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Original Research Article

COMPARATIVE STUDY OF INTRATHECAL HYPERBARIC LEVOBUPIVACAINE 0.5% VERSUS HYPERBARIC BUPIVACAINE 0.5% IN SPINAL ANESTHESIA IN ORTHO SURGERY

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Abstract

Background: Levobupivacaine has been found to have a lower risk of cardiovascular and central nervous system (CNS) toxicity compared to Bupivacaine, which is commonly used as a local anesthetic in spinal anaesthesia. Our study sought to examine the clinical effectiveness of hyperbaric levobupivacaine in comparison to hyperbaric Bupivacaine for lower limb Orthopaedic surgeries. **Materials and Methods:** Sixty patients, ranging in age from 18 to 60 years, who were scheduled for lower limb Orthopaedic surgeries and had a physical status class of 1 or 2 according to the American Society of Anaesthesiologists (ASA), were divided into two equal groups through a random assignment process. In group L patients were given 3 ml intrathecal hyperbaric 0.5% levo bupivacaine. Group B received 3 ml intrathecal hyperbaric 0.5% bupivacaine. The groups were evaluated for sensory and motor block characteristics using pinprick and Bromage scale. We also documented any observed hemodynamic changes and side effects. **Result:** It was found that the average time for the onset of sensory block in group B was 2.52 minutes, slightly lower than the 2.66 minutes observed in group L. However, further analysis revealed that this difference was not statistically significant, with a p value of 0.40. In group B, the average time for the onset of motor block was 3.51 minutes, slightly lower than the 3.68 minutes observed in group L. However, the p value of 0.50 indicated that this difference was not statistically significant. In group B, the average duration of analgesia was 191.47 minutes, while in group L it was 180.37 minutes. The p value was found to be less than 0.05, indicating a statistically significant difference. The mean pulse rate changes and blood pressure changes were similar in both groups and were not found to be statistically significant. **Conclusion:** Hyperbaric 0.5% Levobupivacaine was found to be a comparable alternative to hyperbaric 0.5 % bupivacaine in patients undergoing lower limb orthopedic surgery.

INTRODUCTION

Developing countries face a multitude of challenges when it comes to anesthetic drugs, supplies, and monitoring equipment.[1] Choosing a safe, reliable, and effective sole anesthetic technique can help tackle these challenges. This technique has the potential to deliver effective anesthesia and pain relief for surgical procedures, potentially eliminating the need for General Anesthesia (GA) in these cases. Spinal anesthesia is commonly employed for a range of surgical procedures, such as brief lower abdominal and inguinal hernia surgeries, as well as orthopedic surgeries. There has been a noticeable increase in the utilization of bupivacaine for spinal anesthesia in outpatient settings in recent years. There has been a noticeable change in attitude towards spinal lidocaine due to increasing worries about its potential neurotoxicity. Spinal bupivacaine is recognized for its decreased incidence of postoperative

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complications. On the other hand, when higher doses of 7.5 mg or more are administered to achieve proper anesthesia, it can lead to extended patient stays after outpatient surgery.[2,3]

Hyperbaric racemic bupivacaine is widely used in spinal anesthesia due to its long-lasting effects and its ability to provide both motor and sensory blockade. However, there are some drawbacks linked to the utilization of hyperbaric racemic bupivacaine in spinal anesthesia. This medication may cause a decrease in blood pressure and a decrease in heart rate. Additionally, it is important to be aware of the potential for serious heart complications due to its strong impact on heart cells.[3-6] Accidental intravascular injection can have serious consequences, including severe myocardial depression and potentially cardiac arrest. Reviving a patient who has suffered from cardiovascular collapse caused by bupivacaine can be a highly difficult task with uncertain outcomes.

Levobupivacaine is the S (-) enantiomer of racemic bupivacaine and is known for its reduced toxicity to the heart and CNS.[7,8] Recent reports have conducted comparisons between intrathecal levobupivacaine and bupivacaine, revealing a lower occurrence of hypotension with levobupivacaine.[9] Research findings indicate that hyperbaric levobupivacaine is found to be 38% less potent compared to hyperbaric bupivacaine in the context of caesarean section procedures.[10] Using it in this specific setting may have distinct advantages, as its properties could lead to a more reliable and predictable distribution.

