*Original Article*

Indian Journal of Anaesthesia and Analgesia
2017, 4 (3, Part-I), 689-694
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.4317.24

# Evaluation of Hyperbaric Intrathecal Ropivacaine and Levobupivacaine versus Racemic Bupivacaine in Patients with Infra-Umbilical Surgery: A Comparative Study

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**Abstract**

*Introduction:* Spinal anaesthesia is popular anaesthetic technique for lower abdominal and lower extremity surgery. Lidocaine and bupivacaine has been commonly used as anaesthetic agents. Ropivacaine had been found to be relatively cardiostable. Levobupivacaine is a long-acting local anaesthetic. Hyperbaric solutions of local anaesthetics, were compared to isobaric ones, were faster in onset of sensory and motor block, and improved quality of anaesthesia. *Aim and Objectives:* To evaluate the efficacy of hyperbaric intrathecal ropivacaine, and levobupivacaine versus racemic bupivacaine, for spinal anaesthesia in patients admitted for infra-umbilical surgeries. *Material and Methods:* The present randomized control study was carried out between Jan. 2013– Dec. 2013, on 120 patients admitted for elective infra-umbilical surgeries. The patients were allocated to three groups: Group I: Bupivacaine 0.5%, 15 mg (3 ml), Group II: Ropivacaine 0.75%, 22.5 mg (3 ml) + 0.5 ml, 25% dextrose, and Group III: Levobupivacaine 0.5%, 15 mg (3 ml) + 0.5 ml, 25% dextrose =3.5 ml. *Results:* Onset of sensory block was significantly faster with levobupivacaine onset to T10 in 1-2 minutes and 67.5% in 3-4 minutes than bupivacaine than ropivacaine. Level and time required for sensory block was similar with all three drugs. In group I mean time of maximum level of analgesia was 17.12±3.5607 minutes, In group II mean time was *17.47±5.4935* minutes and in group III was 17.10±4.5487 minutes. Onset of motor block was faster with levobupivacaine and bupivacaine than ropivacaine. Mean and SD of time of motor onset in groups I, II and III is 6.125±1.265 minutes, 7.275±1.585 minutes and 5.475±1.086 minutes respectively. Degree of motor block as well as quality of anaesthesi were similar in the three treatments. *Conclusion*: Intrathecal ropivacaine produced a shorter duration of motor and sensory block. Hyperbaric levobupivacaine was more haemodynamically stable.

**Keywords:** Ropivacaine; Levobupivacaine; Infraumbilical; Spinal Anesthesia.

## Introduction

August Hilderbrandt [1] heralded a new era in providing anaesthesia for infra-umbilical and lower limbs surgeries. Spinal anaesthesia is popular and common anaesthetic technique used for lower abdominal surgeries and lower extremities. The advantages of awake patient, minimum drug cost, relatively less side effects, made the spinal anesthesia, the choice for many surgical procedures, even for day care surgeries [2]. After cocaine, many local anaesthetic drugs were used in spinal anaesthesia. Lidocaine and bupivacaine were the two commonly used anaesthetic agents for spinal anaesthesia.

Lidocaine has been used for minor procedures due to faster onset and short duration, however, it is still responsible for higher incidence of transient neurological syndrome [3]. Bupivacaine is more cardiotoxic and associated with prolonged motor block [4]. Ropivacaine is found to be relatively cardiostable comparing with bupivacaine in animal and healthy volunteers [5,6]. Potency ratio of ropivacaine and bupivacaine is 1:1.5. Recovery from anaesthesia motor block is also faster leading to more

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**Received on** 11.04.2017, **Accepted on** 18.04.2017

useful in ambulatory surgery [7]. Levobupivacaine is a new long-acting local anaesthetic that has been recently introduced in the clinical practice. Because of its significantly decreased cardiovascular and central nervous system toxicity, levobupivacaine seems to be better alternative to the bupivacaine [8,9,10]. Hyperbaric local anaesthetics, when compared to isobaric ones, were found to have faster onset of sensory and motor block and improved quality of anaesthesia [11].

