

Effect of Intrathecal Isobaric Levobupivacaine and Hyperbaric Bupivacaine in Lower Limb Orthopaedic Surgery - A Comparative Study

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Abstract: *Background and aims:* Levobupivacaine is less cardiotoxic and has less CNS side effects. This study aims to compare the intrathecal block characteristic, hemodynamic stability and adverse effect of isobaric levobupivacaine and hyperbaric bupivacaine in lower limb orthopaedic surgery. *Methods:* 90 patients with ASA grade I/II between the age group 18-65 yrs under going lower limb orthopaedic surgery were included in this hospital based observational study. Patients were divided into two groups of equal size (n = 45). The patients were given spinal anaesthesia in sitting position and after confirmation of needle in the subarachnoid space the drugs were administered. Group B received 17.5 mg hyperbaric bupivacaine and Group L received 17.5 mg isobaric levobupivacaine. Both groups were compared regarding sensory-motor block characteristics, hemodynamic profile, adverse effects, supplemental analgesia and success rate. *Results:* Both agents produced effective spinal anaesthesia to accomplish surgery without supplementation in all 90 (100%) patients. Onset of sensory and motor block was faster in bupivacaine. Duration of sensory and motor block and analgesia was longer in bupivacaine however there was no need for supplement analgesia during the intra operative period. Incidence of hypotension and side effects were less in levobupivacaine. *Conclusion:* Isobaric levobupivacaine is a suitable alternative to hyperbaric bupivacaine in spinal anaesthesia as it provides effective sensory motor blockage and stable hemodynamic profile and significantly decreased cardiovascular and central nervous system toxicity.

Keywords: isobaric levobupivacaine, hyperbaric bupivacaine, subarachnoid block.

1. Introduction

Spinal anaesthesia was pioneered in humans by a German surgeon Dr August Bier on August 15th 1898 using Quinke method of entering the intrathecal space. Spinal anaesthesia—also known as subarachnoid block, intradural block, and intrathecal block—is a type of neuraxial regional anaesthesia. It involves injecting local anaesthetics, typically with a fine gauge needle, into the subarachnoid (intrathecal) area with or without an adjuvant such as opioids. Intrathecal block provides an excellent operating conditions for surgeries of lower limbs. Intrathecal block is easy to perform and is better for attenuating stress response than general anaesthesia. However spinal anaesthesia is associated with its side effects like hypotension, bradycardia, post dural puncture headache, urinary retention, nausea and vomiting, backache and nerve injury (1, 2). Hyperbaric bupivacaine 0.5%, an amide local anaesthetic is presently the most common drug used for spinal anaesthesia.

Hyperbaric bupivacaine in 8% glucose is often used. Plain, or glucose-free, bupivacaine has been frequently referred to as “isobaric” in the literature, even after Blomqvist and Nilsson³ demonstrated its hypo-baricity. More recently, several studies have confirmed that plain bupivacaine is indeed hypobaric in comparison with human CSF [4, 5, 6] Clinically, this manifests as an unpredictable median sensory block height with a large inter-individual spread and is occasionally associated with block failure when the spinal block has not spread high enough for surgery [7, 8]. For this reason, hyperbaric bupivacaine is favoured in spinal

anaesthesia. Levobupivacaine is the S (–)-enantiomer of the local anaesthetic bupivacaine. It is an amide local anaesthetic which has a pharmacological profile similar to bupivacaine, but with lesser risk of neurotoxicity and cardiotoxicity. [9, 10]

When administered for lower limb surgery it has been shown to have motor blockade of lesser intensity when compared to bupivacaine. It is considered more potent than ropivacaine due to its greater lipid solubility.

2. Materials and Methods

This was a hospital based observational study carried out under the department of anaesthesiology, Jorhat Medical College and Hospital in the study period of one year from June, 2021 to May, 2022 with the prior permission and approval from the institutional Ethical Committee. Study population was patient undergoing elective lower limb orthopaedic surgery. Sample size calculation was done as per last year records, considering the inclusion and exclusion criteria average number of case per month were 15. So the expected sample size for the proposed study was 90 for 6 months of data collection period. Patients was divided into two groups group L (n=45) received intrathecal isobaric levobupivacaine and group B (n=45) received intrathecal hyperbaric bupivacaine.

For patient selection inclusion criteria were:

1. Patients who are willing to give written informed consent.

2. ASA (American society of anaesthesiologist) grade I and grade II patients.
3. Patients aged 18-60 years irrespective of gender
4. Elective orthopaedic lower limb surgery.

