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Original Research

Prospective Evaluation of Intrathecal Isobaric Levobupivacaine 12.5 mg versus Hyperbaric Bupivacaine 10 mg for Caesarean Section: A Comparative Efficacy Study

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ABSTRACT:

Background: Neuraxial anesthesia has gained widespread acceptance as a technique for caesarean sections. A range of local anesthetics and opioids has been employed, either independently or in conjunction. For spinal anesthesia in expectant mothers undergoing caesarean sections, there is a suggestion to use smaller opioid doses along with local anesthetics administered intrathecally. This approach is favored over epidural anesthesia because of its faster onset, superior muscle relaxation, and the reduced dosage of local anesthetics needed in caesarean procedures. It provides a dependable and high-quality block.**Methods**:This study, conducted in the Department of Anaesthesia, employed a prospective randomized, double-blinded design. Written informed consent was obtained from all participating parturients. A total of 180 parturients, meeting the inclusion criteria and undergoing elective caesarean sections under spinal anesthesia, were enrolled in the study.**Results**:All 180 patients participating in this double-blinded, randomized comparative study successfully completed the research, with no dropouts. The results are presented below, illustrating the distribution of demographic profiles in the two study groups. Importantly, there were no statistically significant differences in age, weight, or height distribution between the study groups, as evidenced by 'p' values > 0.05. Consequently, the groups were deemed comparable in terms of age, weight, and height.**Conclusion**:Conclusively, it appears that levobupivacaine serves as a viable and effective alternative to intrathecal bupivacaine in infra-umbilical surgeries, such as elective caesarean sections. This alternative demonstrates a reduced toxic potential while maintaining an excellent quality of analgesia.

Keywords: Intrathecal anaesthesia, sensory block, motor block, caesarean section.

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INTRODUCTION

Neuraxial anesthesia has undergone significant advancement and has now firmly established itself as a cornerstone technique for performing caesarean sections[1]. The utilization of various combinations of local anesthetics and opioids, either independently or in tandem, has become a standard practice in this context. Notably, for spinal anesthesia in elective caesarean sections, a nuanced approach involves the administration of smaller doses of opioids in conjunction with local anesthetics via the intrathecal route[2]. This strategy aims to optimize the anesthesia experience for parturients undergoing elective caesarean sections, emphasizing the importance of tailoring the anesthetic protocol to the specific requirements of the procedure.The preference for spinal anesthesia over epidural anesthesia in caesarean cases is grounded in its distinctive advantages, including a rapid onset of action, superior muscle relaxation, and a reduced demand for local anesthetics. This not only streamlines the administration process but also contributes to a more efficient and effective anesthesia outcome. Furthermore, the reliability and high-quality block achieved with spinal anesthesia underscore its suitability for caesarean deliveries.Central neuraxial techniques have evolved to become indispensable components of contemporary anesthetic practices, offering viable alternatives to the traditional use of general anesthesia when deemed appropriate. Within

this landscape, subarachnoid block has emerged as the predominant choice for administering neuraxial anesthesia during caesarean deliveries due to its procedural simplicity and efficacy.Bupivacaine, a well-established long-acting local anesthetic, has, however, raised concerns related to cardiac toxicity, particularly under conditions of high concentration or inadvertent intravascular administration[3]. Responding to these safety considerations, levobupivacaine, identified as the S (-) isomer of bupivacaine, has been developed as a compelling alternative. The rationale behind this development lies in the accumulating evidence suggesting a lower propensity for cardiotoxicity and neurotoxicity with levobupivacaine, positioning it as a safer and more favorable choice in the realm of anesthesia applications. This ongoing refinement of anesthetic techniques and agents reflects the commitment to enhancing patient safety and optimizing outcomes in the field of obstetric anesthesia.Bupivacaine, a widely employed local anesthetic in regional anesthesia, is commercially available as a racemic mixture comprising its enantiomers—levobupivacaine, the S (-) isomer, and dextrobupivacaine, the R (+) isomer. Unintentional intravascular injection of this racemic mixture can lead to severe perturbations in the central nervous and cardiovascular systems. Notably, the observed adverse effects have been primarily associated with the R-isomer of bupivacaine[4,5]. In contrast, the levo-rotatory isomer, levobupivacaine, demonstrates a seemingly safer pharmacological profile with reduced cardiac and neurotoxic effects. This enhanced safety is attributed to its faster protein binding rate.

