

# Sinusectomy And Primary Closure Versus Excision And Primary Closure In Pilonidal Sinus Disease: A Retrospective Cohort Study

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## Abstract

Background: Various surgical procedures are existing for the treatment of pilonidal sinus diseases (PSD), but the best surgical approach is still controversial. Minimally invasive surgical procedures become more popular than the sophisticated complex surgery. The aim of the study is to evaluate the efficacy of sinusectomy with primary closure (SPC) in primary or recurrent cases comparing to the excision and primary closure (EPC) technique. Material and Methods: This single-center retrospective cohort study was conducted with two cohort groups in which 351 patients with PSD underwent either SPC or EPC procedure. The two procedures were compared according to the presence of short term complications and recurrence of PSD. Results: Of the patients, 134 underwent PC surgery, and 217 underwent SPC surgery. The length of stay and the wound healing time were statistically significantly longer in the patients underwent PC surgery. The occurrence of the wound site infection and the abscess were statistically significantly higher in PC surgery; however, the seroma was statistically significantly more common in SPC group. The recurrence rate was 18.7% for EPC approach, and 5.5% for SPC. Conclusion: SPC is an efficient procedure for the treatment of patients with PSD have both simple and complicated disease patterns.

## TITLE

## SINUSECTOMY AND PRIMARY CLOSURE VERSUS EXCISION AND PRIMARY CLOSURE IN PILONIDAL SINUS DISEASE: A RETROSPECTIVE COHORT STUDY

### 1. Introduction

Pilonidal sinus disease (PSD) is one of the common inflammatory process of the natal cleft with an incidence of 26 per 100 000 population<sup>[1]</sup>. It mainly affects the young adults between the 15 – 25 years old and the female to male ratio is between 3:1 and 4:1 <sup>[2-4]</sup>. PSD can result in no apparent symptoms is specified by one or more non-inflamed pits in the natal cleft and incidentally identified; an abscess formation; or a chronic form<sup>[5]</sup>.

PSD is a chronic and inflammatory disease of the sacrococcygeal region<sup>[6]</sup>. Although the exact pathogenesis of PSD is still controversial, the most widely accepted view of its pathogenesis is that shed hairs cause a foreign body reaction and inflammation after penetrating into subcutaneous cysts in the natal cleft<sup>[2, 7]</sup>. Rigidity of body hair, two or less number of baths in a week, time spent more than six hours on a seat per day<sup>[8, 9]</sup>, deep natal cleft and family history were found as predisposing risk factors for PSD <sup>[8, 10]</sup>.

Many treatment modalities have produced since 1950's <sup>[11]</sup>, the optimal treatment approach of this disease is one of the most widely discussed points in the surgery <sup>[3, 12]</sup>. Surgical treatment of PSD differing from the simple incision, curettage, drainage, secondary healing to excision-flap sliding<sup>[3]</sup>. Excision and open wound healing is the method one of the most frequently used in the world and this method still continues to be used because it is simple, easy to learn and reproducible <sup>[13]</sup>. However, the main handicap is quite a long wound

healing time, is reported as 1.5 to 3 months, and a delayed return to school or work [5, 13]. Midline closure shortens significantly the healing time, but it causes a considerable incidence of wound dehiscence ranging between 14 and 74% [5, 13, 14]. Of the off-midline procedures, the Karydakis flap [15], the Limberg flap [16], and cleft lift [17], gained popularity and overcame the disadvantages of midline closure regarding with wound dehiscence. Though these flap procedures have been widely desired techniques by surgeons, the off-midline procedures have led to patients to feel various concerns due to the sophisticated nature of the procedures, resulting in long hospital stay and the cosmetic problem [6, 18-20].

Minimally invasive procedures for the treatment of PSD was described firstly by Lord and Miller 1965 [21]. In parallel with the technical improvement in the surgery, the various minimally invasive approaches have been produced such as follicle removal [22], using trephine instead of knife to clean the underlying cavity [23]. All these techniques have important advantages such as quick healing and fast return to work, but it could be applied in previously untreated patients with mild disease and the high recurrence rate was estimated as 20 to 25% [13].

