Section: Anaesthesia

Original Research Article

TO CONDUCT A COMPARATIVE ANALYSIS OF THE EFFECTS OF INTRATHECAL BUPIVACAINE AND LEVOBUPIVACAINE ON PATIENTS HAVING CAESAREAN SECTION

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Abstract

Background: Spinal anaesthesia is a strategy used to achieve balance during a caesarean delivery. This treatment offers complete muscular relaxation and rapid onset of anaesthesia. The aim is to conduct a comparative analysis of the effects of intrathecal bupivacaine and levobupivacaine on patients having caesarean section. **Materials and Methods:** A cohort of 120 pregnant females, classified as Grade-II according to the American Society of Anesthesiologists, and scheduled for Caesarean section under spinal anaesthesia, were chosen to participate in the research. The research excluded patients who had a previous occurrence of pre-eclampsia and eclampsia, uncontrolled diabetes mellitus, heart disease, morbid obesity, spinal deformities, coagulation abnormalities, and pregnant females who had a height below 150 cm or above 170 cm. **Result:** The mean time it took to reach sensory blockade up to the T6 level was greater in Group B (163.08±21.85 seconds) compared to Group L (141.05±19.96 seconds). Additionally, the time it took to reach the maximum height of sensory block was similarly greater in Group B (249.99±25.85 seconds) compared to Group L (217.88±23.39 seconds). The group L had a quicker decline of sensory block until the L2 Level. The highest level of sensory blockage obtained in both groups was T4. A total of 55 patients in group B and 48 patients in group L reached their maximal height by T4. A statistically significant difference ($p<0.01$) was seen in the time it took to obtain a motor blockage until a Bromagen score of 3. Group B had a mean time of 311.47±12.28 seconds, whereas group L had a mean time of 421.61±11.74 seconds. and the duration before the motor blockage regressed was significantly longer in group B (159.85±4.63 minutes) compared to group L (129.96 ± 5.69 minutes). **Conclusion:** Both bupivacaine and levobupivacaine were determined to be effective in achieving the intended effects of anaesthesia and analgesia. Levobupivacaine exhibited a prompt initiation of sensory block, but a delayed initiation of motor blockade. Additionally, it demonstrated a substantial reduction in both the duration and intensity of sensory and motor impairment compared to bupivacaine, perhaps facilitating early mobilisation. Levobupivacaine has roughly equivalent efficacy to bupivacaine in generating sensory and motor blockade, with similar onset time and superior hemodynamic stability.

INTRODUCTION

Caesarean births often need the use of spinal anaesthesia. It is a simple, cost-effective, and rapidly causes anaesthesia and complete muscle relaxation.[1] Hyperbaric bupivacaine is a frequently used local anaesthetic (LA) for SA. The drug is recognised for causing a long-lasting motor blockade and is linked to adverse effects such as low blood pressure, slow heart rate, and feelings of nausea and vomiting caused by the expansion of the sympathetic block. Unintentional injection into a vein may lead to fatal toxicity affecting the heart and central nervous system.[2,3] Levobupivacaine is a more contemporary local anaesthetic that has received approval for intrathecal injection in recent years. Levobupivacaine is the optically active form of bupivacaine, consisting only of the S (-) enantiomer.[4] Levobupivacaine is a potent local anaesthetic that has a lengthy duration of action and a somewhat gradual start. Compared to bupivacaine, it has a reduced tendency to block inactive cardiac sodium and potassium channels, as

well as a quicker dissociation rate.[5] Its rapid protein binding rate results in decreased cardiac toxicity when taken in excessive amounts or administered intravenously. Levobupivacaine in its pure form has the same pressure as cerebrospinal fluid (CSF).[6-8] It has more influence on motor fibres in comparison to sensory fibres. It has moderate motor effects in comparison to bupivacaine. The benefits of levobupivacaine include extended sensory blockade, quicker recovery from motor blockade, and reduced hypotension, making it a viable choice for obstetric surgery.[9] Several studies have shown a reduction in the occurrence of adverse effects such as low blood pressure, slow heart rate, nausea, and vomiting while using this particular medication for spinal anaesthesia during caesarean section, as compared to bupivacaine.

