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Spinal Anaesthesia with Bupivacaine versus Levobupivacaine with Buprenorphine 100mcg Additive in both - A Double Blind Randomized Study of Anesthetic Efficacy

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Abstract
Background and Aim: *This study aims comparision of analgesic potency and haemodynamic effects of intra-thecal hyperbaric bupivacaine with buprenorphine versus isobaric levobupivacaine with buprenorphine in infra-umbilical surgeries.*
Method: *Total 120 patients between 18 and 60 years, ASA I or II, undergoing lower abdominal and lower limb surgeries under subarachnoid block were selected; group B (n=60) received bupivacaine 0.5% heavy 3 ml intrathecally with buprenorphine 100 mcg as additive while the group L (n=60) received levobupivacaine 0.5% isobaric 3 ml with buprenorphine 100 mcg.*
Observation: *Both the groups were similar in terms of age, gender, height, weight, ASA grade and surgery. There was no statistical significance in terms of onset, maximum level, time to achieve maximum level, total duration and two segment regression in sensory and motor blockade. Heart rate, SBP, DBP, MAP were significantly higher in the L group throughout the surgery. And no statistical significant difference was found in VAS, NPS, time for rescue analgesia and total analgesic doses in intra and postoperative period.*
Conclusion: *Addition of intrathecal buprenorphine as adjuvants to 0.5% isobaric levobupivacaine in spinal anaesthesia produced similar onset of sensory and motor block compared to hyperbaric bupivacaine with buprenorphine but it had preserved better hemodynamics in the former group.*
Keywords: *Levobupivacaine, buprenorphine, spinal anaesthesia, hemodynamic effects.*

Introduction

Spinal anaesthesia is performed to provide for surgical procedures carried on lower limbs, pelvis and lower abdomen. Spinal anaesthesia creates an intense sensory and motor block that can effectively be achieved with a small amount of local anaesthetic drug.[(1,2,3)] Introduction of hyperbaric solutions of bupivacaine have further increased its reliability in intrathecal spread and given it its great popularity for spinal anaesthesia in day-to-day anaesthetic practice. However, it is markedly cardiotoxic, and hypotension is a very common occurrence due to its rapid and potent spinal sympathetic blockade requiring vasopressor

support[4]. The cardiotoxicity of bupivacaine shows enantio-selectivity, i.e. it is more pronounced with the R (+) enantiomer. Levobupivacaine[5,6,7] is the S (-) enantiomer of bupivacaine. It was developed in an attempt to retain the anaesthetic properties of bupivacaine, while reducing its systemic and local toxicity and improving the hemodynamic stability in the recipient. Being more lipophilic than morphine, buprenorphine has low medullary bioavailability after neuraxial administration so that the occurrence of side effects is lesser, making it an attractive alternative.

Material and Methods

The study population was composed of adult male & female patients between the age of 18 and 60 years (both inclusive), with an American Society of Anesthesiology (ASA) grading of I or II, who underwent for lower abdominal and lower limb surgerys under subarachnoid block. The study was initiated after getting permission from the institutional ethics committee. The study was conducted on 120 patients. Patients were randomly allocated in this double-blind clinical study into 2 groups of 60 patients each. 60 patients (GROUP B) received an injection of Bupivacaine heavy 0.5% 3ml with Injection Buprenorphine 100 mcg as an additive intrathecally while the other group of 60 patients (GROUP L) who received Injection Levobupivacaine isobaric 0.5% 3ml with Injection Buprenorphine 100 mcg as an additive intrathecally. SAB was given with a 25-gauge Quincke spinal needle in midline, inserted at the L2–L3 or L3–L4 intervertebral space with patient in sitting position. The haemodynamic variables HR, SBP, DBP, MAP and SpO2 were recorded before spinal anaesthesia at needle puncture and thereafter every 5 min until the end of the procedure. The highest level of sensory blockade and time taken to achieve the same was noted in each group. In postoperative unit, patients were monitored for haemodynamic parameters every 30 min until the sensory and motor variables were back to normal. The patients were asked to assess their level of pain according to the VAS (Visual analogue sale) every 15 min for 120 min, then half hourly for 180 min, after 12 hours and at 24 hours of surgery in both groups. Rescue analgesia in the form of injection tramadol hydrochloride (2 mg/kg) IV will be supplement on complaining of pain (NRS >3) in both groups. Total duration of analgesia was considered from the time of subarachnoid administration of the drug to the time at which patient demand first dose of rescue analgesia. Patients were monitored for any side effects or complications such as hypotension, bradycardia, nausea, vomiting, block site hematoma, pruritis, and local anaesthetic toxicity like light-headedness, neurological changes like dizziness, tinnitus, disorientation, drowsiness, respiratory depression, and cardiovascular depression, sedation, urinary retention, backache for 24 hours.

