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A Comparison of the Results of the Karydakis Flap Procedure and Primary Closure in the Treatment of Pilonidal Sinus Disease Over the Short and Long Term: A Randomized Clinical Study

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In the current prospective study, we compared the results of the Karydakis flap procedure (KFP) and primary closure (PC). This study compared the short and long-term results of the KFP and PC techniques. The sample of this study was a total of 352 patients (302 male: 85.7%; median age: 24 years) who underwent reconstruction after pilonidal sinus excision in our clinic. The reconstruction was performed using the KFP (group 1, n = 176, 50%) or PC (group 2, n = 176, 50%). The following data on the patients was obtained; sex, age, body mass index (BMI), duration of operation and hospital stay, length of time patient could walk without pain, length of time patients could sit on toilet without pain, complications (e.g., infection, recurrence). No significant difference was found between groups 1 and 2 with respect to sex, age, BMI, and duration of operation. Moreover, length of time patients could walk and sit on toilet without pain was similar in both groups. On the other hand, the rate of recurrence was significantly lower in group 1 (n = 4, 2%) compared with group 2 (n = 20, 11%, $P < 0.001$). KFP is preferable to PC since it is easier to learn and perform and has lower complication and recurrence rates.

Key words: Pilonidal sinus – Primary closure – Karydakis operation

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Pilonidal sinus disease (PSD) is a common chronic disease of younger ages, which is often associated with considerable discomfort and morbidity. Although various surgical techniques are currently used for the treatment of PSD, no clear consensus as to optimal treatment has so far been reported in the literature.[1,2] Despite controversy about the best surgical technique for the treatment of PSD, an ideal operation should be simple, not requiring a prolonged hospital stay, have a low recurrence rate, cause minimal pain, and have a short course of wound care to reduce the time spent off work.[2–5] Over the past few decades, surgeons have increasingly come to appreciate the importance not only of flattening the natal cleft but also of achieving an off-midline closure for the prevention of midline recurrences in the management of PSD.[2,6–8] Oblique or asymmetric closure techniques such as the Karydakis flap procedure(KFP) are based on these principles.[6,7] The use of excision and closure using transposition or advancement flaps has received growing attention in recent years due to the low recurrence rates that have been reported using these techniques.[4,8–10]

In the comparison of the results of PSD surgery, important parameters include complications during the early period and recurrences during the late period. To our knowledge, no study has been conducted to compare the long-term results of the KFP and primary closure (PC) techniques. Therefore, in the current prospective randomized controlled study, we compared the short and long–term results of the management of PSD using KFP and PC methods.

Patients and Methods

Study design

This was a prospective randomized controlled trial using the parallel-group and balanced randomization methods [1:1]. The study was conducted in the department of colon and rectum of Ankara Numune Training and Research Hospital, Ankara, Turkey. The local ethical approval was obtained, and the study was conducted according to the tenets of the Declaration of Helsinki (2006/1275). The patients were randomly assigned to 2 groups. Patients who underwent KFP (n = 176, 50%) were included in group 1 and those who underwent PC (n = 176, 50%) were included in group 2. Randomization was performed using a pseudorandom number generator with individual assignments concealed in sequential numbered sealed envelopes that were opened in order when assignments were made. An independent observer undertook the randomization and allocation of patients to the groups, and the surgeon was informed of the type of surgery to be performed at the time of induction of anesthesia.

Study population

Eligible participants were patients presenting with PSD treated in the surgical unit of the department of colon and rectum/general surgery from January 2001 to February 2008. Patients with acute inflammation and/or abscess formation were treated with antibiotics and drainage, and then taken into surgery. Definitive surgery was performed no less than 3 weeks after evident sepsis had been eradicated. Both KFP and PC were thoroughly explained to all patients, together with the benefits and risks involved. Written informed consent was obtained from patients who agreed to receive either of the procedures and participate in the study. Patients who declined to undergo either procedure were excluded from the study. The other exclusion criteria were: being younger than 15 years of age and having a collagen tissue disease. In addition, one patient who had bilaterally generalized sinus pore out of the navicular area was excluded.[11]

Surgical technique

All patients received spinal or epidural anesthesia with the patient in the jackknife position and the buttocks strapped apart. The buttocks were shaved immediately before surgery and the surgical area was disinfected with 10% povidone-iodine solution. All patients were administered a single dose of cefazolin 1 g parenterally 30 minutes before the skin incision.

