

## Comparison of Outcomes of Open and Closed Surgical Procedures in Pilonidal Cysts Excision: A Randomized Clinical Trial Study

Pilonidal Kist Eksizyonunda Açık ve Kapalı Cerrahi İşlemlerin Sonuçlarının Karşılaştırılması: Randomize Bir Klinik Çalışma Çalışması

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### ABSTRACT

**Background:** Treatment of pilonidal sinus involves the use of various surgical procedures, most of which are associated with many complications and problems. Meanwhile, open and closed surgical procedures are two common surgical procedures for the treatment of patients with pilonidal sinus disease. The aim of this study is to compare the outcomes of open and closed surgical procedures in pilonidal cysts excision.

**Methods:** This study was a randomized clinical trial that was performed on patients with pilonidal sinus referred to Shahid Beheshti Hospital of Yasuj University of Medical Sciences, Yasuj, Iran. Patients having inclusion criteria were assigned to 2 groups; first group for open surgical procedure (n:30) and second group for closed surgical procedure (n:30) using a simple randomized method. The data gathering tools were a demographic data form and a visual analog scale (VAS). Two types of open and closed surgery procedures were performed randomly on patients. Data were analyzed by SPSS-16 software using mean, standard deviation, independent t-test, Chi-square or Fisher exact test.

**Results:** The results showed that the outcomes of recurrence of the disease ( $P = 0.001$ ), wound infection ( $P = 0.003$ ), and duration of surgery ( $P = 0.001$ ) in open surgical procedure were significantly lower than the closed surgical procedure.

**Conclusions:** Considering the better outcomes of open surgical procedure in terms of patient satisfaction after surgery and lower additional costs, the open surgical procedure is suggested for the treatment of pilonidal sinus - if one of these two methods should be selected by the surgeon.

**Key Words:** Pilonidal sinus, Open procedure, Closed procedure, Randomized Clinical Trial

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### ÖZET

**Amaç:** Pilonidal sinüs tedavisi, çoğu birçok komplikasyon ve problemle ilişkilendirilen çeşitli cerrahi prosedürlerin kullanılmasını içerir. Bu arada, pilonidal sinüs hastalığı olan hastaların tedavisi için açık ve kapalı cerrahi prosedürler iki yaygın cerrahi prosedürdür. Bu çalışmanın amacı pilonidal kist eksizyonunda açık ve kapalı cerrahi işlemlerin sonuçlarını karşılaştırmaktır.

**Yöntem:** Bu çalışma, İran Yasuj Tıp Bilimleri Üniversitesi Shahid Beheshti Hastanesine sevk edilen pilonidal sinüslü hastalar üzerinde gerçekleştirilen randomize bir klinik çalışmadır. Dahil edilme kriterlerine sahip hastalar 2 gruba ayrıldı; basit bir randomize yöntem kullanılarak açık cerrahi prosedür için birinci grup (n: 30) ve kapalı cerrahi prosedür için ikinci grup (n: 30). Veri toplama araçları bir demografik veri formu ve bir görsel analog ölçek (VAS) idi. Hastalara rastgele iki tip açık ve kapalı cerrahi prosedür uygulandı. Veriler, ortalama, standart sapma, bağımsız t-testi, Ki-kare veya Fisher kesin testi kullanılarak SPSS-16 yazılımı ile analiz edildi.

**Bulgular:** Sonuçlar açık cerrahi prosedürde hastalığın nüksü ( $P = 0.001$ ), yara enfeksiyonu ( $P = 0.003$ ) ve cerrahi süresinin ( $P = 0.001$ ) sonuçlarının kapalı cerrahi prosedüre göre anlamlı derecede düşük olduğunu gösterdi.

**Sonuç:** Açık cerrahi işlemin ameliyat sonrası hasta memnuniyeti ve daha düşük ek maliyetler açısından daha iyi sonuçları göz önüne alındığında, pilonidal sinüs tedavisi için - bu iki yöntemden biri cerrah tarafından seçilecek - açık cerrahi işlem önerilmektedir.