*Aim and Objectives*

The aim of the present study was to evaluate the hyperbaric ropivacaine and the hyperbaric levobupivacaine versus racemic bupivacaine for spinal anaesthesia in infra-umbilical surgeries, with respect to onset, level, regression, and duration of sensory and motor block, the quality of analgesia, and the hemodynamic changes.

## Material and Methods

The present study was carried out after approval of The Ethical Committee of (Dr. Shankarrao Chavan Govt. Medical College, Nanded (M.S) ) Randomized control study was carried out in tertiary care centre, between Jan. 2013–Dec. 2013. The study included total 120 patients who were posted for elective infra-umbilical surgeries. Before starting of the study, density of resultant solutions were measured in The Standard Institutional Laboratory using the density meter.

### *Anesthetic Groups*

*Inclusion Criteria:* Elective patients of ASA grade I and II, of age between 18-60 yrs, Patient with no co-morbidity, Height- 150 cm to 175 cm , Weight-40 kg to 75 kg.

*Exclusion Criteria*: Allergy to drug being used, H/O or lab. Test suggesting coagulopathy, Central neurological disease, Infection at local site, On anti-coagulant therapy. 120 patients were randomly allocated into three groups:

Group I: Bupivacaine 0.5%, 15 mg (3 ml) + 0.5 ml normal saline,

Group II: Ropivacaine 0.75%, 22.5 mg (3 ml) + 0.5 ml, 25% dextrose,

Group III: Levobupivacaine 0.5%, 15 mg (3 ml) + 0.5 ml, 25% dextrose.

*Anesthetic Technique*

Under strict aseptic conditions intrathecal anaesthesia was performed in the left lateral position, in L3-L4 intervertebral space. The time of injection of the drug was noted and considered as time 0 min.

Sensory block was assessed by pin prick sensation. Motor block was assessed by mBs in all patients. Surgery was started when loss of pinprick sensation to T7 was appeared. Blood pressure(B.P.) and heart rate(HR)–were recorded at 0,2,3,5,10,15,20, 30,40,50,60,70,80, and 90 min., and then at 15 min. in the postoperative period until block were regressed.

Hypotension was considered if arterial SBP falls below 30% of baseline and was treated with injection of Mephentermine was used as necessary.

*Quality of Anaesthesia*

It was assessed depending upon the amount of pain that patient could tolerate and need of supplemental analgesic, the changes in vital parameters and visual analog scale (VAS) was used.

*Statistical Analysis*

All data were presented as mean ± SD. Data were assessed by one way analysis of variance (ANOVA) test. Statistical significance was defined as 'P' < 0.05.

## Results

The study included total 120 patients who were posted for elective infra-umbilical surgeries. The data was entered into the proforma and then subjected to statistical analysis. The results are presented in table form.

**Table 1:** Shows mean and SD of time of onset to T10 in minutes

| Group | No. of patients | Mean Time of Onset to T10 level (minutes) (Mean ± SD) | P Value By (ANOVA) | Comparison In groups (TURKEY-KRAMER) |
|---|---|---|---|---|
| I | 40 | 2.85 ± 0.7355 | <0.001 | I & II P <0.001 |
| II | 40 | 4.17 ± 0.7808 | Significant | I & III P >0.05 |
| III | 40 | 3.05 ± 0.8149 | | II & III P <0.001S |

*Onset of Anesthesia*

Onest of anesthesia was recorded in 35% of the patients (1-2) minutes and in 65% of the patients (3-4) minutes in Group I. In group II, 62.5% of the patients had onset to T10 in (3-4) minutes, and 37.5% in (5-6) minutes. In group III, 27.5% of the patients had onset to T10 in (1-2) minutes, and 67.5% in (3-4) minutes, (Table 1). P value is <0.001 and which was statistically significant.

*Maximum Level of Sensory Block*

In group I,35% of the patients achieved T4 level. In group II , *47.5%* of achieved at T5. In group III 2.5% of the patients achieved maximal level of analgesia at T3, 25% of the patients achieved T4 level. 'P' value is >0.05 and it is statistically non-significant by ANOVA test.

