




Karydakis Flap as a Simple Surgical Method in the Treatment of Pilonidal Disease V.S Open Surgery with Average 30-month-follow up: A Clinical Trial

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Abstract

Background: Two common types of treatment for pilonidal disease include open and closed surgery. Closed surgery can be done with a Karydakis flap. The aim of this study was to compare the outcomes of pilonidal sinus management between Karydakis flap and open surgery.

Methods: This clinical trial was conducted on patients diagnosed with pilonidal sinus referred to the surgical clinics of Imam Reza Hospital in Mashhad from 2021 to 2022. Patients were nonrandomly divided into closed and open surgical treatment groups. Demographic information was collected from patients' medical records, the severity of the disease was obtained from operation notes, and time to recovery and time to return to work was obtained during follow-up visits. Pain intensity was collected on the first, tenth, and one month after surgery. To describe the data, the number and percentage for qualitative variables and mean \pm standard deviation for quantitative variables have been used. Normality of variables investigated by Shapiro-Wilk test. A comparison of quantitative variables was done with an independent sample t-test. The comparison of pain changes within each group was done using Friedman's test. A comparison of qualitative variables in two groups was done with the Chi-Square test. The significance level of the tests is 5%, and the software used is SPSS25.

Results: Sixty patients (43 men and 17 women) with a mean age of 23.90 ± 6.57 years were included. The frequency of wound paresthesia ($P=0.023$), and recovery delay ($P<0.001$) was lower in closed surgery compared to the open surgery group, and the frequency of discharge and superficial SSI (Surgical Site Infection) was higher in closed surgery ($P=0.038$). Pain severity decreased during the study ($P=0.029$) among the closed surgery group.

Conclusion: Closed surgical treatment was associated with shorter hospitalization time and return to work time than open surgery. Therefore, Karydakis flap can be a simple and acceptable method for the treatment of pilonidal sinus.

Keywords: Pilonidal Sinus, Surgical Flap, Clinical Trial

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↑What is “already known” in this topic:

Prior to this work we thought the open method was the best and the closed method was with complications which they were afraid to do.

→What this article adds:

This work clarified that if the closed method is performed with the correct technique, it will be with lesser complications and be a practical procedure.

Introduction

The incidence of pilonidal disease is about 26 per 100,000 individuals (1). The pilonidal disease mainly occurs in men and predominantly in white patients (2). The disease usually occurs in teens, decreasing after the age of 25, and rarely occurs after the age of 45 (3).

Local stimulation at the lesion site, family history of pilonidal disease, sedentary lifestyle, and obesity have been reported in a significant percentage of patients (4). Other risk factors for pilonidal disease include male gender, hirsutism, Caucasians, sedentary occupations, and the presence of hair in the natal cleft (3, 4). This acquired chronic disease that results in significant morbidity and associated healthcare costs can be managed by surgical interventions. Several methods have been proposed to manage this disease, and reported surgical techniques range from wide excision with or without primary closure to closure with various flaps (3). The purpose of these methods is to eliminate the underlying causes of hair regrowth and reduce recurrence. However, the long-term recurrence rate (more than 5 years) is between 10 and 30%, and recurrence is associated with significant complications (5-7). The number and variety of techniques published about pilonidal disease is proof of the complexity of treating this disease, and no single method is reported to be superior in all aspects (7). The most effective emergency treatment of pilonidal abscess is simple incision and drainage (8). However, surgical management of chronic and recurrent disease is more controversial. Several studies support one excisional therapy over another, but many of these studies are underpowered due to the lack of a control group or short-term follow-up (3, 4, 7, 9). In addition, pilonidal sinus resection with or without primary closure can be performed in different ways, by making a medial or lateral incision (4).

The mainstay of surgical management for the pilonidal disease is the removal of the entire pilonidal sinus and epithelialized ducts. However, optimal wound closure after excision is controversial. Primary closure can be performed using midline or off-midline techniques (9). Complex reconstructive procedures using flaps are usually used for patients with extensive disease or those who do not respond to more simple surgeries (including excision and suture closure of the midline) (10). These reconstruction strategies allow resection of more involved tissues and promote wound healing by reducing tension. Additionally, these techniques facilitate wound closure on the incision side, which is typically moist, hypoxic, and full of bacteria. In cuts outside the midline, the healing time was significantly shorter (3).