Levobupivacaine has a lower affinity for cardiac sodium channels and shows higher plasma protein binding affinity compared to the dextro isomer. By doing so, it reduces the risk of cardio- toxicity. Levobupivacaine has been discovered to possess a pressure similar to cerebrospinal fluid, leading to a more reliable distribution of the drug. By incorporating this into your routine, you can effectively decrease the likelihood of experiencing low blood pressure and a slow heart rate. Levobupivacaine also results in quicker motor recovery in comparison to racemic bupivacaine. Levobupivacaine has numerous advantages that make it a highly appealing option for spinal anesthesia, in comparison to racemic bupivacaine.[11-14]

In recent years, levobupivacaine has become increasingly popular as a safer alternative to its racemic parent for regional anesthesia.

As part of our study, we carried out a thorough investigation to evaluate how hyperbaric levobupivacaine affects the effectiveness of the block, haemodynamic changes & complications in comparison to hyperbaric Bupivacaine in lower limb orthopaedic surgery under spinal anaesthesia using a randomized, double-blind approach.

MATERIALS AND METHODS

A total of 60 patients who were scheduled for orthopedic surgeries below the umbilicus were included in the study after obtaining their informed written consent.

We have obtained approval from the ethical committee. study enrolled patients aged 18 to 60 years with American Society of Anesthesiologists Physical Status (ASA) Class 1 & 2.

Patients who were ineligible for neuraxial anesthesia, had allergies to the study drugs, were pregnant, had spinal deformities, or showed signs of raised intracranial pressure were excluded from the study. A pre anesthetic evaluation was performed the evening before surgery, along with the necessary investigations. Prior to the surgery, the patients were given a pre-medication of alprazolam 0.5 mg and ranitidine 150 mg tablets to be taken orally at bedtime the night before. Prior to surgery, they were required to fast for 6 hours for solid food and 2 hours for clear liquids. During the surgery, the patient's basic vital signs were documented. The monitoring was conducted using a multiparameter monitor equipped with pulse oximetry, Electrocardiogram (ECG), and Non- invasive Blood pressure (NIBP) capabilities. An 18-gauge cannula was used to obtain an intravenous line.

A lumbar dural tap was performed in the L3-L4 interspace using a midline approach. The procedure involved the use of a 23- or 25- gauge Quincke's needle, following local skin infiltration with 2% xylocaine. Ensuring a smooth and unobstructed flow of CSF, the drug was administered cautiously, with careful attention to avoid any blood aspiration. After the injection was finished, patients were instructed to lie down on their backs. As part of the surgical procedure, all patients received intravenous fluids, specifically either normal saline or ringer lactate solution. Patients were divided into two groups based on the medication administered.

Group L: received intrathecal 3 ml hyperbaric 0.5% levo bupivacaine

Group B: received intrathecal 3 ml hyperbaric 0.5% bupivacaine with

The study drug was prepared by an anesthesiologist who played a role in randomization, but did not have any further involvement in the study. The anesthesiologist who administered the test drug also served as the observer of the parameters. Therefore, both the observer and the patients were kept unaware of the study drug.

The following parameters were studied:

Demographic Data

Onset of sensory block: Onset of sensory block- This was taken as the time from the deposition of drug to the evidence of analgesia to pinprick at T12 level.

Onset of motor blockade: Time taken from onset of paresis to the loss of power i.e. patient was not able to lift the legs.

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Modified Bromage scale: 0 = no motor blockade, 1 = hip blockade, 2 = hip and knee blockade, 3= hip, knee and foot blockade.

Duration of analgesia. Time when the patient first complains of pain after spinal block

Quality of intraoperative anesthesia Includes:

- Score 0: No sensation at the site of surgery.
- Score 1: Sensation at the site of surgery but no pain.
- Score 2: Painful sensation at the site of surgery with supplemental analgesics.

Postoperative complications if any.

Statistical analysis

The data was compiled and entered into a spreadsheet computer program (Microsoft Excel 2019) and then exported to the data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). Quantitative variables were reported using measures such as means and standard deviations or median and interquartile range, depending on their distribution. The presentation of qualitative variables was in the form of counts and percentages. Confidence level and level of significance were set at 95% and 5% respectively for all tests.

RESULTS

The demographic profile of the patients, including age, sex, weight, height, and type of surgeries, did not exhibit any statistically significant differences between the two groups in our study. The baseline vital parameters were comparable in both groups.

In group B, the average time for the onset of sensory block was 2.52 minutes, slightly faster than the 2.66 minutes observed in group L. However, the p value of 0.37 indicated that this difference was not statistically significant. In group B, the average time for the onset of motor block was

3.51 minutes, slightly lower than the 3.68 minutes observed in group L. However, the p value of 0.54 indicated that this difference was not statistically significant.