Sinusectomy was first described by Soll et al. 2008 [24]. The main advantage of this procedure to pit picking and other variations is a complete excision of sinus tract and that is performed by close tracing of the tract instead of wide excision [5, 25]. The promising recurrence rate was observed after sinusectomy, the overall recurrence rate was reported as 7% by Soll et al. according to the long term outcome of 257 patients [25].

The aim of the present study was to assess the efficacy of sinusectomy and primary closure (SPC) in all cases include primary or recurrent patients, simple or complicated with multiple pits or multiple sinus tracts. To compare the results of SPC and regarding with the incidence of postoperative recurrence and the incidence of complications, the procedure of excision and primary closure (EPC) was chosen due to most commonly used treatment modality in complicated and non-complicated cases for a long time.

## 2. Material and Methods

### 2.1. Study design

This study is a single-center retrospective cohort study to compare a novel minimally invasive surgical approach with EPC procedure in patients with pilonidal sinus disease (PSD). The study was conducted in accordance with the Declaration of Helsinki and in line with the Strengthening the Reporting of Cohort Studies in Surgery (STROCSS) criteria [26]. After the ethical approval was obtained from Bezmialem Foundation University Clinical Research Ethics Committee, the study was performed between 01.10.2018 and 31.12.2018.

There were two cohort groups in which the patients with PSD underwent two different surgeries. One of the surgical procedures is SPC as a minimally invasive surgical procedure, and the other one is EPC.

### 2.2. Patients

All the patients underwent PSD surgery in our secondary level state hospital between 01.01.2013 and 31.12.2017, were evaluated for eligibility. The patients with missing data, under 18 years old age, who had any immune system disease, and who were treated other treatment procedures, were excluded from the study. The patients underwent either SPC or EPC surgery was included in the study. The authors did not involve in the selection of the surgery type of the patient. The patients' initial, perioperative and follow-up data were gathered from the electronic health records.

### 2.3. Variables and outcomes

Age and sex of the patients, the type of disease (primary/recurrent), the number of orifices were recorded. The primary outcome of this study was the recurrence risk of the PSD after surgery. The secondary outcomes of the study were, the duration of surgery, the presence of short-term postoperative complication, and the patient outcomes that were studied included length of stay in the hospital and wound healing time between the surgical procedures. The duration of surgery was defined as the time interval from incision until the dressing is applied. The short-term postoperative complications were classified as present or absent for seven

days postoperatively, and included seroma, wound site infection and abscess. We combined the complications as a new variable of having any type of this complication for using in regression models.

## **2.4. Study size**

We did not calculate a priori sample size. All the patients admitted to the general surgery department and diagnosed with the PSD during the study period, were evaluated to enroll in the study.

## **2.5. Surgical procedures**

All the patients were hospitalized one day before surgery, and the body hair on the surgical area was removed using an electric clipper in the morning of the operation. An enema was performed approximately six hours before, and 1 g of cefazolin sodium was administered intravenously 30 minutes before the surgery in all patients. All the surgeries were performed under spinal anesthesia. The patient was placed in a prone jack-knife position. The intergluteal fold was separated by tape, and the intergluteal cleft was exposed. The operation area was cleansed at least twice using a polyvinyl iodine soaked gauze. Then a polyvinyl iodine soaked gauze was placed into anal area to prevent the possible contamination. The orifices were probed using a stylet, and diluted methylene blue was injected to assess the resection area.

### **2.5.1. Sinusectomy and primary closure**

An ellipsoid incision was made separately in such a way that tissue loss will be minimal, and enclosing all primary and secondary sinus orifices at both sides separately using a No. 11 surgical blade. With the help of the stylet, the fistula tract was excised subcutaneously with blunt and sharp dissections (Figure 1a, 1b). Attention was paid not to leave any diseased tissue at the margins after excision, and bleeding points were cauterized for hemostasis. The subcutaneous dead space that forms after the excision was closed subcutaneously with absorbable sutures. Subsequently, the wound at both sides of the fistula was dressed with subcutaneous absorbable suture (Figure 1c, 1d).

### **2.5.2. Excision and primary closure**

A complete excision of the sinus tracts was performed down to the sacral fascia. Following the hemostasis, a penrose drain was placed on the sacral fascia. Subcutaneous and cutaneous layers were closed absorbable sutures. On the first postoperative day, the penrose drain was removed, and early mobilization with small steps was initiated.