The exclusion criteria were:

1. Patients refusal
2. Patients receiving cardiovascular medications, deformities of spinal cord, head injury, bleeding disorders.
3. Patients allergic to local anaesthesia.
4. Emergency surgeries

The study variables were heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, SpO₂ (saturation of peripheral oxygen) monitoring, onset time and duration of sensory blockade, onset time and duration of motor blockade, duration of analgesia, any side effects. Written and informed consent was taken from all patients

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. Data was presented in terms of mean \pm SD and t test was applied for testing the significance.

Technique of Anaesthesia:

A detailed history was taken from the patients and their relatives and a thorough general and physical examination was done. This was recorded in the proforma attached herewith. The patients and their relatives were explained about the study procedure in their understandable language and an informed consent was taken. Thorough pre-operative evaluation was done. Patients were kept fasting for 6 hours on the night before the surgery. Patients were given tab alprazolam 0.25 mg at night before the day of surgery. On arrival to the operation theatre, standard monitors were connected including NIBP, ECG, SPO₂ to the patients and baseline parameters were recorded. Intravenous access was secured with 18 gauge i. v cannula and the patients were preloaded with ringer lactate solution (500ml). All patients were premedicated with i. v Pantoprazole (40mg).

Under all aseptic precautions lumbar puncture was performed with 25 G Quinke's needle in the L3-L4 space in sitting position and after confirming for clear and free flow of CSF the study drugs was injected as per group according to random assignment.

Group L (n=45)-Patient received intrathecally 3.5 ml 0.5 % (17.5 mg) isobaric levobupivacaine. Group B (n=45) – Patient received intrathecally 3.5 ml 0.5 % (17.5 mg) hyperbaric bupivacaine.

Then the patients were placed in supine position. The sensory level was assessed using pinprick method, and readiness to surgery was considered after the complete loss of pinprick sensation at T10 level. The degree of motor block was evaluated with four-point modified Bromage score.

3. Results and Observations

On comparing the mean onset of sensory block it was observed that In Group-B, the mean onset of sensory block in min (mean \pm s. d.) of patients was $2.1733 \pm .3033$. In Group-L, the mean onset of sensory block in min (mean \pm s. d.) of patients was $2.5156 \pm .3330$. The difference in the mean onset of sensory block was found statistically significant between both the group. ($p < 0.0001$).

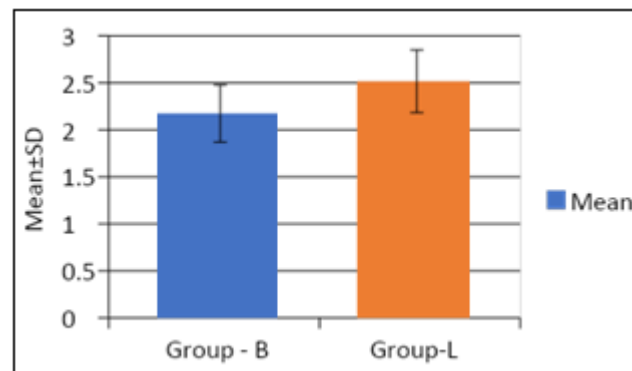


Figure 1: Onset of sensory block

On comparing the mean onset of motor block it was observed that In Group-B, the mean Onset of motor block (Min) (mean \pm s. d.) of patients was $3.7622 \pm .4174$. In Group-L, the mean Onset of motor block (Min) (mean \pm s. d.) of patients was $4.3267 \pm .5471$. The difference in the mean onset of motor block was statistically significant between both the groups ($p < 0.0001$).

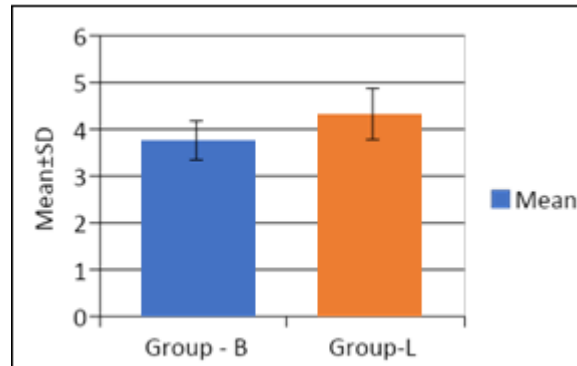


Figure 2: Onset of motor block

On comparing the mean duration of sensory block it was observed that In Group-B, the mean Duration of Sensory Block (Min) (mean \pm s. d.) of patients was 153.2889 ± 10.5348 . In Group-L, the mean Duration of Sensory Block (Min) (mean \pm s. d.) of patients was 137.0000 ± 6.5331 . The difference in the mean Duration of Sensory Block (Min) between the Group was statistically significant ($p < 0.0001$).