**Anahtar Sözcükler:** Pilonidal sinüs, Açık prosedür, Kapalı prosedür, Randomize Klinik Çalışma

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## INTRODUCTION

Pilonidal sinus is a chronic inflammatory disease, in which the subcutaneous cavity or cavities that contain hair and granulation tissue get to the surface of the skin. This disease typically occurs along the midline of the sacrococcygeal region, and considering its prevalence, it is an important factor in hospitalization and surgery among young people (1). According to the reported statistics, 26 out of every 100000 persons are infected with pilonidal cysts worldwide (2). The prevalence of this disease is higher in the third decade of life and is rarely seen in people over 45 years of age. Males are three times more likely to be infected than women and its incidence is higher in overweight and hairy subjects (3). There are two theories about the pathogenesis of pilonidal sinus. The first theory is the fetal growth disorder theory. According to this theory, the cause of this disease is the burial of the epidermal remains at the time of insertion in the midline. The second theory is the theory of acquired origin of pilonidal sinus disease. According to this theory, the hairs of this area penetrate in the sebaceous glands or hair follicles by the end of the drill-like region, and thus the hairs penetrate the dermal and subcutaneous tissues and make small cavities. Then the cavity is contaminated by skin organisms and the infectious process begins (4). The clinical symptom often associated with chronic inflammation and secretion. The diagnosis is clinical and may be asymptomatic, with a cyst or open sinus without pain, acute abscess, or chronic illness (5). A wide range of treatments has been proposed for the improvement of pilonidal sinus which consists of conservative methods such as phenol injection to complex methods such as dermal-muscle flaps (Gluteus maximus flap). But none of these methods has reduced the recurrence rate of the disease to zero. Treatment of Pilonidal sinus can be an ideal method that, in addition to low recurrence rate, can be associated with low complications and shorter treatment duration so that patient can return to her/his workplace as soon as possible. Currently, surgery is a common treatment method worldwide (6,7). In the treatment of pilonidal sinus, the surgical wound may be left open to heal. Proponents of this approach believe that reducing the pressure on the wound facilitates wound healing and prevents its recurrence (8). In the open surgical procedure, the complications after surgery are greater and the patient has pain for several weeks at the time of sitting and should be dressed continuously (2). Background excision and primary wound healing is a simple method for the pilonidal disease improvement, although this method is associated with infection and an increased recovery period (9). Alternatively, the wound may be closed and its healing would be done with primary closure. Surgical procedures can be categorized by the midline closure (with injuries found in the intergluteal cleft) or other procedures (where the wound is placed somewhere outside the midline region). Proponents of primary closure believe that in this method, the tissues heal quickly (10). The closure procedures have been able to reduce the duration of wound healing significantly. Basically, in these methods, after the lesion excision, the wound is simply sutured or repaired by using plastic surgery procedures such as the use of a variety of flaps or Z-Plasty (11-13). Each method has its own advantages and disadvantages, and one cannot explicitly prefer one to another. Studies in this field have always emphasized this issue. For example, Jabbar et al. in their study showed that the primary closure with the Limberg flap, as well as open procedure are only suitable treatments for pilonidal sinus disease in terms of decreasing wound infection (14). Also, the results of the study conducted by Kamran et al. indicate that both open and closed surgical procedures are effective. However, the open procedure is better than the closed surgical procedure, due to the lack of recurrence and the amount of wound contraction (15). Therefore, due to differences in other studies regarding the preferred method of open and closed surgery for sinus pilonidal, further investigation is needed in this regard. An ideal procedure should be simple and cost-effective with a few complications. In the studies of the available literature regarding the comparison of two open and closed procedures, different results and outcomes have been expressed regarding the recurrence rate, the hospitalization duration, and surgical complications. Therefore, the present study was conducted to compare the outcomes of open and closed surgical procedures in Pilonidal Cysts excision in Shahid Beheshti Hospital of Yasouj University of Medical Sciences.

