



Epidural anesthesia for pilonidal sinus surgery: ropivacaine versus levobupivacaine

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Background: Epidural anesthesia is one of the best options for lower abdominal and lower limb surgery. However, there have been insufficient reports regarding the use of epidural anesthesia for pilonidal sinus surgery. The present study was performed to compare the clinical profiles of epidural block performed with 0.75% levobupivacaine and 0.75% ropivacaine in this procedure.

Methods: Thirty patients undergoing pilonidal sinus surgery were randomly allocated into two groups: one group received levobupivacaine and the other received ropivacaine at 0.75% in a volume of 10 ml. Arterial blood pressure, heart rate, oxygen saturation, the onset time of analgesia and duration of block, highest sensory block level, perioperative and postoperative side effects, and patients' and surgeons' satisfaction were recorded.

Results: Hemodynamic stability was maintained in both groups throughout surgery. The onset time of analgesia (the time from epidural injection of local anesthetic to reach L₂ sensorial block) was 6.26 ± 3.49 min in the levobupivacaine group and 4.06 ± 1.75 min in the ropivacaine group (P = 0.116). The duration of sensorial block (time for regression of sensory block to L₂) was 297.73 ± 70.94 min in group L and 332.40 ± 102.22 min in group R (P = 0.110). Motor block was not seen in any of the patients in the study groups. Patients' and surgeons' satisfaction with the anesthetic technique were mostly excellent in both groups.

Conclusions: In patients undergoing pilonidal sinus surgery, both levobupivacaine and ropivacaine produce rapid and excellent epidural block without leading to motor block or significant side effects. Although not statistically significant, the onset time of anesthesia was shorter and the duration of effect was longer with ropivacaine than with levobupivacaine in this study.

Key Words: Epidural anesthesia, Levobupivacaine, Pilonidal sinus surgery, Ropivacaine.

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Introduction

Anorectal surgical procedures are among the most common surgical operations; more than 90% of these procedures are performed on an ambulatory basis [1,2]. This surgery is performed frequently in adolescents and adults in Turkey. Local infiltration anesthesia, spinal anesthesia, and general anesthesia are commonly used anesthetic techniques for anorectal surgery [3-5].

However, there are a number of difficulties with these anesthesia techniques. Local infiltration anesthesia is frequently in-

adequate to provide painless surgery and is not comfortable for the patient. In this situation, the surgeon does not work under the best conditions and may be unable to complete the surgery easily and successfully. Therefore, the dose of local anesthetic has to be increased, which may lead to toxicity [6,7].

General anesthesia is used frequently. However, putting overweight patients into the prone position is especially difficult. Moreover, patients undergoing general anesthesia may experience complications due to this position leading to vertebral and limb injuries [8]. In addition, muscle relaxants must be given when general anesthesia is applied for endotracheal intubation. Postoperative nausea and vomiting are also problems after general anesthesia. These issues lead to an increased economic cost and delayed discharge from hospital [9,10].

Due to its more rapid onset, spinal anesthesia is commonly used for this procedure; however, spinal anesthesia is not safe for all patients (e.g., those with ischemic heart disease, and renal or hepatic diseases in which hypotension is harmful). Spinal anesthesia may be associated with significant side effects, such as hypotension, bradycardia, shivering, nausea, vomiting, significant headache, backache, and urinary retention [11]. The side effects of epidural anesthesia are similar to those of spinal anesthesia, but are less common and less serious [12]. However, few studies have addressed the use of epidural anesthesia for this procedure.

Levobupivacaine and ropivacaine are new long-acting local anesthetics that were developed following reports of bupivacaine-related severe toxicity. Both of these agents are pure left isomers, and based on their three-dimensional structure they have less toxicity to both the central nervous system and the heart. The clinical profiles of levobupivacaine and ropivacaine are similar to that of racemic bupivacaine, and the minimal differences among the three agents are mainly related to the slightly different anesthetic potency. They produce effects similar to other local anesthetics via reversible inhibition of sodium ion influx in nerve fibers [13-15]. We prefer to use both of these drugs because of their similarity.

The primary aim of this study was to compare the onset time of ropivacaine and levobupivacaine and to evaluate their other effects. The secondary aim was to assess the efficiency of epidural anesthesia in pilonidal sinus surgery.