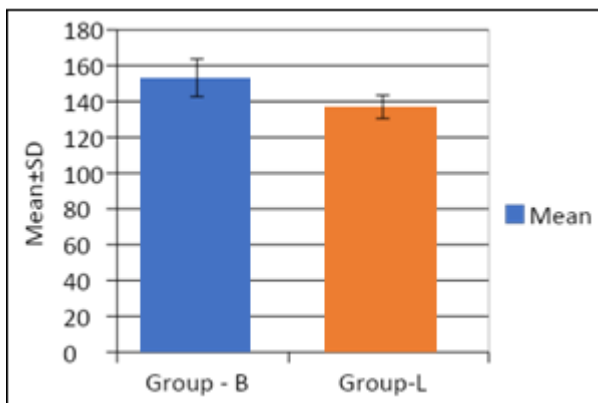


Figure 3: Duration of sensory block

On comparing the mean duration of analgesia it was observed that In Group-B, the mean Duration of analgesia (mean±s. d.) of patients was 165.3333±18.4588. In Group-L, the mean Duration of analgesia (mean±s. d.) of patients was 149.4667±4.9936. Difference in the mean Duration of analgesia with Group was statistically significant (p<0.0001).

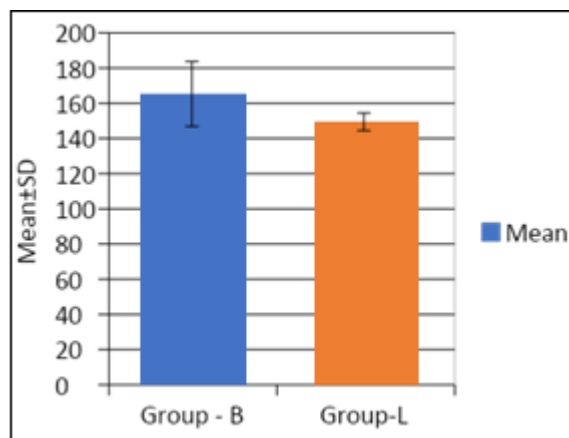


Figure 5: Duration of analgesia

On comparing the mean duration of motor block it was observed that In Group-B, the mean Duration of Motor Block (Min) (mean±s. d.) of patients was 190.7778±79.4140 In Group-L, the mean Duration of Motor Block (Min) (mean±s. d.) of patients was 144.8222±5.7536. The difference in the mean Duration of Motor Block (Min) between the Group was statistically significant (p=0.0002).

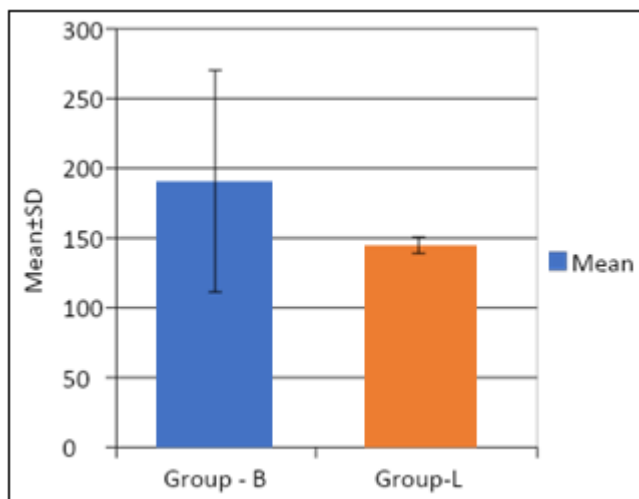


Figure 4: Duration of motor block

On comparing the variation of heart rate between the two groups it is seen that the Herat rate is significant (p<0.05) at 5 mins, 25 mins, 100 mins, 110 mins and 120 mins between both the groups. Whereas Heart rate is not significant (p > 0.05) at base line, immediate after spinal, 10 mins, 15 mins, 20 mins, 30 mins, 40 mins, 50 mins, 60 mins, 70 mins, 80 mins and 90 mins between both the groups.