Levobupivacaine, chemically represented as ((2s)-1-Butyl-N-2,6-dimethylphenyl)piperidone-2-carboxamide, belongs to the amino amide family of local anesthetic drugs within the n-alkyl substituted pipecoloxylidide category. Its chemical structure ($C_{18}H_{28}N_2O$) reflects its role and composition in anesthesia applications. Notably, the primary binding site for levobupivacaine is Alpha 1-Glycoprotein, and it exhibits a higher protein binding capacity (97%) compared to racemic bupivacaine (95%).In the context of subarachnoid block, levobupivacaine demonstrates a comparable sensory, motor block, and recovery profile to bupivacaine, especially at lower concentrations. Noteworthy is its ability to induce a more selective neurological block with minimal impact on motor function. Several studies have suggested a reduced incidence of side effects, such as hypotension, bradycardia, nausea, and vomiting, when levobupivacaine is used for spinal anesthesia during caesarean sections compared to traditional bupivacaine.In the current study, the authors aim to explore and compare the effects of bupivacaine and levobupivacaine in patients undergoing lower segment caesarean section under spinal anesthesia[6-8]. This research seeks to contribute valuable insights into the comparative efficacy and safety profiles of these two local anesthetics, potentially informing clinical practices and improving patient outcomes in the context of obstetric anesthesia.

MATERIALS AND METHODS

This prospective, randomized, double-blinded study was conducted within the Department of Anaesthesia. The enrollment process involved obtaining written informed consent from all parturients, resulting in a total of 180 eligible individuals who met the inclusion criteria for undergoing caesarean section under spinal anesthesia. The decision to recruit 90 patients for each group was based on a comprehensive literature review of related textbooks conducted before estimating the sample size. This approach accounted for a 10% anticipated dropout rate from the study groups.Inclusion criteria for participation in the study encompassed patients with ASA physical status I and II who were selected for elective caesarean sections. Conversely, exclusion criteria were defined to exclude patients with factors that could potentially confound the study results. Excluded conditions and circumstances included patient refusal, known cardiac diseases (such as ischemic heart disease, heart failure, valvular heart diseases, and conduction disorders), known renal, hepatic, or coagulation disorders, any neurological disorder, the use of specific medications (beta-blockers, antipsychotic drugs, sedatives), spinal deformities, trauma, local infection, allergy to amino amide local anesthetics, pre-eclampsia, eclampsia, and twin pregnancies. This meticulous selection process aimed to ensure a homogeneous study population and enhance the internal validity of the research findings.A comprehensive pre-anaesthetic evaluation was conducted for each parturient, involving a detailed history inquiry, physical examination (including weight and height measurements), spine assessment, airway examination, and routine preoperative investigations. Additionally, all parturients received oral ranitidine 150 mg on the night before and on the morning of the surgery, and fasting from midnight before the surgery was strictly observed.Utilizing a table of random numbers, the 180 enrolled patients were allocated into two groups, with 90 individuals in each group. This prospective, double-blinded study focused on parturients classified under ASA physical status I and II.Group L, consisting of 90 patients, received 0.5% isobaric levobupivacaine (2.5 mL or 12.5 mg), while Group B, also comprising 90 patients, received 0.5% hyperbaric bupivacaine (2 mL or 10 mg)[9]. The study drugs were meticulously prepared by an anesthesiologist who was not otherwise involved in the study, ensuring a high standard of drug preparation. Moreover, to maintain the integrity of the study, the anesthesiologist responsible for administering the block and observing its effects remained blinded to the treatment group assignments. This rigorous blinding process was implemented to minimize bias and enhance the scientific validity of the study results.Continuous

hemodynamic monitoring was maintained throughout the study. The level of sensory block was assessed bilaterally based on the response to pinprick stimuli, utilizing the Hollmen Scale in the anterior axillary line. Sensory block assessments were conducted at 2 minutes post-injection and then at 1-minute intervals thereafter. Permission to proceed with the surgical operation was granted once a sensory level between T4 and T6 had been achieved.

The onset time of sensory block was meticulously recorded. Motor block assessment was carried out using the modified Bromage Scale at 2 minutes post-injection and subsequently at 1-minute intervals. Both the onset time and the highest scale of motor block achieved were documented.Heart rate and blood pressure were recorded using standard non-invasive monitoring devices, initially before the intrathecal injection and subsequently at 5-minute intervals[10]. This robust monitoring protocol provided a comprehensive evaluation of the hemodynamic changes and sensory-motor effects induced by the administered anesthetics, contributing to a thorough understanding of the pharmacological impact of levobupivacaine and bupivacaine in the context of spinal anesthesia for caesarean sections.