Materials and Methods

Institutional approval from Medeniyet University Goztepe Training and Research Hospital and patient's written informed consent to participate in this study were obtained. Patients with neurological or neuromuscular disease, bleeding disorders, infection at the injection site, clinically significant cardiovascular, respiratory, renal, hepatic, or metabolic disease, history of allergic reactions to any local anesthetic drug and patients who

refused epidural anesthesia were excluded from the study. A total of 30 patients who were scheduled for pilonidal sinus surgery and American Society of Anesthesiologists (ASA) physical status I-II between 18 and 51 years of age was enrolled in this prospective, randomized study.

Patients were randomly assigned to receive one of the two local anesthetic drugs for epidural anesthesia. Patients were randomized using computer-generated random numbers, and information regarding the randomization was stored in sealed, consecutively numbered envelopes.

Routine preoperative evaluation of each patient was performed the day before surgery. The method of anesthesia was explained to the patients and questions about the procedure were answered. No premedication was given to the patients. In the operating room, an 18-G intravenous cannula was inserted and 15 ml/kg balanced crystalloid solution was administered to all patients. Standard monitoring was used throughout the study, including electrocardiography, non-invasive blood pressure, heart rate, and pulse oximetry (KMA 275; Petas, Ankara, Turkey).

All patients received epidural anesthesia using a standard midline approach in the sitting position. The insertion area was prepared using antiseptic solution and then 2 ml of 2% lidocaine were applied into the skin and subcutaneous tissue to induce local anesthesia. Then, 3-4 ml of 0.9% NaCl solution was injected through an 18-G Tuohy needle to find the epidural space at the L₃-L₄ or L₄-L₅ interspaces using the loss of resistance technique. Patients in group L received 10 ml of 0.75% levobupivacaine (Chirocaine[®], Abbott Laboratories, Chicago, IL, USA) and those in group R received 10 ml of 0.75% ropivacaine (Naropin[®], Astra Zeneca, Wilmington, DE, USA) for epidural anesthesia. After negative aspiration of blood, 3 ml of the study drug were injected as a test dose. Approximately 3-5 min later, the remaining dose was administered. An epidural catheter was not applied. After completion of epidural injection, patients were placed in the supine position. Mean arterial pressure (MAP), heart rate (HR), hemoglobin O₂ saturation values (SpO₂) were recorded every 5 min throughout surgery. An observer blinded to the group assignments recorded the evolution of sensory block (using the pinprick sensation test) and motor block by modified Bromage scale (0. No impairment; 1, unable to raise extended legs but able to move knees and ankles; 2, unable to raise extended legs as well as unable to flex knees, able to move feet; 3, unable to flex ankle, feet, or knees) [16]. The onset time of analgesia (the time from epidural injection of local anesthetic to reaching L₂ sensorial block), and levels of sensorial and motor block were recorded every 2 min. Maximum sensorial and motor block levels were also recorded. Patients were then moved into the prone position.

It was planned to treat bradycardia (HR < 50 beats/min) with

atropine (0.01 mg/kg), and hypotension (decrease in systolic arterial blood pressure 30% lower than baseline) with intravenous boluses of crystalloid solution or ephedrine (5–10 mg).

Patients were not sedated during surgery. It was planned to administer 1 µg/kg fentanyl as a supplementary analgesic if required. Perioperative and postoperative side effects, such as hypotension, bradycardia, shivering, nausea, vomiting, headache, backache, and urinary retention, were assessed for 2 h. A three-point scoring system was used to evaluate patients' and surgeons' satisfaction with the anesthetic technique, in which 1 is poor, 2 is good, and 3 is excellent, as graded by a blinded investigator in the operating theater immediately after the operation or in the postoperative care unit.

Sample size estimation ($\alpha = 0.05$ and $\beta = 0.1$) indicated that 22 patients per group were needed to detect a 2-min reduction in the onset time of analgesia, equivalent to one standard deviation (SD) from pilot data. The data obtained were analyzed using SPSS version 20.0 for Windows (SPSS, IL, Chicago, USA).

Table 1. Patients' Characteristics and Duration of Surgery in the Two Groups

	Group R n = 15	Group L n = 15	P
	mean ± SD	mean ± SD	
Age	28.66 ± 7.56	26.93 ± 10.34	0.328
Height	173.20 ± 5.79	175.80 ± 9.71	0.204
Weight	76.73 ± 9.47	79.93 ± 16.28	0.787
Duration of surgery	47.86 ± 16.12	46.26 ± 14.01	0.786
Male	13 (86.7%)	15 (100%)	0.483
Female	2 (13.3%)	0	

Data are presented as means ± SD. There was no significant difference between the groups. R: Ropivacaine, L: Levobupivacaine.

