



Bilaterally parallel elliptic flap versus Karydakis flap in primary pilonidal sinus disease: a randomized controlled trial

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Abstract

Purpose Pilonidal sinus disease is a disease that especially affects the young population and causes loss of workforce. Although many treatment methods have been defined, there is still no “gold standard” treatment method. Our objective was to evaluate the postoperative results of bilateral parallel elliptical flap and Karydakis flap in the surgical treatment of pilonidal sinus.

Methods This study was conducted at the Colorectal Surgery Department of Ankara Numune Training and Research Hospital. It designed a prospective randomized controlled study. Patients that underwent surgery due to pilonidal sinus were included in the study. The patients were randomly divided into two groups. Surgery was performed with the bilateral parallel elliptical flap (BPEF) technique in one group and the Karydakis flap (KF) technique in the other group. Postoperative pain, length of hospital stay, wound complications, time taken to return to work/school, and recurrence incidence were evaluated.

Results A total of 102 patients were included in the study, 49 in the BPEF group and 53 in the KF group. The length of hospital stay was similar in the BPEF and KF groups (1.41 ± 0.81 and 1.45 ± 0.84 , respectively; $p > 0.05$). There was less postoperative pain in the BPEF group (2.47 ± 1.02 vs 3.57 ± 1.10 , $p < 0.05$). Wound complications were observed in nine patients in the BPEF group (18.2%) and 14 patients in the KF group (26.2%). The time to return to work/school was shorter in the BPEF group (21.06 ± 6.37 vs 27.04 ± 7.45 ; $p < 0.05$). Recurrence developed in two (4%) patients in the BPEF group and three (5.6%) patients in the KF group ($p > 0.05$).

Conclusions The patients who underwent surgery with the bilateral parallel elliptical flap technique had less pain and a shorter time to return to work/school after the operation. The postoperative complication and recurrence rates were similar in both groups.

Trial registration clinicaltrials.gov identifier: NCT05851690. (5/11/2023) (retrospectively registered).

Keywords Pilonidal sinus disease · Flap · Karydakis · Bilateral parallel elliptic

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Introduction

Sacrococcygeal pilonidal sinus disease (PSD) varies in different ways, such as an asymptomatic pilonidal cavity, an acute infection, or a chronic inflammation and drainage associated with an open wound of varying size [1]. It is thought to be an acquired condition due to the presence of pilar in the natal cleft although the exact pathogenesis of pilonidal sinus disease is unclear [2]. This condition is especially seen in young men and negatively affects the quality of life of patients and prevents them from performing their work and school activities [3]. PSD has been reported to affect approximately 6.6% of the young population in Turkey [4]. The treatment options for PSD range from the use of antibiotics alone to reconstructed excision with tissue flaps [5]. Although the optimal surgical treatment option remains controversial, expectations from the ideal surgical treatment include low recurrence and postoperative complication rates, early wound healing, short hospital stay, early return to work, and good cosmetic outcomes [3].

George Karydakakis described the lateral advancement flap technique as the first off-midline closure technique, which later became known as the Karydakakis flap (KF) [6]. Studies on the use of the KF technique conducted within the last 15–20 years have reported recurrence rates to be 0–6% after 10 years of surgery [7]. As a different technique, the bilateral parallel elliptic flap (BPEF) defined by Yuksel et al. [8] was reported to have a recurrence rate of 1.7% after a mean follow-up of 21.4 months. In addition to straightening the natal cleft, the importance of off-midline closure has gained more importance for the prevention of midline recurrences, which constitutes one of the major problems. Excision and closure using transposition or advancement flaps have received increasing attention in

recent years due to the low recurrence rates reported for these techniques [3, 8–11].

The aim of this study was to compare the efficacy of the BPEF and KF techniques in the surgical treatment of PSD and evaluate the long-term outcomes of patients.

Methods

Patient data

This randomized controlled study was initiated with the approval of the ethics committee of Ankara Numune Training and Research Hospital (approval date: 15.06.2016, number: E-16–975). A total of 110 patients who underwent surgery due to PSD at Ankara Numune Training and Research Hospital between 6/2016 and 1/2017 were included in the study (Fig. 1). The registration number of the trial is NCT05851690. Patients with a history of previous pilonidal sinus surgery, an acute pilonidal abscess, or immunodeficiency, those using immunosuppressive drugs, and those that refused to participate in the study were not included. The patients were informed about the clinical details of the surgical procedures, and their written consent was obtained. Computer-based randomization was performed for these patients using their admission numbers by surgeons. Preoperatively, antibiotic prophylaxis with 1 g intravenous cefazolin was administered to all the patients. The BPEF technique was used as previously described by Yuksel et al. [8] and the KF technique as described by Karydakakis [6]. Two colorectal surgeons performed both of the procedures.

