A prospective randomized trial comparing modified Limberg flap and cleft lift procedure in the treatment of uncomplicated sacrococcygeal pilonidal disease

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Background
Sacrococcygeal pilonidal disease (SPD) is a common and frustrating problem, but there is still no consensus on the optimal treatment. Many studies recommend off-midline closure if any excision is to be done. The aim of this study was to compare the modified Limberg flap (MLF) and cleft lift procedures.

Patients and methods
From February 2010 to February 2013, the authors prospectively studied 200 patients with SPD who presented at two hospitals. The patients were randomly assigned to undergo either MLF transposition ($n = 100$) or the cleft lift procedure ($n = 100$). Surgical findings, complications, recurrence rates, and degree of patient satisfaction were compared.

Results
Operation time was longer in the MLF group. There was no significant difference between the two groups in terms of time to complete healing, time off work, complication rate, and recurrence rates. The two groups reported similar rates of satisfaction. Length of hospital stay was slightly longer in the MLF group because of delay in drain removal. During the follow-up period of 21.5 ± 6.8 months for group 1 and 22 ± 7.6 months for group 2, a single case of recurrence (1%) was detected in group 2 versus two patients (2%) in group 1.

Conclusion
On the basis of the results of this study, the MLF technique and the cleft lift procedure appear to generate comparable results in the management of SPD. Both techniques are safe and easy to learn and have now become our standard procedures for treating chronic, symptomatic SPD.

Introduction

Sacrococcygeal pilonidal sinus disease (SPD) is a common chronic disease occurring in the natal cleft of the sacrococcygeal region and it is more common among young adults [1]. It is generally considered an acquired pathology caused by the presence of hair within a deep natal cleft [2]. Thus, for treatment and prevention, these causative factors must be eliminated [3]. A number of therapeutic strategies have been proposed, ranging from mostly conservative methods to more dramatic procedures such as fasciomyocutaneous flap techniques that incorporate specialized vascular supplies [4]. Although different surgical approaches have been used to manage SPD, none of these approaches eliminate the postoperative morbidity, including delayed wound healing, discomfort, and high rate of recurrence, which range between 1 and 43% in different studies [5]. Wide excision carried out to the sacrococcygeal fascia with an open wound is probably the most popular treatment with a recurrence rate of 5–13% [6]. Management of the resultant defect in the tense sacral region appears to be the most important issue in the surgical treatment of pilonidal disease

because this step is closely related to postoperative morbidity and recurrence [7,8]. A midline scar seems to put patients at higher risk for poor wound healing and recurrence [9]. A theoretical option aiming to improve surgical outcomes and reduce the median recurrence rate involves the lateralization of the natal cleft [2,9]. Skin flaps have been described to cover a sacral defect after wide excision; this keeps the scar off the midline and flattens the natal cleft. The techniques available include cleft closure, advancement flap (Karydakis procedure), local advancement flap (V-Y advancement flap), and rotational flap [Limberg flap, modified Limberg flap (MLF), gluteus maximus myocutaneous flap] [10–12]. Although the rhomboid excision and Limberg flap techniques promise successful results, the recurrence rate following Limberg flap procedures has been reported to range

from 0 to 7% and has primarily been encountered at the lower portion of the incision left on the intergluteal sulcus [13,14]. The MLF procedure for pilonidal disease was described by Mentes and colleagues in 2004. The recurrence rate in his study was 0% and healing time was 2 weeks [12,15]. Asymmetric closure techniques have been described by both Karydakis [16] and Bascom [17]. Bascom describes a thin skin flap mobilization, leaving the deep inflamed tissue in place, and skin closure. Both methods share excellent results. Karydakis reports a less than 1% recurrence rate and Bascom reports a 100% healing rate after minor revisions or a second cleft lift in 9–10% of his patients with refractory pilonidal sinus disease [18]. The best operations that allow the wound to be closed lateral to the midline and induce flattening of the natal cleft are MLF and Bascom cleft lift. However, there have been few clinical studies comparing the two, and information as to which of these two approaches is better is lacking. In this prospective study, the results and perioperative findings including short-term and long-term outcomes were analyzed and compared with the evaluation of patient satisfaction and comfort toward the surgical techniques.

Patients and methods

We conducted a prospective study during the period from February 2010 and February 2013.

A total of 232 patients with symptomatic pilonidal disease were referred to our outpatient clinics. In all, 200 of them were eligible for the study as the patients who presented with acute pilonidal abscesses were excluded from the study and all patients were healthy adults without coexisting disease of American Society of Anesthesiologists (ASA) category 1.

