Official title : Comparison of Un-roofing Curettage With Rhomboid Excision and Modified Limberg Flap in the Surgical Treatment of Pilonidal Disease; A Retrospective Cohort Study

Brief title : Comparison of Un-roofing Curettage With Rhomboid Excision and Modified Limberg Flap

The trial was registered at clinicaltrials.gov (NCT04334681).

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STUDY PROTOCOL AND STATISTICAL ANALYSES

Study Population

Our study adhered to the Helsinki Declaration developed by the World Medical Association for medical research involving human material and data. The study protocol was approved by the University of Health Sciences Hamidiye Scientific Research Ethics Committee. Written informed consent was obtained from the participants. The trial was registered at clinicaltrials.gov (NCT04334681). This study retrospectively reviewed the data of 313 patients, older than 18 years, who underwent unroofing curettage (UC) and rhomboid excision and MLF surgeries at Konya Training and Research Hospital between January 2013 and January 2017.

Patients with common gluteal pilonidal disease, collagen tissue disease, and irregular diabetes mellitus were excluded. The data of 278 patients who did not have deficiencies in file and follow-up information were divided into the UC group (n, 135) and rhomboid excision and MLF group (MLF group; n, 143) and analyzed.

Preoperative antibiotic prophylaxis and anesthesia type

The hospital staff shaved all patients' hair around the natal cleft just before surgery. No antibiotics were used in either group.

Patients in the MLF group were operated on under spinal anesthesia. In the UC group, patient preference and the anesthetist's recommendation determined the type of anesthesia that was used. The local anesthetic agent was 2% prilocaine hydrochloride diluted with distilled water in a 1: 2 ratio. The patients who had reservations with local anesthesia were operated under spinal anesthesia.

Surgical procedure

The same surgeon performed all operations in the UC group. Operations in the MLF group were performed by another surgeon who conducted the study.

During both procedures, patients were placed in the prone position; the buttocks' cheeks were pulled laterally with adhesive tape, providing good exposure of the intergluteal area. The surgical site was disinfected with povidone-iodine solution.

Unroofing curettage procedure: A probe was passed through the sinus orifices for guidance; the skin was cut and the roof was opened. The hairs and necrotic debris in the sinus cavity were removed. Curettage was performed without excising the granulation tissue at the pit's base because excessive excision delays healing. We achieved hemostasis with monopolar diathermy. A drain was not used in this procedure. The cavity was filled with fine gauze soaked in standard saline solution (0.9% sodium chloride) as much as possible, and the dressing was closed **Modified Limberg flap procedure:** Pilonidal cyst and flap lines were marked with a sterile skin pen. The lower end of the rhombus was 1.5 cm lateral to the midline. The size of the fasciocutaneous flap was equal to the size of the rhombus. Under the guidance of methylene blue, the rhombus was excised up to the presacral fascia, and the fasciocutaneous flap was transposed medially. A suction drain was placed under the flap. Subcutaneous tissue was approximated with 2-0 absorbable braided polyglactin sutures. The skin was sutured with 3-0 nonabsorbable monofilament polypropylene stitches. Depending on the amount of discharge, the drain was removed on postoperative day 3 or 4. Sutures were removed 2 weeks postoperatively

Postoperative care

Patients who underwent the surgery under local anesthesia were discharged on the same day. Patients on whom spinal anesthesia was used stayed in the hospital for 1 or more days.

Antibiotics were not given to the patients in either group. An analgesic containing diclofenac sodium (50 mg bid) was prescribed, and patients were recommended to take it if they experienced pain.

Dressings were changed in the outpatient clinic for the first 3 days in the UC group. Afterward, the process of dressing was explained to the patient's relatives, and the dressing process was continued at home. We called the patient for follow-up at 7–10-day intervals.

In the MLF group, the wound was checked at 2-day intervals after discharge from the hospital. The surgeon removed the sutures after observing for complete wound epithelization. All patients in either group were followed up for wound complications for 1 month after discharge from the hospital.

Patients were contacted via telephone for follow-up at 6 months and 1 year postoperative. Following this, they were then contacted for an annual check. The patients were questioned regarding their degree of satisfaction with the surgery and the postoperative results (graded as excellent, good, not bad, and bad).[5] Surgeons recorded information on treatment, the healing process, follow-up examinations, readmission, reoperation, and revision on follow-up forms.

Statistical analyses

All statistical analyses were conducted using SPSS for Windows, version 22 (IBM Corp, Armonk, NY). Firstly, Kolmogorov–Smirnov and Shapiro–Wilk normality tests were performed. If the normality assumption could not be achieved in any group, nonparametric test methods were chosen. Secondly, the Mann–Whitney U test was performed to compare the obtained variables between groups.

The chi-square and Fisher exact tests were used to analyze the relationships or differences of categorical variables between groups.

Comparative results and other demographic characteristics between groups were presented with the ratio of qualitative variables. Quantitative variables are represented by means. A value of $p < 0.05$ was considered statistically significant.