All the surgeries were performed by two surgeons who had more than ten years' experience in PSD surgery. Hair removal did not continue postoperatively for the patients. The postoperative antibiotics were not administered routinely. Patients were discharged with diclofenac sodium 75 mg twice daily on the first postoperative day. All patients were examined third and seventh day postoperatively. All short term complications were treated with appropriate modalities, included wound care and antimicrobial therapy for the wound-site infection, drainage and antimicrobial therapy for the abscess, and puncture with an injection syringe for the seroma. The patients were followed-up for the recurrence by the outpatient follow-up visit, or by the telephone contact if there was no available data about the patient's follow-up visit.

## **2.6. Statistical analysis**

Statistical analyses were performed using SPSS version 23 (IBM Corp. in Armonk, NY). There was no missing data of the variables of interest for the patients included in the study. Shapiro-Wilk test was used to evaluate the distribution of the data. Descriptive data are present as the median with the interquartile range (IQR) for non-normally distributed numerical variables, and the frequency (n) and the percentage (%) for categorical variables. The Mann-Whitney U test was used for comparing non-normally distributed data between two study groups. Pearson Chi-square test was used for comparing categorical variables. The recurrence risk was determined by univariate and four multivariate logistic regression models that were developed to estimate the recurrence risk using the demographics, baseline characteristics, perioperative characteristics and presence of postoperative complication as potential confounders. In the model 1, age and sex were included; in the model 2, sinus type and number of orifices were included in addition to variables

of model 1; in the model 3, duration of surgery, length of stay and wound healing time were included in addition to variables of model 2; in the model 4, presence of any type of complication was included in addition to variables of model 3. The Odds Ratios (ORs) with 95% confidence intervals (CIs) were assessed for comparing recurrence risk between surgical procedures.  $p < 0.05$  was considered as statistically significant level.

### 3. Results

During the study period, 484 patients were assessed for eligibility for the study. After excluding 133 patients from the study, a total of 351 patients were included in the study with a median follow-up of 23 months (IQR: 20-26 months). Of the patients, 134 underwent EPC surgery, and 217 underwent SPC surgery, and the same number of the patients were analyzed because of no lost to follow-up (Figure 2). The distributions of age were found statistically similar among the groups. The patients in the SPC group more frequently were male, had recurrent sinus, and had statistically significantly more sinus orifice than the patients in the EPC group ( $p < 0.001$ ,  $p < 0.001$  and  $p < 0.001$ , respectively) (Table 1).

The length of stay and the wound healing time were statistically significantly longer in the patients underwent EPC surgery ( $p < 0.001$  and  $p < 0.001$ , respectively); however, the duration of surgery was statistically significantly longer for SPC procedure ( $p = 0.010$ ) (Table 2).

The occurrence of the wound site infection and the abscess were statistically significantly higher in EPC surgery ( $p = 0.001$  and  $p < 0.001$ , respectively); however, the seroma was statistically significantly more common in SPC group ( $p = 0.004$ ) (Table 3).

Recurrence occurred in 25 patients (18.7%) through the median follow-up period of 23 months in the patients underwent EPC surgery, in 12 patients (5.5%) through the median follow-up period of 22 months in the patients underwent SPC surgery. The crude OR of recurrence for SPC procedure was 0.255 (95% CI=0.123-0.528) ( $p < 0.001$ ). The adjusted ORs of recurrence for SPC procedure were 0.241 (95% CI=0.115-0.506) for model 1, 0.044 (95% CI=0.015-0.132) for model 2, 0.083 (95% CI=0.020-0.348) for model 3, and 0.074 (95% CI=0.017-0.313) for model 4 ( $p < 0.001$ ,  $p < 0.001$ ,  $p = 0.001$  and  $p < 0.001$ , respectively) (Table 4).

