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The importance of natal cleft in recurrence in pilonidal sinus surgery: a randomized prospective study

Cleft in recurrence in pilonidal sinus surgery

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Abstract
Aim: Recurrence and complications are significant postoperative problems in pilonidal sinus (PS) surgery. This study investigated the relationship between resection margins and scaphoid flap width in PS surgery using a modified Limberg flap and cleft lift technique.
Methods: The study included 104 male and female patients aged 18 years and older diagnosed with chronic and primary pilonidal sinus. Patients in one randomly selected group underwent split corneal lift (n = 52), and patients in the other group underwent modified Limberg flap (n = 52).
Results: Operation duration, drain duration, hospitalization duration, and normal activity duration differences between patient groups were statistically significant ($p<0.05$). In the 1st week after the operation, maceration and wound dehiscence in the cleft lift group were 3.8%, whereas 17.3% in the modified Limberg flap, with statistically significant differences ($p < 0.05$). Maceration at the 2nd week rate was 5.8% in the cleft lift group and 13.5% in the modified Limberg flap, with a statistically insignificant difference ($p>0.05$). Recurrence rate at 6th month was 1.9% in the cleft lift group and 3.8% in the modified Limberg flap group, and the difference was insignificant ($p > 0.05$).
Conclusion: There was no difference in the recurrence rate during the first year after surgery between the two surgical techniques. The cleft corneal lift technique showed more favorable patient outcomes in terms of early postoperative wound dehiscence, maceration, time to vacuum drainage removal, duration of surgery, length of hospital stays, and return to normal activities.

Keywords
pilonidal sinus, natal cleft, modified Limberg flap, cleft lift

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Introduction

Pilonidal sinus is an inflammatory disorder localized in the sacrococcygeal region that can be acute or chronic, and in which one or more sinus openings can be observed.[1] Pilonidal sinus develops as a chronic inflammatory process in the intergluteal groove and is most common in young patients.[2] The anatomical site where the pilonidal sinus is most commonly found is the coccyx region, also known as the sacral region.[3] A higher incidence is reported in men and in various occupational groups.[4] The average age of onset is early years in men and in women, and is rare in patients aged 45 years and older.[5] Acute pilonidal abscess is the most common clinical finding at the first presentation to a patient. Abscesses are recorded in approximately 30% of outpatient visits to the clinic.[6] The discharge is often painless, and patients complain of soiling their underwear. On examination, a small swelling and induration in the sacrococcygeal region are found.[7]

The most common complication in patients with PS is recurrent infection. Malignancy in pilonidal sinusitis is very rare, but cases of warty carcinoma and squamous cell carcinoma have been reported.[8,9] If signs of inflammation or infection are present, antibiotics are prescribed and warm compresses are recommended.[10,11] The abscess is usually located on the right or left lateral to the midline. Because of the delayed healing of the midline wound, the incision should be made laterally and longitudinally.[12,13,14] Secondary infections are considered to be the cause of early recurrence, while ineffective treatment of the underlying pathophysiological process is the cause of late recurrence.[15] To reduce or prevent recurrence in pilonidal sinus surgery, it is necessary to preserve midline scar tissue, prevent wound infection, avoid dead zones in the wound, and regularly depilate the sacrococcygeal area.[16] The choice of flap technique should be determined by the sinus shape, its complexity, and the method of filling the remaining space.[17] This study investigated the relationship between resection margins and flap width in the scaphoid region using a modified Limberg flap and gap-lifting surgical techniques in pilonidal sinus surgery, as well as recurrence and complications.

Materials and Methods

Research Model

This prospective, randomized, controlled study was designed to investigate the relationship between disease recurrence and complications associated with the use of the modified Limberg flap and buccal canal lift surgical technique, including resection margins and scaphoid flap width, in the surgical treatment of pilonidal sinus. Two groups were compared.