Before starting our study, approval was obtained from the ethics committee of each hospital, and each patient was informed about the goal and nature of the study, and written consent was obtained.

Patients were randomized through a computer-generated schedule to undergo either the MLF (group 1) or cleft lift procedure (group 2).

Surgical procedure

All patients were admitted to the hospital on the day of surgery. The natal cleft was shaved at the time of surgery. Patients underwent surgery under general anesthesia. A dose of prophylactic cephalosporin was given intravenously during the induction of anesthesia. The patient was placed in the prone Jack-Knife position with legs apart, an elevating cushion beneath the pelvis,

with two adhesive straps in each gluteal region to allow better visualization of the natal cleft. The operation side was cleaned with 10% povidone-iodine.

Group 1: rhomboid excision and the modified Limberg flap technique

MLF operation was performed according to the technique described by Mentes *et al.* [12]. At the beginning of the procedure we marked the incision and wide rhomboid excision including postsacral fascia, taking care to remove all sinus tracts en block plus a rim of healthy tissue surrounding the cyst and sinuses. The inferior apex of the excised rhomboid area was placed ~1.5–2 cm lateral to the midline on the side opposite to the donor area. A right or left fasciocutaneous Limberg flap was elevated off the gluteal fascia contralateral to the asymmetric lower corner with careful dissection to avoid damaging the feeding arteries located in the inferior aspect of the flap. Then the flap was transposed medially to fill the defect without tension. The defect on the gluteal region was closed primarily. The subcutaneous layers were approximated with 2-0 vicryl interrupted over a vacuum drain, and the skin was closed with 2-0 proline interrupted sutures, which were removed on postoperative day 14, as shown in Fig. 1.

Group 2: Bascom cleft lift technique

The operative technique was essentially performed as previously described by Dr John Bascom [17].

The airless cleft (defined as the region of the natal cleft that is warm, moist, and airless when the patient is seated) was marked. The patients were placed in prone position with the buttocks taped apart to expose the deep intergluteal cleft. An ellipse of skin 4-cm wide including all pilonidal sinus openings and scars was removed

Figure 1
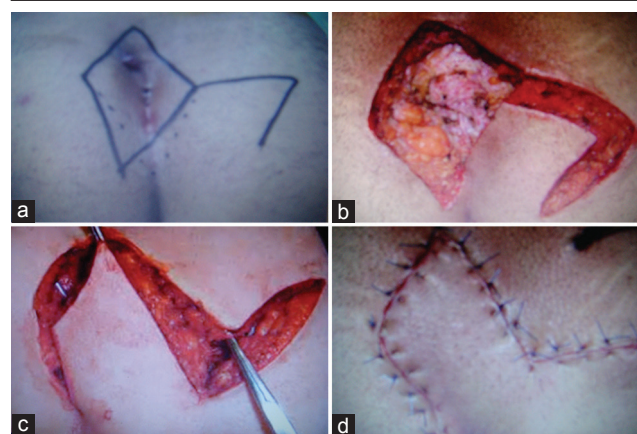
(a) Incision marking, (b) Elevation of the flap, (c) Rotation of the flap, (d) Wound closure.

asymmetrically from the most affected side of the intergluteal cleft while sparing subcutaneous fat. The sinuses remaining in the deeper tissues were curetted thoroughly. The covering skin flap from the opposite side was undermined and elevated to a distance required to allow primary closure of the defect away from the midline without tension. Hemostasis is maintained and a suction drain was placed deep in the entire length of the wound. The subcutaneous tissue was approximated in two layers with an absorbable suture while the skin was closed with a nonabsorbable intradermal suture that was removed after 14 days, as shown in Fig. 2.

Postoperative care and follow-up
Oral intake was started 6 h after surgery and patients were allowed to walk 12 h after surgery but instructed not to overextend the sacral region until they were free of pain and tension.

Vacuum drain was removed when 24 h output was 10 ml or less; patients were kept in the hospital for one more day to observe the wound and then discharged.

Patients were instructed to avoid prolonged sitting until 4 weeks postoperatively to avoid wound disruption, to avoid heavy sports for 3 months, and were asked to improve local hygiene and to depilate hair around their gluteal area.

Patients were seen at our outpatient clinics 2 weeks and 1 month after discharge and regularly examined every 3 months for the first year, and annually thereafter.

Data obtained during the in-hospital period included patient demographics, duration of operation, mobilization time (time needed for the patient to move without pain), length of hospital stay, surgical drain use and removal time, and early complications.