The visual analog scale (VAS), scored from 1 to 10, was administered to the patients to evaluate their postoperative pain levels. The pain scores of the patients were determined on the first postoperative day. The surgeon who operated

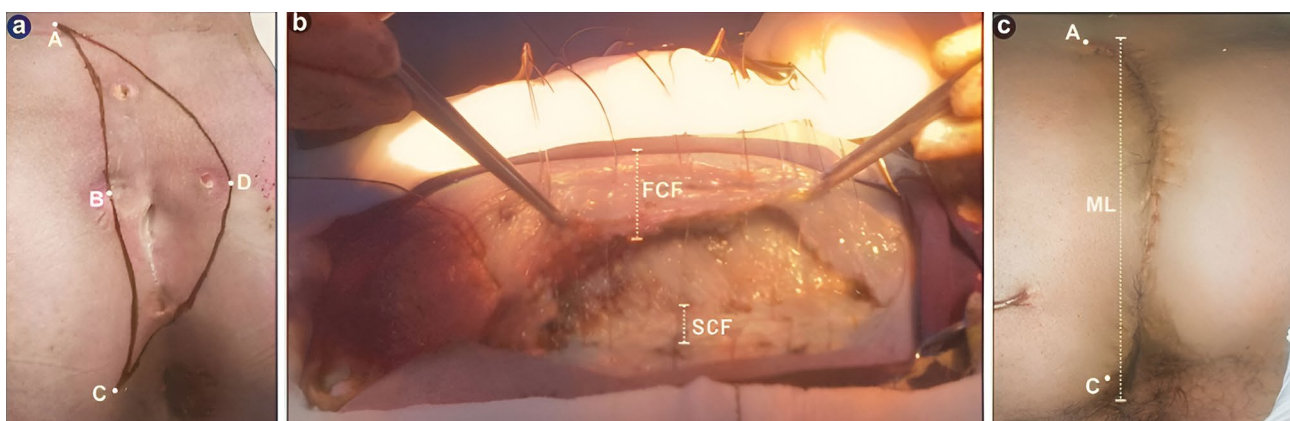


Fig. 1 Flap mapping onto the skin (a), the BPEF starts by excising all sinuses down to the sacrococcygeal fascia using an asymmetric elliptical incision and creating a new fascio-cutaneous flap; b postopera-

tive appearance of the BPEF (c). (FCF, fascio-cutaneous flap; SCF, sacrococcygeal fascia; ML, mid-line) [8]

on the patient obtained the VAS score. The patients were invited to visit the hospital on the seventh, 15th, and 30th postoperative days to perform a physical examination and controls. Subsequent follow-ups were carried out by phone interviews. The last follow-up of the patients was undertaken in February 2020 by phone calls. Complications were classified as wound site infection (WSI), seroma, and wound dehiscence (WD). When calculating the time to return to work/school, the day when wound healing was completed and the patients returned to their routine daily life as it was before surgery was considered. The diagnosis of recurrent disease was made by physical examination. Surgical methods were compared in terms of complications, length of hospital stay, VAS score, recurrence, and time to return to work.

Surgical technique (bilateral parallel elliptic flap)

This procedure consists of a bilaterally parallel elliptical excision, mobilization of the full-thickness fascio-cutaneous flap from the median line of the wound, fixation of the base of flap to the sacrococcygeal fascia by methods of overlapping, and suture of its edge to the lateral side. At surgery, patients were placed in a prone jack-knife position, with the buttocks strapped apart with the use of adhesive tapes. Firstly, we shaved the sacrococcygeal area, and we cleaned this area with povidone-iodine. The extent of the sinus was assessed by a stylet, and a small amount of methylene blue was injected into the sinus to outline the cavity. The area to be excised (ABCD) was mapped on the skin as in the pattern shown in Fig. 1a, including the orifices of the sinus tracts. This incision consisted of two elliptical shapes in the plane parallel to each other. In this way, we aimed for less tissue loss, less tension, and a smaller cavity. Secondly, the excision was carried out downward to the sacrococcygeal fascia, and laterally until normal fat tissue was reached. Thirdly, a fascio-cutaneous flap was harvested from the gluteal muscle on the ABC line (Fig. 1a, b). The flap's area was equal to that of excised area (ABCD) (Fig. 1b and b). Then, we removed the adhesive bands, and we advanced this flap from the medial line laterally beyond the ADC line

