

# Randomized clinical trial comparing primary closure with the Limberg flap in the treatment of primary sacrococcygeal pilonidal disease

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**Background:** The purpose of the study was to compare the outcome of excision and primary closure with that of rhomboid excision and the Limberg flap procedure in patients with primary sacrococcygeal pilonidal disease (SPD).

**Methods:** Two hundred consecutive patients with SPD were randomly allocated to undergo either excision and primary closure (group 1,  $n = 100$ ) or rhomboid excision and the Limberg flap procedure (group 2,  $n = 100$ ). Duration of operation, postoperative pain, time to first mobilization, length of hospital stay, postoperative complications, time to resumption of work, recurrence and time to recurrence were recorded for all patients.

**Results:** Duration of operation was longer in group 2 than in group 1 ( $P = 0.001$ ). However, postoperative pain was less ( $P < 0.001$ ), mobilization earlier ( $P < 0.001$ ), duration of hospital stay shorter ( $P < 0.001$ ), time to resumption of work shorter ( $P < 0.001$ ) and postoperative complications fewer ( $P < 0.001$ ) in group 2. During a median follow-up of 28 months, no recurrence was detected in patients in group 2 versus 11 patients in group 1 ( $P = 0.001$ ).

**Conclusion:** Because of its low complication rate and acceptable long-term results, rhomboid excision and the Limberg flap procedure is preferable to simple excision and primary closure in the treatment of SPD.

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## Introduction

Sacrococcygeal pilonidal disease (SPD) is a common condition that affects younger patients. It causes discomfort that may interfere with education or employment, sometimes for prolonged periods. The aetiology is uncertain, but relates to the implantation of loose hair into the depth of the natal crease. Factors that influence this are the nature of the hair itself, the force of implantation and the vulnerability of the skin<sup>1</sup>.

More than half of the patients affected present with a sacrococcygeal abscess. A number of surgical treatment options exist: simple incision and drainage, lying open, marsupialization, excision and primary closure, or rhomboid excision and the Limberg flap procedure<sup>2–5</sup>. Simple excisional techniques are associated with high morbidity and recurrence owing to the continuing presence

of the natal cleft. Recurrence rates of 7–42 per cent have been reported following excision and primary closure<sup>6,7</sup>, while a number of studies have reported a recurrence rate of 0–3 per cent after rhomboid excision and Limberg flap repair<sup>8–11</sup>. There has, however, been no randomized clinical study to compare rhomboid excision and the Limberg flap procedure with other conventional procedures for SPD. The aim of this study was to perform a prospective randomized clinical trial to compare rhomboid excision and the Limberg flap procedure with excision and primary closure in the treatment of SPD.

## Patients and methods

Between June 2001 and August 2002, 224 patients with symptomatic SPD were seen. Some 200 patients were eventually enrolled in the study. Chronic discharge was the

most common presentation (82 per cent); other symptoms included pain (37 per cent), abscess (14 per cent), pruritus (10 per cent) and bleeding (2 per cent). Patients with contraindications for general anaesthesia (two patients), those who had undergone previous surgery for SPD (17 patients) and those who did not accept randomization (five patients) were excluded. After obtaining written informed consent, patients were randomly allocated to undergo either excision and primary closure (group 1,  $n = 100$ ) or rhomboid excision and the Limberg flap procedure (group 2,  $n = 100$ ) by means of a computer-generated table of random numbers. The randomization was carried out by an independent computer consultant. Ethics committee approval was obtained for the study.

All patients were operated on under general anaesthesia. The operative field was shaved and cleaned with antiseptic povidone–iodine solution.

In group 1, the lesion was excised with a vertical elliptic incision to the level of the sacrococcygeal fascia. After placing deep approximating 0 polyglactin sutures (Vicryl™; Ethicon, New Jersey, USA), the skin was approximated with 3/0 polyglactin interrupted subcutaneous sutures (Vicryl™; Ethicon, New Jersey, USA) and the skin edges were closed with 3/0 polypropylene interrupted mattress sutures (Propilen®; Dogsan, Trabzon, Turkey).

In group 2, the lesion was excised with a rhomboid-shaped incision (Fig. 1 – abcd) with each side equal in length. After extension of line cb and axis db, line be was created equidistantly between lines bc' and bd', with a length equal to the sides of the rhomboid excision. Line ef was drawn parallel to the ac axis, and was also of the same length. The depth of the rhomboid excision was extended to the gluteal fascia at lines be and ef. The rhomboid flap (cbef) was then rotated from the gluteal fascia to the excised area (abcd) without tension. Subcutaneous tissue and the skin were sutured separately with interrupted sutures (Vicryl™; Ethicon, New Jersey, USA; Propilen®; Dogsan, Trabzon, Turkey, respectively) (Fig. 2). At the end of the procedure, a suction drain was inserted. Methylene blue was not used to identify the tracks in either group. A single dose of antibiotic prophylaxis was used immediately before incision.