*Time of Maximum Level of Sensory Block*

In group I mean time of maximum level of analgesia was 17.12±3.5607 minutes, In group II mean time was 17.47±5.4935 minutes and in group III was 17.10±4.5487 minutes. P value was > 0.05 and which was statistically not significant.

*Time Taken for Regression to T10 Level*

In group I, 60% of the patients, the time taken for regression to T10 was 140-159 minutes. In group II, in 57.5% of the patients was 120-139 minutes and in group III , in 55% of the patients was 140-159 minutes and 17.5% of the patients, the time taken for regression to T10 was 160-180 minutes. 'P' value was < 0.05 and it was significant by ANOVA test.

**Table 2:** Shows Maximum Level of sensory block

| Maximum level of sensory block | Group- I | | Group- II | | Group- III | | P value (ANOVA) |
|---|---|---|---|---|---|---|---|
| | No. of patients | % | No. of patients | % | No. of patients | % | |
| T3 | 1 | 2.5 | 4 | 10 | 1 | 2.5 | Not Significant P>0.05 |
| T4 | 14 | 35 | 5 | 12.5 | 10 | 25 | |
| T5 | 10 | 25 | 19 | 47.5 | 13 | 32.5 | |
| T6 | 8 | 20 | 8 | 20 | 8 | 20 | |
| T7 | 4 | 10 | 3 | 7.5 | 7 | 17.5 | |
| T8 | 3 | 7.5 | 1 | 2.5 | 1 | 2.5 | |
| Total | 40 | 100 | 40 | 100 | 50 | 100 | |

**Table 3:** Shows Time of Maximum Level of sensory block

| Groups | No. of patients | Time of Maximum Level of sensory block(min.) (Mean ± SD) | P Value By (ANOVA) |
|---|---|---|---|
| I | 40 | 17.12 ± 3.5607 | > 0.05 |
| II | 40 | 17.47 ± 5.4935 | Not Significant |
| III | 40 | 17.10 ± 4.5487 | (0.8578) |

**Table 4:** Shows mean and SD of Time taken for Regression to T10:

| Groups | No. of patients | Mean and SD Time of Regression To T10 (minutes) (Mean ± SD) | P Value By (ANOVA) | Comparison In groups (TURKEY-KRAMER) |
|---|---|---|---|---|
| I | 40 | 145.38 ± 13.063 | <0.05 | I & II P <0.05 Significant |
| II | 40 | 136.78 ± 12.169 | Significant | I & III P >0.05 Non Significant |
| III | 40 | 146.65 ± 14.156 | (0.0018) | II & III P <0.05 Significant |

**Table 5:** Showing Quality of Block

| Quality of Block | I | | II | | III | |
|---|---|---|---|---|---|---|
| | No. of patients | % | No. of patients | % | No. of patients | % |
| Adequate | 35 | 87.5 | 31 | 77.5 | 35 | 87.5 |
| Inadequate | 5 | 12.5 | 9 | 22.5 | 5 | 12.5 |
| Failed | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 40 | 100 | 40 | 100 | 40 | 100 |

In group I, II and III, 87.5% ,77.5% and 87.5% of the patients had adequate quality of the block respectively.

*Time of Motor Block Onset in Minutes*

In group I, 62.5% of the patients had time of motor onset in 6-8 minutes and in group II, 55% of the patients in 6-8 minutes and in group III, 52.5% of the patients in 6-8 minutes. Mean and SD of time of motor onset in groups I, II and III is 6.125±1.265 minutes, 7.275±1.585 minutes and 5.475±1.086 minutes respectively. 'P' value was <0.001 and it was significant by ANOVA Test.

*Total Duration of Motor Block in Minutes*

The table shows that in group I, 40% of the patients had total duration of motor block in 238-257 minutes and in group II 65% of the patients in 198-237 minutes and in group III 45% of the patients in 198-237 minutes. 'P' value was <0.05 and was statistically significant by ANOVA test.

