

Previously operated recurrent pilonidal sinus treated with crystallized phenol: Twenty-year experience in a cohort study

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ABSTRACT

Objective: Postoperative recurrent pilonidal sinus disease is troublesome, and its treatment is a challenge. In this study, it was aimed to present the long-term efficacy of crystallized phenol treatment on postoperative recurrent pilonidal sinus disease through our results collected within the last 20 years.

Material and Methods: Two hundred and twenty-seven patients who had been previously operated on and suffered from recurrent pilonidal sinus disease were enrolled. The operation was applied in our outpatient clinic under local anesthesia. Demographic data of the patients, number of crystallized phenol treatment, duration of follow-up and recurrence numbers were prospectively recorded. Treatment success and factors affecting recurrence were examined

Results: Our success rate was found as 71.5%. This success rate belongs to the group of patients who never quit treatment and complied with the treatment. The patients were followed up for a mean 45.8 months. Of the post-crystallized phenol treatment recurrences, 72.4% took place within the first five years, while 97.4% did so within the first 10 years. Mean number of crystallized phenol applications was 2.6. The longer the duration of the disease before treatment, the more recurrence was observed after treatment (p= 0.02). There was no correlation between the number of previous operations and recurrence after treatment. As the number of sinus openings increased, so did the number of applications (p= 0.001).

Conclusion: Crystallized phenol treatment yields promising long-term results in recurrent pilonidal sinus disease as well and may be recommended as the first choice in recurrent pilonidal sinus disease treatment since it is an effective non-operative treatment modality.

Keywords: Recurrent pilonidal disease, nonoperative treatment, crystallized phenol

INTRODUCTION

Recurrent pilonidal sinus disease (rPSD) is annoying for both surgeons and patients compared to primary disease. Although many surgical treatment methods in primary pilonidal sinus disease (pPSD) have been reported, long-term recurrence rates after treatment are between 40.2% and 67.9% according to different surgical types (1). Many treatment modalities have been advocated in the treatment of rPSD; however, there is still no consensus in the literature. In addition, a more radical surgical method is generally preferred by surgeons for the failure of the first surgical procedure in rPSD. Due to this approach, various complications such as wound infection, hemorrhage and flap detachment are seen (2).

Some minimally invasive techniques are used alone or as an adjunct to surgery. Injection of various substances into the sinus cavity such as 80% phenol, fibrin glue and cyanoacrylate and destruction of the sinus cavity with laser probe have provided acceptable low recurrence rates compared to simple sinus excision (3-6). Phenol 80% injection has been reported to be applied only in the treatment of pPSD and not of rPSD (3,7). In the nonoperative treatment of pilonidal sinus disease (PSD), crystallized form of phenol has been used for the first time in the world by Dogru O et al. (8), and they have reported the success rate of crystallized phenol treatment (CPT) in pPSD as 95.1%. Aygen et al. (9) have successfully applied CPT in rPSD treatment in a limited number of patients and in a short follow-up period. However, there are no large studies in the literature showing the long-term effects of CPT in rPSD.

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In this study, it was aimed to reveal the long-term efficacy of CPT in rPSD after surgery by publishing our 20-year experience.

MATERIAL and METHODS

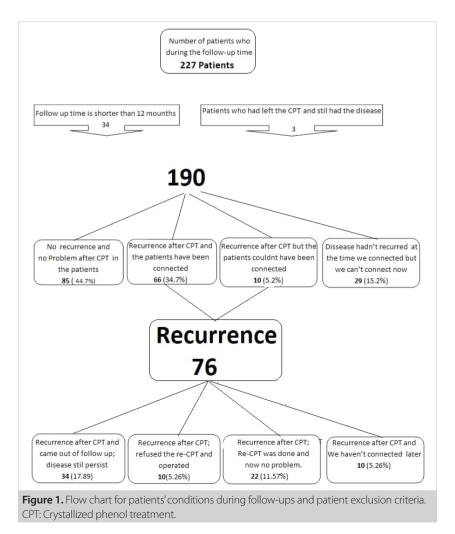
Patient Selection

This cohort study was performed in accordance with the declaration of Helsinki protocol and recorded in clinical trials website numbered NCT04423510. The work was reported in line with the STROCSS criteria (10). Patients who were presented to the general surgery clinic of Firat University Medical Faculty and SBU Konya Training and Research Hospital between March 1995 and January 2015 for previously operated recurrent sinus pilonidal disease were included in the study. Data were collected prospectively and analyzed retrospectively. The aim of this intervention was therapeutic. Informed consent form was obtained from all of the patients. A total of 227 previously operated rPSD patients were included in the study. Of these, 37 patients who discontinued the treatment without any other treatment and at the beginning of the study with a follow-up period of less than 12 months were excluded from the study. The analyzes were