Results

There was no statistically significant difference observed in the distribution of patients based on age, gender, height, weight, ASA grade and type of undergoing surgery. There was no statistically significant difference in terms of onset, maximum level achieved, time to achieve maximum level, total duration and time required for two segment regression in sensory and motor blockade.

Mean heart rate was significantly higher among patients in Group L at 10, 15, 30, 45, 60, 90 and 120 min intraoperatively.

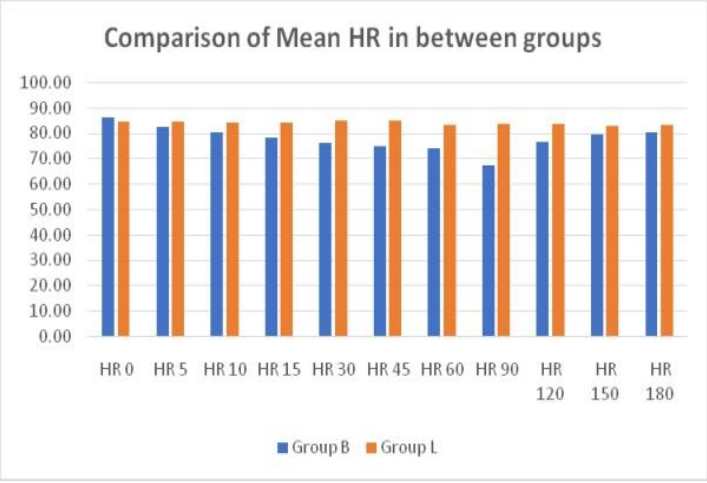

Fig.1- Graph showing Comparison of Mean Heart Rate

Mean systolic blood pressure was significantly higher among patients in Group L at spinal times 10,15,30,45,60 and 90min.

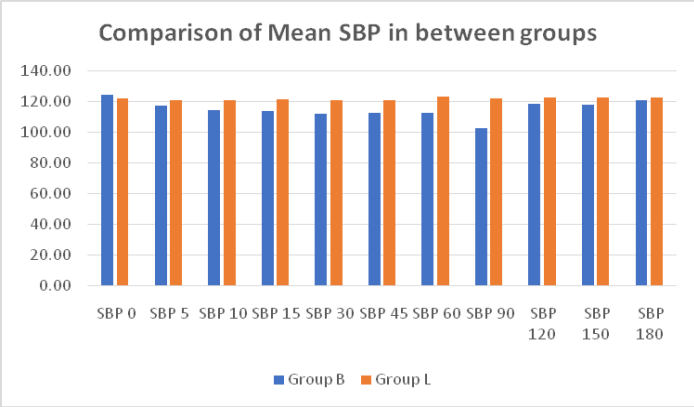

Fig.2 - Graph showing comparison of Mean SBP in between Group B and Group L

Mean diastolic blood pressure was significantly higher among patients in group L at spinal times 5, 10, 15, 30, 45,60,90 and 120 min.

