

**COMPARATIVE EVALUATION OF INTRATHECAL ADMINISTRATION OF
ROPIVACAINE, LEVOBUPIVACAINE AND BUPIVACAINE IN PATIENTS
UNDERGOING LOWER LIMB SURGERIES**

Dr.Harshitha M S¹, Dr.Upasana Tiwari², Dr. Sanjay R³, Dr.Pallavi S R^{4*}

^{1, 2,3,4*}Senior Resident, Department of Anaesthesiology, Shimoga Institute of Medical Sciences,
Shimoga.

Corresponding Author: Dr.Pallavi S R

Abstract

Introduction: Subarachnoid block is probably the most widely used regional anesthetic procedure in routine clinical anesthesiology practice. It provides rapid onset, consistent sensory blockade and adequate muscle relaxation for all types of surgery below the level of umbilicus. This procedure is relatively easier, requires less equipment and very cost effective.

Materials and Methods: After obtaining informed consent from all the patients, Seventy five patients of ASA I and II of age 50 to 70 years of either sex were included in our study. These patients were divided equally into 3 Groups, 50 each. Group I, II and III who received intrathecal 3 ml 0.5% isobaric Bupivacaine (15 mg), 3 ml 0.5% isobaric Ropivacaine (15mg) and 3 ml 0.5% isobaric Levobupivacaine (15 mg) respectively. Patients who refuse for consent, Infection at site of injection, Coagulopathy or any other bleeding disorder, severe Hypovolemia, severe hypotension, increased intracranial tension, severe stenotic valvular heart disease or ventricular outflow obstruction were excluded from our study.

Results: In our study p-value was found to be insignificant regarding age and duration of surgery among all three groups. The mean age of the patients in Group I was 35.125 ± 7.4 years, in the Group II was 34.2 ± 9.0 years in the group III was 34.9 ± 8.0 years and p value was found to be insignificant. The mean onset of sensory block for Bupivacaine 0.5% plain was 6.30 ± 1.20 mins for Ropivacaine 0.5% plain was 6.12 ± 1.00 mins and for Levobupivacaine was 6.25 ± 1.10 mins which was statistically insignificant. The level of sensory block in Group I is Thoracic level 9, in Group II it is Thoracic level 10 & group III is Thoracic level 10. P value is > 0.05 , so there is no significant difference in level of sensory block between the three groups.

Conclusion: It was found that Ropivacaine 0.5% intrathecally provides shorter duration of motor & sensory block compared to Bupivacaine 0.5% & Levobupivacaine 0.5%. Also there were less episodes of hypotension which indicate that 0.5% Ropivacaine & 0.5 Levobupivacaine provides more hemodynamic stability than Bupivacaine 0.5% intrathecally.

Key Words: Subarachnoid block, Bupivacaine, Ropivacaine, Levobupivacaine.

INTRODUCTION

Over the past few years, the use of bupivacaine for outpatient spinal anesthesia has increased because of reports stating the potential neurotoxicity of spinal lidocaine (1). Intrathecal bupivacaine has low (1%) incidence of post operative complications (2), but Bupivacaine has been shown to have selective cardiac effects more pronounced with R-isomer than S-isomer. Long-acting local anesthetics induce marked negative inotropic and lusitropic effects.¹ Among LAAs, levobupivacaine exerts the greater depressant effects but Ropivacaine is less cardio toxic on a mg basis than bupivacaine (3). Ropivacaine and Levobupivacaine are alternative long-acting local anaesthetic with significant central nervous system (4, 5) toxicity thus seem to be an attractive alternatives to bupivacaine.²

Subarachnoid block is probably the most widely used regional anesthetic procedure in routine clinical anesthesiology practice. It provides rapid onset, consistent sensory blockade and adequate muscle relaxation for all types of surgery below the level of umbilicus. This procedure is relatively easier, requires less equipment and very cost effective. Main disadvantages of subarachnoid block are hypotension, lack of ability in precisely controlling the level and duration of block and risk of introduction of infection directly into the cerebrospinal fluid.³