One method that has received attention in the management of pilonidal disease is the Karydakís method. It has been reported that treatment of pilonidal sinus disease in this way is associated with a low recurrence rate and reduces the need for complex flaps (11). Limited studies have shown the superiority of the Karydakís treatment method compared to open surgery (12, 13). Nevertheless, it seems that the results of different management of pilonidal disease depend on the conditions of the surgical facilities in addition to the treatment technique. Therefore, the purpose of

this study was to investigate the results of pilonidal sinus surgery using the Karydakís method in comparison with the open surgery method.

Methods

Patients and study design

Every patient who was diagnosed with pilonidal sinus and returned to Imam Reza Hospital (Mashhad, Iran) during a one-year period since 2021 was included in the present case-control study. After obtaining written informed consent, the researchers assigned the patients to open or closed treatment groups by nonrandom block allocation method (30 patients in each group).

Demographic information, including age, gender, underlying diseases, and history of previous surgery, were recorded in a checklist, and information related to the type of surgery and development of infection, length of hospitalization, and wound bleeding or discharge after surgery were recorded in the checklist. All patients were referred to the same nurse for dressing and underwent dressing with a specific protocol. The patients were followed for 30 months in the form of a visit on the first day in the ward and the first week at the clinic, and then in the first month and one year, then 30 months following the surgery by telephone. During follow-up, recurrence and complications were recorded. In the end, the obtained information was compared between the study groups.

Exclusion criteria included history of abscess and infection and a history of pilonidal sinus surgery. Recurrence in our study means the reappearance of the patient's symptoms after 2 months of surgery, and delay in wound healing means the lack of recovery after 2 months of surgery. In this study, wound healing means complete epithelialization of the wound and no need for dressing. In the procedure, the pain of all patients was asked before taking painkillers the next day. All patients were given 500-milligram acetaminophen tablets four times a day, and they were told to take one tablet in case of severe pain. Primary outcomes include pain, return to work time, wound healing time, and recurrence rate, and secondary outcomes include wound bleeding, wound anesthesia, wound exudation, wound infection, wound seroma, wound hematoma, and skin opening. The safety outcome includes superficial surgical site infection.

Statistical analysis

To describe the data, the number and percentage for qualitative variables and mean \pm standard deviation for quantitative variables have been used. Normality of variables investigated by Shapiro-Wilk test. A comparison of quantitative variables was done with an independent sample t-test. The comparison of pain changes within each group was done using Friedman's test. A comparison of qualitative variables in two groups was done with the Chi-Square test. The significance level of the tests is 5%, and the software used is SPSS25.

Sample size

The sample size is based on the findings of previous articles²⁴ regarding the average time to return to work in open and closed surgery (14.44 ± 8.11 and 24.19 ± 17.08 days, respectively) and considering the first type error of 0.05 and the second type error of 0.2, 30 people were counted in each group.

Procedure

A first-generation cephalosporin was used as premedication and administered 1 h before surgery. All procedures were done under spinal anesthesia. Patients were placed in a prone jackknife position. An asymmetrical ellipse was marked to encompass the pilonidal complex (Figure 1). The upper and lower ends of the ellipse thus marked were at least 2 cm away from the midline. The area thus marked was then excised at full thickness up to the sacral fascia