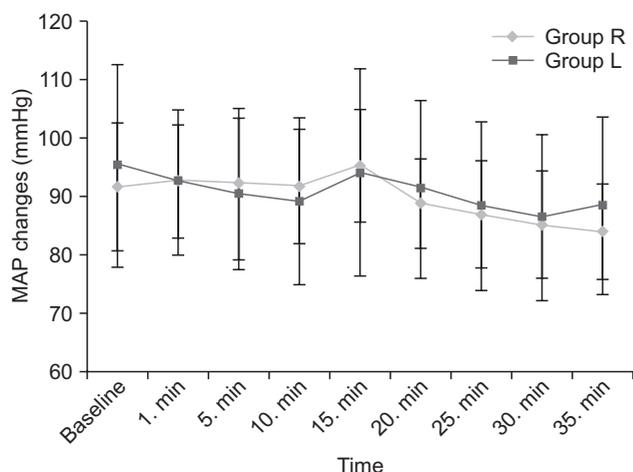


Fig. 1. Mean arterial pressure (MAP) changes during surgery in the two groups. R: Ropivacaine, L: Levobupivacaine.

Demographic data were analyzed using Student's *t* test. Two-way ANOVA for repeated measures was used to analyze changes over time. Ordinal data were analyzed using the Mann–Whitney U test and the χ^2 test with the appropriate corrections. In all analyses, $P < 0.05$ was taken to indicate statistical significance. Continuous variables are presented as means (\pm SD) or medians (range).

Results

No difference in patient characteristics or duration of surgery was observed between the two groups (Table 1). Hemodynamic stability was maintained in both groups throughout the surgery. Neither mean arterial pressure measurements nor heart rate levels showed significant differences between the groups (Figs. 1 and 2). There were statistically significant differences in SpO₂ levels between the groups at 15 and 35 min. However, these differences were clinically insignificant (Table 2).

The onset time of analgesia was 6.26 ± 3.49 min in group L and 4.06 ± 1.75 min in group R ($P = 0.116$) (Table 3). The duration of sensorial block was 297.73 ± 70.94 min in group L and 332.40 ± 102.22 min in group R ($P = 0.110$) (Table 3). Motor block was not seen in any of the patients in the study groups. Supplementary analgesic was required in only one patient in the ropivacaine group (6.6%). None of the patients required general anesthesia to complete the surgery. Mean sensorial block level was T₇ (max. T₂ in 2 patients) in group L and T₈ (max. T₆ in 1 patient) in group R. The duration of sensorial block was 297.73 ± 70.94 min (max. 438 min, min. 165 min) in group L and 332.40 ± 102.22 min (max. 570 min, min. 98 min) in group R. Significant hypotension was observed in only one patient (whose maximum sensorial block level was T₂) in group L at 40 min af-

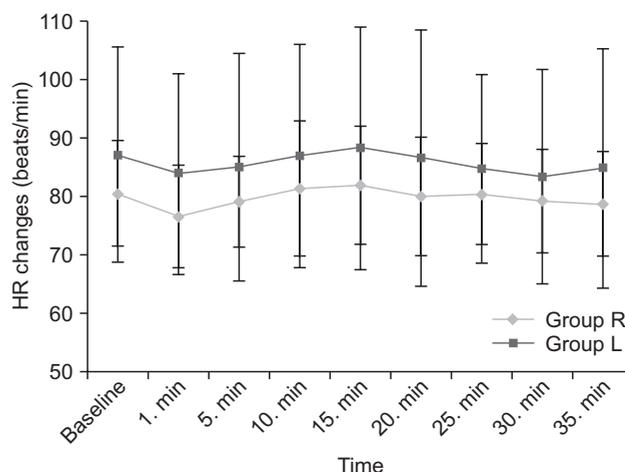


Fig. 2. Heart rate measurements during surgery in the two groups. R: Ropivacaine, L: Levobupivacaine.