In group I, 17.5% of the patients and in group II, 5% and in group III 10% of the patients had hypotension. 7.5% of the patient in group I, 2.5% of the patients in group III had bradycardia.

**Table 6:** Shows mean and SD for time of motor Onset (minutes)

| Groups | No. of patients | Mean and SD of Motor Onset in minutes. | 'P' Value By (ANOVA) |
|---|---|---|---|
| I | 40 | 6.125 ± 1.265 | <0.001 |
| II | 40 | 7.275 ± 1.585 | Significant |
| III | 40 | 5.475 ± 1.086 | |

**Table 7:** Shows mean and SD of total Duration of Motor Block (minutes)

| Groups | No. of patients | Mean and SD of total duration of Motor block (minutes) | P Value By (ANOVA) | Comparison in Groups (Turkey-Kramer) |
|---|---|---|---|---|
| I | 40 | 240.20 ± 21.42 | <0.05 | I & II P <0.05 Significant |
| II | 40 | 226.98 ± 19.19 | Significant | I & III P >0.05 Non Significant |
| III | 40 | 237.35 ± 21.27 | (0.0125) | II & III P <0.05 Significant |

**Table 8:** Distribution of Complications

| Complications | I | | II | | III | |
|---|---|---|---|---|---|---|
| | Number of patients | % | Number of patients | % | Number of patients | % |
| Hypotension | 7 | 17.5 | 2 | 5 | 4 | 10 |
| Bradycardia | 3 | 7.5 | 0 | 0 | 1 | 2.5 |
| Nausea and vomiting | 2 | 5 | 2 | 5 | 3 | 7.5 |
| Peri-op shivering | 3 | 7.5 | 2 | 5 | 1 | 2.5 |

## Discussion

For the purpose of study 120 patients belonging to ASA grade I and II of either gender posted for infra-umbilical surgeries were selected. As shown by Wahedi et al [12] ropivacaine, in the dose of 22.5 mg and As shown by J.F. Luck et al [13] levobupivacaine and bupivacaine in the dose 15 mg are sufficient for infraumbilical surgeries. As shown by Mc Donald et al [14] and Lee et al [15] potency of ropivacaine with bupivacaine and levobupivacaine is 1.5:1.

*Time of Onset of Sensory Block at T10*

In bupivacaine group mean time of onset to T10 was 2.85 minutes, in ropivacaine group was 4.17 minutes and in levobupivacaine group was 3.05 minutes. Casati et al [16] found mean time of onset to T10 among three groups( 10 min), which was statistically not significant (p>0.5). J.F. Luck et al [13] also found no statistically significant difference in mean time of onset to T10 among three groups. Similar results were shown by Kulkarni KR(2014) [6].

*Maximum Level of Sensory Block*

In group bupivacaine 35% of the patients achieved T4 level and in group ropivacaine 47.5% of achieved at T5. In group levobupivacaine 32.5% of the patients had achieved at T5 .' P' value was >0.05 which was not significant. Casati et al [16] found that there was no difference in the maximal level of sensory block. J.F. Luck et al [13] and Cappelleri et al [17] also found similar results to our study .We found no significant

difference in maximal level of sensory block among three groups.

*Time of Maximum Level of Sensory Block*

In group I mean time of maximum level of sensory block was 17.12 minutes and in group II was 17.47 minutes and in group III was 17.10 minutes. P value was > 0.05 and statistically not significant. Casati et al [16] and J.F. Luck et al [13] found similar results. Alley et al [18] used hyperbaric bupivacaine and levobupivacaine in spinal anaesthesia at dose of 12 mg found no significant difference of time of maximum level of sensory block.

*Time for Regression to T10*

In group bupivacaine mean of time taken for regression to T10 was 145.38 minutes, in group ropivacaine136.78 minutes and in group levobupivacaine was 146.65 minutes. J.F. Luck et al [13] found time of regression to T10 in bupivacaine group was 129 minutes, in group ropivacaine 84 minutes, in group levobupivacaine 131 minutes. In our study time for regression to T10 was maximum in levobupivacaine, but it was significantly greater than ropivacaine.