Patients

The study included 104 male and female patients aged 18 years and older diagnosed with chronic and primary pilonidal sinus, admitted to the Department of General Surgery, Gazi University Faculty of Medicine, between February 2018 and June 2019. The study was conducted considering the possibility of general, spinal, and epidural anesthesia in patients. Randomization was performed using the PASS computer program. Patients in one group underwent split-thickness lift (n = 52), while patients in the other group underwent modified Limberg flap (n = 52). Demographic data, education, occupation, weight, and height were recorded in all patients. Preoperative disease duration, history of abscess, and complaints of discharge and swelling were assessed in all patients. To compare the complication rates of cleft grafting and modified Limberg flap, the sample size was calculated using EpiInfo Statcalc statistical software, and the rates were 28% and 7% in the control and other groups, respectively, and the standard deviation was 5%, with a confidence interval of 95% and a power of at least 80%. It was determined that there should be at least 52 patients in the groups.

Inclusion Criteria:

- Age over 18 years
- Diagnostic chronic or primary PS
- Patients with chronic PS who underwent abscess drainage

Exclusion Criteria:

- Patients under 18 years
- Patients with acute PS abscess
- Recurrent cases
- Patients with immunosuppressive diseases

Operation Procedures

All patients underwent preoperative skin cleansing with depilatory cream and perioperative intravenous cefazolin 1 g. Surgeries were performed under spinal anesthesia. After anesthesia, patients were placed in the prone position. The scaphoid region was identified and delineated as described previously. Lateral tension was applied to the gluteal muscles using large adhesive strips attached to the edge of the operating table. This improved visibility and manipulation of the operative field. The operative field was swabbed three times with polyvinyl iodine-soaked sponges. All patients received 50 mg diclofenac sodium for postoperative pain control. All patients received daily postoperative dressings. Drains were removed when the drainage fluid volume decreased to less than 30 ml. Postoperative hospital stay, complications at 7 and 14 days, clinical data such as wound infection, suture removal time, wound dehiscence, and maceration observed during follow-up, and time to patient return to normal activity were recorded.

Cleft Lift

Bascom's cleft palate repair procedure began with the removal of the lesion through an asymmetric elliptical or non-elliptical skin incision, including the sinus openings, leaving the midline fat intact. The wound edges were then brought together and sutured to reduce their depth.

Modify Limberg Flap

After the patient was positioned on the operating table in the jackknife position and the scaphoid region was delineated, both gluteus maximus muscles were fixed to the edge of the operating table with bilateral tapes to expose the operative field. A modified Limberg flap technique was used. This modification was motivated by the observation that the likelihood of wound infection and wound dehiscence in this area is higher if the inferior edge of the Limberg flap is located above the midline.

Ethical Approval

This study was approved by the Ethics Committee of the Faculty of Medicine, Gazi University (Date: 12.02.2018, Decision No: 91).

Statistical Analysis

Nominal and ordinal data were described by frequencies. Measurement data were described by means, standard deviations, and ranges. In the analysis of variance, the Chi- Square test was used to assess differences between ordinal and nominal data. The Kolmogorov-Smirnov test was used to check the normality of measurement parameters. The t-test for independent samples was used to assess differences between normally distributed parameters, and the Mann-Whitney U test was used to assess differences between non-normally distributed parameters. All analyses were performed using SPSS 25.0 for Windows with a 95% confidence interval and a significance level of 0.05.

Reporting Guidelines

The study was reported in accordance with STROBE guidelines.

Results

82.7% of the cleft lift group and 88.5% of the modified Limberg flap group were males. The age mean of the cleft lift group was lower, whereas the BMI mean and complaint duration means were higher. 15.4% of patients in the cleft lift group and 26.9% of the modified Limberg flap group had a drainage history. Gender, age, BMI, complaint duration, and drainage history differences between groups were statistically insignificant (p>0.05) (Table 1).

The operation duration mean in the modified limber flap group (31.5 ± 3.5) was higher than the cleft lift group (46.3 ± 4.8). Similarly, the drain duration mean in the modified limber flap group (4.2 ± 0.7) was higher than the cleft lift group (5.2 ± 1.0). Pain levels of both groups were similar, and differences were statistically insignificant (p>0.05). Hospitalization duration mean in the modified limber flap group (1.1 ± 0.3) was higher than the cleft lift group (1.3 ± 0.6). The normal activity duration mean in the modified limber flap group (15.1 ± 2.3) was higher than in the cleft lift group (21.6 ± 2.5). Operation duration, drain duration, hospitalization duration, and normal activity duration differences between patient groups were statistically significant (p<0.05) (Table 2).