RESULTS

All 180 patients enrolled in this double-blinded, randomized comparative study successfully completed the entire duration of the study, with no dropouts observed. The results are detailed below, outlining the distribution of demographic profiles within the two study groups. Importantly, no statistically significant differences were noted in terms of age, weight, or height distribution between the study groups, as evidenced by a 'p' value exceeding 0.05. Consequently, the groups were deemed comparable to each other in these demographic aspects.The distribution of the onset of sensory block, onset of motor block, duration of surgery, and duration of analgesia in the two study groups is presented. Statistically significant differences were observed in the onset of sensory block, onset of motor block, and duration of analgesia. However, no statistically significant difference was found in the duration of surgery.

Specifically, the onset of sensory block was faster in Group B (5.23 ± 0.87) compared to Group L (5.52 ± 1.10). Similarly, the onset of motor block was faster in Group B (5.57 ± 0.75) compared to Group L (7.00 ± 0.95). Notably, there was no significant difference in the duration of surgery between the two groups.These findings contribute valuable insights into the comparative efficacy and temporal aspects of sensory and motor block onset, duration of surgery, and duration of analgesia between the two study groups, shedding light on the distinct characteristics of levobupivacaine and bupivacaine in the context of spinal anesthesia for caesarean sections.

The duration of analgesia (in minutes) was found to be significantly longer in Group L compared to Group B, with a 'p' value less than 0.05. This statistically significant difference indicates that the analgesic effect persisted for a longer duration in patients receiving levobupivacaine.

Furthermore, a statistically significant difference was observed between Group L and Group B in pulse rates at any time of measurement, except at baseline and 30 minutes. The student's independent t-test revealed a 'p' value less than 0.05, indicating that the pulse rates were different between the two groups.Similarly, a statistically significant difference, with a 'p' value less than 0.05, was noted in mean arterial pressure at any time of measurement except baseline and 20 minutes, as determined by the student's independent t-test. This suggests variations in mean arterial pressure between patients in Group L and Group B.

In terms of side effects, such as nausea, vomiting, hypotension, and bradycardia, there were more occurrences in Group B. This is indicative of a higher incidence of these adverse effects in patients who received bupivacaine compared to those who received levobupivacaine.These findings underscore the differences in the duration of analgesia and the occurrence of side effects between the two study groups, providing valuable insights into the clinical implications and comparative outcomes of using levobupivacaine and bupivacaine in the context of spinal anesthesia for caesarean sections.

Table 1: Demographic Features of the Patients

S. No	Parameters	Group L, (n=90)	Group B, (n=90)	P value
1	Age in years	22.22 ± 2.6	22.11 ± 2.4	0.83
2	Weight (Kg)	60.82 ± 2.97	62.29 ± 3.77	0.51
3	Height cm)	153.79 ± 3.88	153.84 ± 3.82	0.84

Table 2: Onset of Sensory Block, Onset of Motor Block, Duration of Surgery, Duration of Analgesia

S. No	Variables	Group L, (n=90)	Group B, (n=90)	P value
1	onset of sensory block (min)	5.72 ± 1.10	5.13 ± 0.87	0.001
2	onset of motor block (min)	7.00 ± 0.95	5.47 ± 0.75	0.001
3	duration of surgery (min)	44.47 ± 2.42	44.18 ± 2.76	0.60
4	Duration of analgesia (min)	124.49 ± 2.64	120.58 ± 2.51	0.001

Table 3: Comparison of Side Effects between the Two Groups

S. No	Side Effects	Group- L	Group- B	Total
1	Nausea and vomiting	8 (8.8%)	10 (11.11%)	18(10%)
2	Shivering	6 (6.66%)	8 (8.88%)	14 (7.77%)
3	Hypotension	12 (13.33%)	16 (17.77%)	28 (15.55%)
4	Bradycardia	4 (4.44%)	8 (8.88%)	12 (6.66%)

DISCUSSION

The principal aim of our investigation was to meticulously evaluate and compare the onset and duration of effective anesthesia and analgesia between levobupivacaine and bupivacaine in the context of elective caesarean deliveries. Our evaluation extended beyond the temporal aspects of anesthesia and analgesia, encompassing vital signs such as pulse rate and blood pressure (including systolic, diastolic, and mean arterial pressure) throughout the perioperative period.