Postoperative wound care consisted of regular shaving of the operative field and hygienic measures. Skin sutures were removed on the tenth postoperative day.

The duration of operation, postoperative pain, time to first mobilization, length of hospital stay, duration of incapacity for work, postoperative complications (infection, flap oedema, wound dehiscence), and postoperative recurrence and time to recurrence were recorded. Duration of operation was defined as the length of time between the

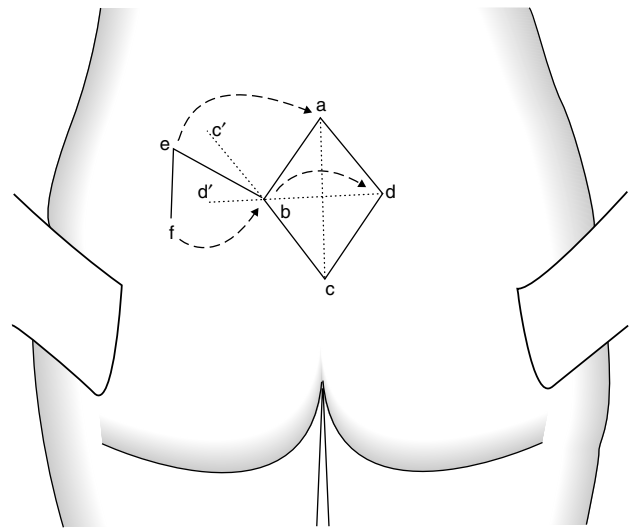


Fig. 1 Rhomboid excision of the Limberg flap

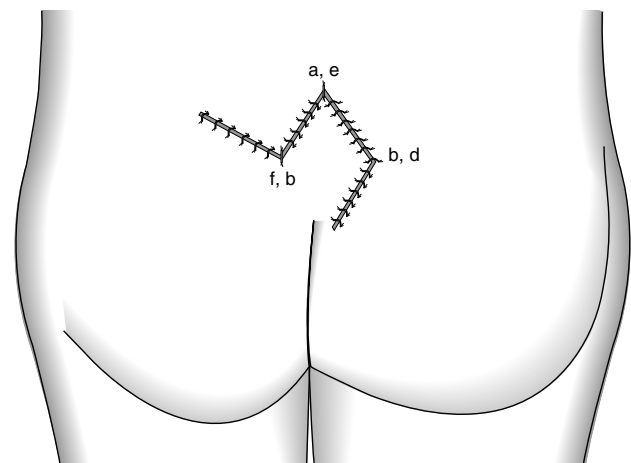


Fig. 2 Final view of the Limberg transposition flap

first incision and placement of the last suture. Postoperative pain was assessed according to a visual analogue scale (VAS) from 0 (no pain) to 10 (worst pain imaginable) on the first postoperative day. Patients were discharged from hospital when the drain had been removed and intramuscular analgesia was no longer required. Duration of incapacity for work was defined as the time from the date of surgery to the date on which the patient returned to normal activities including employment and leisure activities. A questionnaire was used to assess the duration of recovery.

The patients were seen 1 week and 1 month after surgery, and then every 3 months for at least 23 months during the follow-up period. The incidence of recurrence was recorded.

## Statistical analysis

Student's *t* test was used for comparison of age between the groups. Differences in sex, complications, recurrence rate and number of recurrences were analysed with the  $\chi^2$  test. Time to first mobilization, length of hospital stay, duration of incapacity to work, follow-up period, duration of operation and VAS pain scores were analysed with the Mann–Whitney *U* test. Results are presented as medians with 25 and 75 per cent interquartile ranges (i.q.r.). Based on an expected recurrence rate reduction from 15 to 2 per cent, about 90 patients were required in each arm to detect a significant difference with a minimum  $\alpha$  error of 5 per cent and a  $\beta$  error of 10 per cent.

## Results

Group 1 consisted of 83 male and 17 female patients with a mean age of 28 (17–43) years, and group 2 comprised 85 male and 15 female patients of mean age 26 (15–60) years. No patient was lost during follow-up and all of the patients had been attended and evaluated. Median follow-up was 29 (23–38) months in group 1 and 28 (23–36) months in group 2, 28 (23–38) months for the whole series. There were no significant differences between the two groups with respect to age, sex or length of follow-up ( $P = 0.152$ ,  $P = 0.701$  and  $P = 0.881$  respectively).