In the 1st week after the operation, maceration and wound dehiscence in the cleft lift group were 3.8%, whereas 17.3% in the modified Limberg flap, with statistically significant differences (p<0.05). Infection rate was 3.8% in the cleft lift group and 5.8% in the modified Limberg flap, with statistically insignificant difference (p>0.05). Maceration at the 2nd week rate was 5.8% in the cleft lift group and 13.5% in the modified Limberg flap, with a statistically insignificant difference (p>0.05). Wound dehiscence at the 2nd week rate was 3.8% in the cleft lift group and 11.5% in the modified Limberg flap, with a statistically insignificant difference (p>0.05). The recurrence rate at the 6th month was 1.9% in the cleft lift group and 3.8% in the modified Limberg flap group, and the difference was insignificant (p>0.05) (Table 3).

Discussion

This study compared the modified Limberg flap and the split sinus lift technique in the surgical treatment of chronic pilonidal sinus in terms of recurrence and postoperative characteristics. For this purpose, a prospective analysis of 104 patients was performed, 52 of whom had CFS diagnosed using both techniques. The results showed that although the recurrence rate in the first year was not significantly different, the split sinus lift technique provided more favorable postoperative results.

Table 1. Demographic properties, complaint duration and drainage history of patient groups and difference analysis results

	Cleft Lift (n=52)	Modified limberg flap (n=52)	p value
Gender, n (%)			
Male	43 (82.7)	46 (88.5)	0.587[a]
Female	9 (17.3)	6 (11.5)	
Age, mean ± SD	26.6±7.02 (18-41)	27.2±11.1 (18-64)	0.459[b]
BMI, mean ± SD (min-max)	24.9±2.4 (20-31)	24.8±2.3 (20-33)	0.810[b]
Complaint duration, month, mean ± SD	13.5±12.0	13.3±9.1	0.694[c]
Drainage history, n (%)	8 (15.4)	14 (26.9)	0.138[a]

a. Chi-Square Test, b. Mann Whitney U Test, c. Independent Samples t-test, BMI: Body Mass Index, SD: Standard Deviation.

Table 2. Operation outputs of patient groups and difference analysis results

Mean ± SD (min-max)	Cleft Lift (n=52)	Modified limberg flap (n=52)	p value
Operation duration, min	31.5±3.5 (25-45)	46.3±4.8 (35-55)	0.000[a]
Drain duration, day	4.2±0.7 (3-5)	5.2±1.0 (3-10)	0.000[a]
Pain VAS	4.7±0.9 (3-7)	4.7±0.9 (3-7)	0.937[a]
Hospitalization duration, day	1.1±0.3 (1-3)	1.3±0.6 (1-3)	0.000[a]
Wound healing, day	10.3±1.5 (8-15)	10.8±2.1 (9-20)	0.105[a]
Normal activity duration, day	15.1±2.3 (15-25)	21.6±2.5 (15-30)	0.000[a]

a. Mann Whitney U test, VAS: Visual Analog Scale, SD: Standard Deviation.

Table 3. Post operation control outputs of patient groups and difference analysis results

	Cleft Lift (n=52)	Modified limberg flap (n=52)	p value
Maceration at 1st week, n (%)	2 (3.8)	9 (17.3)	0.029[a]
Wound dehiscence at 1st week, n (%)	2 (3.8)	9 (17.3)	0.029[a]
Infection at 2nd week, n (%)	2 (3.8)	3 (5.8)	0.359[a]
Maceration at 2nd week, n (%)	3 (5.8)	7 (13.5)	0.162[a]
Wound dehiscence at 2nd week, n (%)	2 (3.8)	6 (11.5)	0.229[a]
Recurrence at 6th month, n (%)	1 (1.9)	2 (3.8)	0.336[a]

a. Chi-Square Test.

