusion	The results of this study indicate that recurrence and success rates are similar between the relatively newer SILaC method and phenolization technique. Rate of complications is also similar. Both treatment methods can be safely and effectively used for the treatment of PSD.
Keywords	Pilonidal sinus disease; orifice; sinus tract; phenol; laser; SILaC

Öz

Amaç	*Bu çalışmada pilonidal sinüs hastalığının (PSD) tedavisinde fenol uygulaması ile sinüs lazer yardımıyla kapatma (SiLaC) yöntemlerini karşılaştırmayı amaçladık.*
Gereç ve Yöntemle	*Fenol grubunda 73, lazer grubunda 68 hasta olmak üzere toplam 141 hasta iki gruba ayrıldı. Hastaların demografik özellikleri, sigara içme durumu, komorbidite varlığı, apse drenajı öyküsü, geçirilmiş PSD cerrahisi, nüks durumu, tekrar ameliyat ihtiyacı, postoperatif komplikasyonlar, orifisin orta hattan uzaklığı ve sinüs trakt sayısı retrospektif olarak kaydedildi ve gruplar arasında karşılaştırıldı.*
Bulgular	*Demografik özellikler ve hastalıksız sağkalım (DFS) açısından iki grup arasında istatistiksel olarak anlamlı bir fark gözlenmedi. Daha önce pilonidal sinüs cerrahisi geçirmiş hastalarda, sigara içen hastalarda ve komplikasyon gelişen hastalarda DFS istatistiksel olarak anlamlı derecede daha kısa idi. Her iki grup arasında nüks oranı benzerdi. Daha önce geçirilmiş pilonidal sinüs cerrahisi, sigara kullanımı ve komplikasyonlar ,hastalıksız sağkalımı etkileyen faktörler olarak saptandı. Sinüs traktlarının sayısı ve orifisin orta hatta olan mesafesi nüksü etkileyen faktörlerdi. ROC eğrisi analizine göre orifis mesafesi >1.4 cm için cut-off değeri rekürens gelişimini %100 duyarlılık ve %92.91 özgüllük ile öngörmüştür.*
Sonuç	*Bu çalışmanın sonuçları, nispeten daha yeni olan SILaC yöntemi ile fenolizasyon tekniği arasında nüks ve başarı oranlarının benzer olduğunu göstermektedir. Komplikasyon oranları da benzerdir. PSD tedavisinde her iki yöntem de güvenli ve etkin bir şekilde kullanılabilir.*
Anahtar Kelimeler	*Pilonidal sinüs hastalığı; orifis; sinüs yolu; fenol; lazer; SILaC*

INTRODUCTION

Pilonidal sinus disease (PSD) is a common chronic, benign disease of the natal cleft. PSD was described for the first time by Dr. Andersson in 1847.[1] PSD usually affects young adults (in general 15-30 years old) and is twice more common in men than in women. Male to female ratio has been reported as 3:1 to 4:1.[2,3] The reported incidence of PSD is 6/100.000 and the reported prevalence is 8.3%.[4,5] In the past, it was believed to be a congenital disease, but recent studies have revealed that PSD is an acquired condition.[6] PSD usually presents as a chronically discharging abscess or sinus tract. The disease leads to significant morbidity by impairing quality of life (QoL). It also can cause pain and local sepsis. Risk factors for developing PSD include obesity, family history, dietary habits, male sex, prolonged sitting and poor hygiene, but the most important factor is excessive hair in the natal cleft.[7] Although there are numerous treatment methods for the management of PSD, none of them has been proven to be superior over others. Therefore, the final decision on the treatment choice may be complicated for both the patient and physician. An ideal treatment method for PSD should be simple and easy to perform, should provide shorter hospitalization and short period to return to daily activities, work, school etc. should result in less complications and recurrence rates.[8-10]