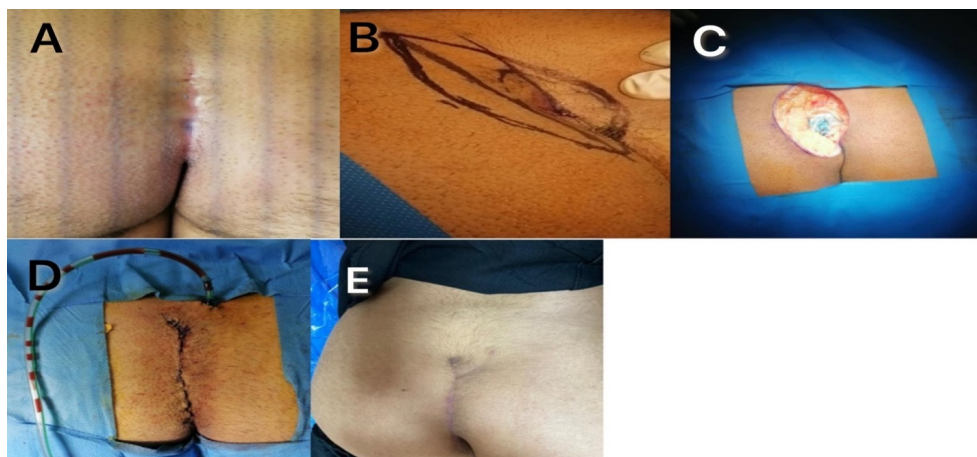


Figure 1. Karydak procedure for pilonidal disease. Left upper: preoperative condition, middle-upper: preoperative planning, right upper: complete sinus resection, left lower: primary closure with the Karydak technique, right lower: outcome after 2 months

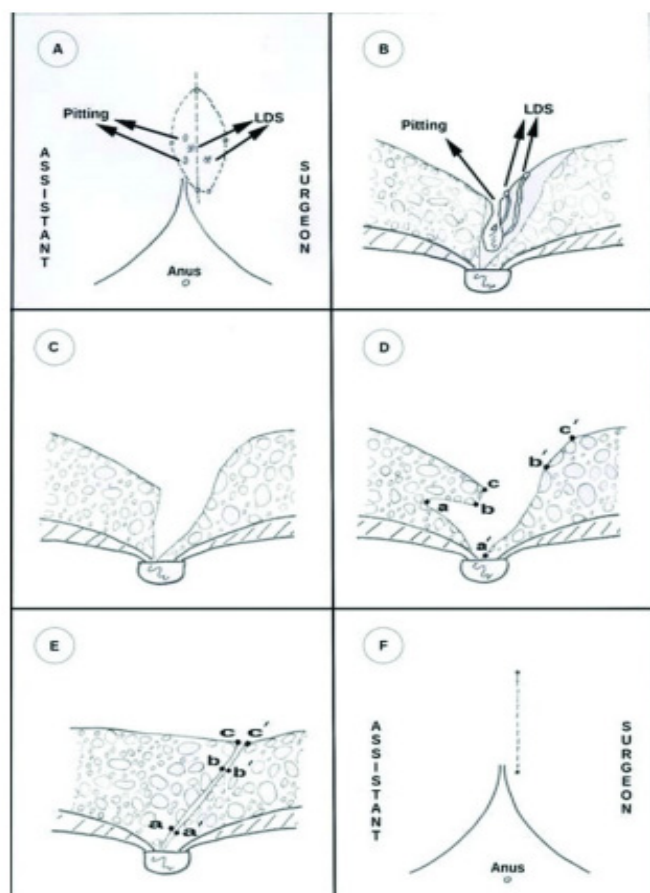


Figure 2. Karydak flap procedure. Different stages of design and surgery using the Karydak flap method: A and B (initial design and resection route and the position of the surgeon and the surgeon's assistance regarding the surgical incision It is marked LDS (Sinus Discharging Lateral). C (After resection. (D) The points to be sutured together are seen after preparing the flap. (E and F) Scar is place at the end of the operation.

with a straight edge on the side of flap mobilization and a sloping edge on the other side. This is followed by mobilization of the flap across the midline. A layer of 1-0 polyglactin sutures was placed, and the needle was passed into the sacral fascia in the midline and then into the V junction of the flap, which was secured. A suction drain was placed and brought out well laterally. In Figure 2, the Karydakís flap method is schematically explained. In the open procedure, the sinus is excised at full thickness up to the sacral fascia.

Results

Demographic information is available in Table 1. According to this table, The mean \pm standard deviation of the patients enrolled in the present study was 23.9 ± 6.5 years, and most of them were male (43 patients, 71.7%). The mean \pm standard deviation of BMI was 26.58 ± 4.06 in our study. Among the study population, five persons had a history of trauma (8.3%), and two patients had a family history of pilonidal disease (33.3%). Moreover, family history of the disease and trauma were not significantly different among study groups ($P>0.05$). Twelve patients (40%) in the open surgery group faced delayed wound healing, while none of the patients in the closed surgery group faced delayed healing ($P<0.001$). Based on Table 2, The duration of wound healing and return to work in the closed surgery group was significantly less than that of the open surgery group (10 days versus 101 days and 13 days versus 58 days) ($P<0.001$). The duration of surgery in the open surgery group was significantly less than in the closed surgery group ($P<0.001$). The pain score was significantly reduced in the closed surgery group ($P=0.029$), and the reduction in the pain score was significantly greater than the open surgery group during the first week ($P<0.001$) and from the first week to the 4th week ($P<0.001$). Although the pain score was not significantly different among study groups,

the closed surgery group reported significantly greater pain reduction on the first ($P<0.001$) and 10th day ($P=0.002$) following surgery in contrast to the open surgery group.