During follow-up, patients were asked to answer a questionnaire that included postoperative visual analogue scale for pain from 0 (no pain) to 10 (worst pain), questions on time taken to be able to sit without pain, time taken to be able to walk without pain, time taken to feel completely healed, degree of satisfaction, and whether they would recommend this surgical technique to other pilonidal sinus patients.

Postoperative complications (seroma, flap edema or necrosis, wound dehiscence) and recurrence were recorded. All obtained data were entered into another specially prepared chart.

The operation was considered early failure if the patient suffered from purulent discharge, abscess formation, or complete wound disruption that required further treatment within 4 weeks of the operation.

Statistical analysis
Data on both groups were collected and statistically analyzed using SPSS for Windows 10 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were described as mean ± SD and qualitative data as frequency and proportion. To test the statistically significant difference between groups, the Student t-test was used to compare quantitative data and the χ^2-test and Fisher's exact test were used for qualitative data.

A P value of less than 0.05 was taken to indicate statistical significance.

Results
A total of 200 patients were included in our study, 155 male and 45 female. They were randomly divided into two groups. Group 1 underwent MLF; the median age of the group was 23 years (range

Figure 2
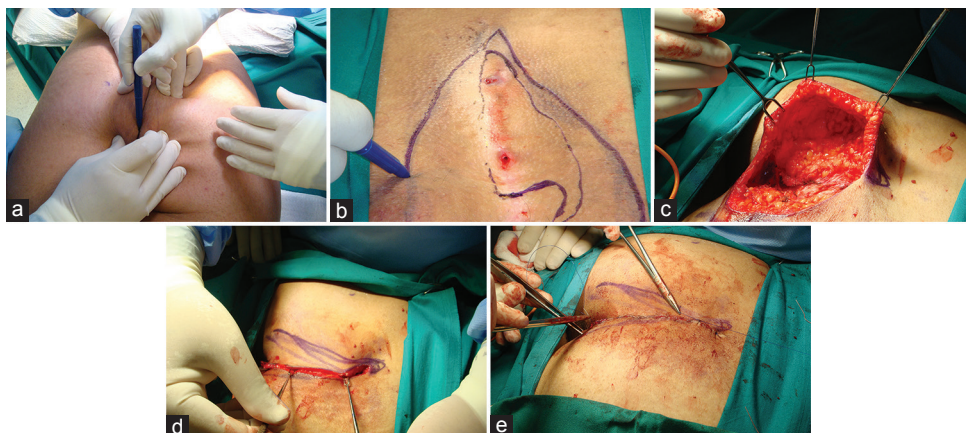
(a) Approximation of buttocks, (b) Incision marking (c) Elevation of the flap, (d) Approximation of two edges, (e) Wound closure.

18–44 years). Group 2 underwent Bascom cleft lift procedure with a median age of 22 years (range 19–52 years). Intermittent discharge and pain were the main presenting symptoms in both groups. There were no significant differences between the two groups in terms of demographic data, duration of disease, and symptoms of presentation, as shown in Table 1.

Data collected during the in-hospital and early postoperative period are shown in Table 2.

Significant difference was found between the two groups in term of operative time (46.3 ± 10.3 min for MLF vs. 34.5 ± 14.7 min for Bascom cleft lift procedure, $P < 0.001$) and hospitalization period, with patients in the MLF group staying longer in the hospital because of delay in drain removal. No significant difference was found between the two groups in terms of pain score, period off work, and healing period. With respect to the incidence of early complications, there was no significant difference between the two groups. Most of the complications were detected during the period of hospitalization or during the first outpatient visit. Five patients in the MLF group and three patients in the Bascom cleft lift group suffered from minor collection (seroma and/or hematoma), but prolonged antibiotic use and/or simple drainage solved the problem. Temporary flap edema occurred in seven patients in both groups but no flap necrosis was detected. Four patients in each group experienced variable degrees of healing failure and wound separation. Three patients in the Bascom cleft lift group had minimal superficial wound separation requiring only top dressing without packing, which healed completely without surgical intervention, and the fourth had more significant breakdown that failed to heal by secondary intention and was considered as recurrence. Regarding the MLF group, two patients required partial suture removal and healing by secondary intention, but the other two had complete reopening of the wound and failure to heal, which was considered as recurrence.

The data collected through the questionnaire are shown in Table 3.

Both groups showed comparable results with no significant difference regarding the use of analgesia and time taken to be able to sit on a chair or ride a car without pain. Patients in both groups showed similar degrees of satisfaction as two patients in each group were not satisfied (patients who suffered wound dehiscence and recurrence) and four patients in each group will not recommend the procedure to others.