Phenol application is considered a conservative method in the treatment of PSD and some clinics use this method as the first choice. Phenol is a sclerosing agent that destroys the epithelium and sinus debris, promoting healing of the sinus.[11] Crystallized phenol application is easy to perform, readily accessible, and inexpensive method with low recurrence rates.[12] In addition, phenolization can be performed on an outpatient basis under local anesthesia. Its success rate has been reported between 60-100%.[13] However, there is no sufficient data on long-term results with this method. In 2016, Dessily et al. described a promising sinus laser-assisted closure (SiLaC) method for the treatment of PSD with 87.5% success and 2.9% recurrence. Studies conducted since then have reported similar success and recurrence rates[14,15] However, there is still no high level evidence on both short and long term outcomes that will contribute to the development of evidence based guidelines for using laser technique in the treatment of PSD. In order to achieve a consensus on an ideal or optimal method that could be used as a gold standard, further studies with short and long term results are needed on every method used to treat PSD. Therefore, the objective of this study was to compare phenol application and sinus laser-assisted closure (SiLaC) methods for the treatment of PSD.

MATERIAL and METHODS

Before the beginning, the study protocol was approved by the local ethics committee of our hospital with the 07/07/2021 dated and 2011-KAEK-25 2021/07-11 numbered decision. Informed consent was waived as the study was retrospective. However, the necessary permission was obtained from the hospital management to use patient files. This study was conducted in accordance with the ethical principles of 1964 Declaration of Helsinki and later amendments.

Patients

A total of 141 patients aged 18-50, who presented to our hospital due to PSD and treated in our clinic either with phenol application or diode laser methods between June 2019 and January 2021 were included in this retrospective study.

Patients were divided into two groups with 73 patients being in the phenol group and 68 patients in the laser group. Patients' demographic characteristics including age, gender and body mass index (BMI), smoking status, presence of co-morbidities, history of abscess drainage, previous PSD surgery, recurrence status, need for re-operation, postoperative complications (wound dehiscence, infection, and hematoma), distance of orifice from the midline and number of sinus tract were retrospectively recorded and compared between the groups. Data used in this study were obtained from the hospital information management

system and hospital archives.

Patients who underwent recurrent operation due to PSD, complicated PSD cases, those with chronic diseases (hypertension, diabetes mellitus, COPD etc.), hematological and psychiatric disorders or cancer history, patients who had received radiotherapy to the pelvic region, and those with missing information were excluded from the study. Choice of the treatment method based on the patient's preference. The follow-up duration was 11 to 26 months. Primary outcome of the study was success and recurrence rates. Success rate was calculated by taking into account disease free survival over the follow-up period.

Statistical Analysis

SPPS (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) software was used for performing statistical analysis The Shapiro–Wilk test was used to assess normality of the variables. Nominal variables were expressed as median (minimum:-maximum) values. According to the normality test results, Mann Whitney-U test was used to compare the study groups. Categorical variables were compared by Chi-square test and Fisher's Exact test. Survival times were analyzed with the Kaplan-Meier method and the log-rank test was used to compare survival times across groups. Cox regression analysis was performed to determine the factors affecting the development of recurrence. In order to estimate the sensitivity and specificity of orifice distance in predicting the presence of recurrence, receiver operator characteristic (ROC) curve analysis was performed. $p<0.05$ values were considered statistically significant.

Surgical Procedures

A single dose of antibiotic (2 g intravenous cefazolin sodium) was administered immediately before the surgical incision in all patients.

Sinus Laser-Assisted Closure (SiLaC)

The patients were placed in a prone position. The operative area was shaved. The buttocks were separated with plasters optimizing the view. After scrubbing the skin, the different pits were enlarged with a scalpel and a mosquito clamp and the hairs, debris and granulation tissue were removed from the sinus by a curette. The pilonidal sinus tract was swept with a special brush to ensure that the tract was completely cleared of the hairs, debris and granulation tissue. Hemostasis was obtained using electrocautery and external compression. Then a radial diode laser probe (Neolaser®; Atak Cerrahi Ürünler, Istanbul, Turkey) at 1470 (nm) wavelength was used. The laser energy was 10 Watts (average 6.5 Watts). The fiber delivers energy homogeneously at 360 in a continuous way. While the probe is withdrawn at an approximate speed of 1 mm per second, the sinus shrinks and closes. If the tract is not closed after the first withdrawal, the procedure was repeated. At the end of the procedure, a compress protects the pits. The patients were allowed to leave the hospital on the day of the operation. In the post-operative period, no particular care is required except covering the pits with a compress after washing the region or after taking a shower. The patients were called for control fifteen days later, at which time the complete closure of the sinus cavity and presence of no discharge was considered as recovery.