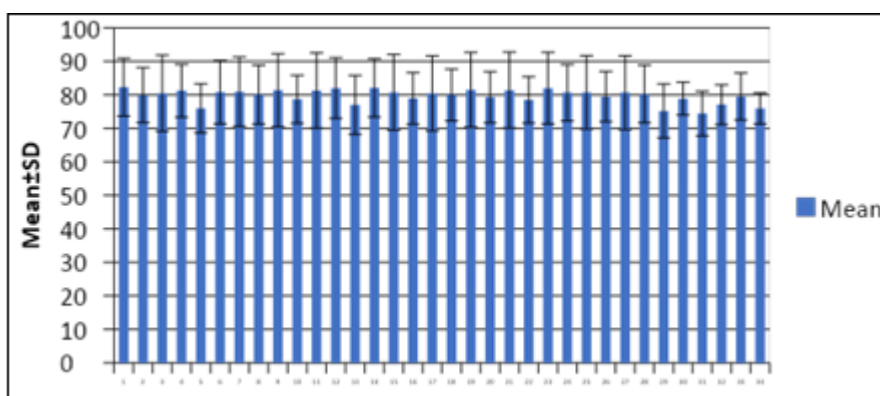


Figure 6: Heart rate

On comparing the variation of systolic blood pressure between the two groups it is seen that the systolic blood pressure is significant (p<0.05) at base line, immediate after spinal, 5 mins, 10 mins, 15 mins, 20 mins, 25 mins, 40 mins,

50 mins, 100 mins, 110 mins and 120 mins between both the groups. Whereas systolic blood pressure is not significant (p > 0.05) at 30 mins, 60 mins, 70 mins, 80 mins, and 90 mins between both the groups.

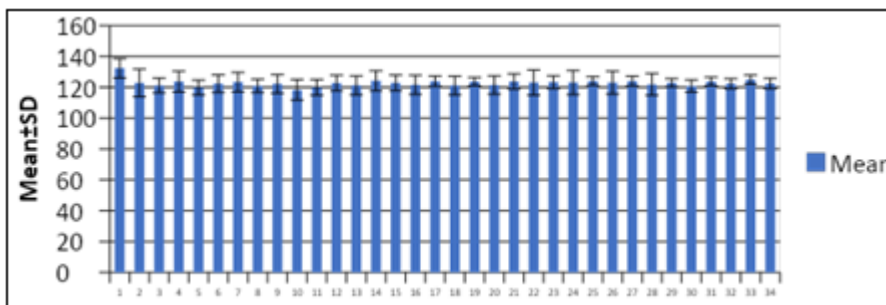


Figure 7: Systolic blood pressure

On comparing the variation of distolic blood pressure between the two groups it is seen that the diastolic blood pressure is significant ($p < 0.05$) at immediate after spinal, 5 mins, 10 mins, 15 mins, 20 mins, 25 mins, 70 mins, 100

mins and 120 mins between both the groups. Whereas diastolic blood pressure is not significant ($p > 0.05$) at base line, 30 mins, 40 mins, 50 mins, 60 mins, 80 mins, 90 mins and 110 mins between both the groups.

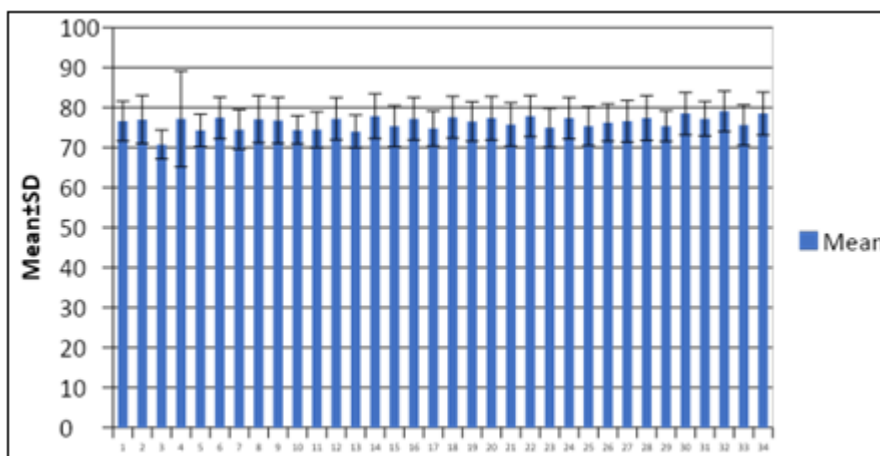


Figure 8: Diastolic blood pressure

On comparing the variation of the mean arterial pressure between the two groups it is seen that the Mean arterial pressure is significant ($p < 0.05$) at Base line, immediate after spinal, 5 mins, 10 mins, 15 mins, 20 mins and 25 mins

between both the groups. Whereas Mean arteria pressure is not significant ($p > 0.05$) at 30 mins, 40 mins, 50 mins, 60 mins, 70 mins, 80 mins, 90 mins 100 mins, 110 mins and 120 mins between both the groups.