(Fig. 1c). After this maneuver, we sutured this flap with 0 polyglycolic acid suture onto the sacrococcygeal fascia by using the method of overlapping (Fig. 2). We performed a relaxation incision into subcutaneous tissue when we felt tension. Then, the subcutaneous tissue was sutured with a polyglycolic acid suture. Finally, we closed the skin with the use of an interrupted polypropylene suture (Fig. 1c) [8]. In both surgical procedures, a drain was placed when the pit was close to the anal canal, the subcutaneous fatty tissue was thick, or the pits were on both sides of the intergluteal sulcus. The drain was removed when the output was < 20 ml/day.

Sample size calculation

The sample size was based on the study of Sewefy et al. who observed that return to work in the standard Karydakis procedure was 12.6 ± 4 as compared to 10.2 ± 1.4 in Karydakis procedure with tie-over compressing sutures [12]. Taking these values as a reference, the minimum required sample size with 95% power of the study and a 5% level of significance is 35 patients in each study group. To reduce the margin of error and increase the strength of the study, all patients who were admitted to the general surgery clinic underwent surgery due to pilonidal sinus disease between the dates determined before the study and met the inclusion and exclusion criteria were included in the study.

Statistical analysis

While evaluating the findings obtained from the study, the Statistical Package for the Social Sciences (SPSS) for Mac, v. 26.0 was used for statistical analyses. Descriptive analyses were presented as mean, standard deviation, median and minimum–maximum values for quantitative variables, and numbers and percentages (%) for qualitative variables. Student's t-test was conducted to compare quantitative data for normally distributed parameters and Fisher's exact chi-square test for the comparison of qualitative data. A *p*-value of < 0.05 was considered statistically significant.

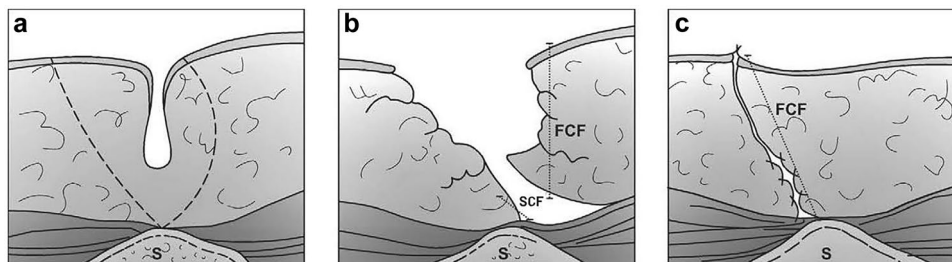


Fig. 2 Excision of the disease and primary closure is one of the new fascio-cutaneous advancement flap (BPEF) technique options (a); the midline sinus is excised by asymmetric elliptical incision and a new flap is created by undercutting the fascia at the medial wound edge

and (b), advancing it across the midline. By doing this, the natal cleft is flattened and the entire suture line is positioned lateral to the midline (c) [8]. (FCF, fascio-cutaneous flap; SCF, sacrococcygeal fascia; S, sacrum)

Results

Among 250 patients with pilonidal sinus disease who were initially evaluated, 110 patients were included in this prospective, randomized clinical study. Six patients who had undergone surgery with the BPEF technique and two with the KF technique were lost to follow-up and thus excluded from the study. As a result, the study was completed with 49 patients in the BPEF group and 53 patients in the KF group. The process of patient selection and exclusion is illustrated in the CONSORT flow chart.

The demographic characteristics of the two groups were similar. Of the patients in the BPEF group, 85.7% ($n=42$) were male, and 14.3% ($n=7$) were female. Eighty-three percent ($n=44$) of the patients in the KF group were male, and 17% ($n=9$) were female ($p>0.005$; Table 1). The mean age of the patients was 25.39 ± 9.93 years for the BPEF group and 26.79 ± 8.31 years for the KF group ($p>0.005$; Table 1). The mean length of hospital stay was 1.41 ± 0.81 days in the BPEF group and 1.45 ± 0.84 days in the KF group ($p>0.005$; Table 1). Before wound closure during surgery, a drain was placed in 51% ($n=25$) of the patients in the BPEF group and 41.5% ($n=22$) of those in the KF group ($p>0.005$).