Discussion

SPD is a chronic inflammatory disease that generally affects adults under the age of 45 years [19].

Pilonidal sinus disease was believed to be caused by congenital remnant [20,21].

Nowadays SPD is believed to be an acquired disease explained by endocrine changes with the initiation of puberty, as the secretion of sebaceous glands becomes more viscous, accumulation of keratin distends the hair follicles in the midline [14,22], increased depth of intergluteal sulcus leads to anaerobic media and

Table 1 Demographic data and presentation of disease

Characteristic	Modified Limberg flap (group 1) (*n*=100)	Bascom cleft lift (group 2) (*n*=100)	*P* value
Age (years)	23 (18-44)	22 (19-52)	NS
Male: female	80/20	75/25	NS
Follow-up (months)	21.5±6.8	22±7.6	NS
Symptom duration (years)	1.6	1.5	NS
Preoperative symptoms			NS
Discharge	80	78	
Pain	65	67	
Pruritus	6	4	
Granulation tissue	4	3	

Table 2 Outcome after surgical treatment

Clinical outcome	Modified Limberg flap (group 1) (*n*=100)	Bascom cleft lift (group 2) (*n*=100)	*P* value
Operative time (min)	46.3±10.3	34.5±14.7	<0.001
Mobilization time	1.6	1.5	1.000
Pain score (VAS)	3.4±1.5	3.7±1.6	0.495
Hospital stay (days)	3.8±1.6	2.1±1.2	<0.001
Period off work	21.4±7.5	18.7±7.6	0.087
Healing period (days)	19.6±16.7	23.5±8.5	0.148
Early complications (*n* (%))	13 (13)	10 (10)	0.467
Seroma and/or hematoma	5	3	
Flap edema	4	3	
Wound dehiscence	4	4	
Recurrence (*n* (%))	2 (2)	1 (1)	

VAS, visual analogue scale.

Table 3 Comparison of the results obtained using a questionnaire

	Modified Limberg flap (group 1) (*n*=100)	Bascom cleft lift (group 2) (*n*=100)	*P* value
Use of analgesia (days)	4.6±1.5	4.3±1.4	NS
Sitting without pain (days)	10±5.3	9.2±4.2	NS
Degree of satisfaction			NS
Excellent	80	83	
Good	16	13	
Poor	2	2	
Unsatisfied	2	2	
Number of patients recommending operation to others (*n* (%))	96 (96)	96 (96)	NS

increased anaerobic bacterial content [3,23], and the vacuum effect between heavy buttocks sucks the anaerobic bacteria, hair and debris into subcutaneous fat tissue and initiates the pilonidal disease [14,24].

Moreover, studies have reported that obesity, excessive sweating, bad hygiene, long period of sitting, and hirsutism can cause SPD [14,21,25].

Most standard techniques for treating SPD have a significant failure rate because they fail to address the underlying factors that result in persistent nonhealing or recurrence [26]. The ideal technique should be simple, quick, and cost-effective, should not require a long hospital stay, should involve easy wound care, low complication and recurrence rates, and should allow the patient to return to normal activities rapidly [27,28].

Complete excision of the sinus is widely practiced, but controversy remains about what to do with the wound after excision [10]. Recurrence rate after excision with packing, with marsupilization, and with primary closure was 22, 23, and 25%, respectively [14]. Almost all of the postoperative recurrences and complications were encountered in the midline, and the problems related to a continuing natal cleft after pilonidal sinus surgery have prompted surgeons to discover techniques to eliminate the gluteal furrow [3].

Since Karydakis and Bascom emphasized the principles of off-midline closure and flattening of the natal cleft owing to the importance of depth of the natal cleft, the recurrence rate of pilonidal disease has significantly decreased, but these techniques may fail in those with branching fistulas far from midline, extending to each side of the buttocks [14,16,29].

The aim of this technique is to relocate hair follicles away from the midline and to prevent the frictional forces associated with insertion in the natal cleft. Initially, the rhomboid flap technique was reserved for complex or recurrent pilonidal disease not responding to simple conservative operative techniques, but it has been subsequently recommended as first-line management for all types of chronic SPD [2,30]. The only weak point of the classical rhomboid excision and Limberg flap transposition is that the lower pole of the flap stays in the intergluteal sulcus, and all of the recurrences are encountered at this site [14]. Different modifications of Limberg flap have been proposed to overcome this problem: Mentes *et al.* [12] obtained 0% recurrence rate and 0.8% wound infection rate without any dehiscence or flap necrosis. Kaya *et al.* [28] found 4.2% recurrence, 5.3% wound infection rate, and 1.1% wound dehiscence rate. Afsarlar *et al.* [14] reported 0% recurrence.