The pharmacokinetic characteristics are better, whereas the clinical characteristics are equivalent to those of bupivacaine. It exhibits lower neurotoxicity and cardiotoxicity in comparison to bupivacaine. The advantage of its baricity is that it produces a block that is less sensitive to positioning.[10] Furthermore, there is a suggestion to provide reduced amounts of bupivacaine with intrathecal opioids for the purpose of inducing spinal anaesthesia in pregnant women undergoing caesarean sections.[11] Combining the administration of opioids with local anaesthetics via the neuraxial route enhances the effectiveness of pain reduction during surgery and also extends the period of postoperative pain management.[12] Thus, Fentanyl offers superior pain relief during surgery and is a safer substitute for morphine. Fentanyl dosages ranging from 10 µg to 25 µg are often used in the spinal region for anaesthesia during caesarean deliveries.[13] There are no harmful consequences associated with it, and it seems to be safe for both the mother and the infant.[14] The research author conducted a comparison between the impact of hyperbaric bupivacaine and isobaric levobupivacaine on patients who were having lower segment caesarean section under spinal anaesthesia.

MATERIALS AND METHODS

This research was done in a prospective, randomised, and double-blind manner after permission by the hospital's ethics committee. Consent was gained from all participants after providing them with relevant information. A cohort of 120 pregnant females, classified as Grade-II according to the American Society of Anesthesiologists, and scheduled for Caesarean section under spinal anaesthesia, were chosen to participate in the research. The research excluded patients who had a previous occurrence of pre-eclampsia and eclampsia, uncontrolled diabetes mellitus, heart disease, morbid obesity, spinal deformities, coagulation abnormalities, and pregnant females who had a height below 150 cm or above 170 cm.

Methodology: Patients were assessed pre-operatively and complete clinical history, general physical examination were documented. All standard investigations were carried out. The patients were kept fasting for 6 hours before to the planned time of operation. Prior to surgery, the patients were given ranitidine 150 mg orally the night before and ranitidine with metoclopramide intravenously 2 hours before the operation.

Electrocardiography (ECG), pulse oximetry (Spo2), and Non-Invasive Blood Pressure (NIBP) were set up for monitoring in the operating room. Vital parameters were measured and recorded as the first values. An intravenous line was established using a properly sized intravenous cannula. Patients were assigned randomly to either group B or group L using sealed envelopes containing code numbers. Group B patients (n=60) were administered 10 mg of hyperbaric bupivacaine, whereas group L patients (n=60) got 10 mg of isobaric levobupivacaine.The study medication was prepared and given by a separate anaesthesiologist who was not engaged in the research. The anaesthesiologist responsible for gathering and analysing data was unaware of the group assignment.

Following strict aseptic and universal precautions, SA (spinal anaesthesia) was provided to the patient while they were in a seated posture, specifically in the L3-L4 interspace, using a 25G Quincke spinal needle. The study medication was then injected. Subsequently, the patient was positioned in a supine orientation. The sensory block was evaluated by applying a cotton ball saturated with ethyl alcohol every minute for a duration of 5 minutes. Subsequently, the assessment was repeated every 5 minutes for a total of 30 minutes. Following the operation, the sensory block was reevaluated at intervals of 15 minutes until it returned to the L2 dermatome level. Loss of cold feeling to T6 dermatome level was regarded sufficient for initiation of operation. The time taken for the sensory blockade to reach the T6 dermatome level was measured, which is the interval between the delivery of the medication via the spinal canal and the propagation of the sensory block up to the T6 level. The study documented the highest level at which the sensory block was obtained, the time it took to reach this maximum level, and the length of the sensory block (the time interval from the injection of the medication into the spinal canal to the point when the block receded to the L2 level). The degree of motor block was evaluated using the modified Bromage Score (MBS).