Phenol Injection

We performed the same steps with SILAC until tissue hemostasis for phenol injection. The surrounding skin was protected by a coating of Furacin (Furacin Soluble Dressing Pomad, Eczacıbaşı İlaç San ve Tic A.Ş., İstanbul, Turkey) and Anestol ointment (Anestol Pomad, Sandoz İlaç San ve Tic. A.Ş, İstanbul, Turkey) to protect the skin against possible contact with phenol. Liquid phenol 90% (Galenik Ecza, Izmir, Turkey) was injected with 1 or more 1 mL syringes, depending on the volume of the sinus tract. Phenol was left in place for 1 min and aspirated afterwards. This was repeated once. The excess was mopped away with the debris. This maneuver was repeated 2 or 3 times, depending on the width of the sinus. Finally, the wound was closed with a gauze pack. The patients were called for

control fifteen days later, at which time the complete closure of the sinus cavity and presence of no discharge was considered as recovery.

RESULTS

A total of 141 patients were divided into two groups based on the treatment method applied. Accordingly, 73 (51.80%) patients were assigned to the Phenol group and 68 (48.20%) patients to the Laser group. The median age was found as 24.00 (17:50) years in the Phenol and 25.50 (15-49) years. No statistically significant difference was observed between the two groups in terms of median age (p=0.857). While the phenol group consisted of 17 (23.30%) female and 56 (76.70%) male patients, these numbers were 14 (20.60%) and 54 (79.40%) in the laser group. There was no significant difference between both groups in gender (p=0.699). The median BMI value did not differ significantly between the groups (26 [19:32] and 25 [22:32], respectively; p=0.131). Demographic and clinical characteristics of the two groups are given in Table 1.

Table 1. Demographic and Clinical Features According to Groups

		PHENOL (n=73)	LASER (n=68)	p
Age (years)		24(17:50)	25.50(15:49)	0.857[a]
Gender	Female	17(23.30%)	14(20.60%)	0.699[b]
	Male	56(76.70%)	54(79.40%)	
BMI (kg/m2)		26(19:32)	25(22:32)	0.131[a]
Smoking		33(45.20%)	35(51.50%)	0.457[b]
Comorbidity		2(2.70%)	3(4.40%)	0.672[c]
History of abscess drainage		41(56.20%)	45(66.20%)	0.223[b]
Previous pilonidal sinüs surgery		7(9.60%)	14(20.60%)	0.067[b]
Recurrence		8(11%)	6(8.80%)	0.672[b]
Re-operation		8(11%)	6(8.80%)	0.672[b]
Complication		9(12.30%)	6(8.80%)	0.500[b]
Distance of orifice from midline (mm)		4(0:35)	7(0:50)	0.268[a]
Disease duration (months)		7(2:25)	8(1:48)	0.297[a]
Number of sinus tracts		2(1:5)	2(0:5)	0.879[a]

Data were presented as median (minimum:maximum) and n(%) values
a: Mann Whitney U Test, b: Chi-square Test, c: Fisher's Exact Test

Disease free survival (DFS) duration was found as 25.72±0.76 months in the phenol and 24.38±0.63 months in the laser group. No statistically significant difference was found between the two groups in terms of DFS. DFS was statistically significantly shorter in the patients with previous pilonidal sinus surgery (14.74 months vs. 27.15 month, p<0.001). DFS was statistically significantly shorter in the smoker patients compared to non-smoker patients (22.11 months v.s. 27.16 months, p=0.013). Again, DFS was significantly shorter in the patients with complications compared to those without complications (18.20 month v.s. 26.39 month, p=0.019). Risk factors associated with DFS are shown in Figure 1.

Figure 1. Risk factors for Disease Free Survival (DFS)

A cox regression analysis was carried out in order to determine the factors affecting the development of recurrence (Table 2). The variables were first subjected to univariate cox regression analysis and the variables meeting p<0.25 condition were included in the multivariate cox regression analysis. The variables were selected using the forward elimination approach and in the final step, the variables in the model are given in Table 2. When the table is examined, it was determined that a one-unit increase in the number of sinus tracts reduces the recurrence risk by 65%, and a one-unit increase in the distance of the orifice from the midline increases the recurrence risk 1.22 times.