### 4. Discussion

PSD is a widespread disease and usually affects young population<sup>[3]</sup>. Although lots of surgical methods have been defined for treatment of PSD, golden standard surgical technic is not available yet<sup>[14]</sup>. The main problem of all techniques is recurrence rate after the applied procedure. There are a few surgical procedures report the long term recurrence rate is less than 10% in the literature<sup>[2, 25, 27-32]</sup>, and these rates are defined as low recurrence. If the long term recurrence rates are more than 10% and less than 20%, these rates are defined as acceptable, reasonable or allowable<sup>[23, 33, 34]</sup>. Lastly, if the long term recurrence rates are above the 20%, it is generally defined as unsatisfactory or unacceptable and these procedures are slowly being abandoned over time<sup>[13, 35-37]</sup>. Sinusectomy is one of the techniques in the pilonidal sinus surgery have the low recurrence rate, Soll et al. reported the long term recurrence rate as 7%<sup>[25]</sup>. In the present study, the recurrence rates were found as %18.7 and %5.5 in patients underwent to EPC and SPC, respectively.

The number of midline or peripheral orifices, previous surgical treatment, wound infection after surgery and chronic disease have been found risk factors to increase the recurrence rate after the surgery<sup>[34, 38]</sup>. Though sinusectomy was recommended in uncomplicated patients with one to three midline pits in German national guideline<sup>[13]</sup>, the number of orifices and recurrent case are significantly higher in the SPC group than the EPC group in present study. Even so, the recurrence rate was lower in SPC procedure, and a lower risk of recurrence was found in all multivariate analysis models. These all findings suggest our hypothesis that sinusectomy procedure could be performed in all patients with uncomplicated and also complicated cases have higher number of orifices, sinus tracts and recurrent condition.

In addition to low recurrence rate, the ideal surgical approach have low risk of local complication, low cosmetic concern, short inpatient duration, short wound healing time and fast return time to school or work<sup>[12, 28, 34, 39]</sup>. The sophisticated surgical procedures in the treatment of PSD such as excision and

primary closure have increased risk of wound dehiscence, wound infection and abscess formation [28]; off-midline closure have increased hospital stay and wound healing time [12]. Similar to the findings of previous studies, the patients were treated with the EPC have higher wound infection and abscess formation than the patients were treated with SPC in our study. It was reported that seroma or hematoma can occur as an early complication of the sinusectomy procedure [7, 25], but it can usually be successfully treated by local and simple intervention. Seroma was significantly higher in SPC procedure, but all patients with seroma were treated with the simple drainage, and the development of wound infection or abscess formation were not observed during the follow-up in these patients. Short hospitalization and short wound healing time were observed in patients treated with sinusectomy in our study and that were compatible with the reported outcomes in previous studies [32, 40]. All these satisfying secondary gains were observed in patients treated with sinusectomy encourage the widespread use of this technique in patients with PSD.

The economic effects of the sophisticated surgical techniques, they could be performed inpatients healthcare setting and required several days' hospitalization, to the insurance system or to the patient's own economic status should also be considered [4, 5]. Minimally invasive procedure could be applied as an outpatient intervention or if it is performed as an inpatient intervention, it commonly requires short-term hospitalization of the patients [32]. Therefore these procedures result in lower workload on healthcare system and lower medical cost [4, 32]. In addition to the better patient outcomes, this point of view also leads the minimally invasive procedures become more popular than the sophisticated surgery [32, 40]. The development of new sinusectomy techniques, video assisted ablation and endoscopic pilonidal sinus treatment are modern variations of this technique [31, 39, 41-43], supports this perspective mentioned.

There are a few limitations in the present study. Firstly, BMI of patients and its effects on results were not evaluated, though BMI was found as a risk factor for the development of both symptoms and complications [44]. Secondly, several studies have evaluated the pleasure of patients using by subjective scale or intervention. We have not performed any patient's visual scale, the authors concluded that the low recurrence-free survival should be the main goal of the applied surgery. Another limitation of the study is the retrospective design of the study not allowing us to perform case-matching. We performed a multivariate analysis to compensate this limitation. Nevertheless, due to the lack of data, we could not include some variables (comorbidities, amount of body hair, obesity, occupational factors, prolonged sitting, poor hygiene etc.) that may affect the recurrence risk in the multivariate models.

## 5. Conclusion

Though there is no gold standard approach in surgical treatment of PSD, it is emphasized that sinusectomy is a growing trend that has been adapted. SPC is an efficient procedure for the treatment of patients with PSD have both simple and complicated disease patterns. More comprehensive and prospective studies should be performed to ascertain the best surgical option.