In group B, a higher percentage of patients (95%) experienced a grade 3 motor blockade compared to group L, where only 64.50% of patients experienced the same. Additionally, 37% of patients in group L experienced a grade 2 motor blockade. These differences are statistically significant (p value = 0.03). Regarding Quality of Intraoperative Anesthesia in group L, the majority of patients (76.5%) had a score of 0, while remaining 23.5% of patients had a score of 1. This difference was statistically significant (p value<0.005).

For patients in group B, a notable 13.5% achieved a sensory level of T6. A majority, 53.5%, reached a sensory level up to T8, while 33.5% achieved a sensory level of T10. In group L, a small percentage of patients reached a sensory level of T6, while a majority of them achieved a level of T8. A significant number of patients also achieved a sensory level of T10. However, the difference between two groups was not statistically significant. The maximal upper spread of sensory blockade reached T6 in 16.5% of patients in group B and 20.5% in group L. In group B, it reached T8 in 76.5% of patients, while in group L it was only 24.5%. Additionally, T10 was reached in only 6.5% of patients in group B. The level of maximum upper spread of sensory blockade was found to be similar in both groups, with no statistically significant difference (p value> 0.5).

The mean two segment regression time in group B was 132.50 minutes, slightly longer than the 130 minutes observed in group L. However, this difference was found to be statistically insignificant (p value = 0.5). The mean and standard deviation of the total duration of sensory blockade in Group B were 209.10, while in Group L they were 198.22, respectively. The total duration of motor blockade in Group B was 189.4±12.5 mins, while in Group L it was slightly shorter at 181.3±12.5 mins. In group B, the average duration of analgesia was 191.47±24.50 minutes, while in group L it was 180.37±29.89 minutes. The p value was found to be less than 0.01, indicating a statistically significant difference. The mean pulse rate changes and blood pressure changes were similar in both groups and were not found to be statistically significant. The intraoperative complications between the two groups were similar and did not show any significant statistical difference.

According to [Table 4], there have been reports of adverse events. There was a higher occurrence of hypotension observed with bupivacaine (6 out of 30) compared to levobupivacaine (4 out of 30). No significant variations were noted in the occurrence of bradycardia, nausea, or vomiting.

Table 1: Demographic data

Variables	Bupivacaine Group (n = 30)	Levobupivacaine Group (n = 30)	P value
Age (yr)	27.4 ± 4.22	28.12 ± 4.54	0.49
Height (m)	1.48 ± 0.19	1.75 ± 0.06	0.20
Weight (kg)	74.8 ± 09.44	76.9 ± 10.10	0.1
Male/Female	13/17	14/16	0.32

*Statistically significance at p≤0.05

Table 2: Comparison of sensory block and motor block

Variables	Bupivacaine Group (n = 30)	Levobupivacaine Group (n = 30)	P value
Mean onset of sensory block (mins)	2.52 ± 0.33	2.66 ± 0.56	0.40
Mean onset of motor blockade (mins)	3.51± 0.03	3.68 ± 0.11	0.54
Duration of Anesthesia			

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Minimum	161.21±25.22	154.32±26.10	*0.05
Maximum	229.10±32.84	216.48±31.77	
Mean + SD	191.47±24.50	180.37±29.89	

*Indicates statistically significance at p≤0.05

Table 3: Quality of Anesthesia

Quality of Anesthesia	Bupivacaine Group (n = 30) (Percentage)	Levobupivacaine Group (n = 30) (Percentage)	P value
Excellent (score = 3)	25 (83.3)	26 (86.6)	
Satisfactory (score = 2)	4 (13.3)	4 (13.3)	
In-adequate (score = 1)	1 (3.3)	0	
Failure (score = 0)	0	0	0.23

*Statistically significance at p≤0.05

Table 4: Complications during surgery

Complications	Bupivacaine Group (n = 30)	Levobupivacaine Group (n = 30)	P value
Hypotension	6	4	0.23
Bradycardia	2	1	0.12
Nausea	0	0	-
Vomiting	0	0	-

*Statistically significance at p≤0.05

DISCUSSION

There are numerous benefits to using regional anaesthesia instead of general anaesthesia. These include decreased bleeding caused by low blood pressure, improved pain relief during and after surgery, the patient remaining awake, reduced need for injectable opioids, lower rates of nausea and vomiting, decreased risk of blood clots, heart attacks, respiratory issues, and kidney failure. Levobupivacaine is the pure S (¬-) enantiomer of racemic bupivacaine. It was developed as an alternative anaesthetic agent to bupivacaine. Levobupivacaine possesses comparable blocking properties and a wider safety margin as a result of its reduced potential for toxicity.