performed in a total of 190 patients (Figure 1). In addition to the demographic data of the patients, other parameters such as smoking, whether they sit a lot due to occupation (sitting at work for at least six hours a day), skin tone (whiter, darker), presence of positive family history, BMI (kg/m², patients were divided into BMI< 30 and BMI> 30), and pilosity levels were also recorded. Pilosity levels were classified as mild, moderate and severe according to the pilosity levels scale of Dogru et al. (8). The presence of purulent discharge from the sinus opening and the presence of signs of inflammation or abscess formation in this region were evaluated as acute PSD. The presence of serous discharge from the sinus opening and absence of abscess formation were evaluated as chronic PSD. We investigated whether the factors mentioned above affect the number of applications and recurrence after CPT.

The Protocol of CPT

Treatment procedure was applied to all patients as described by Dogru et al. (8). One day before the procedure, the patients were asked to clean the hair from the waist to the middle of the thighs



with depilatory creams or epilation. No antibiotics and analgesic agent were used during intervention. After local anesthesia was performed around the holes, a thin mosquito clamp was inserted into the sinus, the hairs were removed, and the skin around the hole was covered by nitrofurantoin pomade (Furacin, Eczacıbaşı llaç San. ve Tic. AŞ, İstanbul, Turkey) to prevent chemical irritation. Then crystallized phenol was introduced into the sinus with the same clamp. When an abscess was detected, the abscess was drained first and simultaneous CPT was performed. Patients were allowed to return to their daily activities after the procedure. This procedure was performed every three weeks. If there was discharge from the wound during follow-up examination, the procedure was repeated. The closure of the sinus hole and complete disappearance of the discharge was accepted as healing. After the treatment, follow-up was started. Follow up was done first yearly than with five-year intervals. All of our patients' contact information was recorded by us, and we tried to reach the patients every five years by any means (phone or e-mail). We tried to follow them up by contacting them periodically, whether they contacted us or not. According to this follow-up, patients were analyzed being divided into three groups (1-5 years, 5-10 years, 10-20 years). Patients who could not be reached by any means of communication were included in the unreachable group. Patients were recommended to have hair removal at the wound site once a month for six years.

Post Procedure Follow-up

Number of crystallized phenol application, presence of recurrence and number of recurrences after CPT and follow-up data were evaluated. Recurrence of the sinus hole which was found to occur again at least six months after being determined to be closed was considered as recurrence. If no recurrence was observed during the follow-up or if post-CPT recurrence was healed after treatment, CPT was considered successful.

Statistical Analysis

Distribution of the variables was measured with Kolmogorov Smirnov test. Mann-Whitney U test was used in the analysis of quantitative independent data. Chi-square test was used to analyze the categorical independent data, and Fisher's exact test was used when the conditions for Chi-square test were not met. SPSS (Version 22.0) program was used in the analyses.

RESULTS

During the follow-up period, 85 (44.7%) patients survived without any problems. Among the 66 patients with relapsed disease and who were reachable, CPT was applied again in 22 (11.5%), and 10 (5.26%) patients preferred to have surgery due to recurrent disease after CPT and currently have no problems. Thirty-four (17.89%) of the patients who had relapsed and could be reached received no treatment after the recurrence, and the disease is still present. Twenty-nine (15.2%) patients who could not be reached subsequently had no recurrence within the time they could be contacted. Thus, the number of patients with a successful treatment was 136. Our success rate was 71.5%, which is a result of 20 years.

Demographic information of the patients is shown in Table 1. Mean duration of the disease from surgery to recurrence was 22.2 months. Recurrence was seen most frequently after excision and primary closure. Mean number of previous operations was 1.3 (1-5).

Table 2 shows sinus properties, application data of the procedure, factors accused in etiology and follow up data. Mean duration of follow-up was 45.8 months (range= 12-240 months). Our mean number of applications was 2.6, and mean duration of applications was 8.3 weeks.