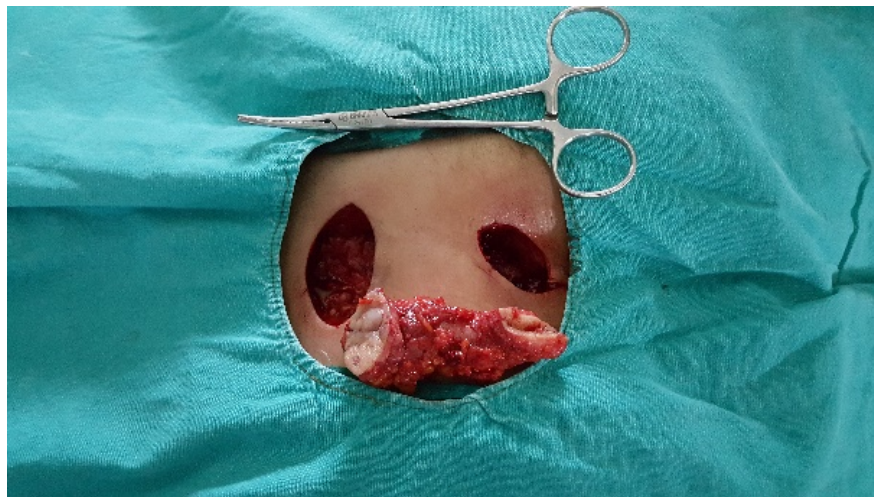
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A  
B



C  
D

**Figure 1. Sinusectomy and primary closure surgery. (A) Fistulized pilonidal sinus, (B) Excision of sinus tract, (C) Closed incision, (D) Postoperative 90<sup>th</sup> day control**

**Figure 2. Flow diagram of the study**

**Table 1. Demographics and baseline characteristics of the patients**

Variables	Excision and primary closure (n=134)	Sinusectomy and primary
Duration of surgery (minutes), Median (IQR)	41.0 (30.0-55.0)	45.0 (40.0-50.0)
Length of stay (days), Median (IQR)	3.0 (2.0-3.0)	1.0 (1.0-2.0)
Wound healing time, (days), Median (IQR)	17.0 (11.0-28.0)	9.0 (8.0-10.0)

Note: IQR: interquartile range

**Table 2. Perioperative characteristics of the patients**

Variables	Excision and primary closure (n=134)	Sinusectomy and primary closure (n=21)
Duration of surgery (minutes), Median (IQR)	41.0 (30.0-55.0)	45.0 (40.0-50.0)
Length of stay (days), Median (IQR)	3.0 (2.0-3.0)	1.0 (1.0-2.0)
Wound healing time, (days), Median (IQR)	17.0 (11.0-28.0)	9.0 (8.0-10.0)

Note: IQR: interquartile range

**Table 3. Short-term complications in the patients**

Complications	Excision and primary closure (n=134)	Sinusectomy and primary closure (n=21)
Seroma, n (%)	1 (0.7)	20 (9.2)
Wound site infection, n (%)	36 (26.9)	7 (3.2)
Abscess, n (%)	11 (8.2)	4 (1.8)

**Table 4. Recurrence risk in the patients**

		Excision and primary closure (n=134)	Sinusectomy and primary closure (n=21)
Recurrence, n (%)	Recurrence, n (%)	25 (18.7)	12 (5.5)
Recurrence risk	Recurrence risk		
	Crude OR (95% CI)	ref	0.255 (0.123-0.528)
Model 1	Adjusted OR <sup>(a)</sup> (95% CI)	ref	0.241 (0.115-0.506)
Model 2	Adjusted OR <sup>(b)</sup> (95% CI)	ref	0.044 (0.015-0.132)
Model 3	Adjusted OR <sup>(c)</sup> (95% CI)	ref	0.083 (0.020-0.348)
Model 4	Adjusted OR <sup>(d)</sup> (95% CI)	ref	0.074 (0.017-0.313)

Note: OR: odds ratio, CI: confidence interval, ref: reference

<sup>(a)</sup> Adjusted for age and sex

<sup>(b)</sup> Adjusted for age, sex, sinus type and number of orifices

<sup>(c)</sup> Adjusted for age, sex, sinus type, number of orifices, duration of surgery, length of stay and wound healing time

<sup>(d)</sup> Adjusted for age, sex, sinus type, number of orifices, duration of surgery, length of stay, wound healing time and presence of any type of complication