Pilonidal sinus occurs three to four times more frequently in men than in women and is more common in people with heavy body hair.[18] In Kooistra's study.,[19] 73.7% of patients were men, while in McCallum's.[20] series this figure was 80%. In our study, 82.6% of patients in the cleft lift group were men, while in the modified Limberg flap group, it was 88.4%. In this regard, the demographic data of our study are consistent with the literature. A study conducted at the University of Minnesota showed that most students with PD were more obese than those without PD.[21] Sondenna et al., in their study of 322 patients, found an obesity rate of 37%.[22] A study by Karydakis in the Greek army showed that the increased rates of PD may be due to the increased weight of the soldiers.[23] Cubukcu et al found no significant difference in BMI between patients with and without PD.[24] Dutkiewicz et al found a mean BMI of 26.13 kg/m^2.[25] In our study, the mean BMI was 24.86 kg/m^2 in the gap lift group and 24.84 kg/m^2 in the modified Limberg flap group. In our study, maceration and wound dehiscence in the cleft lift group were 3.8%, whereas 17.3% in the modified Limberg flap occurred in the first week. The infection rate was 3.8% in the cleft lift group and 5.8% in the modified Limberg flap. Maceration at the 2nd week rate was 5.8% in the cleft lift group and 13.5% in the modified Limberg flap. Wound dehiscence at the 2nd week rate was 3.8% in the cleft lift group and 11.5% in the modified Limberg flap. Recurrence rate at the 6th month was 1.9% in the cleft lift group and 3.8% in the modified Limberg flap group, and the difference was insignificant. According to the obtained results, although the recurrence rate in the first year did not differ significantly, the gap-tightening method gave more positive results in favor of the patient in the postoperative period.

Recurrence is one of the most significant complications in PS cases and deserves attention for both cost and patient comfort. In our study, although the recurrence rate in the first year was not significantly different, the split sinus lift technique provided more favorable postoperative results. These results suggest that more comprehensive information about recurrence can be obtained with larger patient numbers and in multicenter studies.

Limitations

The most significant limitation of the study is the high number of patients lost to follow-up in the patient follow-up system. Because Türkiye has both private and public hospitals, patients frequently change healthcare facilities, resulting in a high number of patients lost to follow-up. Another limitation is the retrospective nature of the study.

Conclusion

It has been suggested that the scaphoid region represents a limitation that should be considered when planning the flap width in lateral flap surgery, and the success rates of traditional surgeries performed in this region have been found to vary. No difference in the first-year recurrence rate was observed between the two surgical techniques. However, the cleft lip lift technique has shown more favorable patient outcomes in terms of early postoperative wound dehiscence, maceration, time to vacuum drainage removal, duration of surgery, length of hospital stays, and return to normal activities.

Ethics Declarations
The authors declare that all procedures performed in this study were conducted in accordance with institutional, national, and international ethical standards.

Animal and Human Rights Statement
All procedures involving human participants were conducted in accordance with the Declaration of Helsinki and its later amendments.

Informed Consent
Written consent forms were obtained from the patients.

Data Availability
The datasets used and/or analyzed during the current study are not publicly available due to patient privacy reasons but are available from the corresponding author on reasonable request.

Conflict of Interest
The authors declare that there is no conflict of interest.

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None.

Author Contributions (CRediT Taxonomy)
Conceptualization: H.B., S.L.
Methodology: H.B., S.L.
Data Curation: H.B.
Formal Analysis: H.B.
Investigation: H.B., S.L.
Writing – Original Draft: H.B.
Writing – Review & Editing: S.L.
Supervision: S.L.

Scientific Responsibility Statement
The authors declare that they are responsible for the article's scientific content, including study design, data collection, analysis and interpretation, writing, and some of the main line, or all of the preparation and scientific review of the contents, and approval of the final version of the article.

Abbreviations
BMI: Body mass index
PS: Pilonidal sinus
SPSS: Statistical Package for the Social Sciences

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