Karydakis versus Limberg flap reconstruction for the treatment of recurrent pilonidal disease: a prospective randomized controlled trial

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Background
Pilonidal disease is common among adults and is associated with a high recurrence rate, patient discomfort, and high morbidity.
Objective
This study aims to assess the perioperative findings, early postoperative outcomes, and the satisfaction level in patients with recurrent pilonidal disease, who have been subjected to either Karydakis flap or Limberg flap techniques.
Patients and methods
This was a prospective randomized controlled study. The study was conducted on patients with pilonidal disease visiting the Mansura University Hospital, Egypt during the period from February 2014 to September 2017. The patients were randomly assigned to undergo either Karydakis flap or Limberg flap groups. The follow-up period ranged from 18 to 28 months, and the mean follow-up period was about 23 months. Surgical findings, complications, recurrence rates, and the degree of patient satisfaction using a 10-point Likert type scale were analyzed and compared.
Results
In total, 120 (115 men and five women) patients with a median age of 22 years (range: 18–40 years) participated in this study. There were no significant differences between the two groups in terms of complications rate, length of hospital stay, or recurrence rate. Patients in the Karydakis group reported faster healing and felt completely healed postoperatively.
Conclusion
The two groups reported similar rates of satisfaction.

Keywords:
Karydakis flap, Limberg flap, pilonidal disease, surgical treatment

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Introduction

Sacrococcygeal pilonidal disease (SPD) is a common surgical problem primarily affecting young men between puberty and early thirties. The disease frequently occurs as a chronic infection of the skin in the region of the buttock crease. It is highly prevalent among young military recruits [1] and is estimated to affect 26 per 100 000 individuals. There are numerous conservative treatment techniques such as painstaking clearance, hair control by shaving, or depilation with topical agents; however, these options have a lot of limitations. Therefore, surgery is still the primary method of treatment of the disease. Surgical management is usually simple, inexpensive, and is associated with a short hospital stay and rapid wound recovery [2]. Moreover, it has minimal postoperative complications such as wound infection and recurrence rate from surgical management [3,4]. Here, recurrence refers to the condition when the patient experiences major wound dehiscence, pus discharge, or complains of a new sinus tract during the follow-up period after the patient has progressed into a complete healing phase. The surgical process requires a wide excision with or without marsupialization, which results in low recurrence rate. However, it also leads to a large midline wound that needs months to heal and may affect the patients' quality of life [1]. Till date, there is no universally accepted appropriate and effective method for SPD treatment, and it is still a matter of controversy. So, numerous surgical techniques such as excision with primary midline closure, Karydakis flap (KF), Limberg flap (LF), V-Y plasty, and Z-plasty have been studied [1,5,6]. Most of the flap techniques primarily involve lateralization of the midline and