Discussion

The present study showed that the surgical treatment of pilonidal sinus by Karydakís flap compared to open surgery was associated with a higher rate of superficial SSI in the perioperative period and a lower rate of delayed healing in Karydakís flap, while open surgical treatment was associated with less discharge in this time. Moreover, the duration of wound healing and return to work in the closed surgery group was significantly less than in the open surgery group. The pain score on the first day and the first week after surgery in the closed surgery group was significantly higher than the open surgery group, but in the first month, the pain score was equal in both groups.

Various closed surgical methods using flaps have been proposed for the treatment of pilonidal sinus and the main advantage of using Karydakís flap is the simplicity of this method and no need for advanced flaps (14). Unlike other methods, including Limburg or Bascom, this method does not require extensive dissection, and the scar is regular and in the form of a smooth line, which is more acceptable in terms of aesthetics (15, 16). In the present study, closed surgical treatment of the pilonidal sinus with Karydakís flap was associated with fewer complications than open surgery. In the study of Petersen et al., which was conducted on 188 cases of pilonidal sinus (91 cases of open surgery and 97 cases of closed surgery with Karydakís flap) with one month of follow-up, the overall incidence of complications in the closed surgery group was significantly higher than the open surgery group (16). Yildiz et al. studied 257 Turkish patients with pilonidal sinus, and the most common surgical complication of the Karydakís method was serum secretion from the wound reported in 57.58% of patients

Table 1. Comparison of the demographic characteristics of the subjects between the closed and open surgery groups

| Variable | Level | Closed group | Open group | P-value |
|--------------------------|-------------|------------------|------------------|--------------------|
| Age (years) | | 23.67 ± 6.57 | 24.13 ± 6.58 | 0.694 [†] |
| BMI (kg/m ²) | | 25.51 ± 3.78 | 27.65 ± 4.12 | 0.726 [†] |
| Sex | Male | 18(60.0%) | 25(83.3%) | 0.045 [‡] |
| | Female | 12(40.0%) | 5(16.7%) | |
| Education | High School | 9(30.0%) | 8(26.7%) | 0.722 [‡] |
| | Diploma | 10(33.3%) | 13(43.3%) | |
| | University | 11(36.7%) | 20(38.3%) | |

Note: Data Presented as mean \pm SD

[†]Independent t-test was used for comparison.

[‡]Chi-square test was used for comparison.

Table 2. Comparison of duration of surgery, time to wound healing and time to return to work, and pain between closed and open surgery groups

| Variable | | Closed Group | Open Group | P-Value |
|---|-----------------------------------|------------------|-------------------|----------|
| Surgery Duration (Minute) | | 61.1 ± 5.29 | 28.67 ± 6.15 | <0.001 |
| Healing Duration (Days) | | 10.63 ± 2.53 | 101.17 ± 36.4 | <0.001 |
| Duration Of Returning Back To Work (Days) | | 13.33 ± 3.15 | 58.03 ± 22.56 | <0.001 |
| Pain Score | 1 st day | 7.50 ± 0.86 | 3.77 ± 1.94 | <0.001 |
| | 7 th day | 3.23 ± 1.22 | 2.37 ± 1.61 | 0.002 |
| | 1 st month | 0.27 ± 0.52 | 0.73 ± 1.39 | 0.266 |
| | 1 st year | 1.17 ± 0.87 | 1.73 ± 1.015 | 0.043 |
| | **Within group comparison P value | 0.029 | 0.624 | |

Note: Data Presented as mean \pm SD

(17). While the result of our study was consistent with the results of the Yildiz et al. study, the frequency of discharge from the wound in our study (60%) was similar to the study of Yildiz et al. (17).

