DOI: 10.14260/jemds/2014/2220

ORIGINAL ARTICLE

A COMPARATIVE STUDY OF INTRATHECAL HYPERBARIC BUPIVACAINE 0.5% & INTRATHECAL ISOBARIC ROPIVACAINE 0.5% FOR QUALITY AND DURATION OF ANAESTHESIA AND POST-OPERATIVE ANALGESIA IN PATIENTS UNDERGOING LOWER LIMB SURGERIES

C. Radhika Rani[1], N. S. V Rama Krishna[2], V. Harinath Babu[3], A. S. Kameswara Rao[4]

HOW TO CITE THIS ARTICLE:
C. Radhika Rani, N. S. V Rama Krishna, V. Harinath Babu, A. S. Kameswara Rao. "A Comparative Study of Intrathecal Hyperbaric Bupivacaine 0.5% & Intrathecal Isobaric Ropivacaine 0.5% for Quality and Duration of Anesthesia and Post-Operative Analgesia in Patients Undergoing Lower Limb Surgeries". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 11, March 17; Page: 2886-2891,
DOI: 10.14260/jemds/2014/2220

ABSTRACT: BACKGROUND: Spinal anesthesia is the standard technique for lower limb surgeries. Ropivacaine, a long acting amide type of local an aesthetic reduces potential toxicity, improves relative sensory and motor blockade and has higher threshold for cardiotoxicity and neurotoxicity. **AIM:** To compare the efficacy and advantages of isobaric Ropivacaine over hyperbaric Bupivacaine. **DESIGN:** Randomized double-blinded trial. **METHODS:** Sixty patients were randomly allocated to receive intrathecally either 3ml of 0.5% hyperbaric bupivacaine (Group C) or 3ml of 0.5% isobaric ropivacaine (Group B). **RESULTS:** Both the groups were demographically statistically insignificant. Onset of sensory block at L1 ($p=0.000$) and the median time of onset of sensory block at T10 ($p<0.01$) was statistically significant. Group B achieved lower levels of peak sensory block compared to group C ($p<0.0001$). The time taken to achieve maximum motor blockade (group B 9±2.03 min and group C 5±1.55 min) and the time of onset of maximum motor block were delayed with group B compared to group C ($p=0.000$). The mean duration of analgesia ($p<0.05$) and the mean duration of motor blockade ($p<0.05$), return of Bromage to zero ($P=0.000$) with group B was less when compared to group C and was statistically significant. **CONCLUSION:** Isobaric Ropivacaine 0.5% (study group B) provides lesser grade of motor blockade and shorter duration of both sensory and motor blockade for short duration orthopaedic surgeries where prolonged motor blockade is quite undesirable and early mobilization can be planned.

KEYWORDS: Spinal anesthesia, Ropivacaine, Bupivacaine, Lower limb surgeries.

INTRODUCTION: Spinal anesthesia is the standard technique for lower limb surgeries.[1] Neuraxial block techniques are widely used for lower extremity major orthopaedic surgery and offer several benefits compared to general anaesthesia.[2] Neuraxial anesthesia provides superior pain control and reduces mortality and other serious complications like myocardial ischemia, thromboembolism, early postoperative delirium and cognitive dysfunction in patients undergoing major general and orthopaedic surgery compared to general anaesthesia.[3-7]

Local anesthetics are traditional drugs used for Neuraxial block. Ropivacaine, a long acting amide type of local an aesthetic agent was first produced as a pure S (-) type of enantiomer [8] and is developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles.[9] It is less lipophilic[10] and has significantly higher threshold for cardiotoxicity and neurotoxicity than Bupivacaine in animals[11] and healthy volunteers.[12]

DOI: 10.14260/jemds/2014/2220

ORIGINAL ARTICLE

AIMS AND OBJECTIVES: To compare the clinical efficacy and advantages of isobaric Ropivacaine (0.5%) over hyperbaric Bupivacaine (0.5%). Primary objectives were to assess and compare the onset of sensory and maximum motor blockade and the duration of both postoperative analgesia and motor blockade. Secondary Objectives were to assess and compare the hemodynamic changes and adverse effects.