The motor block was evaluated concurrently with the sensory block. The onset time of motor blockage was measured as the duration between the intrathecal delivery of the medication and the attainment of a Bromage score of 3. The duration of the block was recorded as the time interval between the injection of the intrathecal medication and the point at which the Bromage score returned to zero.

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The patient's haemodynamic parameters were collected at baseline (before the block), every minute until 5 minutes, and then every 5 minutes until the completion of the procedure. Episodes of hypotension, bradycardia, nausea, and vomiting were documented. Hypotension was defined as a decrease of 20% in systolic blood pressure compared to the initial value. An intravenous bolus of 5 mg of Ephedrine was delivered immediately to address low blood pressure. Additionally, if the heart rate decreased below 50 beats per minute or less than 20% of its initial value, an intravenous dose of 0.3 mg of Atropine was administered as required. The episode of nausea and vomiting was managed by administering a 4mg intravenous injection of ondansetron.

The groups were compared by doing a Student's t test on the normally distributed continuous variables. The groups were compared using either the Chi-square test or Fisher's exact test, depending on the nature of the nominal categorical data. A p-value of less than 0.05 was regarded to indicate statistical significance.

RESULTS

The analysis includes data from all 120 participants who were included in the research. The age, weight, height, and length of operation of the patients were similar in both groups, as shown in [Table 1]. The mean time it took to reach sensory blockade up to the T6 level was greater in Group B (163.08±21.85 seconds) compared to Group L (141.05±19.96 seconds). Additionally, the time it took to reach the maximum height of sensory block was similarly greater in Group B (249.99±25.85 seconds) compared to Group L (217.88±23.39 seconds). The group L had a quicker decline of sensory block until the L2 Level. The highest level of sensory blockage obtained in both groups was T4. A total of 55 patients in group B and 48 patients in group L reached their maximal height by T4. A statistically significant difference ($p<0.01$) was seen in the time it took to obtain a motor blockage until a Bromagen score of 3. Group B had a mean time of 311.47±12.28 seconds, whereas group L had a mean time of 421.61±11.74 seconds. and the duration before the motor blockage regressed was significantly longer in group B (159.85±4.63 minutes) compared to group L (129.96 ± 5.69 minutes). The following information is shown in [Table 2].

The haemodynamic parameters measured indicated that there was no change in the average heart rate in both groups. Although there was a modest decrease in mean arterial pressure (MAP) in group B compared to group L, this decrease was not statistically significant.

Although the occurrence of hypotension and bradycardia was more common in group B compared to group L, the difference was not statistically significant. The occurrence of nausea was substantially higher in group B, as seen in Table 3].

Table 1: Patient characteristics

Patient parameters	Group B (n=60) Mean±SD	Group L (n=60) Mean±SD	p value
Age (Yrs)	25.11±2.85	25.07 ± 2.37	0.24
Height (in cm)	158.01±3.69	158.11±3.74	0.36
Weight (in Kg)	61.99±3.87	50.87±4.25	0.22
Duration of Surgery (min)	58.17±5.85	55.36±5.91	0.27

Table 2: Characteristics of sensory and motor block

Sensory and motor block evaluation	Group B Mean±SD	Group L Mean±SD	p value
Time to achieve sensory blockade till T6 Level (Sec)	163.08±21.85	141.05±19.96	0.07
Time to achieve maximum height of sensory block (Sec)	249.99±25.85	217.88±23.39	0.06
Time of regression of sensory block till L2 Level (Min)	195.55±5.81	170.25±5.61	<0.001
Maximum height of sensory blockade	T4(55) T6(5)	T4 (48) T6 (9) T2 (3)	0.19
Time to achieve motor blockade till Bromage score 3 (Sec)	311.47±12.28	421.61±11.74	<0.001
Time to regression of motor blockade (min)	159.85±4.63	129.96 ± 5.69	<0.001