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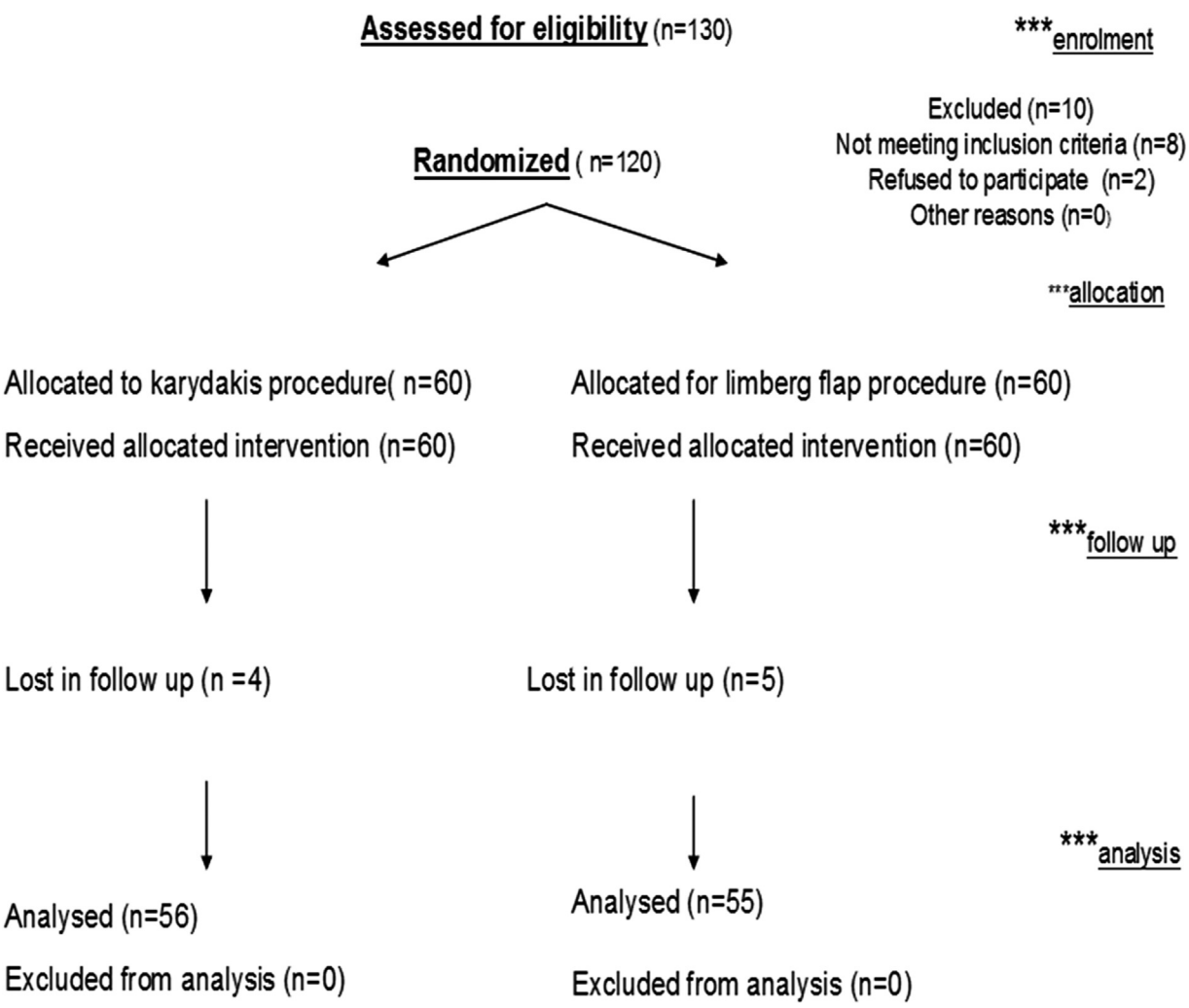
Figure 1



Flow diagram of the process through the phase of a randomized trial (i.e. enrollment, intervention allocation, follow-up, and data analysis).

flattening of the natal cleft as they decrease the overall postoperative morbidity and recurrence rate [1,7–9]. However, there is still a lack of consensus regarding the most effective flap procedure. Therefore, further studies should examine and compare the effectiveness of these techniques. KF and LF techniques are two of the most common procedures used in our hospital, and surgeons contributing to this study have considerable experience in these techniques.

This prospective study aims to evaluate early postoperative outcomes and satisfaction of patients with recurrent SPD who underwent either KF or LF techniques.

Patients and methods

Consecutive patients who were treated for recurrent SPD by either KF or LF in our hospital from 2014 to 2017 were enrolled in the study (Figs 1–3). Patients with a disease process that required unroofing and drainage procedures at the time of admission were excluded from the study. Informed consent was

Figure 2

Recurrent disease after excision and primary closure.

Figure 3

Recurrent disease after excision with healing by secondary intention.

Figure 4

Karydakis flap closure.

obtained from all the patients after they were explained the nature of the disease and its possible treatment. The study was approved by the local ethics committee. The primary outcome measure of this study was sign of early postoperative complications (i.e. complications occurring within 30 days from operation) including wound infection and wound healing failure. Here, wound healing failure refers to pus discharge, abscess formation, or complete wound dehiscence, which needs active management during the early postoperative phase (30 days).

The medical history of all the patients was recorded, and careful physical examination was performed on all of them.

The patients were randomly divided into two groups using a computer-generated table. To avoid selection bias, the randomization results were put into opaque envelopes numbered sequentially and opened later by a healthcare professional not engaged in the operating room. The patients in group 1 underwent excision and KF, and the patients in group 2 underwent LF. The surgical procedure options, complication rates, hospitalization, and time taken for returning to work were analyzed. Nine patients could not be followed up because they moved aboard.