Among the rPSD patients treated with CPT, 72.4% recurrences occurred in the first five years and 97.4% in the first 10 years (Table 3). Maximum recurrence was three times after CPT treatment, which was observed in one patient. In Table 3, the distribution of the total number of recurrences in patients with recurrence and data of the patients who could not be reached during follow-up are given with an interval of five years along with the patients who could be followed by us. The most recurrence was observed between 1-5 years and then decreased gradually to 2.6% between 10-20 years. The number of unfollowed patients was similar to this, and there were no patients who were unfollowed between 10-20 years. The number of patients with recurrence after CPT and undergoing re-CPT was 32 (42.1%). Mean number of applications of these patients were 2.38 ± 2.88 (1-16), and mean healing time was 9.41 ± 17.08 weeks (1-92). The number of patients who had recurrence the second time and underwent re-reCPT was 6 (7.89%). Mean number of applications of these patients were 2.33 \pm 1.96 (1-6), and mean healing time was 7.17 \pm 6.16 (3-20). The remaining one patient who had recurrence three times underwent rereCPT. When compared to the first CPT performed in the patient with recurrent disease after CPT, fewer applications and shorter application time were required for treatment after each recurrence. In our series, we had 22 patients who accepted our re-CPT again after CPT recurrence and with whom we never lost contact, and now their condition is fine (Figure 1).

Forty percent of the patients recovered after a single procedure; however, we had to perform 14 procedures in two patients. The number of patients on whom we performed 10 or more procedures was only six (Table 4).

Table 5 shows whether demographics, habits and duration of disease affected recurrence after CPT. Patients with habits (cigarette smoking) had a higher rate of recurrence after CPT compared to those without any habits (p= 0.04). The longer the duration of the disease before treatment, the more recurrence was observed after CPT (p= 0.02). There was no correlation between the number of previous operations and recurrence after CPT.

Table 1. Demographic data of patients					
Demographic data	Min-Max	Median	Mean ± SD/n (%) 26.3 ± 8.0		
Age	18 - 50.0	24.0			
Sex					
Male			173	91.1%	
Female			17	8.9%	
Duration of disease (month)	0 - 240.0	12.0	22.2 ± 34.3		
BMI	17.9 - 38.8	26.8	27.2 ± 4.1		
BMI< 30			150	78.9%	
>30			40	21.1%	
Habits (cigarette smoking)					
None			91	47.9%	
Yes			99	52.1%	
Previous operation type					
Excision and primary closing			94	49.5%	
Limberg flap			68	35.8%	
Karidakis flap			18	9.5%	
Sinus excision and opening			8	4.2%	
V-Y flap			2	1.1%	
Sinus excision procedures			102	53.7%	
Flap procedures			88	6.3%	
Min: Minimum, Max: Maximum SD: Standard	deviation, n: Number.				

	Min-Max	Median	Mean \pm SD/n (%)		
Number of total openings	1.0 - 12.0	2.0	1.9 ±	1.6	
Follow up duration (month)	12.0 - 251.0	36.0	45.8 ± 32.2		
Number of previous operations	1.0 - 5.0	1.0	1.3 ± 0.6		
Number of applications	1.0 - 14.0	2.0	2.6 ± 2.4		
Time of application (week)	1.0 - 144.0	6.0	8.3 ± 13.0		
Over-sitting story					
None			83	43.7%	
Yes			107	56.3%	
Skin tone					
Whiter			108	56.8%	
Darker			82	43.2%	
Pilosity levels					
Mild			11	5.8%	
Moderate			99	52.1%	
Severe			80	42.1%	
Family history					
None			107	56.3%	
Yes			83	43.7%	
Condition of sinus					
Chronic			173	91.5%	
Acute			16	8.5%	

Table 3. Distribution of the total number of recurrences in patients with recurrence and data of the patients who lost contact during follow up

Follow-up time (Years)	Number of patients with recurrence n (%)	Number of patients who lost contact n (%)		
1-5	55/72.4	26/66.7		
5-10	19/25.0	13/33.3		
10-20	2/2.6	0/0		

Table 4. Application data of patients						
Number of Applications	Frequency	Percent	Cumulative Percent			
1	82	43.2	43.2			
2	34	17.9	61.1			
3	20	10.5	71.6			
4	30	15.8	87.4			
5	12	6.3	93.7			
6	3	1.6	95.3			
7	2	1.1	96.3			
9	1	0.5	96.8			
10	1	0.5	97.4			
11	1	0.5	97.9			
12	2	1.1	98.9			
14	2	1.1	100.0			
Total	190	100.0				

Table 6 shows the effect of other features on recurrence after CPT. Recurrence after the procedure was not associated with the number of openings, positive family history and number and duration of applications (p> 0.05).

