Student's Journal of Health Research Africa
Vol. 4 No. 9 (2023): September 2023 Issue
https://doi.org/10.51168/sjhrafrica.v4i9.668
Original article

A COMPARATIVE ANALYSIS WAS CONDUCTED TO ASSESS THE IMPACT OF EPIDURAL ADMINISTRATION OF LEVOBUPIVACAINE 0.5% AT A VOLUME OF 20 ML AND ROPIVACAINE 0.75% AT THE SAME VOLUME IN SURGICAL PROCEDURES INVOLVING THE LOWER LIMBS. A PROSPECTIVE STUDY.

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Abstract.

Introduction:

The emergence of levobupivacaine and ropivacaine has marked a new phase in advanced pain management techniques. This study aimed to create a comparative framework and assess the effects of epidural levobupivacaine and ropivacaine in surgeries of the lower limb.

Methodology:

The study involved 100 patients, evenly split into two different groups where each group was assigned 50 candidates. The assignment of patients to these groups was carried out randomly using a lottery-based approach. In Group Levo (n=50), patients were administered 20 ml of 0.5% Levobupivacaine via the epidural pathway, whereas in Group Ropi (n=50), 20 ml of 0.75% Ropivacaine was administered through the same route.

Results:

The time it took for the sensory block to begin was measured hinged on the completion of the injection until the patient no longer perceived the pinprick sensation. The mean of the onset of time of sensory block reaching up to the T10 level was 12.04±2.71 minutes in group Levo and 11.13 ± 3.10 minutes in group Ropi. Nonetheless, this variation was determined to significantly lack statistical aspects.

Conclusion:

The results of our study indicated that both drugs exhibited similarities in sensory block attributes. These attributes include the average time it took for the sensory blockade to begin and the duration until the highest sensory point was reached.

Recommendation:

During follow-up and discharge planning, limbs should be checked for numbness and/or weakness, and the patient should be asked about urine retention or headache. Usual medication can be resumed on the day of the procedure. If there is significant limb weakness, sensory loss, or headache, an unplanned overnight admission may be necessary.

Keywords: Ropivacaine, Levobupivacaine, sensory blockade, and duration of blockade, Submitted: 2023-09-15 Accepted: 2023-09-30

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1. INTRODUCTION.

Anesthesiologists play a crucial role in ensuring patient comfort, closely monitoring their condition, and maintaining optimal physiological levels during medical procedures. As anesthesia techniques have evolved, various approaches have emerged, often combining different drugs to achieve effective pain relief [1]. The introduction of levobupivacaine and ropivacaine marked a significant milestone in pain management, ushering in this modern era of advanced analgesic methods.

The utilization of central neuraxial blockade has become a standard procedure for alleviating intraoperative and postoperative pain in contemporary medical practice [2]. Epidural anesthesia, a significant component of this approach, not only delivers efficient anesthesia and analgesia during surgery but also offers sustained pain relief in the postoperative phase. This contributes to quicker patient mobilization and reduces adverse effects [3]. Consequently, due to its multiple benefits, epidural anesthesia has become a customary choice for orthopedic surgeries.

Epidural anesthesia stands as a prominent regional technique for surgeries involving the lower limbs, abdomen, pelvis, and vascular system. Its advantages over spinal anesthesia are noteworthy, particularly its ability to support surgeries of extended duration when an epidural catheter remains in place [4]. Additionally, it serves as a valuable method for post-operative pain management.

For a considerable period, the go-to choice for effective epidural anesthesia and subsequent relief in post-operative pain has been bupivacaine. However, recognition of bupivacaine's potential life-threatening cardiotoxicity prompted the quest for an alternative local anesthetic. This led to the development of ropivacaine, a relatively new amide [5]. While ropivacaine shares chemical homology with bupivacaine and mepivacaine, it distinguishes itself by having a propyl group on the tertiary nitrogen atom of the piperidine ring instead of a butyl group [6].

Ropivacaine, which was introduced in 1996 and subsequently in India in 2009, demonstrates decreased cardiotoxicity and central nervous system toxicity in comparison to bupivacaine [7]. It delivers effective analgesia akin to bupivacaine and demonstrates a more rapid regression of motor block compared to sensory block. These characteristics position ropivacaine as a promising candidate for epidural administration, making it well-suited for epidural anesthesia [8, 9]. This study aimed to create a comparative framework and assess the effects of epidural levobupivacaine and ropivacaine in surgeries of the lower limb.

2. METHODS.

2.1. Study design.

This research was carried out at a tertiary care center using a prospective study design for one year. The study included a total of 100 patients, with 50 individuals allocated to each group through a random lottery-based method. In Group Levo, 50 patients were administered a 20 ml epidural injection of 0.5% Levobupivacaine. In contrast, Group Ropi, also comprising 50 patients, received a 20 ml epidural dosage of 0.75% Ropivacaine.