Surgical procedure

For preparing the surgical site, the hair around the natal cleft was shaved off in the evening before the day of the surgery. Operation was performed after administration of general or spinal anesthesia. A single dose of a third-generation cephalosporin was given intravenously before starting the surgery. The patients were placed in a prone position with the cheeks of the buttocks strapped apart, and the surgical area was disinfected using 10% povidone–iodine.

Karydakis flap reconstruction group (group 1)

KF reconstruction was performed in conformity with the original procedure described by Karydakis [10]. A vertical eccentric elliptical incision was carried out down to the postsacral fascia. Then the unhealthy tissue was removed along with the normal tissue around the cyst and sinus tracts. The medial edge of the wound was mobilized by undercutting the adipose tissue at a depth of 1 cm. The flap was then stretched across the midline to the postsacral fascia, and its lateral edge was sutured. A single hole was created, and a closed suction drain was inserted underneath the flap. Interrupted 2-0 absorbable sutures were used to fix the flap to the fascia and for skin approximation (Fig. 4). Care was taken to ensure that the flap was adequately mobile at 1.5 cm from the midline and sutured without any form of tension to make the final wound lateral to the midline.

Limberg flap closure group (group 2)

In this technique, a rhombic shape was drawn on the skin with the long axis in the midline using a sterile skin-marking pen to include all the pathological area. Then, the flap line was mapped on the skin. The excision was extended down to the level of the postsacral and gluteal fascia with complete removal of all pathological area. The Limberg fasciocutaneous flap, which is located on the adjacent right buttock, was used to cover the rhombic defect.

Figure 5

Limberg flap closure.

After complete homeostasis by electrocautery and removal of adhesive tapes, full mobilization of the flap was carried out, and the repair was completed without any kind of tension. A suction drain was introduced under the flap through a separate stab incision. The wounds were sutured in three layers. The fascial and deep subcutaneous layers were approximated with interrupted 2-0 Vicryl sutures, whereas the superficial subcutaneous layer was approximated with inverting sutures of 2-0 Vicryl sutures. The skin was closed with 2-0 Prolene sutures (Fig. 5).

Follow-up and data analysis

Oral intake was allowed after 6 h of operation, and the patients were encouraged to walk after 8 h. The closed suction drains were removed in the outpatient clinic when the 24-h suction output was less than 10 ml. The wounds were inspected on days 3 and 6 after the operation. Postoperative infection was defined as the development of cellulitis and/or purulent discharge from the wound edges or drains. To define the postoperative time-off work, the patients were asked to start their daily activities when they were comfortable. The degree of satisfaction for each patient was measured as excellent, good, and not satisfied. Overall patient satisfaction regarding surgery and the cosmetic results were also recorded using a 10-point Likert-type scale (1=least satisfied, 10=most satisfied).

All patients were discharged on the second postoperative day in normal circumstances and were advised to keep the sacrococcygeal area clean. All patients were on postoperative antibiotic coverage for 5 days. Skin sutures were removed on the 14th postoperative day. Follow-up examinations were made at the end of the 1, 6, and 12 months after surgery. Beyond 1.5 years, the patients were monitored by phone calls at every 6 months interval. The duration of hospital stay, early wound complications, time to return to normal daily activities, recurrent disease, time of recurrence, and patient complaints including numbness and dissatisfaction were recorded. In case of wound infection or hematoma, the wound was drained by removal of a few sutures, covered with daily dressings, and then oral antibiotic was given for 5 days.

Statistical analysis

The statistical analysis of data was done by using Microsoft Excel program and SPSS, version 10 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were presented in the form of mean±SD, whereas the qualitative data were presented in the form of frequency and proportion. The *t*-test was used to compare the qualitative data of the two groups. Paired sample *t*-test was used to compare one group at different times. χ^2-test was used for qualitative data. Correlation coefficient was determined to detect the association between variables. *P* values less than 0.05 were considered statistically insignificant.

Results

The study flowchart is shown in Fig. 1. Of the 130 consecutive patients who visited the hospital during the recruiting period, 120 (115 men and five women) patients with a median age of 22 years (range: 18–40 years) were evaluated and enrolled in the study. These patients were randomly divided into two groups (60 patients in the Karydakis group and 60 patients in the Limberg group).