Table 2. SpO₂ Measurements at Various Time Points from Pre-anesthesia to 35 min after Epidural Injection

	Group R	Group L	p
	n = 15	n = 15	
	mean ± SD	mean ± SD	
SpO ₂ Baseline	98.00 ± 0.75	98.13 ± 0.91	0.520
SpO ₂ 1 min	98.00 ± 0.84	98.26 ± 1.09	0.200
SpO ₂ 5 min	98.13 ± 0.74	98.13 ± 0.91	0.840
SpO ₂ 10 min	98.73 ± 0.88	97.93 ± 1.48	0.082
SpO ₂ 15 min	99.06 ± 0.70	98.26 ± 1.03	0.026*
SpO ₂ 20 min	98.93 ± 0.79	98.86 ± 1.24	0.825
SpO ₂ 25 min	98.73 ± 1.03	99.13 ± 1.12	0.173
SpO ₂ 30 min	98.73 ± 0.96	99.00 ± 1.41	0.203
SpO ₂ 35 min	98.53 ± 0.99	99.26 ± 1.09	0.014*

Data values are presented as means ± SD. *Statistically significant difference between the groups ($P < 0.05$, Mann-Whitney U-test). R: Ropivacaine, L: Levobupivacaine.

ter epidural injection; it was treated successfully by intravenous infusions of crystalloid solution and ephedrine 10 mg.

Patients' satisfaction with the anesthetic technique was excellent in 12 patients and good in 3 patients in group L, and excellent in 10 patients and good in 5 patients in group R. All except one patient in each group reported that they would accept the same anesthetic procedure for future operations. Surgeons' satisfaction with the anesthetic technique was excellent for 14 and good for 1 surgeon in each group. Side effects, such as bradycardia, hypotension, shivering, nausea and vomiting, headache, backache, urinary retention, and neurological complications, were not seen in any patient in either group.

Discussion

This study was designed to compare two local anesthetics with respect to hemodynamic stability, onset of action, level and duration of block, perioperative and postoperative side effects, and patients' and surgeons' satisfaction, and to evaluate the efficiency of epidural anesthesia, which has fewer side effects than spinal anesthesia in pilonidal sinus surgery. In the present study, hemodynamic stability was maintained in both groups throughout the surgery. Although not statistically significant, the onset time of analgesia was shorter in group R than group L, and the duration of sensorial block was longer in group R than group L. Motor block was not seen in any of the patients. Supplementary analgesic was required in only one patient in the ropivacaine group.

There is only one previous report in the published literature regarding patients undergoing pilonidal sinus surgery with epidural anesthesia. Pala et al. [17] compared conventional epidural anesthesia with segmental epidural anesthesia, which was achieved with small doses of local anesthetics, in pilonidal

Table 3. Onset Time of Analgesia and Duration of Sensorial Block

	Group R	Group L	p
	n = 15	n = 15	
	mean ± SD	mean ± SD	
Onset time of analgesia (min)	4.06 ± 1.75	6.26 ± 3.49	0.116
Duration of sensorial block (min)	332.40 ± 102.22	297.73 ± 70.94	0.110

Data are presented as means ± SD. There was no statistically significant difference between the groups ($P > 0.05$, Mann-Whitney U-test). R: Ropivacaine, L: Levobupivacaine.

sinus surgery. Patients were divided into two groups: Group I, conventional epidural anesthesia with 75 mg bupivacaine (0.5%); Group II, low-dose epidural anesthesia with 30 mg bupivacaine (0.5%). Sensory block onset time was shorter in Group I, sensory block offset time, time of discharge from the post-anesthetic care unit, time to the first urination and analgesic requirement were shorter in Group II. Maximum sensory and motor block levels were lower in Group II. The authors concluded that in pilonidal sinus surgery low-dose epidural anesthesia induces adequate sensorial block, and because motor block did not develop, discharge criteria were achieved in the early postoperative period. Various doses of bupivacaine (0.5%) for epidural anesthesia in this procedure were compared and found to yield adequate sensorial block. However, we compared the same dose of two local anesthetic drugs for epidural anesthesia. Our findings suggested that epidural anesthesia is a suitable technique for pilonidal sinus surgery, and the two drugs had almost identical anesthetic effects.