MATERIALS AND METHODS: The study was initiated after obtaining permission from the Institutional Ethics Committee. Written and informed consent was obtained from all patients. A prospective, randomized, double blinded comparative study was carried out on 60 patients undergoing lower limb orthopedic surgeries at KONASEEMA INSTITUTE OF MEDICAL SCIENCES and RF from September 2011 to September 2013.

Patients with ASA-I and II grade, age between 20 & 60 years, who have come for elective procedures and are willing to give informed consent, were included. Patients with conditions that preclude spinal anesthesia, Psychiatric disorders, chronic pain at puncture site, who are unable to communicate and had history of Hypersensitivity & drug allergy were excluded. Patients were randomly allocated into 2 groups of 30 each (GROUP B- 3 ml intrathecal 0.5% isobaric Ropivacaine and GROUP C- 3 ml intrathecal 0.5% hyperbaric Bupivacaine).

Pre-anesthetic assessment was done along with all the investigations. Preparation of patients included a fasting of 6 hrs. On arrival into the operation theatre, all patients were preloaded with lactated ringer's solution at 15 ml/kg. Patients were monitored with non-invasive B.P, Pulse Oximeter and ECG. Spinal anesthesia was performed with 23 gauge Quincke needle at L3/4 interspace with patients in sitting position and drug was injected after free flow of clear CSF. Patients were made to lie down supine immediately on the OT table without any tilt. After intrathecal drug injection, Pulse, Blood pressure, SpO_2, Respiratory rate and ECG were recorded at every 1 minute for 5 minutes; then every 5 minutes for another 25 minutes; then every 15 minutes till the procedure is completed. The onset of sensory anesthesia was tested by pinprick.

Sensory anesthesia was defined as the loss of sharp sensation to pinprick test (23-gauge hypodermic needle).Time taken for onset of sensory anesthesia at L1 level after intrathecal injection was tested for every 15 seconds till onset at this level is achieved, then every 1min till the peak level was achieved. Peak sensory level and time to achieve peak sensory level were recorded. Time taken for onset of maximum motor blockade i.e. the time taken from the time of spinal to the time to achieve maximum grade of motor blockade was noted.

Maximum grade of motor blockade achieved using modified Bromage score was also noted. Time to return of Modified Bromage score to zero was recorded. Visual Analogue Scale (VAS) was used for assessment of post-operative pain relief at 30, 60, 90, 120, 150, 180, 240, 360 minutes. At VAS score of ≥4, rescue analgesia was given in the form of Inj. Diclofenac Sodium 75 mg IM. Duration of analgesia is defined as the time taken from the time of spinal anesthesia to the first request of rescue analgesia. Duration of motor blockade was defined as the time taken from the time of spinal anesthesia to the return of modified bromage score of grade 0.

A fall of systolic blood pressure (SBP) to less than 20% baseline was considered as hypotension and was treated with rapid infusion of RL and 3 mg aliquots of Injection Mephentermine intravenously if there was no response to fluid administration. Bradycardia was considered when heart rate dropped to less than 60/minute or less than 20% of baseline pulse and was treated with

DOI: 10.14260/jemds/2014/2220

intravenous Atropine Sulphate 0.6mg. Any intra-operative and postoperative complications were recorded and treated accordingly. All patients were observed in the post anesthesia care unit for next 6 hours. Patients who were unable to micturate were done ultrasound scan of the bladder to detect urinary retention. Urinary retention was defined as the bladder volume more than 600 ml together with inability to micturate and these patients were catheterized when these criteria were met.

STATISTICAL ANALYSIS: Basic descriptive statistics have been evolved to study the central tendency and the variability among the variables. Results are expressed as the number, percentages, mean ± SD. $p< 0.05$ was considered to be statistically significant.