## MATERIALS and METHODS

### *Ethical Considerations*

The present study was approved by the Ethics Committee of the Yasuj University of Medical Sciences, Yasuj, Iran (ethics code: IR.YUMS.REC.1398.021). In data collection stage, the study objectives were clarified to each participant and written informed consent was obtained from all participants.

### *Study design and data collection*

The present study was a randomized clinical trial that was conducted during May to March 2018, on patients with pilonidal sinus referred to Shahid Beheshti Hospital of Yasuj University of Medical Sciences. Patients who were diagnosed with pilonidal cyst by a surgeon member of the research team and having inclusion criteria were selected for the study. The data gathering tools were a demographic data form and a visual analog scale (VAS). The demographic data form consisted of two parts of individual information and surgical specification of the patients. The first part contained personal information such as age, gender, marital status, and weight. The second part also included surgical specifications such as postoperative wound infection, duration of operation, return to work, hospitalization duration, and recurrence rate. The visual analog scale was used to determine the pain intensity of the patient. This scale is a 10 cm ruler, written at the left end of it, "painless" and at the right end of it, "the most severe pain". The patient, according to the pain severity within the last 48 hours, points to the continuum. The amount of pain is measured by the researcher using the visual-linear pain scale standardized for pain measurement (16,17). On this scale, the patient's pain is divided into 0 to 10 (0-1; painless, 2-3; low pain; 4-5; severe pain; 6-7; very severe pain; 8-9; maximum Pain, 10; intolerable pain). The visual analog scale of pain has been used in several studies to assess the patient's pain severity and has high reliability and validity. First, the researcher informed the participants about the research goals and the confidentiality of the information and explained that their placement in each of the groups (open or closed surgical procedure) was completely identical and random. Before the surgery, a demographic data form was completed in both groups of patients. In order to prepare the two groups before surgery, a brief description of the type of surgery was first given to the patients. Then, this right was given to a patient which, if desired, would change the type of procedure that had already been prescribed to him.

### *Sample size estimation*

The sample size was estimated to be 60 patients according to the similar study conducted by Rashidian et al. (18), considering the power of 95% and the significant level of 5% during the study and considering the probability of exclusion by about 10%.

### *Inclusion and exclusion criteria*

The inclusion criteria included informed consent for participation in the study, ages ranging from 15 to 45 years, and having pilonidal sinus diagnostic criteria (presence of cysts in an abnormal cleft with or without tissue inflammation surrounding the sinus formation site with pain and Bleeding). The exclusion criteria were as follows: lack of willingness to continue the study, non-referral for follow up, patients with disabilities, uncontrolled diabetic patients, patients who had already undergone pilonidal cysts surgery, patients with immunodeficiency or treating with immunosuppressive drugs, patients with acute pilonidal abscesses, and smoking.

### *Subjects and experimental protocol*

A total of 60 patients with pilonidal cyst who met the inclusion criteria were enrolled in this study. Then, they were randomly assigned by a random number table into one of the two groups; first group for open surgical procedure ( $n:30$ ) and second group for closed surgical procedure ( $n:30$ ). Then all patients received spinal anesthesia in sitting position with 10 mg Marcaine (Bupivacaine) (between the lumbar spines of L4-L5). Then, after being assured of the success of the anesthetic, they were placed in the prone position. During operation, oxygen saturation of the arterial blood, heart rate, and blood pressure were monitored.

After spinal anesthesia, monitoring vital signs of the patient, and careful shaving of hair, at first, the skin of the surgery area was washed with Betadine scrub and dried and then it was colored with green Betadine. At the same time, for all patients, 1 g of Cefazolin was injected as prophylaxis. After these steps, an oval incision was made around the sinus tract hole in Midline at a distance of 1 cm from each side. Then, an Allis forceps were placed at the upper angle of the skin to be removed and the sinus was cut off as Enbloe. Subcutaneous tissue was then excised down and laterally to the deep fascia.