The demographic profiles of the participants, including age, weight, and height, were diligently examined, and our findings revealed a commendable degree of comparability between Group L (levobupivacaine) and Group B (bupivacaine). Additionally, the duration of surgery, a crucial parameter in assessing the efficiency of the anesthetic agents, exhibited no significant difference between the two groups, as indicated by a calculated p-value of 0.60. This underscored the equivalence of the surgical durations in both cohorts[11].The investigation then delved into the critical components of anesthesia onset and progression. The onset of sensory block, gauged by the time taken to reach T6, exhibited noteworthy differences between the two groups. Group B demonstrated a faster onset compared to Group L, with statistical analysis revealing a significant difference (p=0.001). A similar trend was observed in the onset of motor block, where Group B displayed a quicker progression to the maximum level compared to Group L, and this difference was statistically significant (p=0.00). These findings illuminate the nuanced variations in the onset of sensory and motor blocks between levobupivacaine and bupivacaine.Moreover, our study aligns with the observations of Mantouvalou et al., indicating a reduction in mean arterial blood pressure after spinal injection, a phenomenon that reached statistical significance specifically in the bupivacaine group. Additionally, a significant decrease in heart rates was noted across all groups following the injection of local anesthetic agents.

In conclusion, our investigation not only contributes valuable insights into the temporal dynamics of anesthesia and analgesia but also sheds light on the intricate interplay between levobupivacaine and bupivacaine in terms of their impact on vital signs during elective caesarean deliveries[12]. These findings hold potential implications for refining anesthetic protocols and optimizing patient outcomes in obstetric anesthesia practice.

The comprehensive investigation conducted by Erdil et al. delved into the nuanced effects of levobupivacaine and bupivacaine on key hemodynamic parameters, shedding light on their respective influences on mean arterial pressure (MAP) and pulse rate throughout the perioperative period. The meticulously observed differences in MAP values between the bupivacaine and levobupivacaine groups, with lower values in the former from 10 minutes post-injection until 30 minutes, provided crucial insights into the distinctive cardiovascular responses elicited by these two anesthetic agents. Conversely, the levobupivacaine group exhibited significantly lower MAP values at specific time intervals (25, 35, 55, and 60 minutes) compared to baseline, indicating varied hemodynamic profiles.The scrutiny of pulse rate dynamics revealed a parallel decrease in both groups compared to baseline, attaining statistical significance at 25 minutes in the levobupivacaine group and 15 minutes in the bupivacaine group[13]. These findings underscore the subtle yet noteworthy impact of levobupivacaine and bupivacaine on heart rate throughout the surgical procedure, contributing valuable information to the understanding of their cardiovascular effects.

Examining the incidence of side effects provided additional insights into the safety profile of these anesthetic agents. Nausea and vomiting were reported in 9% of patients in Group L and 11% in Group B, while shivering occurred in 7% of patients in Group L and 9% in Group B. These observations are crucial in guiding clinical decision-making, considering the importance of minimizing adverse effects, especially in the context of obstetric anesthesia.The study's exploration of the minimum effective local anesthetic dose of levobupivacaine, determined through an up-and-down sequential design study as 11.7 mg, challenges the traditional dosage of 15 mg for spinal anesthesia. This emphasizes the significance of individualizing doses to achieve optimal anesthesia while mitigating potential adverse effects, thereby contributing to the ongoing refinement of anesthesia protocols.

Aligning with the findings of Turkmen et al[14]., the study affirmed the comparable duration of analgesia between the two groups, consolidating evidence across studies and reinforcing the consistency of results regarding the efficacy and safety of levobupivacaine and bupivacaine in the specific context of spinal anesthesia for obstetric procedures. This collective body of evidence not only enhances our understanding of these anesthetic agents but also provides a foundation for refining clinical practices

and optimizing patient outcomes in obstetric anesthesia.

CONCLUSION

The findings from the present study highlight that intrathecal administration of isobaric levobupivacaine at a dose of 12.5 mg resulted in a delayed onset of sensory and motor blocks, coupled with a prolonged duration of analgesia, when compared to the administration of hyperbaric bupivacaine at a dose of 10 mg in patients undergoing elective caesarean sections. Importantly, all patients in both groups maintained hemodynamic stability, indicating the safety and tolerability of both anesthetic agents in the studied population. Furthermore, the occurrence of adverse effects in both groups was comparable, suggesting a similar side effect profile.In conclusion, the study supports the notion that levobupivacaine could serve as an effective alternative to intrathecal bupivacaine for infra-umbilical surgeries like caesarean sections. The observed characteristics of levobupivacaine, including a delayed onset of sensory and motor blocks and a longer duration of analgesia, contribute to its potential advantages in certain clinical scenarios. Additionally, the reduced toxic potential and maintenance of excellent analgesic quality position levobupivacaine as a promising option for spinal anesthesia in caesarean sections, potentially offering improved safety and patient comfort. These findings provide valuable insights for clinicians in tailoring anesthetic choices for patients undergoing elective caesarean sections, with an emphasis on optimizing both efficacy and safety.

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