Data collected during the in-hospital and early postoperative period are shown in Table 1.

The male-to-female ratio for the Karydakis group and the Limberg group was 57 : 3 and 58 : 2, respectively. No differences were detected between the two groups in terms of patient age, sex, and the type of anesthesia used. There were 95 (79%) patients who had undergone midline closure and the remaining 25 (21%) had recurrence after primary excision with healing by secondary intention.

The mean duration of operation differed significantly in the two groups. The duration of operation was 52.7

Table 1 Comparison between the results obtained via the follow-up period

Variables	Karydakis group (*n*=60)	Limberg group (*n*=60)	*P* value
Age (years)	22 (18–40)	22 (19–35)	0.58
Sex (male/female)	57/3	58/2	0.64
Type of anesthesia			
Spinal	52 (86.7)	53 (88.3)	0.78
General	8 (13.3)	7 (11.7)	
Operative time (min)	49.2±5.5	52.7±7.9	0.005
Surgical complications			
Wound infection	2 (3.3)	1 (1.7)	0.44
Collection	1 (1.7)	2 (3.3)	
Dehiscence	2 (3.3)	1 (1.7)	

Data are expressed as median (range), *n* (%), or mean±SD.

Table 2 Comparisons between results obtained within 30 days of surgery

Variables	Karydakis group (*n*=60)	Limberg group (*n*=60)	*P* value
Time taken to return to work (days)	20.25±6.01	22.38±4.5	0.030
Time of complete healing (days)	30.2±8.9	32.6±6.7	0.07
Recurrence rate	0	0	
Degree of satisfaction			
Excellent	47 (78.3)	40 (66.7)	0.35
Good	10 (16.7)	16 (26.7)	
Unsatisfied	3 (5.0)	4 (6.7)	

Data are expressed as mean±SD or *n* (%).

±7.9 min for the LF and 49.2±5.5 min for the KF (*P*=0.005). The difference between the two groups regarding the incidence of early complications was not significant (*P*=0.44). The diagnosis of these complications was carried out during the patients' outpatient visits. One (1.7%) patient in the LF group and two (3.3%) patients in the KF group were diagnosed with wound infection. The infection in the LF group necessitated early partial suture removal and healing by secondary intention. This was also required for only one patient of the KF group. The other patient of the KF group developed complications that needed a lengthy period of antibiotic use and simple drainage. There was neither partial nor total flap necrosis; hence, additional surgical interference was not required. Notably, these complications did not exceed grades I and II according to Dindo's classification of surgical complications [11].

The time of return to work was not significantly different between the two groups. It was 20±6.01 and 22.38±4.8 days for the Karydakis group and Limberg group, respectively (*P*=0.030). The time to report the feeling of complete healing was significantly shorter in the KF group (30.2±8.9 days) in comparison with the LF group (32.6±6.7 days). No recurrence was observed in both groups in the mean follow-up period. The degree of satisfaction was not significantly different between the two groups (*P*=0.35) (Table 2). Forty-seven (78.3%) out of 60 prospectively evaluated patients in the KF group classified their level of satisfaction as 'excellent', 10 (16.7%) classified it as 'good', and three (5.0%) rated it as 'unsatisfied.' In contrast, 66.7% of the patients in the LF group classified their satisfaction level as 'excellent', 26.7% as 'good', and 6.7% as 'unsatisfied'.

Discussion

According to the theory postulated by Karydakis, SPD occurs when three main factors coexist: (i) invader loose hair, (ii) force that facilitates the hair insertion into the skin, and (iii) vulnerability of that underlying skin (this is related mostly to the depth of intergluteal sulcus). Many authors reported that the main causes of SPD recurrence after complete excision are also related to the above-mentioned factors [12]. In addition, it has been reported that the frequency of bathing affects the incidence of SPD. The risk of developing SPD is higher among patients who bath less than or equal to two times a week than those who bath at least three times per week [13]. Moreover, ethnicity plays a role in SPD development since the disease is rare among Asian and Black people [14]. Furthermore, a group of researchers declared that obesity is not an important risk factor, but this conclusion is debatable since the study investigated young military recruits, in which obesity is usually underrepresented [12]. In addition, a study that investigated 632 patients with SPD concluded that there is no statistically significant