Bupivacaine is a long acting local anesthetic, available as a racemic mixture of its enantiomers dextrobupivacaine and levobupivacaine. It has been the gold standard for intrathecal use in spinal anesthesia for many years.¹ Bupivacaine has been associated with cardiotoxicity when used in large concentration or when accidentally administered intravascularly.⁴

Levobupivacaine and ropivacaine are the two recently introduced alternatives to bupivacaine in clinical practice. Levobupivacaine is the pure s(-) enantiomer of racemic bupivacaine. It produces equivalent sensory block but shorter duration of motor block than intrathecal bupivacaine.³ It has a lower risk of cardiovascular toxicity than bupivacaine because of its negative inotropism and less affection for cardiac sodium channels.⁵

Ropivacaine is another enantiomer with less cardiovascular toxicity than bupivacaine, which also produces equivalent sensory block but shorter duration of motor block than intrathecal bupivacaine.⁵ In this study we compared to intrathecally Bupivacaine 0.5% & Levobupivacaine 0.5 %, Ropivacaine 0.5 % provides shorter duration of motor & sensory block and provides more hemodynamic stability and less chances of hypotension than Bupivacaine 0.5% and Levobupivacaine 0.5%.

MATERIALS AND METHODS

After obtaining informed consent from all the patients, Seventy five patients of ASA I and II of age 50 to 70 years of either sex were included in our study. These patients were divided equally into 3 Groups, 50 each. Group I, II and III who received intrathecal 3 ml 0.5% isobaric Bupivacaine (15 mg), 3 ml 0.5% isobaric Ropivacaine (15mg) and 3 ml 0.5% isobaric Levobupivacaine (15 mg) respectively. Patients who refuse for consent, Infection at site of injection, Coagulopathy or any other bleeding disorder, severe Hypovolemia, severe

hypotension, increased intracranial tension, severe stenotic valvular heart disease or ventricular outflow obstruction were excluded from our study.

All patients underwent pre-anesthetic check-up where detailed history was taken, they were physically examined and relevant routine and special investigations were carried out. Informed and written consent for anesthetic procedure was taken from patient for surgery.

They were kept nil orally for at least 6 hours prior to starting the procedure. Heart rate, blood pressure, respiratory rate, oxygen saturation and electrocardiogram were noted. After intravenous cannulation, injection Ondansetron 4milligrams, ranitidine 50 milligrams and 500 ml ringer lactate solution were given.

Under all aseptic precautions, subarachnoid block was given with patient placed in the lateral position with affected limb uppermost by midline approach between third and fourth lumbar space via 25 Gauge Quincke's spinal needle. On confirmation of free flow of cerebrospinal fluid the calculated drug was injected slowly. After injection patient was immediately turned supine. No tilt was given. All patients received oxygen at 4 liters per minute by oxygen mask.

Continuous monitoring of B.P, HR, RR, SpO2 and ECG was done during intra-operative period at regular intervals. Onset of sensory blockade and motor blockade was noted in all the patients.

Determination of onset of sensory block was done by pin prick technique; while assessment of motor blockade was done using Bromage Scale:

Grade 0 – able to raise the lower limb straight (straight leg raising test).

Grade I – Able to perform knee joint movement but not at hip joint movement.

Grade II - Able to perform movement at ankle joint but neither at hip joint nor at knee joint.

Grade III – Able to perform toe movement, but unable to perform ankle, knee and hip joint movement.

Grade IV – No movement at lower limb.

Postoperative Observation: H.R, B.P., R/R, SpO2 and ECG were observed till the requirement of 1st rescue analgesic dose. Duration of sensory and motor blockade was observed postoperatively and duration of 1st rescue analgesia was noted in all the patients. Observations were duly recorded, tabulated and then statistically analyzed by unpaired t-test between the groups. P value < 0.05 was considered clinically significant.

Patients were observed for side effects like hypotension, bradycardia, respiratory depression, nausea/vomiting, tightness in chest, respiratory difficulty and convulsions.

RESULTS

In our study p-value was found to be insignificant regarding age and duration of surgery among all three groups.