#### Open surgical procedure

In this method, after wound examination and control of bleeding and ensuring that all the sinus tracts were removed, the wound was washed with saline and packed open.

#### Closed surgical procedure

In this method, after wound examination and control of bleeding and ensuring that all the sinus tracts were removed, subcutaneous hair was released in the junction with the deep fascia, as far as allowing it to close the tension edges. The suture was then inserted in the wound margins (about 1cm or slightly more) to bring together the entire thickness of the flap released from the skin and subcutaneous tissue. Then a second bite of the fascia was sutured at the wound bottom and then the suture was continued deep into the opposite flap. Thus, 4 to 5 sutures were made by 1.0 nylon thread (Round) for the patient's wound. Suture threads without being knotted were held on both sides of the wound with a clamp. The surgical wound was then closed with 2.0 nylon thread (cut) using the Vertical Mattress method. Finally, two sterile gauzes were placed on the wound as dressing, and the two end of 1.0

nylon thread that had been previously sutured, knot tightened so that the dead space around the wound would be deleted.

In both surgical procedures, post-operative patients were transferred to recovery with a good general condition. Then, they completed the second part of the demographic data form, which was related to the duration of the operation. Then, the rest of the information, such as post-operative infection, time to return to work, hospitalization duration during various visits at 7, 14 and 21 days after surgery was completed. Finally, one year later, by calling patients and visiting them the recurrence of the disease in all patients were examined. In addition, all patients were examined for pain 6 hours after surgery. In all patients, the pain intensity was recorded based on the Visual Analog Scale (VAS).

#### Analysis of data

Finally, the data were analyzed by SPSS™ software version 22.0 (IBM Corporation, Armonk, NY, USA) using descriptive statistics (mean and standard deviation), independent t-test, Chi-square or Fischer's exact test.

## RESULTS

A flow diagram of patient is shown in Figure 1. Of the 60 patients studied, all of them met the inclusion criteria. The results showed that out of 60 patients, 40 were men (66.7%) and 20 were women (30.3%). The mean age of subjects was  $25.72 \pm 6.55$  years. The mean weight of patients was  $72.15 \pm 7.13$  kg. In this study, 41 were married (68.3%) and 19 (21.7%) were single.