difference between patients and controls in terms of BMI [15]. However, another study reported that obese patients have better outcomes after Karydakis technique with regard to healing time, the period of hospital stay, and time needed to return to work than the nonobese counterparts [16]. Eventually, although hair removal is generally described for patients to decrease the risk of pilonidal sinus disease, it has been reported that imperfect hair removal could increase the recurrence risk. Furthermore, the ideal way of hair removal has not been established yet [17]. In KF, we used an asymmetrical excision and primary closure aiming for lateralization of the incisional line away from the midline. This kind of repair produces a flattened gluteal furrow that prevents hair penetration into the natal cleft and leads to acceptable cosmetic results. Furthermore, if any postoperative infection occurs, the defect will not be as large as LF.

The LF was originally reserved for complex and recurrent pilonidal disease, but it is also being used widely as a plastic technique for primary SPD. It involves the creation of a flap to achieve primary closure and obliteration of any deep natal cleft. So, it relocates hair follicles away from the midline and prevents any frictional forces to be involved in the creation of a new disease. Although the Limberg technique has many advantages, such as low recurrence and complication rates, it lacks cosmetic appeal, especially among female patients [4,18,19].

The documented incidence of recurrence after the KF ranges from 0 to 4.6%, whereas it is up to 4.8% after the classic LF [4,20]. Regarding the use of suction drainage, many surgeons have approved its use in decreasing the incidence of postoperative complications such as fluid collection and wound dehiscence. However, studies that investigated the effect of a suction drain on the recurrence rate of SPD have provided conflicting results [21]. Some reports highlighted that the use of suction drain is associated with low recurrence rate [22]; however, others reported that there is no such association [23,24]. During a mean follow-up of 23 months of 111 patients after surgery, we used drains in both the groups. We suggest that it is one of the reasons for the low complication rates in our series.

The length of hospital stay is a good indicator for assessing the success of a pilonidal surgery and patients' satisfaction. Studies reported different durations regarding the hospital stay in both the procedures. A randomized controlled trial that investigated 150 patients reported that the mean hospital stay is shorter in the Karydakis group than the Limberg group [25]. However, other reports concluded that LF is associated with a shorter period of hospitalization than KF [4]. In our study, we discharged all the patients from both the groups on the second postoperative day unless there were any complications such as infection. None of the patients experienced readmission in our study. So, we agree with Erosy *et al.*'s [26] findings that the mean hospital stay duration after flap procedures could be shortened safely as long as the patients are regularly checked in the outpatient clinics.

In a study examining the modified LF by Mentes *et al.* [27], an infection rate of 0.8% was noted. However, Karydakis [10] stated in his original report that the rate of wound infection was 8.5%. The rate of early postoperative wound infection in our study was similar for both the groups, and most cases were treated successfully with antibiotics and simple wound drainage. There was a significant difference in the time needed to return to work (P=0.3) in KF; however, the time required for patients to feel completely healed was comparable in both the groups in this study (P=0.07). Conversely, a prospective, randomized study concluded that the time of return to work in Karydakis and Limberg procedures is 23.29±6.42 and 20.61±7.89, respectively [28]. Further studies are required to address this discrepancy.Mahdy *et al.* [29] reported that the classic and modified Limberg techniques are superior to the primary closure technique in terms of patients' satisfaction and comfort [30]. Moran *et al.* [31] reported that 92% of patients who were subjected to excision and closure with KF were satisfied with the operation results. In our study, 78.3% of patients in the Karydakis group rated their satisfaction level as 'excellent', whereas only 40% of patients in the Limberg group rated their feeling level as 'excellent'. This may be due to the low cosmetic ability of LF. The main limitation of our study is the small sample size. In future, a large sample size should be studied to arrive at a rational conclusion. Another limitation of the study is the monocentric nature of the study. Future study should be conducted in multiple centers across the country to be valid over a wide demography.

Conclusion

LF and KF reconstruction have no significant superiority over each other in terms of in-hospital stay, the rate of complications, and return to full physical activity. Although we recommend flap techniques for the treatment of recurrent SPD,

certain parameters, such as recurrence rate and cosmetic outcome, must be evaluated when choosing a particular flap. Our institution still prefers KF for its excellent cosmetic effects, early return to work, and higher satisfaction outcomes.

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Conflicts of interest
There are no conflicts of interest.

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