*Time Taken for Motor Onset*

Mean time of motor onset in groups I, II and III was 6.125 minutes, 7.275 minutes and 5.475 minutes respectively. 'P' value was <0.001 and it was significant. J.F. Lucket al [13] found similar results to our study. While M. Mantouvalou et al [19] found onset of motor block was significantly faster in bupivacaine group (8 min) compared with (12 min) in ropivacaine group and (11 min) in levobupivacaine group. This was not comparable to our study.

*Time Taken for Total Duration of Motor Block*

In our study, In group bupivacaine mean of total duration of motor block was 240.20 minutes, in group ropivacaine was 226.98 minutes and in group levobupivacaine was 237.35 minutes. 'P' value was <0.05 and was statistically significant. Casati et al [16] and J.F. Luck [13] found Comparable results to our study. While M. Mantouvalou et al [19] found that ropivacaine presented a shorter duration of motor block.

*Intraoperative and Post Operative Complications*

In our study, In group bupivacaine, 17.5%, in group ropivacaine 5% and in group levobupivacaine, 10% of the patients had hypotension. 7.5% of the patient in group bupivacaine had bradycardia, 2.5% of the patients in group levobupivacaine had bradycardia. So ropivacaine and levobupivacaine group were more cardiostable than bupivacaine group. Casati et al [16] and J.F. Luck et al [13] in their study found similar results. M. Mantouvalou [19] found that hypotension was only significant in bupivacaine group (42.5%) than ropivacaine and levobupivacaine groups (25% and 17.5% respectively). Bradycardia was also significant in bupivacaine group.

*Quality of Anaesthesia*

In our study, In group Bupivacaine, ropivacaine and levobupivacaine 87.5% ,77.5% and 87.5% of the patients had adequate quality of the block respectively. Quality of anaesthesia is superior in bupivacaine and levobupivacaine groups than ropivacaine group. Casati et al [16] and J.F. Luck et al [13] quality of anaesthesia were comparable in each groups. M. Mantouvalou et al [19] 1 patient in each group required general anaesthesia due failed block.

*Change of Peri-Operative Cardio-Vascular Parameters*

In our study, haemodynamic parameters were stable in all three groups. Casati et al [16] haemodynamic parameters were comparable in all three groups. J.F. Luck et al [13] bupivacaine group required ephedrine greater than other two groups. Hence ropivacaine and levobupivacaine groups had better haemodynamic stability (p=0.001).

*Time of First Rescue Analgesic*

In our study, in bupivacaine group mean of time taken for rescue analgesic was 326.68 minutes, In group ropivacaine was 306.68 minutes and in group levobupivacaine was 329.05 minutes. 'P' value was < 0.05 and it was significant.

**Summary**

We can summarize that Onset of sensory block was significantly faster with levobupivacaine than bupivacaine and ropivacaine. Maximum level of sensory block was similar with all three drugs. Time required for maximum level of sensory block was similar with all three drugs. Regression of sensory block at umbilicus was significantly greater with levobupivacaine. Complete regression of sensory block was faster with ropivacaine. Onset of motor

block was faster with levobupivacaine and bupivacaine. Degree of motor block was similar with all three drugs. Duration of motor block was significantly greater with bupivacaine. Quality of anaesthesia was similar with all three drugs. Hypotension was more with bupivacaine. No any major adverse event was associated with all three drugs. Ropivacaine and levobupivacaine groups were haemodynamically more stable .

## Conclusion

It was concluded that in equipotent dose intrathecal hyperbaric ropivacaine produced a shorter duration of motor and sensory block than intrathecal hyperbaric bupivacaine and levobupivacaine. Ropivacaine was haemodynamically more stable and can be used for shorter duration surgical anaesthesia than that of bupivacaine is desired. Hyperbaric levobupivacaine has effect more or less similar to hyperbaric racemic bupivacaine but was more haemodynamically stable, thus levobupivacaine can be preferred for long duration surgery.

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