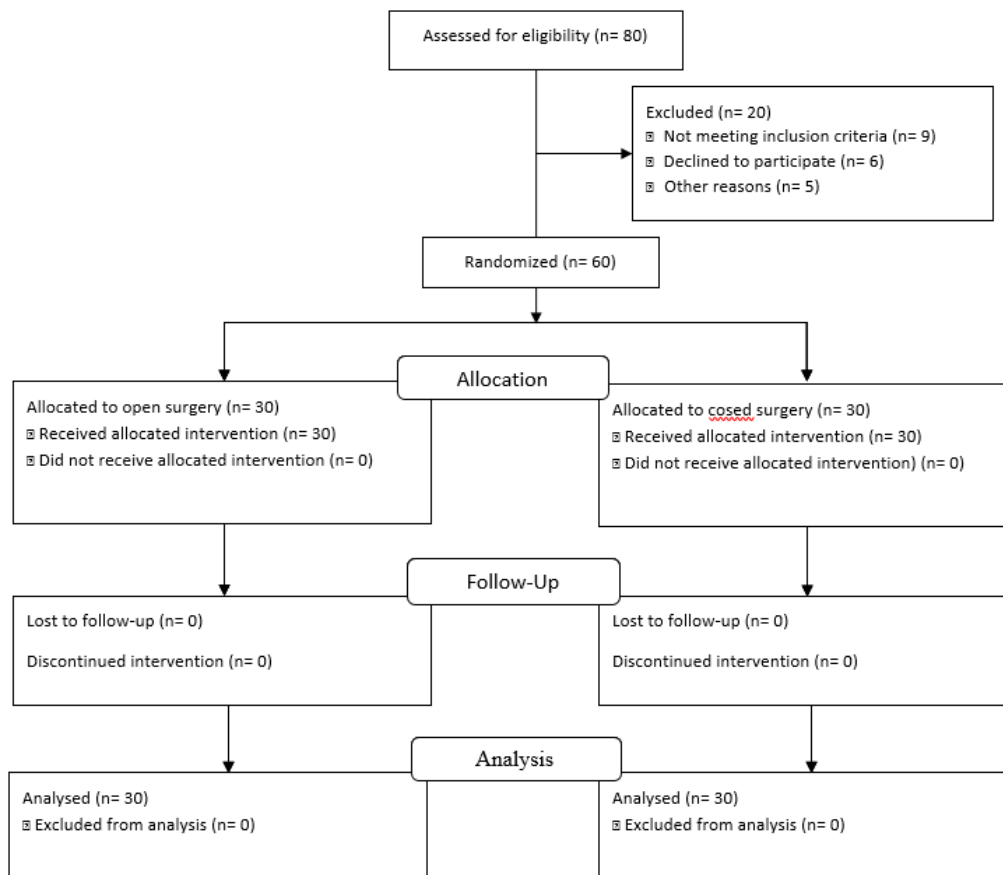


Figure 1. Consort flow diagram for inclusion of patients

The comparison of demographic variables before and after surgery between the two groups of the open and closed surgical procedure showed no significant difference except age (Table 1).

**Table 1.** Comparison of the mean of preoperative demographic variables between open and closed surgical procedures

Variable		Open surgical procedure group	Closed surgical procedure group	P-value
		Frequency (percent)		
Sex	Male	21 (70%)	19 (63.3%)	0.372
	Female	9 (30%)	11 (36.7%)	
Infection	Single	8 (26.6%)	19 (63.3%)	0.739
	Married	22 (73.4%)	11 (36.7%)	
Age	Mean ± SD	24.38 ± 4.60	27.06 ± 8.51	0.029
Weight		71.25 ± 7.35	73.06 ± 6.92	0.451

Table 2 showed that in the closed surgical procedure, the time of return to work (14.53±4.55 days versus 33.41±3.16 days) and the severity of postoperative pain (1.42 ± 0.51 versus 3.79 ± 0.75) were significantly less than

open surgical procedure ( $P = 0.001$ ). However, the duration of surgery (16.25 ± 5.46 versus 27.63±4.51 min) in the open surgery group was significantly less than the closed surgery group ( $P = 0.001$ ).

**Table 2.** Comparison of mean variables of pain intensity, time to return to work, duration of surgery between open surgical procedure and closed surgical procedure

Variable	Open surgical procedure group	Closed surgical procedure group	P-value
	Mean ± SD		
Intensity of pain	3.79 ± 0.75	1.42 ± 0.51	0.001
Time back to work	33.41 ± 3.16	14.53 ± 4.55	0.001
Duration of surgery	16.25 ± 5.46	27.63 ± 4.51	0.001

As shown in Table 3, there was no recurrence in pilonidal sinus disease in the open surgery group, while in the closed surgery group there were 4 cases of recurrence ( $P = 0.001$ ). Postoperative wound infection was only observed in

the closed surgery group and the open surgery group was significantly less infected than the closed surgery group ( $P = 0.003$ ).

**Table 3.** Comparison of the mean of recurrence and infection after surgery between two open surgical procedure and closed surgical procedure

Variable		Open surgical procedure group	Closed surgical procedure group	P-value
		Frequency (percent)		
Recurrence	Yes	0 (0)	4 (13.3%)	0.001
	No	30 (100%)	26 (86.7%)	
Infection	Yes	0 (0)	2 (6.7%)	0.003
	No	30 (100%)	28 (93.3%)	