When the patients were compared in terms of pain on the first postoperative day using the VAS scores, it was found that the patients in the BPEF group felt less pain than those in the KF group, and this was statistically significant (2.47 ± 1.02 vs 3.57 ± 1.10 $p<0.005$; Table 1). The mean time to return to work/school was 21.06 ± 6.37 days for the BPEF group and 27.04 ± 7.45 days for the KF group. A statistically significantly higher rate of patients in the BPEF group returned to their daily routines earlier compared to the KF group ($p<0.005$; Table 1).

The rates of postoperative complications in the BPEF and KF groups were determined as 14.2% vs 15% for seroma, 2% vs 5.6% for WSI, and 2% vs 5.6% for WD, indicating no statistically significant difference ($p>0.005$; Table 1). During the follow-up, recurrence was observed in two (4%) patients in the BPEF group and three (5.6%) patients in the KF group, with no statistically significant difference between the two groups ($p>0.005$; Table 1). Recurrence occurred after an average of 24 ± 16.97 months in the BPEF group and 14 ± 2 months in the KF group. There was no statistically significant difference between the two techniques in terms of recurrence time ($p>0.005$; Table 1).

Table 1 Characteristics of the patients according to the surgery groups

	BPEF ($n=49$)	KF ($n=53$)	p
Sex, n (%)			
Male	42 (85.7)	44 (83)	NS
Female	7 (14.3)	9 (17)	
Age (years), mean \pm SD (min–max)	25.39 ± 9.93 (14–55)	26.79 ± 8.31 (14–42)	NS
Patients' jobs, n (%)			
Student	26 (53)	22 (41.5)	
Desk job	11 (22.4)	13 (24.5)	
Driver	2 (4.1)	5 (9.4)	
Military personnel	2 (4.1)	4 (7.5)	
Police officer	3 (6.1)	3 (5.7)	
Healthcare professional	1 (2.1)	2 (3.8)	
Prisoner	2 (4.1)	3 (5.7)	
Housewife	2 (4.1)	1 (1.9)	
Length of hospital stay (days), mean \pm SD (min–max)	1.41 ± 0.81 (1–4)	1.45 ± 0.84 (1–4)	NS
VAS score for postoperative pain, mean \pm SD (min–max)	2.47 ± 1.02 (1–5)	3.57 ± 1.10 (1–6)	<0.005
Wound complications, n (%)			
Seroma	7 (14.2)	8 (15)	NS
Wound infection	1 (2)	3 (5.6)	
Wound dehiscence	1 (2)	3 (5.6)	
Return to work/school (days), mean \pm SD (min–max)	21.06 ± 6.37 (11–34)	27.04 ± 7.45 (15–49)	<0.005
Recurrence, n (%)	2 (4)	3 (5.6)	NS
Time to recurrence (months), mean \pm SD (min–max)	24 ± 16.97 (12–36)	14 ± 2 (12–16)	NS
Follow-up period (months), mean \pm SD (min–max)	39.90 ± 2.26 (36–43)	40.45 ± 2.24 (36–43)	NS

bold values indicate statistical significance

n number of individuals, % column percentage, SD standard deviation

The postoperative follow-up durations of the patients were similar between the two groups. The mean follow-up period was 39.90 ± 2.26 months for the patients in the BPEF group and 40.45 ± 2.24 months for those in the KF group.

Discussion

There is an ongoing search for the ideal option in the surgical treatment of PSD. After treatment, recurrence and loss of workforce constitute the major problems. Expectations from surgical treatment are low recurrence rates, return to daily life as soon as possible, and acceptable cosmetic outcomes. The Cochrane review published in 2010 reported that the off-midline closure was much more beneficial than the midline closure technique [13]. The consensus among the recently published German, American, and Italian guidelines is that midline closure should not be performed [5, 7, 14]. There are many studies in the literature comparing different surgical techniques. Some studies have compared primary closure and flap procedures, while others evaluated different flap types. However, to our knowledge, our study is the first in the literature to compare the BPEF and KF techniques. In addition, we assessed the short and long-term outcomes of patients who underwent surgery with BPEF and KF, which are both off-midline closure techniques. In terms of the VAS score and early return to work, BPEF was found to be much more advantageous than KF, and this was statistically significant.