RESULTS: Both the groups were demographically statistically insignificant. Onset of sensory block at L1 ($p=0.000$) and the median time of onset of sensory block at T10 ($p<0.01$) was statistically significant. The study group achieved lower levels of peak sensory block compared to control group ($p<0.0001$). The time taken to achieve maximum motor blockade (group B 9±2.03 min and group C 5±1.55 min) and the time of onset of maximum motor block were delayed with group B compared to group C ($p=0.000$) and was statistically significant. The mean duration of analgesia ($p<0.05$), the mean duration of motor blockade ($p<0.05$) and Return of Bromage to zero ($P=0.000$) were achieved in less time in group B when compared to group C and was statistically significant.

SUMMARY OF RESULTS:

	Group B	**Group C**	**p-value**
Time Taken for onset of sensory blockade(min)	6.00 ± 1.82	1.5 ±0.83	0.000
Time Taken to achieve peak sensory level (min)	14.00±1.55	9.20±1.15	0.000
Time Taken to achieve maximum motor blockade(min)	9.00±2.03	5.00±1.55	0.000
Grading of maximum motor blockade	2.50±0.50	2.93±0.25	0.000
Duration of surgery(min)	113±26.92	114±26.27	0.790
Return of Bromage Score to Zero (min)	124±14.82	195±16.13	0.000
Total Duration of analgesia (min)	180 ± 14.73	255 ± 25.83	0.000
Baseline mean systolic blood pressure(mmHg)	127.33±9.1	128.53 ± 9.54	>0.05
Baseline mean diastolic blood pressure(mmHg)	82 ± 5.53	83.4 ± 6.49	>0.05
Baseline mean pulse rate(per minute)	81.93 ± 7.39	83.26 ± 8.95	>0.05

Parameters	**Group B**	**Group C**	**p - value**
	Mean	**Mean**	
Age	39.10±9.53	39.13±10.23	0.58
Gender	23:7	22:8	0.29
Weight (kg)	65±5.27	67.50±5.20	0.21

DOI: 10.14260/jemds/2014/2220

Intraoperative Complications	Group B N	Group C N	P value
Hypotension	2	8	0.0008
Shivering	2	2	
Bradycardia	0	2	

Postoperative Complications	Group B N	Group C N	P value
Shivering	0	4	0.02
Vomiting	1	0	
Urinary Retention	0	4	

DISCUSSION: The primary aim of this study was to investigate the relative efficacy, safety and advantages of isobaric Ropivacaine 0.5% for spinal anesthesia compared to hyperbaric Bupivacaine 0.5%. The demographic characteristics of the patients in the 2 groups, study group B (Ropivacaine 0.5%), Control group C (Bupivacaine 0.5%) were comparable with respect to age, gender, weight, height and ASA status.

The onset of sensory block at L1 was significantly delayed with the group B (6±1.82 min) as compared to group C (1.5±0.83 min) and was statistically significant (p=0.000). P.D.W. Fettes et al [13] had similar results. We found that the median peak level of sensory block with group B was T10 and that of group C was T8 and was statistically significant (p<0.0001). They were in accordance with the study done by Jack W. Van Kleef et al[14] and P.D.W. Fettes et al.[13] In our study the mean duration of analgesia in group B was 180 mins. Jack W van Kleef et al[14] and P. D .W. Fettes et al[13] noted mean analgesia time of 268 mins and 270 mins with intrathecal isobaric Ropivacaine 0.5%. Gautier PE et al found shorter duration of both sensory and motor blockade (p<0.05) which was in accordance with our study. Jack W van Kleef et al[14] and P. D. W. Fettes et al[13] found mean motor blockade time of 178 min and 180 min with intrathecal isobaric Ropivacaine 0.5% .We noted the mean duration of motor blockade with group B was significantly less when compared to group C. The time taken to achieve maximum motor blockade (group B (9±2.03 min) and group C (5±1.55 min) and the difference in onset time of maximum motor block was significantly delayed with group B when compared to the group C (p=0.000). Surjeet Singh et al[15] compared isobaric Ropivacaine 0.75% with hyperbaric Bupivacaine 0.5% under spinal anesthesia and found that the time taken for the onset of complete motor blockade was not delayed statistically (P >0.069).