## DISCUSSION

The present study was conducted to compare the outcomes of open and closed surgical procedures in pilonidal cysts excision in Shahid Beheshti Hospital of Yasouj University of Medical Sciences. In the present study, there is no statistically significant difference between the two groups of open and closed surgery in terms of demographic variables (personal information) including gender, marital status, and weight, except for age, which is consistent with the study conducted by Hemmati et al (3). The findings of this study showed that the mean pain intensity between the two groups of open and closed surgery was significant in the postoperative period. So, it can be concluded that the pain intensity in patients undergoing closed surgery was less than patients with open surgery. In line with the findings of this study, the results of study conducted by Haji Barati et al. (19) showed that the mean pain intensity in the first, second, and seventh days after surgery in the primary recovery group (Closed surgical procedure) was significantly less than the secondary recovery group (open surgical procedure). So, these findings are consistent with the results of the current study. Also, the results of the study conducted by Ertan et al. (20) showed that the mean postoperative pain intensity in the primary closure group (closed surgical procedure) was less than open surgery group and these patients experienced less pain. So, these findings are also consistent with the results of the current study. However, the results of the study carried out by Rao et al. (21) with the aim of comparing two procedures of treating chronic Pilonidal sinus disease with a 5-years follow up showed that postoperative pain intensity on the 4th day in the open surgery group was significantly less than the primary closure group.

Therefore, these findings are not consistent with the results of the present study which show that the severity of postoperative pain in the closed surgery group is less than the open surgery group. Perhaps the reason for this inconsistency is the difference in sample size and follow-up time in their study. Regarding the recurrence rate of disease in the present study, the results showed that there was a significant difference between the open and closed surgical procedures in the postoperative period. The recurrence of the disease in the open surgical procedure after 9-12 months of follow up was less than the other procedure. Therefore, recurrence of the disease was observed only in the closed surgical procedure and its rate was 13.3% and no recurrence was seen in the open surgical procedure. In line with these results, Ummer et al. (22) showed that recurrence of the disease was seen only in the primary closure group and was 18%, and no recurrence was seen in the open surgical procedure. Therefore, their findings are consistent with the results of the present study. Also, Laurent et al. (23), consistent with the results of the present study concluded that 1 and 3 months after surgery, the rate of wound recovery in the closed procedure was more than the open procedure. However, Gailani et al. (24) concluded that excision and primary recovery (closed surgical procedure) had a low and acceptable recurrence rate and it was a cost-effective method since its time to return to work was quick. Therefore, these findings are not consistent with the results of the present study. It can be said that this difference is due to advanced postoperative care and postoperative follow up of that study compared to the present study.

Based on the findings of this study, it was found that the surgical duration between the two groups of open and closed surgical procedure was significant in terms of shortening the duration of open surgical procedure than the closed one. The results were in line with the findings of Amini Moghadam et al (14). They showed that the surgery duration in open surgical procedure (13.9 min) was significantly more than the closed surgical procedure (20.1 min). Regarding the duration of return to work between two groups, the results of this study showed that the duration of return to work in the closed surgical procedure was less than the open surgical procedure and the patients undergoing the closed surgery recovered quickly. Toccaceli et al. (25), after 20 years of experience and primary closure surgery, showed that the primary closure (closed surgical procedure) of pilonidal sinus was associated with good results in terms of the quick recovery and return to the work of patients and could be considered as a selective treatment for the pilonidal sinus. So, their findings are consistent with the results of the present study. Also, the findings of the present study showed that there was no statistically significant relationship between the duration of hospitalization in open and closed surgical procedures. Therefore, the results of this study are in line with the findings of Amini Moghadam et al (14). The results of their study showed that the mean hospitalization duration in the closed and open surgical procedures were 14.8 hours and 15.3 hours, respectively. These results were not statistically different from each other.

## CONCLUSIONS

The results of this study showed that the recurrence rate, postoperative wound infection, duration of surgery, and additional costs in the open surgical procedure are less than the closed surgical procedure. Moreover, the satisfaction rate of patients after the operation, in the open procedure is more than the closed one. Therefore, the open surgical procedure is recommended to surgeons as a preferred method. However, in the closed surgical procedure, only return to work duration and postoperative pain were less than the open surgical procedure.

## Conflict of interest

No conflict of interest was declared by the authors.

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