KFP was performed with an initial asymmetric elliptical incision. The ellipse was based on the side of any secondary opening; if the sinus was entirely central, either side was chosen. The ellipse included all the openings and was placed 2 cm lateral of the midline. The area thus marked was then excised full thickness up to the sacral fascia (Fig. 1a), with a straight edge on the side of flap mobilization and a sloping edge on the other side (Fig. 1b). This was followed by mobilization of the flap across the midline. The medial side of the wound was then undermined just superficial to the underlying gluteus muscle fascia to produce a flap for a distance of at least extending the full length of the

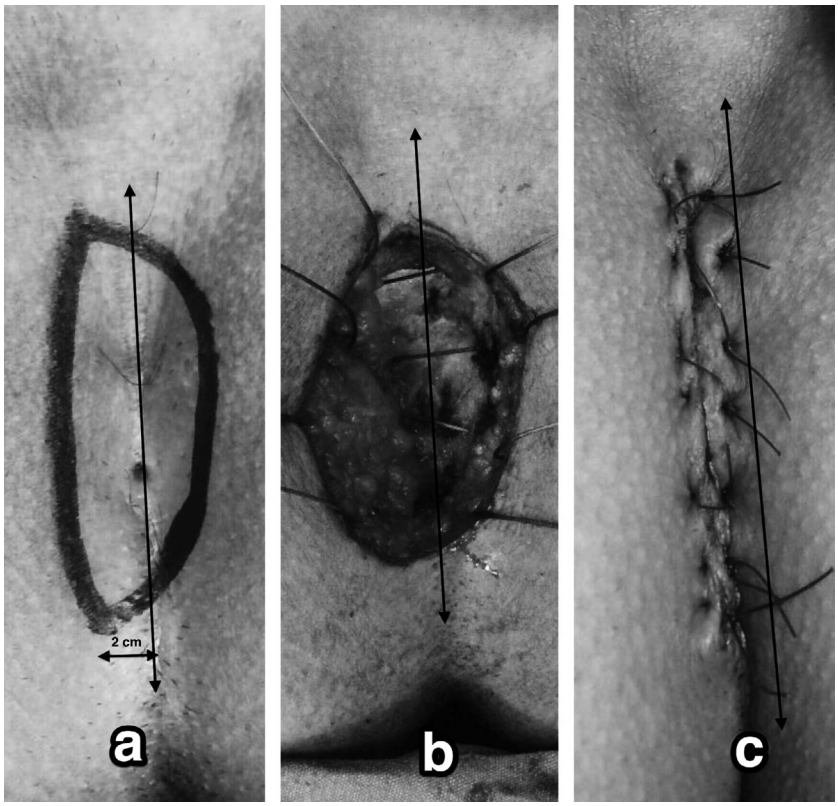

Fig. 1 Flap mapping onto the skin (a), the flap starts by excising all sinuses down to the presacral fascia using an asymmetric elliptical incision and creating a new cutaneous-subcutaneous flap; (b) postoperative appearance of the Karydakis flap (c).

wound. This allowed the flap to reach the contralateral side without tension. A layer of interrupted absorbable Vicryl 0/0 sutures (Ethicon Endo-Surgery, Cincinnati, Ohio) were used to suture the deepest tissue of the flap to the underlying fascia and the corresponding tissue on the fixed side. Then, the subcutaneous tissue was sutured directly to the lateral edge of the tissue. Finally, interrupted vertical polypropylene mattress 2/0 sutures (Ethicon Endo-Surgery) were used for skin closure (Fig. 1c).

Excision and PC was performed as described by Soligher.[12] The sinus tract was totally excised up to the presacral fascia via a symmetric elliptic incision in the midline, and a layer of interrupted absorbable Vicryl 0/0 sutures (Ethicon Endo-Surgery) were used to suture the deepest tissue. Finally, skin closure was undertaken using interrupted vertical polypropylene mattress 2/0 sutures (Ethicon Endo-Surgery).

A closed suction drain was placed in the resultant dead space and sufficiently extended laterally through a separate stab incision. The suction drain was removed when the effluent was less than 20 mL for 24 hours.

After their discharge, patients were instructed to pay meticulous attention to hygiene rules and not to sit or be in a semi-sitting position for 2 weeks. Walking was not restricted. In addition, the following recommendations were made: to use talc powder to prevent moisture, then after complete healing to use depilatory cream for 6 months to remove hairs from the operation site, to avoid prolonged sitting and not to ride a horse or bicycle for 6 weeks after the operation. Sutures were removed on postoperative day 14, and the patients were allowed to return to work by postoperative day 21.