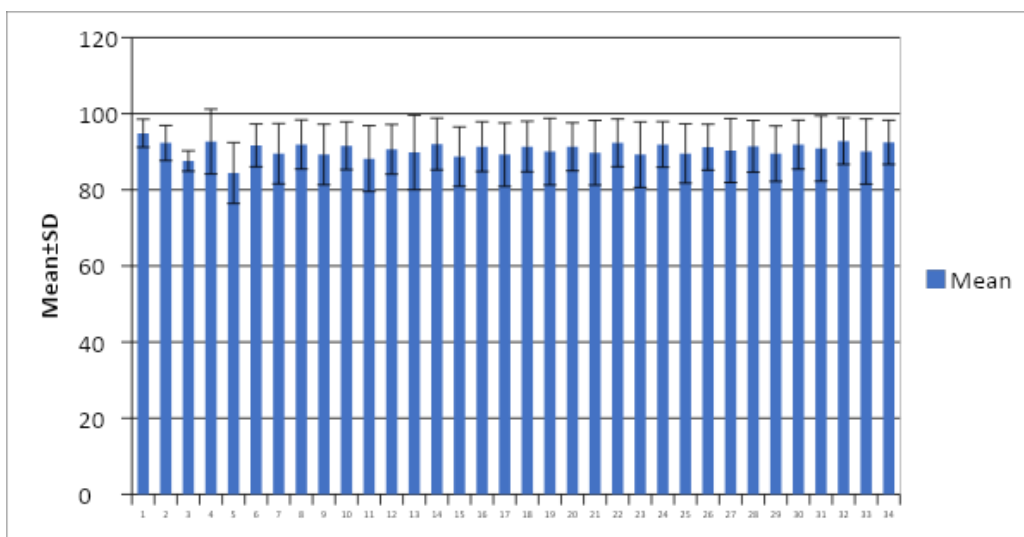


Figure 9: Mean arterial pressure

4. Discussion

Sensory Block: Onset: In our study we found that in Group-B, the mean onset of sensory block in min (mean± s. d.) of patients was 2.1733 ±.3033, while in Group-L, the

mean onset of sensory block in min (mean± s. d.) of patients was 2.5156 ±.3330. Difference of mean onset of sensory block in min with Group was statistically significant ($p < 0.0001$). F. Fattorini¹¹ and colleague in 2006 in their study on orthopaedic surgery found onset time of

bupivacaine was 9 ± 5 minutes and levobupivacaine was 12 ± 6 minutes. **Duration:** In our study we found that in Group-B, the mean Duration of Sensory Block (Min) (mean \pm s. d.) of patients was 153.2889 ± 10.5348 , while in Group-L, the mean Duration of Sensory Block (Min) (mean \pm s. d.) of patients was 137.0000 ± 6.533 Difference of mean Duration of Sensory Block (Min) with Group was statistically significant ($p < 0.0001$). Thepakorn Sathitkarnmanee 12 and their colleagues in the year 2011 in their study for lower limb surgeries found duration of sensory block for bupivacaine was 137.02 ± 40.01 mins and levobupivacaine was 136.14 ± 45.32 mins, statistically insignificant but duration were nearer to our study.

Motor Block: Onset: In our study we found that In Group-B, the mean Onset of motor block (Min) (mean \pm s. d.) of patients was 3.7622 ± 4.174 , while in Group-L, the mean Onset of motor block (Min) (mean \pm s. d.) of patients was 4.3267 ± 5.471 . Difference of mean Onset of motor block (Min) with Group was statistically significant ($p < 0.0001$). Thepakorn Sathitkarnmanee 12 and their colleagues in 2011 in their study for lower abdominal and lower limb surgery found that onset for motor block for bupivacaine was 4.45 ± 3.25 minutes and for levobupivacaine was 4.70 ± 4.56 , which are nearer to our values.