As the number of sinus openings increased, so did the number of applications (p= 0.001). The number of applications was higher in acute cases, compared to chronic cases (p= 0.001). In darker patients, the number of applications was higher compared to whiter patients (p=0.01).

DISCUSSION

Although the first method used in the treatment of PSD is often a surgical, the ideal method for treatment is still controversial (11). The most important criteria showing the success of the technique is the recurrence rate. Long-term recurrence rates after surgical procedures are alarmingly high. In a recent meta-analysis by Stauffer et al. (1), recurrence rates of 67.9% after primary midline closure and 40.2% after flap methods have been reported. Lee et al. (12) have suggested primary closure with sinus excision in the treatment of primary disease and flap procedures for the treatment of recurrences. In a study, using sinus excision and flap reconstruction technique in 55 patients with rPSD, 1 (1.8%) patient has had recurrence, who has been reported to be treated using an open technique (13). The authors have suggested that methods such as flap reconstruction or leaving the wound open should be applied after sinus excision in rPSD. Bali et al. (14),

in their study comparing Karydakis flap and Limberg flap techniques in rPSD, have reported similar recurrence rates; however, they have favored the Limberg flap technique due to its lower rate of complications. These studies have generally evaluated the surgical results of rPSD treatment. Therefore, it is argued that surgical outcomes are more effective on relapse in the treatment of rPSD. There are few studies with minimal follow-up on minimally invasive or nonoperative treatment methods (9,15,16). Bascom (17) has successfully applied the cleft lift procedure, a minimally invasive technique in rPSD, for the first time. In that study, 91.3% success was achieved in 69 patients who underwent cleft lift procedure. In this present study, it was shown that CPT can be applied in the treatment of rPSD with similar recurrence rates with the surgical methods and minimal complications as in pPSD. This study is also the largest series in the world that have the longest follow-up time with crystallized phenol method used in the treatment of previously operated rPSD.

Crystallized phenol treatment is the most commonly used nonoperative treatment for PSD. Crystallized phenol treatment compared with radical excision of the sinus tract is a procedure that can be performed under local anesthesia, requires no hospitalization, allows patients to return to activities in a short time after the procedure, and causes less pain after the procedure. It is cheaper, wound epithelialization is faster and has a lower risk of complications (18). In addition, CPT has similar success rates compared to other surgical procedures (7).

		Recurrence (-)			Recurrence (+)			
Demographic Data	Mean ±	Mean ± SD/n (%) Median Mean ± SD/n (%)		SD/n (%)	Median	р	р	
Age	25.7	± 7.7	24.0	27.3 ± 8.5		27.5	0.234	m
Height (cm)	174.	8 ± 6.9	175.0	174.6 ± 7.1		175.0	0.734	m
Weight (kg)	83.6	± 14.9	82.0	82.6 ± 13.2		82.0	0.594	m
Duration of disease (month)	17.7	17.7 ± 25.8		28.9 ± 43.5		12.0	0.021	m
BMI	27.3	± 4.4	26.9	27.0	± 3.8	26.3	0.759	m
BMI								
<30	89	59.3%		61	40.7%		0.856	X2
≥30	25	62.5%		15	37.5%			
Sex								
Male	103	90.4%		70	92.1%		0.678	X2
Female	11	9.6%		6	7.9%			
Habits (cigarette smoking)								
None	62	54.4%		29	38.2%		0.040	X2
Yes	52	45.6%		47	61.8%			
Previous operation type								
Excision and primary closing	57	50.0%		37	48.7%		0.859	X2
Limberg flap	42	36.8%		26	34.2%		0.711	X2
Karidakis flap	11	9.6%		7	9.2%		0.919	X2
Sinus excision and opening	3	2.6%		5	6.6%		0.184	X2
V-Y flap	1	0.9%		1	1.3%		1.000	X2
Sinus excision procedures	60	58.8%		42	41.2%			
Flap procedures	54	61.4%		34	38.6%		0.760	X2
mMann-Whitney U test/ ^{X2} Chi-square te	st. Min: Minimum	n. Max: Maximur	n SD: Standard d	eviation, n: nu	mber.			