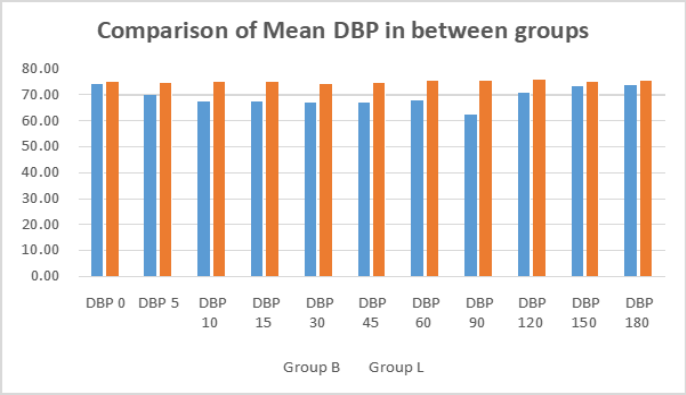

Fig. 3 - Graph showing Comparison of Mean DBP in between Group Band Group L

When compared Group B and Group L; statistically significant change in mean arterial blood pressure was noted from 5 min to 120 mins post spinal anaesthesia.

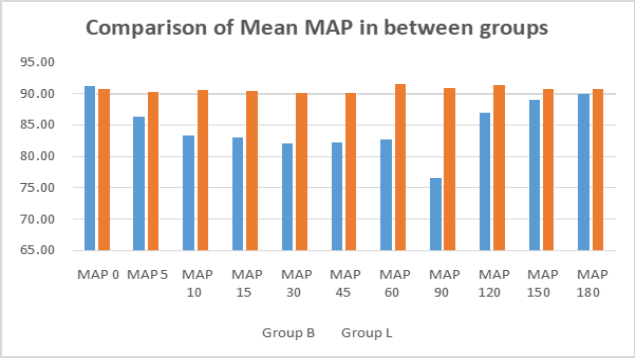

Fig.4 - Graph showing Comparison of Mean MAP in between Group B and Group L

There was no significant difference in the NPS, VAS at 15, 30, 45, 60, 75, 90, 105, 120, 150, 180 min and in the post operative period in both groups. At postop 12hr and 24 hr as most of the patients experienced pain and VAS was towards higher side in both groups. There was no statistically significant difference observed. There was no statistically significant difference in distribution of patients based on timing of 1st analgesic required as well as mean number of doses of analgesics required between the two groups. There were no adverse events observed among patients in either of the groups.

Discussion

The unmatchable reliability and simplicity of subarachnoid block has made spinal anaesthesia a very useful and successful technique in managing all surgical c ases undergoing infraumbilical procedures. In the intrathecal space, opioids activate the opioid receptors present in the gray matter of the spinal cord and thereby exerts their actions. There are several studies that support the combination of local anaesthetics with opioids in providing safe anaesthesia with good analgesia while reducing the dose requirements and adverse effects of each agent. There were no statistically significant differences in age, gender distribution, weight, height, ASA grading, operation duration and type of surgery included between the two groups of the study.

Glasser et al observed the onset time of sensory block was found to be 11 ± 6minutes in the 3.5 ml of 0.5% isobaric levobupivacaine group and 13 ± 8 minutes in the3.5 ml of isobaric 0.5% bupivacaine group, and they reported that there was no statistically significant difference between them. Similarly **Pushpavati *et al*** also found statistically insignificant longer time for onset of sensory blocking in group Levobupivacaine than in group Bupivacaine, but **Erdil et al** and **Fattorini et al** found that time taken for the onset of sensory blockade was significantly longer in group Levobupivacaine than in group Bupivacaine.

We observed no significant difference in the distribution of maximum sensory block among patients in both the groups. Similar to our study, **Fattorini et al** found maximum level of sensory blockade till T8 in both the groups. **Gulec et al** found that time taken to attain maximum sensory blockade was insignificantly longer in group Bupivacaine than in group Levobupivacaine, But **Ayca Sultan Sahin** found significantly higher level of sensory blockade in the group Bupivacaine than in group Levobupivacaine. **Pushpavati *et al*** found no significant difference in the time to achieve maximum of sensory blockade and this could be because the study involved comparison of isobaric Bupivacaine and isobaric Levobupivacaine with buprenorphine. But **Erdil et al** found delayed achievement of maximum level of sensory blockade in group Levobupivacaine than group Bupivacaine contrary to our study.