2.2. Inclusion Criteria.

Individuals eligible for participation were those with ASA grade I and II physical statuses, between the age group of 19-59 years, weighing from 51 to 72 kg, and having a height ranging between 153 to 176 cm. Gender was not a limiting factor. The study included individuals undergoing lower limb surgeries.

2.3. Exclusion Criteria.

Excluded from the study were patients who refused to participate, those categorized as ASA grade III and IV, individuals beside established hypersensitivity patients with localized infections at the injection site, individuals less cooperative, those with coagulopathies, tendencies to bleed,

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and increased intracranial pressure are not suitable candidates for administering local anesthetics.

Once the inclusion and exclusion criteria were confirmed to be met, eligible participants were engaged in the study. Before starting the procedure, initial assessments were conducted. These included recording metrics such as respiratory rate, pulse rate, peripheral oxygen saturation levels, and blood pressure. A peripheral intravenous cannula, sized 18-gauge, was inserted, and a preload of 10 ml/kg of Ringer Lactate solution was administered to all patients.

Patients were positioned in a left lateral posture, and meticulous aseptic protocols were followed to locate the epidural space. This involved applying infiltration with 1% Xylocaine locally, followed by insertion of an 18/16G Tuohy needle using the "loss of resistance" technique, typically at the L3-L4 or L2-L3 interspace. Following this, an 18/16G epidural catheter was advanced into the needle through epidural space by approximately 3 to 4 cm and then affixed to the patient's back using adhesive tape.

Following the confirmation of negative aspiration for both blood and cerebrospinal fluid, a test dose comprising 3 ml of 2% Lignocaine along with 15 μg of adrenaline was administered. Subsequently, the patient's position was adjusted to supine.

In the absence of any unfavorable reactions to the test dose after a 5-minute interval and with the conditions for avoiding vascular and spinal placement not being fulfilled (HR≥100 bpm, sys blood pressure < 90 mm Hg, or the sensory block presence), the administration of the study medications began. This process was carried out gradually over 5 minutes, following the confirmation of negative aspiration for both blood and cerebrospinal fluid.

In group Levo (n=50), a 20 ml dose of 0.5% levobupivacaine was administered epidurally. In group Ropi (n=50), a 20 ml dose of 0.75% ropivacaine was similarly administered via the epidural route.

To assess the extent of the sensory block, a bilateral pinprick technique was employed, utilizing a 27 G needle with a rounded tip. This evaluation was performed at specific intervals: 0.25, 5, 10, 15, 20, 25, 30, and 60 minutes post-injection. Subsequent evaluations were conducted every 30 minutes until the sensory block had completely regressed, and assessments were conducted. Additionally, the quality of the motor block was evaluated using the Modified Bromage Scale at intervals of 0, 10, 20, and 30 minutes post-administration. Subsequently, these evaluations were carried out every 30 minutes until a zero score was achieved in both legs for the patient.

During the entire procedure, continuous surveillance of saturation of peripheral oxygen, respiratory rate, and heart rate was maintained. Hemodynamic parameters, encompassing diastolic blood pressure (DBP), systolic blood pressure (SBP), mean arterial pressure (MAP), and pulse rate, were documented every 5 minutes during the first 30 minutes. Subsequently, reading was taken every 10 minutes for the next 60 minutes. From that point onwards, readings were noted at 30-minute intervals until the conclusion of the surgical procedure.

2.4. Analysis of Statistical Data.

Descriptive data were presented as mean ± standard deviation, while continuous data underwent analysis using "paired or unpaired" i.e., tests. Incidence data were assessed using the "Chi-square test" and the "Fischer Exact Probability" test to identify any statistical distinctions between the groups. A p-value of less than 0.05 was deemed as denoting statistical significance.

3. RESULTS.

A total of 100 patients were included in this study. At the initial stage, several 200 patients were examined for eligibility, however, 100 patients were excluded from this study due to not being eligible. The time it took for the sensory block to initiate was measured from the execution of the target drug injection until the patient could no longer perceive the pinprick sensation. The onset time (mean) of sensory block up to the

T10 level was 12.04±2.71 minutes in group Levo and 11.13 ±3.10 minutes in group Ropi. The results of the study procured are summarized in Table 1. specifying the demographic and surgical aspects of the data as well as the adverse effects caused by the administration of anesthetics. Nevertheless, this variation was determined to lack statistical significance.

Intraoperative complications noted in this study encompassed instances of hypotension, nausea, and shivering. No notable differences were observed in the two groups concerned with the occurrence of these complications.