Although there are studies reporting some nonoperative methods such as hair removal of the natal cleft, perineal hygiene and laser depilation in addition to CPT in the treatment of pPSD, the number of studies demonstrating its efficacy in rPSD is limited (19,20). Dragoni et al. (16) have reported that no recurrence was observed in the two-year follow-up of 10 patients who were applied nd-YAG laser in rPSD. However, the number of patients and the follow-up period was kept short in that study. Aygen et al. (9) have applied CPT in 36 patients with rPSD and achieved a success rate of 91.7% after a mean follow-up of 4.5 years. Our study is a continuation of this study and gives a longer duration of follow-up results with more patients. The success rate of our study was 71.5%. This success rate includes a patient group that did not give up treatment and was compatible with us. The group of patients who did not come for follow-up visits following recurrence after CPT or who refused treatment and had surgery was accepted as unsuccessful. Complete cure was achieved in all patients who were compatible with the treatment. Perhaps, if the patients in the failing group continued

treatment, our success rate would be higher and even higher than the study of Aygen et al. (9). Another reason for the decrease in our success rate compared to the study of Aygen et al is that some patients dropped out of follow-up because of the long follow-up period.

In this study, when we examined the recurrences after CPT, 10 (13.15%) patients stopped to contact us following recurrence after CPT, and 34 (44.73%) patients did not accept our second treatment and the disease was still present in our follow-up, and 10 (13.15%) patients refused our second treatment and underwent surgery (Figure 1). However, 22 (28.94%) patients in this group who relapsed after CPT accepted the additional treatments recommended by our team and never lost contact. All 22 of these patients are now in a healthy state. From these 22 patients, only 3 (13.6%) had second relapses and 1 (4.5%) had a third relapse and treated re-CPT successfully. Thus, it was found that recurrent cases after CPT can be easily treated with crystallized phenol method and will not cause serious complications as in recurrence of surgical treatment.

Table 6. The comparison of sinus characteristics, CPT application data, follow-up time and factors accused in etiology according to recurrence status in the patients

		Recurrence	e (-)	1	Recurrence (+	-)		
	Mean ± SD/n (%)		Median	Mean ± SD/n (%)		Median	р	
Number of total openings	2.1	± 1.9	2.0	1.7 ± 1.1		1.0	0.316	m
Follow up duration (month)	44.6 ± 30.6		35.0	47.7 ± 34.7		37.5	0.363	m
Number of previous operations	1.3 ± 0.7		1.0	1.3 ± 0.6		1.0	0.272	m
Number of applications	2.7 ± 2.4		2.0	2.5 ± 2.4		2.0	0.241	m
Time of application (week)	8.5	± 15.2	6.0	7.9	± 8.6	6.0	0.948	m
Over-sitting story								
None	44	38.6%		39	51.3%		0.083	X ²
Yes	70	61.4%		37	48.7%			
Skin tone								
Whiter	66	57.9%		42	55.3%		0.720	Χ²
Darker	48	42.1%		34	44.7%			
Pilosity levels								
Mild	7	6.1%		4	5.3%		0.020	
Moderate	60	52.6%		39	51.3%		0.938	
Severe	47	41.2%		33	43.4%			
Family history								
None	64	56.1%		43	56.6%		0.952	X ²
Yes	50	43.9%		33	43.4%			
Condition of sinus								
Chronic	107	90.7%		66	88.0%		0.157	X ²
Acute	7	5.9%		9	12.0%			

The success rate of CPT in a single session in pPSD has been reported to be 62-95% in the literature (21). The success rate of a single session in this present study was 44.4%. In ten sessions of application, the success rate reached 97.4%. Our low rates are due to the fact that we applied this treatment in recurrent cases and did not select the cases. Mean number of applications in this study was 2.6. Aygen et al. (9) have reported an average number of applications in rPSD as 3.7. The number of applications is probably low due to the large size of this present study. In patients with recurrence after CPT, mean number of applications after recurrence was 2.3. In other words, we think that the recurrence of the disease does not lead to an increase in the number of applications, but rather it decreases the number of applications. We also found that flap formation performed in the previous surgical procedure had no effect on the number of applications and recurrence after CPT.