Total duration of sensory block was defined as the time taken from the intrathecal administration of drug till the sensory level receded to below T10 dermatome level, was 242.17 min with SD 28.2 in levobupivacaine group and 243.3 min with SD 34.7 in bupivacaine group (p value 0.84). Hence, there was no statistically significant difference observed in total duration of sensory blockade between the two groups. In study conducted by **Glaser and his coworkers** the duration of sensory block (min) was 228±77 in levobupivacaine group which was similar to that in bupivacaine group that was 237± 88 min. **Gozaydin O et al.** study found that that the sensory block disappearing time was 244 mins in bupivacaine group which was higher than in levobupivacaine group i.e. 227 mins but the difference was not statistically significant (p value 0.327). **Kazak and colleagues** in their study found that the time to L1 regression was 172.4±33.5 min in bupivacaine group, 151.3±25.5min in the levobupivacaine group and 143.5±14.3 min in ropivacaine group. Ropivacaine has significantly shorter duration than bupivacaine or levobupivacaine. The duration was prolonged in bupivacaine group similar to our study. In contrary, **Gautier et al.** in their study with intrathecal anaesthesia for caesarean section observed that the mean duration of motor blockade was significantly higher in bupivacaine group compared to levobupivacaine and ropivacaine with values being 142 min, 121min and 116 min respectively with p value being <0.05, i.e. both levobupivacaine and ropivacaine had significantly shorter duration of motor blockade than bupivacaine. **Pushpavati *et al*** reported that there was no statistically significant difference between group Levobupivacaine than in group Bupivacaine with buprenorphine for total duration of SAB.

In our study, heart rate remains fairly constant in both Group B and Group L. There were no side effects like bradycardia in either of the groups. When compared Group B and Group L statistically significant change in mean intraoperative Heart rate was noted from 15 min to 120 mins from baseline, with P value less than 0.01 [< 0.05]. Similarly **Pushpavati *et al*** reported that there was no significant decrease in heart rate in group levobupivacaine. **Fattorini et al, Gulec et al** and **Erdil et al** found that decrease in heart rate was similar in both the group throughout the surgery.

The mean of systolic blood pressure remains fairly constant in both Group B and Group L. There was no side effect like hypotension in either of group. When compared Group B and Group L statistically significant change in mean intraoperative systolic blood pressure was noted from 15 min to 90 mins from baseline, with P value less than 0.01 [< 0.05]. Similar to our study **Pushpavati *et al*** reported that there was no significant decrease in systolic blood pressure in group levobupivacaine. **Herrara *et al.*** showed that incidence of hypotension was statistically significantly higher with bupivacaine (38.3%) compared to levobupivacaine (13.3%). When comparing Group B and Group L statistically significant change in mean intraoperative diastolic blood pressure was noted from 5 min to 120 mins from baseline, with P value less than < 0.05. Mean arterial blood pressure was significantly higher in Group L than the mean of mean arterial blood pressure in Group B which was 86.27 ± 7.95 and 9 0 . 2 ± 5.96 in Group L,

with a P value of 0.003 which was significant. **Pushpavati *et al*** reported that there was no significant decrease in Mean arterial blood pressure in group levobupivacaine. **Erdil et al** found that mean arterial pressures were significantly low in Bupivacaine group than in group Levobupivacaine.

The time from onset of sensory blockade to request for first analgesic dose was 132.42 ± 72.03 min in levobupivacaine group and 137.58 ±52.43 min in bupivacaine group, not statistically significant (p value 0.72). There was no statistically significant difference observed in the distribution of patients based on the timing of the 1st analgesic dose required and the total number of analgesic doses required among the two groups. There was no significant difference in the NPS and VAS throughtout surgery and in post operative period in both groups (P value>0.05).

Improved perioperative analgesia following coadministration of bupivacaine could be explained by a synergistic inhibitory action of this agents on A-gamma and C fiber conduction. No adverse effect was seen among both the groups in intra-op as well as post-op period which may be due to low dose of opioids used.

Conclusion

The average HR, BP and RR were similar in both the groups. However, the group receiving Levobupivacaine had significantly lesser hemodynamic changes in intraoperative period 90 after drug administration, with lesser frequency of hypotension, and lesser requirement of vasoactive drugs. Addition of intrathecal buprenorphine as adjuvants to 0.5% isobaric levobupivacaine in spinal anesthesia produced similar onset of sensory block compared to hyperbaric bupivacaine with buprenorphine but it had preserved better hemodynamics in the former group.

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