Data collection and outcome measures

Data on sex, age, and body mass index (BMI, kg/m^2), as well as history of previous treatment (when applicable), was obtained from all patients.

Duration of operation was defined as the time from the start of skin incision to the end of the last stitch. Duration of hospital stay was noted. Postoperative complications such as seroma, wound dehiscence, and wound infection were noted. A postoperative wound assessment was undertaken

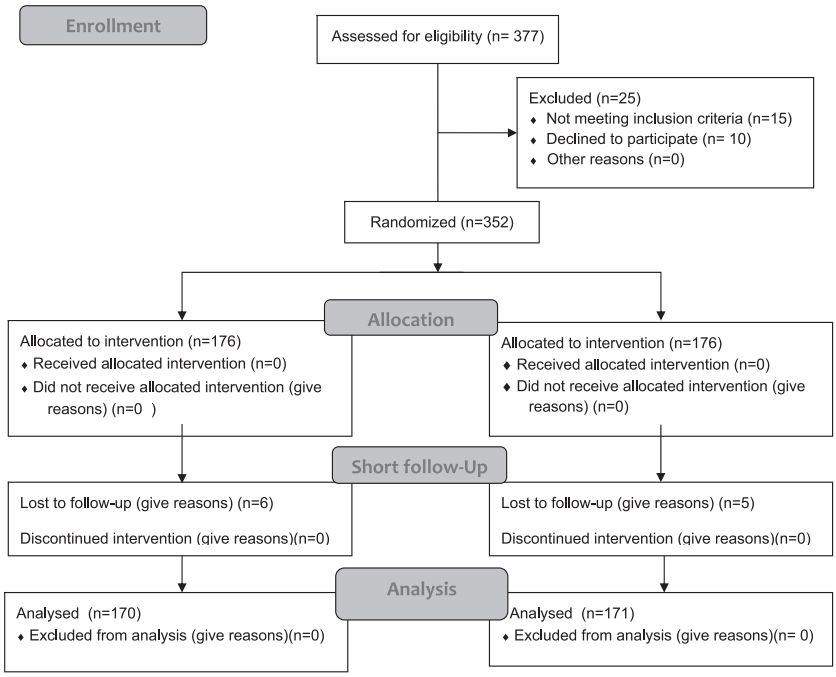

Fig. 2 CONSORT 2010 Flow Diagram

using the asepsis method, in which an overall value above 20 indicated that the wound was infected.[13]

All patients were physically examined on post-operative days 3 and 14 for wound inspection after surgery. Patients were invited to the hospital for a short follow-up 3 months after surgery. They were asked about the length of time they could sit on toilet without pain and length of time they could walk without pain. The responses were documented and analyzed. The long-term follow-up after 3 months was performed either by interviewing the patients every 3 months on the phone or in person at the outpatient clinic to check for recurrences. Patients were followed for 12 to 96 months (median: 56.8 months).

Statistical analyses

Power calculations were performed to test the hypotheses related to the comparison between the treatment groups. The sample sizes of the KFP (n = 170) and PC groups (n = 171) required a power of approximately >0.80 to compare the 2 groups. Statistical analysis was carried out using statistical software (SPSS, version 18, IBM-SPSS, Chicago, Illinois). The Mann-Whitney *U* test and Student's *t*-test were used to compare 2 groups in terms of the continuous variables; and the χ^2 and Fisher's exact test were used for categorical variables. A value of $P < 0.05$ was considered significant. Values were expressed as median (range).

Results

A flow diagram of patient disposition is shown in Fig. 2. Of the 377 patients screened, 15 did not meet the inclusion criteria, and 10 refused to participate in the study. As a result, a total of 352 patients including 302 men (85.7%) and 50 women (14.2%) were randomly allocated to 2 treatment groups. Patient age ranged from 13 to 59 years with a median of 24 years.

Table 1 presents the patient characteristics of each treatment group. No significant differences were observed between the groups regarding age, sex distribution, BMI, and history of recurrent disease.