Some etiological factors such as obesity, chronic disease, family history, cigarette smoking and sedentary lifestyle have been proposed as predisposing factors in the development of pPSD (22). Doll et al. (23) have demonstrated a significantly higher recurrence rate in patients who were operated on for PSD and

had a positive family history of PSD in first degree relatives. In our study, no relationship was found between positive family history and recurrence after CPT. There are conflicting results about the relationship between recurrence and BMI in PSD (22,24). In this present study, there was no significant difference in recurrence after CPT in patients with BMI> 30 compared to the rest of the patients. However, recurrence was higher after CPT in patients with cigarette smoking (p= 0.04). In addition, recurrence rate after CPT increased with increasing duration from postoperative recurrence to CPT (p= 0.02, Table 5). There was no correlation between skin tone and pilosity levels and recurrence after CPT. However, we recommend hair removal with depilatory cream or laser depilation once a month during treatment and for at least six years following treatment. However, some of the patients complied with this recommendation and some did not. Therefore, we cannot say whether hair growth is effective in relapse after CPT. Kaymakçıoğlu et al. (7) have reported that recurrence rate and recovery time increase as the number of sinus openings increases in pPSD. However, in our study, there was no correlation between the number of holes and the number of applications and recurrence after CPT. According to our study, we think that etiologic factors affecting

recurrence in pPSD are not similar in rPSD. This may be due to previous operations.

There are some limitations of this study. Due to the long follow-up period of our study, we could not contact 20% of our patients within a certain period of follow-up. In addition, since it was not a randomized controlled trial, no patient selection criteria were set. We followed up all patients with previously operated rPSD. Therefore, we obtained data from a very large population. Our study may be supported by a randomized prospective study in a more specific operation group or in a more selected patient group.

CONCLUSION

Long-term results of CPT, which has been proven successful in pPSD, are also effective in previously operated rPSD. In addition, although it has a recurrence rate close to surgical interventions, there is no risk of serious postoperative complications. Cigarette smoking, the duration between time of recurrence after surgical treatment and time of presentation are effective in the development of recurrences after CPT. We believe that CPT can be the first choice of treatment in rPSD treatment as it is an inexpensive nonoperative treatment method that can be applied in outpatient settings with minimal labor loss, excellent cosmetic results, minimal pain and rapid return to daily activities.

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ORİJİNAL ÇALIŞMA-ÖZET

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Pilonidal sinüs nedeniyle opere olan ve nüks gelişen hastalarda kristalize fenol tedavi sonuçları: Yirmi yıllık kohort çalışması deneyimi

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ÖZET

Giris ve Amac: Pilonidal sinüste cerrahi sonrası nükslerin tedavisi zor ve can sıkıcıdır. Opere nüks pilonidal sinüs hastalığında kristalize fenol uygulamamızın yirmi yıllık sonuçlarını vererek uzun dönem etkinliğini sunmayı amaçladık.

Gereç ve Yöntem: Pilonidal sinüs cerrahisi geçiren ve nüks nedeniyle başvuran 227 hasta çalışmaya dahil edildi. Müdahale lokal anestezi altında günübirlik müdahale ile yapıldı. Hastaların demografik verileri, sinüs özellikleri, kristalize fenol seans sayısı, takip süresi, nüks ve nüks sayıları prospektif olarak kaydedildi. Tedavinin başarısı ve nüksü etkileyen faktörler incelendi.

Bulqular: Basarı oranımız %71,5 idi. Bu basarı oranı tedaviyi hic bırakmayan ve tedaviye uyum sağlayan hasta grubuna aittir. Hastalar ortalama 45,8 ay takip edildi. Kristalize fenol tedavisi sonrası nükslerin %72,4'ü ilk beş yıl içinde olurken,%97,4'ü ilk 10 yıl içinde gerçekleşti. Ortalama seans sayısı 2,6 idi. Tedavi öncesi hastalık süresi ne kadar uzunsa, tedavi sonrasında o kadar fazla nüks gözlendi (p= 0,02). Önceki operasyonların sayısı ile tedavi sonrası nüks arasında bir ilişki yoktu. Sinüs deliklerinin sayısı arttıkça uygulama sayısı artmıştı (p= 0,001).

Sonuç: Kristalize fenol tedavisi, tekrarlayan pilonidal sinüs hastalığında da umut verici uzun vadeli sonuçlar verir ve etkin bir ameliyatsız tedavi yöntemi olduğu için tekrarlayan pilonidal sinüs hastalığı tedavisinde ilk seçenek olarak önerilebilir.

Anahtar Kelimeler: Nüks pilonidal sinüs, nonoperatif tedavi, kristalize fenol

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