Duration: In our study we found that in Group-B, the mean Duration of Motor Block (Min) (mean \pm s. d.) of patients was 190.7778 ± 79.4140 while in group Group-L, the mean Duration of Motor Block (Min) (mean \pm s. d.) of patients was 144.8222 ± 5.753 Difference of mean Duration of Motor Block (Min) with Group was statistically significant ($p = 0.0002$). Gulen Guler 13 *et al* in 2012 in their study also found similar results where total duration of motor block for bupivacaine was 99 ± 9.13 minutes and for levobupivacaine was 132.66 ± 7.15 minutes.

Duration of analgesia

In our study we found that in Group-B, the mean Duration of analgesia (mean \pm s. d.) of patients was 165.3333 ± 18.4588 while in Group-L, the mean Duration of analgesia (mean \pm s. d.) of patients was 149.4667 ± 4.9936 Difference of mean Duration of analgesia with Group was statistically significant ($p < 0.0001$). Naithani U 14 *et al.* in their study titled Comparison of intrathecal isobaric levobupivacaine with hyperbaric bupivacaine in spinal anesthesia for lower limb orthopedic surgeries, they found that the Duration of sensory block and analgesia were significantly longer in group Bupivacaine compared to that of group Levobupivacaine, $p = 0.0001$ and $p = 0.0014$ respectively while motor were comparable, $p = 0.21$.

Haemodynamic Effects

Systolic blood pressure: In our study we found that the distribution in systolic blood pressure was statistically significant with ($p < 0.05$) at 5 min, 10 min, 15 min, 20 min, 25 min, 40 min, 50 min, 100 min, 110 min and 120 min whereas it was statistically not significant ($p > 0.05$) at 30 min, 60 min, 70 min, 80 min, and 90 min.

Diastolic blood pressure: In our study we found that the distribution in diastolic blood pressure was statistically

significant after spinal at 5 min, 10 min, 15 min, 20 min, 25 min, 70 min, 100 min and 120 min whereas it was statistically not significant ($p > 0.05$) at 30 min, 40 min, 50 min, 60 min, 80 min, and 90 min and 110 min

Mean arterial pressure: In our study we found that the distribution in mean arterial pressure was statistically significant with ($p < 0.05$) at baseline, immediately after spinal at 5 min, 10 min, 15 min, 20 min, 25 min, whereas it was statistically not significant ($p > 0.05$) at 30 min, 40 min, 50 min, 60 min, 70 min, 80 min, 90 min 100 min 110 min and 120 min. In our study we found that hypotension occurred in both the groups, but the decrease in blood pressure was more in bupivacaine group ($p < 0.05$) with more requirement for inj ephedrine ($p < 0.05$), which was statistically significant. In 2012, Gulen Guler 13 *et al* found results which were similar to our study. With 5 out of 30 for group Levobupivacaine and 11 out of 30 for group Bupivacaine showed hypotension, which was significant ($p < 0.05$) with more need for ephedrine. In the study done by Herrera R *et al* (2014) found that haemodynamic changes on patients aged more than 65 yrs for sub arachnoid anaesthesia showed result similar to our study where the incidence of hypotension was significantly higher with $p < 0.05$ in group BUPI (38.3%) compared to group LEVO (13.3%).

Heart Rate: Distribution of mean heart rate were statistically significant at time interval 5, 25, 100, 110, 120 min with ($p < 0.05$) In the study performed by us much difference in the heart rate was not observed except for 1 patients in levobupivacaine had bradycardia and 3 patients in bupivacaine group had bradycardia. In 2012 Gulen Guler 13 *et al* performed a study and found that 2 patients out of 30 patients in the group levobupivacaine and 9 patients out of 30 patients in bupivacaine group showed to have bradycardia which was statistically significant ($p < 0.05$).

Adverse Effects: In our study we found that the incidence of side effects like nausea, vomiting, bradycardia, hypotension were more in bupivacaine group though all got treated with no sequelae. Gulen Guler 13 *et al* in 2012 also found incidence of nausea and vomiting higher in bupivacaine group whereas headache, itching and others had similar incidence in both groups.

5. Conclusion

Our study reveals that 17.5 mg of isobaric Levobupivacaine (3.5 ml of 0.5%) when administered intrathecally provides fast and effective induction of surgical anaesthesia. Isobaric levobupivacaine is a good alternative to hyperbaric bupivacaine in spinal anaesthesia for lower limb orthopedic surgery as it provides effective sensory motor blockage. Isobaric levobupivacaine also shows stable hemodynamic profile with significantly decreased cardiovascular and central nervous system. But for surgery requiring higher sensory blockade, longer duration and emergency operations. . hyperbaric bupivacaine is recommended.

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