The demographic properties and ASA grading showed no statistically significant differences between the two groups. The patients' mean age, weight, height, and gender were comparable in both groups. The time it took for the drug to start relieving pain at the T12 level was measured in minutes, starting from when it was administered. In this study, patients who were given bupivacaine experienced a slightly faster onset of sensory block compared to those who received levobupivacaine. However, the difference was not statistically significant. The sensory block onset time showed some variation in Group B, ranging from 1.5 to 4 minutes, with an average of 2.51 minutes. In Group L, the onset time ranged from 2 to 5 minutes, with an average of 2.62 minutes. These findings align with previous studies conducted by Gulen Guler et al,[15] and J.F. Luck et al,[16] Gautier et al,[17] also reported similar findings during spinal anaesthesia for caesarean delivery. In a recent study, researchers conducted a comparison between levobupivacaine and bupivacaine, focusing on the same doses. The findings revealed that the bupivacaine group had a higher rate of maintaining adequate anaesthesia, with 97% of patients experiencing this outcome. In contrast, the levobupivacaine group had a slightly lower rate of 80%. Additionally, the duration of motor block and analgesia was found to be shorter in the levobupivacaine group. On the other hand, Erdil et al,[18] found that bupivacaine resulted in a higher sensory level. It is possible that the difference in the type of bupivacaine used in their study, baricity instead of hyperbaric, could be the reason for this.

The maximum level of sensory block achieved is similar in both groups in our study. According to studies conducted by F. Fattorni et al,[19] and Glaser et al,[20] there was no significant difference observed between the bupivacaine and levobupivacaine groups in terms of the highest level of sensory block achieved (T8, T8) or the time taken to reach the peak level. The time taken for the two-segment regression of sensory in Group B was 132.50 minutes, while in Group L it was 130 minutes. The difference between the two groups is statistically insignificant, with a p-value of 0.2. This finding is consistent with a study conducted by Christian Glaser et al.[20] In Group B, the time it took for motor block to set in ranged from 2 to 5 minutes, with an average time of 3.58 minutes. According to the study, the quality of intraoperative anaesthesia was found to be excellent in the bupivacaine group, with a score of 0 in 100% of patients. This indicates that there was no sensation at the site of surgery. In the levobupivacaine group, 76.5% of patients had a score of 0, indicating no sensation at the site of surgery, while the remaining 23.5% had a score of 1, indicating sensation but no pain. None of the patients in either group had a score of 2, which indicates painful sensation requiring additional pain relief. This difference was found to be statistically significant (p value 0.005). Bupivacaine offers superior pain relief in comparison to levobupivacaine. In a recent study, Burke et al examined the use of 0.5% levobupivacaine 3 ml for spinal anaesthesia in twenty patients undergoing lower limb surgery. The study was open and non-comparative in nature. In 90% (18/20) of cases, the

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quality of anaesthesia was found to be satisfactory. It was determined that the distribution of the 0.5% levobupivacaine solution was difficult to predict.[21] The overall quality of surgical anaesthesia with levobupivacaine was satisfactory and similar to that of bupivacaine.

The mean value for the total duration of motor blockade and sensory blockade in the bupivacaine group was significantly higher. This observation is similar to a study conducted by J.F. Luck et al,[16] Christian Glaser et al,[20] and Şahin et al.[22] Motor recovery was expedited with levobupivacaine compared to bupivacaine, leading to a shorter time to walk unaided.

The occurrence of post-operative complications was found to be similar in both groups, with no statistically significant difference observed. Other studies have also reported similar findings.[11-14] Due to its higher potency as a local anaesthetic, bupivacaine can lead to a stronger sympathetic blockade, which may increase the likelihood of experiencing hypotension.

CONCLUSION

In conclusion, intrathecal 0.5% hyperbaric levobupivacaine provided excellent quality of anesthesia in the majority of patients undergoing Orthopaedic Surgery. Compared with hyperbaric racemic bupivacaine, it had a shorter duration of sensory and motor block and a lower incidence of intraoperative hypotension. The shorter block recovery time may be a disadvantage for long procedures. However, this can be eliminated with proper patient selection. Hence, levobupivacaine can be a safer alternative to bupivacaine for surgeries under spinal anaesthesia of short duration.

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