In a previous prospective, randomized, observer-blinded study, Peduto et al. [18] compared the onset time and duration of epidural anesthesia produced by levobupivacaine and ropivacaine. Adult ASA I-III patients undergoing elective lower limb procedures were randomized to receive epidural application of 15 ml of 0.5% levobupivacaine ($n = 30$) or 15 ml of 0.75% ropivacaine ($n = 35$). An observer blinded to the groups evaluated the onset time and regression of motor and sensory block, and intraoperative need for fentanyl supplementation (0.1 mg intravenously). Onset time was 29 ± 24 min with levobupivacaine and 25 ± 22 min with ropivacaine. Complete resolution of motor block required 105 ± 63 min with levobupivacaine and 95 ± 48 min with ropivacaine. The time for regression of sensory block to T₁₂ was 185 ± 77 min with levobupivacaine and 201 ± 75 min with ropivacaine. Analgesic supplementation was required in one patient (3.5%) receiving levobupivacaine and in two patients (5.7%) receiving ropivacaine. They concluded that 15 ml of 0.5% levobupivacaine produces an epidural block with the same clinical profile as 15 ml of 0.75% ropivacaine. Although the primary surgical diagnosis and the dosage differed from those of our study, their results were in accordance with those of the present

study with regard to the onset time of analgesia, duration of sensorial block, and supplementary analgesic requirement. However, motor block was obtained with the dose and volume used in the study by Peduto et al. [18]. This was not the desired effect in our study population and no motor block was detected in any of our patients.

Casati et al. [19] compared the onset time and duration of epidural anesthesia, and the quality of postoperative analgesia produced by levobupivacaine, racemic bupivacaine, and ropivacaine in a prospective, randomized, double-blinded study. Forty-five ASA physical status I, II, and III patients undergoing elective total hip replacement received epidural block with 0.5% levobupivacaine ($n = 15$), 0.5% bupivacaine ($n = 15$), or 0.5% ropivacaine ($n = 15$). After a median volume of 15 (10–18) ml in the levobupivacaine group, 14 (10–18) ml in the bupivacaine group, and 15 (10–18) ml in the ropivacaine group, the onset time of sensory block was 31 ± 16 min with levobupivacaine, 25 ± 19 min with bupivacaine, and 30 ± 24 min with ropivacaine. Six patients in the ropivacaine group (40%) showed an intraoperative Bromage score < 2 compared with only three patients in the levobupivacaine group (20%), and no patients in the bupivacaine group. Recovery of pinprick sensation occurred after 214 ± 61 min with levobupivacaine, 213 ± 53 min with bupivacaine, and 233 ± 34 min with ropivacaine. The degree of pain relief was similar in the three groups in local anesthetic consumption and need for rescue analgesia. Motor blockade resolved progressively with no difference among the three groups. The authors concluded that 0.5% levobupivacaine produces epidural block of similar onset, quality, and duration as the same volume of 0.5% bupivacaine and 0.5% ropivacaine. The onset time and duration of epidural anesthesia were similar to those in our study. However, the quality of postoperative analgesia was not recorded in our study. Their results were comparable with our findings, with the exception of motor block.

Koch et al. [20] performed a single-blind phase IIIb study in 88 patients undergoing hip surgery. Twelve German academic hospitals were randomly assigned to three treatment groups to evaluate the efficacy of 0.5% levobupivacaine versus 0.5% bupivacaine and 0.75% ropivacaine administered as epidural anesthesia and 0.125% levobupivacaine versus 0.125% bupivacaine and 0.2% ropivacaine for postoperative analgesia. The study was designed to test the equivalence of the overall profile of levobupivacaine against bupivacaine and ropivacaine. In addition, several clinical safety parameters were assessed. With respect to the onset and offset times of sensory and motor blockade, 0.5% levobupivacaine, 0.5% bupivacaine, and 0.75% ropivacaine showed clinically significant and equivalent profiles for all primary study endpoints. However, the levobupivacaine group showed a higher demand for intraoperative analgesia. The frequency of postoperative analgesia request and pain scale

scores did not differ significantly between groups, but the total drug volume required was lower in the bupivacaine group. No relevant differences between the trial groups concerning safety parameters were observed. The authors concluded that the efficacies of epidural levobupivacaine for hip surgery and postoperative analgesia were equivalent, and these drugs showed a clinical profile comparable to that of bupivacaine and a 50–60% higher concentration of ropivacaine.

The patients in the levobupivacaine group showed a higher demand for intraoperative analgesia, in contrast to our results. Supplementary analgesic was required in only one patient in the ropivacaine group in our study, possibly because of the use of a 50% higher concentration of ropivacaine in their study [20].

In another study, McGlade et al. [21] compared the epidural use of 20 ml of 0.5% ropivacaine and 0.5% bupivacaine in patients undergoing lower limb orthopedic surgery in a double-blinded, randomized, multicenter study involving 67 patients. There was no significant difference between the two groups in any parameter. With the exception of the incidence of complete motor block, their results were in accordance with those of the present study in terms of the onset time of analgesia, duration of sensorial block, and supplementary analgesic requirement. The volume used by McGlade et al. resulted in motor block, which was the desired effect.