In the present study, the surgical procedure of the Karydakakis method was significantly longer than the open surgery, but the hospitalization time and return to work time in this method were significantly shorter than the open surgery method. A similar study from Germany demonstrated that this method is simple, fast, low-risk, and inexpensive, requiring the shortest hospitalization time and with a low recurrence rate (18). The findings of the mentioned study were similar to the results of our study in terms of surgery time but were inconsistent in terms of recurrence rate, hospitalization time, and complications. The reason for this difference can be related to the cross-sectional nature of the mentioned study as well as the difference in the subjects (considering emergency and elective cases in the aforementioned study and considering elective cases in the present study) as well as the difference in the facilities and surgical properties of the medical centers. However, in line with the present study, no case of recurrence was found in the closed surgical method with Karydakakis flap, and the rate of recurrence in previous studies was also reported to be less than 5% (13, 19-21). Similar to our results, in Bali et al.'s study, no cases of pilonidal sinus recurrence were reported (22). In a cohort study conducted by Al-Hadad et al. on 92 cases of pilonidal sinus, the average duration of surgery was 42.3 ± 10 minutes (15). In another study conducted by Bali et al. in Turkey on 34 patients who underwent closed surgery with a Karydakakis flap, the average duration of surgery was 48 minutes (15). The average operation duration in these two studies was less than the average operation duration in the present study (61.10 minutes). The reason for the increase in the duration of surgery is the presence of surgical residents in the operation and the educational nature of our hospital. On the other hand, in a study conducted by Keshvari et al. in Tehran, the average duration of Karydakakis flap surgery was 55.17 minutes, which was significantly longer than the control group (13). The similarity of the duration of surgery in this study from Iran with our study may indicate the effect of hospital conditions and demographic characteristics of patients on the duration of surgery and its consequences. Also, in line with the present study, in a study conducted by Keshvari et al. on 321 patients (161 patients undergoing closure surgery with a Karydakakis flap and 160 patients undergoing surgery for removal and recovery with secondary intention), the average duration of wound healing (16.44 days) and the time to return to work was 14.44 days in the closed surgery group with the Karydakakis flap, which was significantly less than the control group (11).

In the present study, the pain score after surgery in the closed surgery group decreased from 7.50 on the first day to 3.3 on the 7th day and 0.27 on the first month. This was despite the fact that the average pain score in the first, seventh, and first months after open surgery in the present study was 3.77, 2.37, and 0.73. In a study conducted in our country on 135 cases of closed surgery with Karydakakis flap,

the amount of pain on the 15th and 30th days after the operation was reported as 5.58 and 2.22 (23). Also, Keshvari et al. reported that due to the higher score of pain on the first day after surgery in patients who underwent surgery with a Karydakakis flap compared to the group of removal and recovery with secondary intention, this improvement was achieved one week after surgery in the Karydakakis flap group which was significantly lower than the control group (9). However, the trend of pain reduction compared to the control group in the present study was similar to the study by Keshvari et al. (18).

Another study conducted by Keshvari et al. included 179 consecutive patients undergoing Karydakakis flap, followed up for an average of 31.26 ± 21.80 (maximum, 71) months after the operation. Patients were returned to normal activity in an average of 14.49 ± 8.54 days (range, 1-35) was similar to the results of our study (25).

The limitation of the present study was that the patients in the two groups did not match each other completely.

Conclusion

The results of the present study showed that the Karydakakis flap method can be considered a preferred surgical method with faster discharge of the patient and recovery. On the other hand, this method can be associated with the same recurrence rate compared to open surgery. Although the level of superficial infection, duration of surgery, and the pain of the first week in the Karydakakis method are more than open, the discharge from the hospital and return to work is faster, and the acceptable cosmetic result can introduce this method as a suitable method for pilonidal sinus surgery and finally the studies with more volume, it can be helpful in the future.

Authors' Contributions

All authors were involved in designing, developing, and implementing the research.

Ethical Considerations

This work has been approved by the National Research Ethics Committee by the No. IR.MUMS.MEDICAL.REC.1400.831 and the Iranian Registry of Clinical Trials no. for this work was IRCT20210712051862N1.

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Conflict of Interests

The authors declare that they have no competing interests.

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