Table 2. Determination of factors affecting the development of recurrence

	Univariate Cox Regression Model			Multivariate Cox Regression Model		
	Wald	HR(95%CI)	p-value	Wald	HR (95%CI)	p-value
Procedure Group (Phenol)	0.04	0.90(0.31-2.62)	0.843			
Gender (Male)	1.68	3.89(0.50-29.34)	**0.195**			
Age	0.86	0.96(0.89-1.04)	0.355			
BMI	27.65	1.70(1.39-2.07)	**<0.001**			
Number of Sinus Tract	17.39	2.57(1.65-4.01)	**<0.001**	7.56	0.35(0.17:0.74)	**0.006**
Grup Tract			0.544			
Phenol & tract≥2	1.81	4.22(0.52-34.33)	**0.178**			
Laser & tract≥2	2.10	4.83(0.58-40.48)	**0.147**			
Laser & tract<2	0.01	0(0-0.01)	0.967			
Orifice Distance	49.11	1.13(1.09-1.17)	**<0.001**	30.38	1.22(1.14:1.31)	**<0.001**
Disease Duration	8.21	1.07(1.02-1.21)	**0.004**			
History of Abscess Drainage	3.07	50.22(0.63- >100)	**0.080**			
Previous PSD Surgery	20.67	12.78(4.26-38.34)	**<0.001**			
Comorbidity	0.19	0.05(0- >100)	0.659			
Smoking	5.16	4.40(1.23-15.79)	**0.023**			
Repeat Procedure	<0.1	1(0.11-9.05)	>0.99			
Complication	4.74	3.63(1.14-11.60)	**0.030**			

HR: Hazard Ratio, CI:Confidence Interval

Receiver operator characteristic curve analysis was performed to estimate the sensitivity and specificity of orifice distance for predicting the presence of recurrence, and the cut-off point for orifice distance was determined as >1.4 cm. The area under the curve for orifice distance was 0.996 (sensitivity 100%, specificity 92.91%, p<0.001), showing that an orifice distance >1.4 cm was significantly related to an increased risk of the presence of recurrence (Figure 2). After ROC analysis, patients were divided into two groups (>1.4 mm vs. ≤1.4 mm) according to orifice distance, and Table 3 includes comparisons between these groups.

According to the ROC analysis results, it was determined that there was no difference between the patient groups formed by considering the orifice distance in terms of age and gender (p=0.865 and p=0.093). Median BMI was higher in the group with orifice distance >1.4 cm (28 vs. 25; p<0.001). While it was observed that the rate of smoking was higher in the patients in the group with an orifice distance >1.4 cm (69.60% vs. 44.10%; p=0.025), there was no significant difference between the groups in terms of the incidence of co-morbid disease (p=0.187). It was determined that the rate of abscess drainage history was higher in the group with orifice distance >1.4 cm (82.60% vs. 56.80%; p=0.020). While there was no difference between the groups according to the rate of previous pilonidal sinus surgery (39.10% vs. 10.20%; p=0.067), the recurrence rate (60.90% vs. 0; p<0.001) and the re-operation rate (60.90% vs. 0; p< 0.001) were higher in the group with an office distance >1.4 cm. There was no difference between the groups in terms of the complication rate (p=0.072). On the other hand, it was found that the median disease duration was higher in the group with an orifice distance >1.4 cm (9 months vs. 7 months; p=0.005) and the median tract number was also higher in the group with an orifice distance >1.4 cm (3 vs. 2; p<0.001).