In our study, we compared two widely used approaches to determine the most appropriate treatment modality for SPD.

As a rule in surgery, the surgical procedure selected should be as simple as possible. In the present study, the duration of operation was significantly shorter for cleft lift procedure and this was attributed to the shorter time needed for mobilization of a flap without real transposition, although there was only a mean difference of 12 min between the two procedures.

Length of hospital stay is an indicator of higher morbidity of the surgical technique. In our study, the duration of hospital stay in patients treated with MLF was 3.8 ± 1.6 days, which was significantly higher than that for the cleft lift group (2.1 ± 1.2 days). This could be explained by the delay in drain removal in the MLF group because of more dissection and more wide dead space. An overview of the literature published recently shows that the mean length of hospital stay ranged from 2 to 4 days for patients undergoing MLF [4–12–15] and 1–2 days for patients undergoing cleft lift [17,18]. On the basis of our work and others, neither of the two procedures offers a clear advantage over the other.

There were no differences between the two groups in terms of the time required for them to return to work, which was 21.4 ± 7.5 for the MLF group, which was similar to that reported by Can *et al.* [4] and Karaca *et al.* [15], and 18.7 ± 7.6 for the cleft lift group, which is comparable to the results of Rushfeldt *et al.* [18] and Nordon *et al.* [31].

The time required to feel completely healed was longer in the cleft lift group than in the MLF group (23.5 ± 8.5 vs. 19.6 ± 16.7, respectively), but the difference was not significant. This could be attributed to more tension exerted on the midline because of lateral dissection in the cleft lift group. We found that it is difficult to include bilaterally situated orifices in the excised islands in the cleft lift group, and in this situation MLF is preferred. Can *et al.* [4] showed a longer period for healing in the MLF group (36.2 ± 10.1 days), and Karaca *et al.* [15] showed results similar to our study. For cleft lift procedure Nordon *et al.* [31] and Gendy *et al.* [26] showed comparable results.

In the current study, there were no significant differences between the two groups in terms of postoperative pain scores (visual analogue scale scores) (3.4 ± 1.5 in the MLF group and 3.7 ± 1.6 in the cleft lift group).

The main measure in our study was the overall complication rate, and in this regard our two groups were similar with complication rate of 13% in the

MLF group (5% seroma, 4% flap edema without necrosis, and 4% wound dehiscence) and 10% in the cleft lift group (3% seroma, 3% flap edema, and 4% dehiscence). In a series of studies examining the MLF flap, an infection rate of 0.8% was noted; no flap necrosis or wound dehiscence occurred, similar to the results of Mentes *et al.* [12]. Karaca *et al.* [15] reported a complication rate of 4.2%, with only 4.2% seroma and no dehiscence or wound infection, and Yildiz *et al.* [21] reported 6.2% wound dehiscence and seroma. In contrast, for cleft lift procedure Gendy *et al.* [26] and Bascom [17] showed 15 and 10% degree of wound dehiscence, respectively, but 97.4 and 100% showed complete healing later on.

Most of the complications encountered in our patients were recognized at the time of follow-up within the first month postoperatively. These patients did not fully comply with the instructions we provided them regarding regional hygiene, hair removal, and sitting habits.

Preventing recurrence is a major concern in the surgical treatment of pilonidal sinus. The documented incidence of recurrence after cleft lift procedure is between 0 and 2.6% [17,26,31,32] and between 0 and 5.4% in the MLF procedure. [2,4,14,15]. Those results matched with our study as we had one patient with recurrence in the cleft lift group (1%) and two patients in the MLF group (2%). Our successful results after both types of flaps came from the fact that the deep midline is eliminated.

Degree of satisfaction and quality of life of patients after surgery depend on the development of complications. Ertan *et al.* [33] found more satisfaction with the flap technique than with primary closure in the midline. In another study by Mahdy [3], the superiority of the classic and MLF techniques was documented in terms of patient satisfaction and comfort. In our study, patients in the two groups reported a similar rate of satisfaction with most of them rating the procedure as excellent (80 and 83% in the MLF group and cleft lift group, respectively). Ninety-six percent in each group stated that they would recommend the operation to others who have the same diagnosis.

Conclusion
The results of our study suggest that MLF transposition and cleft lift procedure have no superiority over each other. Earlier healing, shorter time off work, low recurrence rate, and shorter hospital stay are the main advantages of both techniques. Both operations are safe, simple, and easy to learn and should be used in noninfected pilonidal sinus disease to cover the excised defect.

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