Yang et al. [22] compared the clinical efficacy and safety of epidural anesthesia produced by 20 ml of 0.5% levobupivacaine and 20 ml of 0.5% ropivacaine for cesarean section. Using this volume, motor block occurred in all patients in the levobupivacaine group and in 27 of 31 patients in the ropivacaine group. Motor block was the desired effect for this procedure for which a volume of approximately 20 ml was found to be sufficient. Motor block was not necessary in the present study, and so we used a lower volume of analgesic drug. There was no difference in the onset time, segmental spread of sensory block, or analgesic supplement requirement between the two groups. However, levobupivacaine produced a longer duration of sensory block than ropivacaine (levobupivacaine 224.1 ± 66.6 min, ropivacaine 176.5 ± 32.8 min, $P < 0.05$). This result was not in accordance with our findings. Although not statistically significant, the duration of sensorial block of ropivacaine was longer than that of levobupivacaine in the present study.

Kountoudi et al. compared 0.5% solutions of levobupivacaine and ropivacaine with regard to alterations in blood pressure and heart rate during surgery. Thirty ASA I–III patients scheduled for elective inguinal hernia repair and undergoing epidural anesthesia were randomized into two groups: group L received 0.5% levobupivacaine, while group R received 0.5% ropivacaine. The volume of local anesthetic given was estimated according to the patient's age and height to provide anesthesia up to the T 7 dermatome. There were no significant differences between the two

groups in the measured parameters (HR, height of the sensory block and duration of surgery). However, MAP was significantly lower ($P < 0.05$) in group L compared to group R at 15 min after epidural block. In the present study, MAP levels were stable in both groups at all measurement points.

Salvi et al. evaluated the analgesic and hemodynamic effects of ropivacaine vs. levobupivacaine in thoracic epidural for coronary artery surgery. Patients scheduled for CABG were randomized to receive ropivacaine (R) or levobupivacaine (L) as a 0.5% bolus (0.1 ml/kg) followed by 0.2% infusion during surgery via an epidural catheter inserted at the T₁-T₂ or T₂-T₃ interspace; sufentanil at 2.5 µg/ml and 1 µg/ml were added to the bolus and infusion solution, respectively. The onset time to achieve T₁-T₆ block was recorded. General anesthesia was then induced. No important differences were seen between the groups; therefore, in this setting 0.5% R and L were equianalgesic, providing excellent analgesia and sympathetic blockade. The authors concluded that the anesthetic and hemodynamic effects of these agents are similar in this clinical setting. Salvi's results were consistent with our findings; moreover, the anesthetic and hemodynamic effects were also similar to those of the present study.

The results of the present study were similar to those of previous works with regard to hemodynamic stability, onset time of analgesia, and duration of sensorial block [18-20,23,24]. The development of motor block was reported by three studies [18,19,21]; however, it was not seen in any patient in our study, likely due to our use of lower drug volumes and concentrations.

In another study, Taspinar et al. [23] compared equipotent

doses of ropivacaine and levobupivacaine regarding discharge criteria and the characteristics of spinal anesthesia in inguinal herniorrhaphy surgery. Combined spinal-epidural anesthesia was performed. Patients were allocated to receive 5 mg of 0.5% ropivacaine or 3.75 mg of 0.75% levobupivacaine, together with 25 µg of fentanyl. The sensory block onset time and time to reach the T₆ dermatome were significantly shorter in group LF, while the time to two-segment regression and time to first analgesic requirement were significantly shorter in group RF. All patients in group LF were Bromage 0. The time to discharge was shorter in group LF, but this difference was not statistically significant. The authors suggested that both local anesthetics could be used in walking spinal technique, that is the patients could stand up and walk right after the operation.

As in other studies, both drugs were shown to be hemodynamically safe with almost identical clinical efficacy. Epidural anesthesia using these two drugs is recommended in patients scheduled for pilonidal sinus surgery because of their advantages, such as the ability to place the patient into the prone position, hemodynamic stability, patients' and surgeons' satisfaction, early mobilization, and lack of side effects.

In conclusion, our findings showed that epidural anesthesia with either levobupivacaine or ropivacaine is a suitable anesthetic technique for pilonidal sinus surgery with respect to hemodynamic stability, onset time of analgesia, duration of sensorial block, lack of motor block and side effects, and surgeon's and patient's satisfaction.

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