4. DISCUSSION.

The duration of analgesia in this study in group Levo was measured at 237.42± 21.31 minutes, whereas in Group Ropi, it was documented as 218.48 ±12.47 minutes. It's important to highlight that there was no significant difference observed statistically in the duration of analgesia between the two groups.

In a distinct study carried out by Concepcion et al., where they assessed different concentrations of Ropivacaine (0.5%, 0.75%, 1%), the duration of analgesia achieved using 0.75% Ropivacaine was documented as 255±73 minutes. This observation is consistent with the outcomes of our research. [10].

Brockway et al. conducted a study in which they investigated different concentrations of Ropivacaine (0.5%, 0.75%, 1%) and juxtaposed them with Bupivacaine (0.5%, 0.75%) [11]. The researchers highlighted that there was minimal distinction in the middle of the groups about the speed at which sensory block initiation took place. They also observed that elevating the concentration of both drugs led to a prolonged duration of analgesia while having little impact on the time it took for the block to initiate or the extent of the block itself. Elevating the concentration of both drugs resulted in a more pronounced level of motor block that persisted for an extended period [11].

Senard et al., determined in studies conducted by them that equivalent dosages of Ropivacaine and levobupivacaine, in postoperative patient-controlled epidural analgesia were administered, which led to analogous distribution, quality, and hemodynamic effects. Nevertheless, patients who received ropivacaine exhibited an earlier initiation of ambulation [12].

Peduto et al. conducted a study that involved a comparison between epidural levo 0.5% and ropi 0.75% for lower limb procedures. The study concluded that both drugs exhibited a similar clinical profile [13]. Additionally, Katz JA et al. observed that there were no substantial discrepancies in sensory or motor effects between bupivacaine (0.5%) and ropivacaine (0.75%) when administered epidurally [14]. This observation highlights their equivalent potency at varying concentrations.

5. CONCLUSION.

Our study revealed that the two drugs exhibited similar characteristics concerning sensory block effects. These parameters encompass the mean time it takes for the sensory block to begin, the duration to reach the maximum sensory level, the highest attained level of sensory blockade, the period for sensory blockade regression across two segments, and the analgesia duration. Furthermore, regarding motor parameters, including the time mean for the motor block to start, the duration of the motor block, and the nature of the motor block, there was a similarity amongst the categories, with no statistically significant differences indicated by the p-value.

When considering hemodynamic parameters and the incidents of aftereffects, both Levobupivacaine and Ropivacaine demonstrated a comparable profile. In light of these findings, both of these drugs present themselves as promising alternatives to Bupivacaine for use in epidural anesthesia.

6. LIMITATIONS.

The limitations of this study include a small sample population who were included in this study. The findings of this study cannot be generalized for a larger sample population.

Table 1: **Demographical and surgical data of the study**

Parameters	**Group Levo**	**Group Ropi**
Demographics		
Age	44.68 ± 12.7	39 ± 15
Height	157.32 ± 5.24	147.21 ± 5.12
Weight	57.21 ± 5.20	58.31 ± 6.50
Sex (M/F)	27/23	24/ 26
ASA grade I/II	47/53	45/62
Surgery type		
Repair of Incisional hernia mesh	4	8
Hernioplasty	14	12
Ovariotomy	4	4
Open prostatectomy	2	4
Appendicectomy	14	14
TAH (Total Abdominal Hysterectomy)	12	8
Maximum Sensory level		
T4 (Count %)	6%	4%
T6 (Count %)	40%	36%
T8 (Count %)	4%	10%
Quality motor blockade		
Adverse effects		
Hypotension	12	10
Nausea	12	6
Shivering	2	4
Nil	24	30

7. RECOMMENDATION.

During follow-up and discharge planning, limbs should be checked for numbness and/or weakness, and the patient should be asked about urine retention or headache. Usual medication can be resumed on the day of the procedure. If there is significant limb weakness, sensory loss, or headache, an unplanned overnight admission may be necessary.

8. ACKNOWLEDGEMENT.

We are thankful to the patients; without them, the study could not have been done. We are thankful to the supporting staff of our hospital who were involved in the patient care of the study group.

9. LIST OF ABBREVIATIONS.

ASA- American Society of Anesthesiologists
HR- Hazard Ratio
DBP- diastolic blood pressure
SBP- systolic blood pressure
MAP- mean arterial pressure
TAH- Total Abdominal Hysterectomy

10. Source of Funding:

The study was not funded.

11. Conflict of interest.

The authors report no conflicts of interest in this work.

12. Publisher details:

Publisher: Student's Journal of Health Research (SJHR)
(ISSN 2709-9997) Online
Category: Non-Governmental & Non-profit Organization
Email: studentsjournal2020@gmail.com
WhatsApp: +256775434261
Location: Wisdom Centre, P.O.BOX. 148, Uganda, East Africa.

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