Table 3. Comparisons between the groups according to the orifice distance

	Orifice Distance		p-value
	>1.4 cm (n=23)	≤1.4 cm (n= 118)	
Age (years)	26(18:49)	24.50(15:50)	0.865[a]
Gender			
Female	2(8.70%)	29(24.60%)	0.093[b]
Male	21(91.30%)	89(75.40%)	
BMI (kg/m2)	28(23:32%)	25(19:32%)	**<0.001**[a]
Smoking	16(69.60%)	52(44.10%)	**0.025**[b]
Comorbidity	2(8.70%)	3(2.50%)	0.187[c]
History of Abscess Drainage	19(82.60%)	67(56.80%)	0.020[b]
Previous PSD Surgery	9(39.10%)	12(10.20%)	0.067[c]
Recurrence	14(60.90%)	0	**<0.001**[c]
Repeat Procedure	14(60.90%)	0	**<0.001**[c]
Complication	5(21.70%)	10(8.50%)	0.072[c]
Disease Duration (months)	9(2:25)	7(1:48)	**0.005**[a]
Number of Sinus Tracts	3(1:5)	2(0:5)	**<0.001**[a]

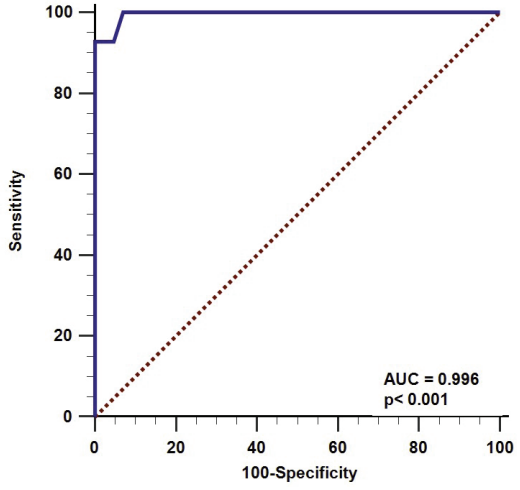

Figure 2. Receiver-operator characteristic (ROC) curves for determining the presence of recurrence. The area under the curve (AUC) for orifice distance is 0.996 with p<0.001.

DISCUSSION

An ideal or optimal minimally invasive method that will be used in the treatment of pilonidal sinus disease (PSD) should be easy to perform, readily accessible, inexpensive, should provide short hospitalization and short time to return to work/daily activities with low recurrence and complications rates and low rate of the need for re-operation. Effectiveness of such a method is measured with the rates of success, recurrence and complications. Based on this, numerous studies have been and are being conducted to compare various techniques. Likewise, in the present study we compared phenol application and diode laser methods in the treatment of PSD.

As mentioned above, PSD primarily affects young adults between 15-30 years old and male to female ratio is approximately 2:1. From this point of view, PSD causes significant labour loss, because the majority of patients with PSD are in their active work life. In the present study, median age was 24.75 years and while 110 (78.01%) patients were male and 31 (21.99%) patients were female (M:F=110:31=3.55). Harju et al. reported the mean age as 29.2 years and M:F ratio as 3.78.[16] In another study by Dogru et al, the mean age was found as 26.9 years and M:F as 7.9.[17] The mean age and M:F ratio were reported as 22.7 years and 5.7 by Georgiou et al., 24.5 years and 2.6 by Dessily.[7,14] Despite small differences, age and gender distribution is consistent across studies, including our study.

PSD recurrence is thought to be related to the depth of the intergluteal groove, which is deeper in obese people, explaining why body mass index (BMI) is one of the risk factors of developing PSD recurrence.18 In our study, the median BMI value was calculated as 25.5 Kg/m2. On the other hand, the mean BMI value was reported as 29 Kg/m2 by Akkurt et al., 23.7 Kg/m2 by Altintoprak et al. and 25.7 Kg/m2 by Calikoglu et al.[10,19,20] The results of these studies and our results are in parallel in terms of BMI values. However, all these numbers are below the limit of obesity, which is 30 Kg/m2. Perhaps obesity and thus BMI play no role in

the development of PSD itself, but rather characteristics of PSD such as the number of sinus tracts, distance of orifice from the midline etc. This could be clarified with further studies on the relationship between obesity and PSD.

It has been reported that smoking has negative impacts on treatment results of PSD.[21] Infection rate is extremely high among smokers following treatment.[22] In addition, recurrence rate has been reported to be high among smokers.[23] In our study, the rate of smokers was as high as 48.22%. Similarly, Calikoglu et al. reported the rate of smokers as 52.9%.[10] In the present study, smoking was found to be among the determinants of recurrence (p=0.023). In addition, smoking was correlated with disease free survival (p=0.013). Our finding is consistent with the literature.