Table 3: Complications

Complications	Group B (n=60)		Group L (n=60)		p value
	Number	Percentage	Number	Percentage	
Bradycardia	20	33.33	8	13.33	0.003
Hypotension	36	60	22	36.67	0.003
Nausea	15	25	5	8.33	0.001
Vomiting	7	11.67	2	3.33	0.15

DISCUSSION

Levobupivacaine, which is the enantiomer of bupivacaine and has a high potency, has received approval for intrathecal administration. Levobupivacaine is advantageous for ambulatory surgery at low concentrations because it creates a selective block in the spinal cord while preserving motor function.[15] Both groups in this research had similar demographic characteristics, including age, weight, and height, and these similarities were not statistically significant. In the current investigation,

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both groups successfully attained the necessary sensory block level for caesarean section. The duration required to attain T6 sensory height was shorter in group L compared to group B (group L-141.05±19.96sec, group B-163.08±21.85sec), suggesting an earlier onset with Levobupivacaine. The experiments conducted by Babu et al and Debbarma et al demonstrated comparable durations.[7,16] Duggal et al observed that the onset time was 3.6±0.08 minutes in the bupivacaine group and 3.87±0.73 minutes in the levobupivacaine group. The duration in this instance was much greater than that documented in this investigation, despite the same dosage administered in both studies.[17] In contrast to our findings, Babu et al, Duggal et al, and Madanmohan et al reported a shorter onset time for bupivacaine compared to levobupivacaine.[7,17,18] Nevertheless, all the research reached the consensus that the sensory block characteristics of both bupivacaine and levobupivacaine are quite similar. The present study found that the time it took to reach the maximum height of the sensory block was longer in group B compared to group L. This finding is consistent with previous studies by Debbarma et al, Madanmohan et al, Kumar et al, and Duggal et al, which also reported longer durations to reach the maximum height. The difference in weight and height of the study subjects may explain the extremely high duration recorded in these studies compared to the present study.[6,16-18] The majority of research, including the current study, have indicated that bupivacaine takes longer to reach its maximum height compared to levobupivacaine. However, Kumar et al and Madanmohan et al reported that levobupivacaine actually took longer to reach this point.[6,18]

The majority of patients in both groups showed a sensory blockage reaching up to the T4 level, which is consistent with the findings of Debbarma et al (T4 in both groups).[16] Babu et al, Duggal et al, and Madanmohan et al, observed that the height of the anaesthesia block was T6 when levobupivacaine was used, and T4 when bupivacaine was used.[7,17,18] The height of the sensory block was noted to be at the T4 level when using bupivacaine, and between the T4 and T6 levels while using levobupivacaine, with an estimated dosage of 10 mg. In the current investigation, the time it took for the L2 dermatome to regress was shorter with levobupivacaine (170.25±5.61 minutes) compared to bupivacaine (195.55±5.81 minutes). Although there was some fluctuation in the length, the majority of studies found that Levobupivacaine had a shorter regression time compared to bupivacaine.[7,16-19] Conversely, Kumar et al. noted a prolonged period of regression while using Levobupivacaine.[6] Bupivacaine continues to demonstrate superior analgesic duration compared to levobupivacaine. The location of the patient, the dispersion of the injection, and the baricity of the solution are all factors that might impact these actions.[16] Several writers have proposed that isobaric levobupivacaine in cerebrospinal fluid (CSF) exhibits no preference for gravitational forces. Hence, the patient's posture after the injection does not have any impact on the amount of sensory block caused by intrathecal isobaric levobupivacaine. This might be a benefit compared to bupivacaine, since it leads to a significant amount of blockage owing to its propensity to spread unexpectedly higher, even after sufficient fixing time.[17]