In this study, BPEF was applied similar to the technique described by Yuksel et al. [8]. In their study, the authors reported the rates of postoperative complications of WSI, WD, and seroma to be 3.5%, 3.5%, and 5.7%, respectively. In the current study, we determined the rates of WSI, WD, and seroma as 2%, 2%, and 14.2%, respectively. Thus, although WSI and WD were observed at similar rates, the rate of seroma was higher in our patients. Yuksel et al. reported the mean time to return to work as 12.6 days, while this duration was much higher in our study (21.06 days). Lastly, Yuksel et al. found the recurrence rate to be 1.7% after an average of 21.4 months of follow-up. In contrast, we determined the recurrence rate to be 4% after an average of 39.9 months of follow-up. The higher recurrence rate in our study can be attributed to the longer follow-up period.

PSD is mostly seen in young adults. This means that the longer the time to return to work/school after surgery, the greater the loss of workforce. Therefore, the time to return to work emerges as a very important factor in the choice of treatment. In the literature, the mean time to return to work after surgery with the KF technique has been reported to vary between 14.4 and 23.29 days [15–17]. In the current study, the mean time to return to work was 27.04 days for the patients who underwent surgery with the KF technique.

Compared to the literature, the longer period taken to return to work in our study may be because the patients in our study waited until complete recovery. For the BPEF group, we found the mean time to return to work as 21.06 days, which was statistically significant compared to the KF group ($p < 0.005$).

Postoperative pain affects the quality of life of patients and their early return to daily activities. The surgical procedure to be preferred should have a minimal effect on the quality of life in the early postoperative period. In previous studies, the degree of postoperative pain has been generally evaluated with VAS. Bali et al. [18] reported a mean postoperative VAS score of 4 among patients that underwent surgery with the KF technique, while the mean VAS score was determined as 4.11 by Alvandipour et al. [10] and 5.58 by Ates et al. [19] on the postoperative 15th day. In our study, the mean postoperative VAS score was found to be 3.57 for the KF group and 2.47 for the BPEF group, and the difference was statistically significant ($p < 0.005$).

Early wound complications and long-term recurrence continue to be troubling possibilities in all procedures. Therefore, the search for a gold standard treatment method still continues. A review of the literature in terms of wound complications and recurrence among patients that underwent surgery with the KF technique shows that the rates of postoperative WSI, WD, seroma, and recurrence were reported to be 8.1%, 2.7%, 35.1%, and 2.7%, respectively, by Alvandipour et al. [10]; 1.8%, 5.6%, 3.7%, and 1.8%, respectively by Caliskan et al. [20]; and 3%, 10%, 5%, and 2%, respectively by Bessa [21]. In the current study, postoperative WSI, WD, seroma, and recurrence were detected at the rates of 5.6%, 5.6%, 15%, and 5.6%, respectively, among the patients who underwent surgery with the KF technique, and 2%, 2%, 14.2%, and 4%, respectively, in the BPEF group. There was no statistically significant difference between the two groups. We consider that the higher rate of seroma in our study is due to our routine use of drains. Other complications and recurrence were observed at similar rates to the literature.

In the literature, the complaints of patients are described as pain, discharge (clear fluid or pus), and local swelling [13, 22]. In our study, patient complaints were similar. We determined the mean length of hospital stay as 1.45 and 1.41 days for the KF and BPEF groups, respectively, indicating no statistically significant difference. Previous studies reported similar results in terms of the mean hospital stay [10, 16, 17].

Conclusion

Due to low recurrence rates, off-midline closure techniques are currently the first choice for the surgical treatment of PSD. In this prospective randomized study, we

compared the KF and BPEF techniques for the first time in the literature. When compared to KF, BPEF presents as a preferable method involving acceptable recurrence rates, early return to work, and less postoperative pain.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00384-023-04475-w>.

Author contribution Sadettin Er, Tezcan Akin, Huseyin Berkem, and Bulent C. Yuksel designed study. Umut F. Turan and Serdar Coban: data acquisition. Umut F. Turan and Sadettin Er: data analysis and interpretation. Umut F. Turan, Serdar Coban, Sadettin Er, Tezcan Akin, Huseyin Berkem and Bulent C. Yuksel: drafting the article. Umut F. Turan and Sadettin Er: Critical revision for intellectual content. All authors reviewed the manuscript and approved its final form.

Data availability The authors confirm that the data supporting the findings of this study are available from the corresponding author, upon reasonable request.

Declarations

Ethical approval This randomized controlled study was initiated with the approval of the ethics committee of Ankara Numune Training and Research Hospital (approval date: 15.06.2016, number: E-16-975). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Conflict of interest The authors declare no competing interests.

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