Group	No of patients	Drug administration
I	50	3ml of 0.5% Bupivacaine plain
II	50	3ml of 0.5% Ropivacaine plain
III	50	3 ml of 0.5% levobupivacaine plain

Table 1: Distribution of 75 patients according to drug injected in subarachnoid space

Age (In years)	Group-I		Group-II		Group-III	
	No	%	No	%	No	%
20-25	6	12%	8	16%	8	16%
25-30	6	12%	8	16%	6	12%
30-35	8	16%	10	20%	10	20%
35-40	10	20%	6	12%	8	16%
40-45	8	16%	10	20%	10	20%
45-50	12	25%	8	16%	8	16%

Table 2: Age distribution of cases

The mean age of the patients in Group I was 35.125 ± 7.4 years, in the Group II was 34.2 ± 9.0 years in the group III was 34.9 ± 8.0 years and p value was found to be insignificant.

Group	No of patients	The Mean Duration of Surgery
Group-I	50	86.7 ± 21
Group-II	50	84 ± 20
Group-III	50	85.4 ± 25

Table 3: The Mean Duration of Surgery between the Three Groups

	Group I	Group II	Group III
Onset of Sensory Block in Mins	6.30 ± 1.20	6.12 ± 1.00	6.25 ± 1.10

Table 4: Onset of Sensory Block in Mins

The mean onset of sensory block for Bupivacaine 0.5% plain was 6.30 ± 1.20 mins for Ropivacaine 0.5% plain was 6.12 ± 1.00 mins and for Levobupivacaine was 6.25 ± 1.10 mins which was statistically insignificant.

	Group I	Group II	Group III
Level of sensory block	T9	T10	T10

Table 5: Level of sensory block

The level of sensory block in Group I is Thoracic level 9, in Group II it is Thoracic level 10 & group III is Thoracic level 10. P value is > 0.05 , so there is no significant difference in level of sensory block between the three groups.

	Group I	Group II	Group III
Mean Onset of Motor Block in Mins	11.50±3.272	15.39±3.166	12.48± 2.99

Table 6: Mean Onset of Motor Block in Mins

	Group I	Group II	Group III
Mean Duration of Motor Blockade in Mins	224.10±18.15	177.10±20.50	232.10±12.00

Table 7: Mean Duration of Motor Blockade in Mins

	Group I	Group II	Group III
Duration of Analgesia	234.40±10.15	202.20±12.50	230.40±11.60

Table 8: Duration of Analgesia

	Group I	Group II	Group III
Incidence of hypotension	16	4	8
Pt. required treatment of hypotension	8	2	4

Table 9: Haemodynamic Stability

Adverse effects	Group	Number of patients
Nausea and vomiting	I	4
	II	4
	III	4
Rigors	I	2
	II	2
	III	4
Vasopressor (>1 bolus of inj. ephedrine, 5mg)	I	8
	II	2
	III	4
Itching	I	0
	II	0
	III	0
PDPH	I	0
	II	0
	III	0
TRI	I	0
	II	0
	III	0

Table 10: Comparison of Incidence of Adverse Effects

DISCUSSION

The mean age in group I (35.125 ± 7.4), group II (34.2 ± 9.0) and group III (34.9 ± 8.0) which clearly showed that they were comparable among themselves and hence statistically insignificant ($p > 0.05$). Studies conducted among the patients of ASA grade I & II. Halena kallio et al (2004) conducted their studies on patients between age group 18 -65 years & ASA physical status I & II (where $n = 50$ in each groups) for Ropivacaine 0.75% & Bupivacaine 0.5% via subarachnoid block for lower limb surgeries.⁶

Ying Y. Lee et al compared 3 drugs with 25 patients in each group. Thus our current study groups were comparable in age & number of patients to studies done previously.⁷

In our current study dose of ropivacaine 0.5% 3ml (15 mg) was selected with Bupivacaine 0.5% 3ml (15mg), levobupivacaine 0.5 % plain (15 mg). J. F. Luck et al also took the same concentration and dose in their study.⁸

In our present study onset of sensory block took 6.30 ± 1.20 for 0.5%. Bupivacaine, 6.12 ± 1.00 for 0.5% ropivacaine & 6.25 ± 1.10 levobupivacaine & there was no intergroup significance. Maximum dermatomal level achieved was T9 in bupivacaine and T10 in ropivacaine and levobupivacaine. Van Kleef et al (1994) also got same level of T10 - T11 with 0.75% ropivacaine.⁹

The time to achieve complete motor blockade (Modified Bromage Scale 1) was shorter in the Bupivacaine group (11.50 ± 3.272) and levobupivacaine group (12.48 ± 2.99) than the Ropivacaine group (15.39 ± 3.166) and the difference was statistically significant ($p < 0.05$) which is shown in table & graph 6. Same observation was made by Mantouvalou et al.