The present investigation demonstrated that the time required to induce motor blockage until MBS-3 was quicker and its length was greater in parturients in Group B compared to those in Group L. The rapid onset may be attributed to the hyperbaricity of bupivacaine. In this research, the duration of motor block recovery was shown to be more varied in the levobupivacaine group. The duration varied between 60 and 200 minutes in a small number of individuals. The outcomes we obtained were almost on par with the findings of Babu et al and Gori et al. However, Duggal et al and Debbarma et al showed a shorter duration for regression.[7,16,17,19] Research has shown that the length of time that the motor block lasts for levobupivacaine is shorter when compared to bupivacaine. The pharmacokinetics of levobupivacaine indicate that it is metabolised by CYP2A2 in the liver and has a greater clearance rate of 28-37 mgkg-1min-1.[16] The stated potency ratio of levobupivacaine to bupivacaine varies between 0.75 and 0.87, according to different authors. The reported ED95 dosage of levobupivacaine for caesarean section under spinal anaesthesia is 12.56 mg.[18] We delivered a sub-ED95 dose of 10 mg of levobupivacaine for CS. Levobupivacaine has less affinity for Aα fibres, which are somatic motor fibres, compared to bupivacaine. This difference in affinity may lead to a smaller degree of motor block.[6] These circumstances may lead to a brief period of motor and sensory block in individuals who are administered levobupivacaine.

There was no notable variation in the haemodynamic parameters among any of the groups. Intermittent occurrences of decline in human resources were noted, however, no substantial alterations were detected during the whole duration of the research. A decrease in mean arterial pressure (MAP) was seen 3-5 minutes after the administration of SA in both groups. The decrease in MAP throughout this autumn was greater in group B compared to group L, however the difference was not statistically significant. A similar finding was documented by Kumar et al. and Madanmohan et al.[6,18]

Although hypotension is a frequently seen consequence after spinal anaesthesia, it has significant relevance in the context of caesarean section. In addition to affecting the mother, hypotension may also impair placental perfusion, posing a potential risk to the foetus. The most prevalent reason for experiencing nausea and vomiting after spinal anaesthesia for caesarean section is hypotension and an additional reduction in cerebral blood flow. The occurrence of low blood pressure, slow heart rate, and feelings of nausea and

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vomiting were more evident in group B as compared to group L.[17,20,21] The occurrence of low blood pressure and slow heart rate after spinal anaesthesia may be attributed to the inhibition of the sympathetic nervous system caused by the anaesthetic. This effect is more pronounced with hyperbaric drugs than to isobaric drugs. The decreased occurrence of nausea and vomiting seen in group L in this investigation may be attributed to the reduced hypotensive effects of levobupivacaine, although this difference did not reach statistical significance.

Previous writers have also noted a similar tendency, where the occurrence of the aforementioned problems was comparatively lower in the levobupivacaine group. Levobupivacaine has an extra characteristic of diminishing the harmful effects on the heart and nervous system. Compared to bupivacaine, it has a lower likelihood of causing myocardial depression and arrhythmias, making it safer.[18,22,23] Isobaric levobupivacaine exhibits reduced sensitivity to patient position post-injection, offering an advantage over bupivacaine. Bupivacaine has a propensity to unexpectedly migrate to higher levels even after sufficient fixation time, leading to elevated spinal levels and subsequent late complications such as hypotension, bradycardia, and nausea.[16]

CONCLUSION

Both bupivacaine and levobupivacaine were determined to be effective in achieving the intended effects of anaesthesia and analgesia. Levobupivacaine exhibited a prompt initiation of sensory block, but a delayed initiation of motor blockade. Additionally, it demonstrated a substantial reduction in both the duration and intensity of sensory and motor impairment compared to bupivacaine, perhaps facilitating early mobilisation. Levobupivacaine has roughly equivalent efficacy to bupivacaine in generating sensory and motor blockade, with similar onset time and superior hemodynamic stability.

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