In our study, we measured treatment success with four factors including recurrence, re-operation, complications and disease free survival. We compared these four factors between phenolization and diode laser methods. Although conventional surgical excision remains the cornerstone of treatment in many countries, its most evident disadvantage is high recurrence rates.[24] One of the most important reasons for the emergence of minimally invasive procedures is to reduce recurrence rates. In our study, the rate of recurrence was found as 11% in the phenol and 8.80% in the laser group. There was no statistically significant difference between the phenol and laser groups in terms of recurrence (p=0.672). In addition, the multivariate cox regression model revealed the number of sinus tracts (p=0.006) and distance of the orifice from the midline (p<0.001) as the factors affecting recurrence. An orifice distance >1.4 cm was found as the cut-off for predicting recurrence with a 100% sensitivity and a 92.91% specificity (p<0.001). Based on our findings, for example an obese, smoker, male patient with multiple sinus tracts who had a history of previous surgery and an orifice distance >1.4 cm may be directed to alternative operation techniques with lower possibility of recurrence.

In our study, the median follow-up duration differed between 11 months and 26 months depending on recurrence, complications and disease free survival. Treatment success was defined as the absence of recurrence and complications in the follow-up period. Accordingly, success rate was found as 89% in the phenol group and 91.2% in the laser group. No significant difference was found between the two methods in terms of success rate (p>0.5). Recurrence and success rates have been the main focus in addition in many other studies comparing various methods in the treatment of PSD. Akan et al. compared surgical Limberg flap technique and crystallized phenol application and reported the recurrence rate as 8% in the flap group and 12% in the phenol group with no significant difference between them.[25] Akkurt et al. compared crystallized phenol application and Karydakis flap technique for the treatment of PSD and reported the recurrence rate as 4.4% for the phenol and 7% for the flap group with no significant difference between them.[19] In a study by Algazar et al. investigating SILaC and Limberg flap methods, recurrence rate was found as 8.3% in the SILaC group and 4.3% in the flap group.[26] Georgiou obtained a success rate of 92% with the PiLaT laser technique.[14] In a randomized-controlled trial, Pronk et al. compared short-term outcomes of radical excision vs. phenolization methods in the treatment of PSD.[27]

Because the differences between above mentioned techniques in terms of recurrence and thus, success rate are small, no definitive conclusion can be drawn from these results. Therefore, large-scale comprehensive studies are needed to find an ideal or optimal method for the treatment of PSD. Once again rates of recurrence, re-operation and postoperative complications are low in both the current study and previous studies. In our study, since the examined parameters were similar between the SILaC and phenol groups and were close to each other, choice of the treatment method is usually left to the patient's preference. Based on the information at hand, both methods can be safely and effectively used as primary treatments.

However, longer follow-up durations may be required to see whether this similarity in recurrence and other parameters will change.

Study Limitations

Major limitation of this study is the relatively small number of patients and its retrospective nature. Postoperative complications could be addressed in detail, but the rate of complication is already low. Additional parameters such as pain score could be evaluated. As strengths of the study, follow-up duration reaching 26 months is longer compared to many studies on this issue. SILaC laser technique and phenolization was compared in a study for the first time. Determination of a cut-off value for predicting the presence of recurrence and disease free survival analysis is another. However, further comprehensive randomized-controlled studies are needed to determine the ideaş or optimal minimally invasive method in the treatment of PSD.

CONCLUSION

The results of this study indicate that recurrence and success rates are similar between the relatively newer SILaC method and phenolization technique. Rate of complications is also similar. Previous pilonidal sinus surgery, smoking and complications are the factors affecting disease free survival. Number of sinus tracts and distance of the orifice to the midline are the factors affecting recurrence. A cut-off value >1.4 can be used to predict the presence of recurrence. Both treatment methods can be safely and effectively used for the treatment of PSD.

Acknowledgement

N/A

Conflict of Interest

The authors declare no conflict of interest to disclose

Funding

This study did not receive financial support

Data Availability: Data used in this study can be provided on reasonable request

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