As shown in Table 2, the difference in operative time and length of time patients could walk and sit

Table 1 Patient demographics and operation features

	KFP (n = 170)	PC (n = 171)	*P* value
Sex, n (%)			
Male	147 (86)	149 (87)	0.6
Female	23 (14)	22 (13)	
Age, y, median (range)	25 (15–56)	24 (13–59)	0.2
BMI, kg/m^2, median (range)	24 (22–28)	24 (22–27)	0.1
Recurrent disease, n (%)	29 (17)	27 (15)	0.62

P values < 0.05 were considered statistically significant.

Table 2 Analysis postoperative period for PSD in KFP versus PC

	KFP (n = 170)	PC (n = 171)	*P* value
Duration of operation, min, median (range)	31 (25–35)	26 (22–31)	0.32
Time to walk without pain, d, median (range)	7 (5–9)	7 (5–10)	0.87
Time to sitting on toilet without pain, d, median (range)	6 (5–9)	7 (5–9)	0.86
Number of complications, n (%)	17 (10)	27 (15)	<0.05
Seroma, n	5	5	0.90
Wound dehiscence, n			
Full–thickness	0	8	0.003
Cuticular	5	3	0.33
Need to resuture	0	8	0.003
Wound infection, n	5	10	0.07
Long-term analyses			
Recurrences, n (%)	4 (2)	20 (11)	<0.001

P values < 0.05 were considered statistically significant.

on the toilet without pain was not statistically significant between the KFP and PC groups. However, a statistically significant difference was observed between the 2 groups in terms of postoperative complication ($P < 0.05$) and recurrence ($P < 0.001$).

No patients in the KFP group had a full-thickness wound dehiscence, but this complication occurred in 8 patients in the PC group ($P < 0.05$; Table 2). The full-thickness wound disruption resulted in loss of alignment between the edges of the wound, which occurred following postoperative days 6 and 9. In these 8 patients, resuturing was performed under local anesthesia. However, resuturing was not successful in any of the patients, and the full thickness wound dehiscence occurred again within 1 week. In these patients, healing by secondary intention took a median of 6 weeks (range, 7–9). The groups did not significantly differ in terms of the occurrence of cuticular disruption in the wound. This condition was managed with daily dressing and eventually healed completely.

Patients in the KFP group also did not differ significantly from those in the PC group with regard to wound infections, which were treated with antibiotics along with daily dressing and did not lead to wound breakdown in any of the patients in this study. In the KFP group, the drain remainder for a median of 2.1 days (range, 1–4) compared with a median of 2.7 days (range, 1–7) in the PC group. No significant difference was found between the 2 groups in terms of subcutaneous fluid collection (Table 2).

There was no statistically significant difference between the groups in the length of time patients could walk and sit on the toilet without pain. However, a statistically significant difference was observed in terms of number of complications ($P < 0.05$). The clinical outcomes of both group treatment modalities are given in Table 2.

The median duration of the long-term follow-up in both study groups was 56.8 months (range, 12–96). A striking difference was observed between the 2 treatment groups in terms of recurrence. PSD recurred only in 4 patients (2%) in the KFP group, whereas recurrence was seen in 20 patients (11%) in the PC group ($P < 0.001$; Table 2). When the patients with recurrence were evaluated, it was seen that sex; BMI; ASEPSIS (additional treatment, serous discharge, erythema, purulent exudate, separation of deep tissues, isolation of bacteria, stay duration as inpatient) score; drainage; and follow-up duration did not affect the recurrence, and only the type of operation had a statistically significant effect on recurrence.

Discussion

In the present randomized controlled study, KFP and PC were compared in the surgical management of PSD, and a significant difference was found between the 2 groups in terms of the short-term results regarding full-thickness wound dehiscence and long-term results regarding recurrence.

The main problem encountered in the treatment of PSD is that currently no procedure can fully prevent recurrence. Factors that increase the frequency of the recurrence of the disease include: inadequate excision, presence of dead space, deep natal cleft, having a large amount of body hair and bad hygiene, early wound infections, wound separation, increased wound pressure, and obesity.[14] Various flap procedures—such as Limberg flap, Z-plasty, W-plasty, D-flap, rotation flap, muscular gluteus maximus flap, adipofascial migrating flap, V-Y flap, and KFP—have been described to reach these aims. However, since these procedures cause several problems, they have been modified.[4,10] The flap procedures have less recurrence rates compared with secondary healing, marsupialization, incision-curettage, and PC,[10,14] which are more complex and take longer time, often resulting in local complications such as wound infection, separation, and

ischemia as well as other less desirable esthetic outcomes.[2,4,15]