In Our study motor block regression started at 90 min in ropivacaine and 180 min in bupivacaine and levobupivacaine group and observed sensory block time of 177, 224, 232 min in ropivacaine, bupivacaine and levobupivacaine groups respectively. McNamee and colleagues compared ropivacaine & bupivacaine at a dose of 17.5 mg and they also found faster recovery from sensory and motor block in ropivacaine group.¹⁰

CONCLUSION

It was found that Ropivacaine 0.5% intrathecally provides shorter duration of motor & sensory block compared to Bupivacaine 0.5% & Levobupivacaine 0.5%. Also there were less episodes of hypotension which indicate that 0.5% Ropivacaine & 0.5 Levobupivacaine provides more hemodynamic stability than Bupivacaine 0.5% intrathecally. No significant changes were reported in pulse rate, respiratory rate & SpO₂ in present study. Adverse events like nausea/vomiting, rigor, and itching were equally distributed in all the groups and statistically insignificant. In no case was urinary retention reported. Previous studies have linked intrathecal ropivacaine with an increased incidence of PDPH. This similar with the findings of Gautier PE (1999).

REFERENCES

1. Greene N. Distribution of local anaesthetic solutions within the subarachnoid space. *Anesth Analg.* 1985;64(7):715-30.
2. Mehta A, Gupta V, Wakhloo R, Gupta, Gupta A, Bakshi R, et al. Comparative evaluation of intrathecal administration of newer local anaesthetics agents Ropivacaine and Levobupivacaine with Bupivacaine in patients undergoing lower limb surgery. *Int J Anaesthesiol.* 2007;17(1).
3. Casati A, Moizo E, Marchetti C, Vinciguerra F. A prospective, randomized, double-blind comparison of unilateral spinal anesthesia with hyperbaric bupivacaine, ropivacaine, or levobupivacaine for inguinal herniorrhaphy. *Anesth Analg.* 2004;99(5):1387-92.
4. Cappelleri G, Aldegheri G, Danelli G, Marchetti C, Nuzzi M, Iannandrea G, et al. Spinal anesthesia with hyperbaric levobupivacaine and ropivacaine for outpatient knee arthroscopy: a prospective, randomized, double-blind study. *Anesth Analg.* 2005;101:77-82.
5. Mantouvalou M, Ralli S, Arnaoutoglou H, Tziris G, Papadopoulos G. Spinal anaesthesia: Comparison of plain Ropivacaine, Bupivacaine and Levobupivacaine for lower abdominal surgery. *Acta anaesthesiol Belg.* 2008;59(2):65-71.
6. Parpaglion R, Frigo MG, Lemma A, Sebastiani M, Barbati G, Celleno D. Minimum local anaesthetic dose (MLAD) of intrathecal levobupivacaine and ropivacaine for caesarean section. *Anaesthesia.* 2006;61(2):110-15.
7. Fasciolo A, Baldini C. Ropivacaine 0.5% vs Levobupivacaine 0.5% in endoscopic urological surgery. *Urologia.* 2011 Jan-Mar;78(1):10-6.
8. Vanna O, Chumsang L, Thongmee S. Levobupivacaine and Bupivacaine in spinal anaesthesia for transurethral endoscopic surgery. *J Med Assoc Thai.* 2006;89(8):1133-9.
9. Foster RH, Markham A. Levobupivacaine: A review of its pharmacology and use as a local anaesthetic. *Drugs.* 2000 Mar;59(3):551-79.
10. McLeod GA. Density of spinal anaesthetic solutions of bupivacaine, levobupivacaine and ropivacaine with and without dextrose. *Br J Anaesth.* 2004;92(4):547-51.