Although the operating time was longer in group 2, the median VAS pain score was significantly lower in this group ( $P < 0.001$ ). Most patients in group 2 were mobilized on the first postoperative day, and the median time to first mobilization was earlier in group 2 than in group 1 (1 (1–1) versus 2 (1–2) days respectively;  $P < 0.001$ ). Morbidity developed in 24 patients in group 1 (infection, ten; flap oedema, 13; wound dehiscence, five) and in three patients in group 2 (infection, two; flap oedema, one) ( $P < 0.001$ ). The median duration of hospital stay was longer in group 1 ( $P < 0.001$ ). The median duration of incapacity for work

**Table 1** Operative and postoperative outcomes

	Group 1	Group 2	<i>P</i> *
Duration of operation (min)	45 (40–60)	60 (60–73)	0.001
Time to first mobilization (days)	2 (1–2)	1 (1–1)	< 0.001
Pain VAS score	4 (3–6)	2 (2–3)	< 0.001
Duration of incapacity for work (days)	19 (15–20)	9.5 (8–12)	< 0.001
Duration of hospital stay (days)	5 (4–6)	2 (2–2)	< 0.001

Values are median (interquartile range). VAS, visual analogue scale.  
\*Mann–Whitney *U* test.

**Table 2** Postoperative complications

	Group 1 ( <i>n</i> = 100)	Group 2 ( <i>n</i> = 100)	<i>P</i> *
Infection	10 (10)	2 (2)	0.017
Flap oedema	13 (13)	1 (1)	0.001
Wound dehiscence	5 (5)	0 (0)	0.022
Recurrence	11 (11)	0 (0)	0.001

Values in parentheses are percentages. \* $\chi^2$  test.

was 19 (15–20) days in group 1 and 9.5 (8–12) days in group 2 ( $P < 0.001$ ) (Table 1).

Recurrence was detected in 11 patients (11 per cent) in group 1, with time to recurrence of between 4 and 11 months. No recurrences were identified in patients in group 2. Complications and recurrence rates are shown in Table 2.

## Discussion

The main purpose of treatment for SPD is to provide a high chance of cure with minimal discomfort, a low complication rate and a low recurrence rate while at the same time avoiding prolonged hospital stay and ensuring a short duration of incapacity for work<sup>12</sup>.

Surgical treatment combines excision of the sinus tracts with or without marsupialization, primary closure or the Limberg flap procedure. Eryilmaz *et al.*<sup>10</sup> have advocated rhomboid excision and the Limberg flap procedure, especially in patients with recurrent or extensive disease. The low recurrence rates, shorter hospital stay and reduced duration of incapacity for work achieved may outweigh the disadvantages related to an unfavourable cosmetic appearance following rhomboid excision and Limberg flap closure.

Postoperative pain scores were significantly lower in group 2 than in group 1, presumably because less wound tension was created with the Limberg flap procedure. Postoperative complications included wound infection and flap oedema in patients who underwent rhomboid excision with the Limberg flap procedure. A wound infection rate of 1.5–6 per cent has been reported in different series<sup>10,13</sup>, and in the present study was 10 per cent in group 1 and 2 per cent in group 2. Lee *et al.*<sup>2</sup> reported a 10 per cent rate of wound dehiscence; in the present study 5 per cent of patients in group 1 had wound dehiscence and no dehiscence was detected in group 2.

In this study, time to first mobilization and duration of hospital stay were shorter in patients treated with rhomboid excision and the Limberg flap procedure, in keeping with the findings of both Urhan *et al.*<sup>14</sup> and Bozkurt and Tezel<sup>15</sup>,

who reported the mean length of hospital stay as 3.7 and 4.1 days, and the mean time to return to normal activity as 7 and 17.5 days, respectively. In contrast, excision and primary closure involves prolonged wound healing and delays return to work. The present study has confirmed a significantly shorter time to return to work in patients treated with the rhomboid excision and Limberg flap.

Recurrence after treatment of pilonidal disease is usually observed within the first 3 years<sup>16,17</sup>. The present results indicate that recurrence may be minimized with rhomboid excision and Limberg flap closure; no recurrence was observed in group 2, whereas the recurrence rate was 11 per cent in group 1. Other authors have reported recurrence rates of 0–3 per cent with Limberg flap repair<sup>11</sup>.

In conclusion, despite a longer operating time, rhomboid excision and Limberg flap closure, with its low complication rate and acceptable long-term results, is preferable to simple excision and primary closure in the treatment of SPD.

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