PSD is a disease frequently affecting those of a younger age with a high rate of morbidity, which results in extended absence from work. It is a chronic inflammatory process of the skin caused by hair, keratin plugs, and debris.[16] It is known that the PSD incidence varies across countries and races. The incidence is also affected by factors such as driving, personal hygiene, and obesity.[17] There are two conflicting theories of PSD pathogenesis: congenital and acquired. It is very important to understand the difference between these two since each requires different principles of treatment.[18] Recently, the acquired theory has been widely accepted. Available evidence strongly supports the view that the classic PSD seen in adults is an acquired condition as a result of a hair insertion process.[6,18]

Karydakis[6] reported that hair insertion at the depth of the natal cleft, the raphe, is the real cause of PSD. The author described 3 main factors that contribute to the hair insertion process: (1) the invader (the loose hair as H factor); (2) the force, which causes hair to insert (the depth and narrowness of the natal cleft together with friction movements between its sides as F factor); and (3) the vulnerability of the raphe as V factor.[18] Karydakis[6] suggested that these factors should be decreased or neutralized to vulnerability of the raphe with replacement to healthy skin, and the midline wound scar should not be at the depth of the natal cleft.

The rate of wound dehiscence reported in earlier studies comparing KFP and PC ranges from 0% to 12%.[19] In the present study, no patients in the KFP group and 8 patients in the PC group had a full-thickness wound dehiscence.

The different findings regarding full-thickness wound dehiscence can be explained by the morphologic differences between the two procedures. PC is not a tension-free operation in which part of the cutaneous and subcutaneous tissues are attached to the underlying strong fascial. Walking may induce either traction on the sutured edges or strong friction between the edges and recipient side edges of the wound, which may lead to dehiscence in some patients. In contrast, KFP involves only removing skin and subcutaneous tissue from the underlying gluteal muscle and fascia and laterally advancing it for a distance of at least 2 cm from the suture line. In such design, the forces on the suture line produced by walking may not be strong enough to disrupt the wound.

One of the important points in the management of PSD is the time to return to normal daily activity. Ertan *et al*[20] compared the Limberg flap procedure with PC with respect to sitting on a toilet without pain, and concluded that flap procedures are more beneficial.[20] In our study, patients were asked how long they could sit on a toilet and walk without pain. No statistically significant difference was found between the 2 groups who reported that they were able to walk without pain in approximately 7 days. Time to sit on a toilet without pain was 6 days in the KFP group and 7 days in the PC group, indicating no statistical difference.

The most important parameter in the management of PSD is the recurrence rate of procedures. Da Silva[15] reported that reconstructive procedures have lower recurrence rates. Mahdy[21] surgically treated 60 patients with PSD between 2003 and 2006, and found no difference in the recurrence rates between flap procedures, and the overall results were better than those obtained from PC. McCallum *et al*[22] conducted a meta-analysis in 2008 and reported that closures made off the midline have lower recurrence rates compared with midline closure. To overcome this problem, Berkem *et al*[10] modified the V-Y plasty technique described. The authors laterally located the incision and detected no recurrence.[10] Karydakis[18] reported the largest series about the procedure in 1992, in which he treated 7451 patients and reported only 55 recurrences, which was less than 1%.[18] The latest study on KFP was by Ates *et al*,[23] who reported that KFP should be preferred to other flap techniques due to the lower postoperative complication rates and recurrences.

In our study, the median follow-up duration was 56.8 months (range, 12–96), during which recurrence was seen in 24 patients, all within the first postoperative year. One of the causes of early recurrence can be penetration of hair into the midline wound. To prevent this possibility, the midline can be deviated and the natal cleft can be flattened. Kitchen[24] pointed out the problems experienced with midline wounds. The authors suggested that the location of the wound at midline and the depth of natal cleft are the most important causes of early migrations of the wound away from the midline. Therefore, KFP, in which the natal cleft can be flattened at least 2 cm away from the midline and heal without tension, has lower complication and recurrence rates. This way, flap complications such as ischemia and necrosis can be minimized.

The only factor influencing recurrence was the type of operation. Age, sex, BMI, drainage, infection,

and follow-up period were found to have no significant impact on recurrence. Wound infection was observed more in the PC group than in the KFP group, but this effect was not significant.

In conclusion, this study has shown that KFP has several advantages and is superior to the PC method in the treatment of PSD. The closure of the excised area with a tension-free, off-midline, and well-vascularized flap produces better results and reduces complication and recurrence rates.

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