Mc Donald and colleagues [16] found that Ropivacaine 0.5% produce sensory block of similar onset and extent as Bupivacaine 0.5% but it was associated with lesser degree of motor block and faster regression of both sensory and motor block. Boztug N et al[17] found that the complete motor block was achieved in only 80% of patients with isobaric Ropivacaine 0.5% and all the patients had complete motor block with isobaric Bupivacaine 0.5%, and was statistically significant (P<0.05). A weaker motor block with Ropivacaine compared to Bupivacaine has also been noted in previous in vitro animal and human epidural studies.

Whiteside et al[19] reported that Ropivacaine provided reliable spinal anesthesia of shorter duration and with less hypotension than Bupivacaine. In our study the lower levels of peak sensory

block which causes lesser number of sympathetic segment blockade contributes to less intraoperative hemodynamic complications.

CONCLUSION: Our study demonstrated that intrathecal isobaric Ropivacaine 0.5% is safe and effective with minimal intra-operative & post-operative side effects and provides lesser grade of motor blockade and shorter duration of both sensory and motor blockade. So, we recommend it for spinal anesthesia for short duration orthopaedic surgeries where prolonged motor blockade is quite undesirable and early mobilization can be planned.

BIBLIOGRAPHY:

1. Dureja G.P, Jayalaxmi T.S. Colloid preloading before spinal and epidural anesthesia. Hospital today 2000; V (11):601-603.
2. Cynthia A. Wong. Spinal and Epidural Anesthesia. 1st edition. New York: McGraw Hill professional pub; 2006; 183.
3. Block BM, Liu SS, Rowlingson AJ, et al. Efficacy of postoperative epidural analgesia: A meta-analysis. JAMA 2003; 290:2455.
4. Liu S, Carpenter RL, Neal JM. Epidural anaesthesia and analgesia: Their role in postoperative outcome. Anesthesiology 1995; 82:1474.
5. Rodgers A, Walker N, Schug S, et al. Reduction of postoperative mortality and morbidity with epidural or spinal anaesthesia: Results from overview of randomized trials. BMJ 2000; 321:1.
6. Moraca RJ, Sheldon DG, Thirlby RC. The role of epidural anaesthesia and analgesia in surgical practice. Ann Surg 2003; 238:663.
7. Matot I, Oppenheim-Eden A, Ratrot R, et al. Preoperative cardiac events in elderly patients with hip fracture randomized to epidural or conventional analgesia. Anesthesiology 2003; 98:156.
8. Kuthiala G, Chaudhary G. Ropivacaine: A review of its pharmacology and clinical use. Indian J Anaesth 2011; 55:104-10.
9. Hansen TG. Ropivacaine: A pharmacological review. Expert Rev Neurother 2004; 4:781-91.
10. Graf BM, Abraham I, Eberbach N, Kunst G, Stowe DF, Martin E. Differences in cardiotoxicity of bupivacaine and ropivacaine are the result of physiocochemical and stereoselective properties. Anesthesiology 2002; 96:1427-34.
11. Dony P, Dewinde V, Vanderick B, Cuignet O, Gautier P, Legrand E, et al. The comparative toxicity of ropivacaine and bupivacaine at equipotent doses in rats. Anesth Analg 2000; 91:1489-92.
12. Knudsen K, Beckman Suurkula M, Blomberg S, Sjovall J, Edvardsson N. Central nervous and cardiovascular effects of i.v. infusions of ropivacaine, bupivacaine and placebo in volunteers.Br J Anaesth 1997;78:507-14.
13. Fettes.P, Hocking G, Peterson M. Comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia. British Journal of Anesthesia.2005; 94 (1):107-11.
14. Van Kleef J, Veering B, Burm A. Spinal anaesthesia with ropivacaine. A Double-Blind Study on the efficacy and safety of 0.5% and 0.75% solutions in patients undergoing lower limb surgery. Anesth Anal 1994; 78:1125-30.
15. Singh S, Singh VP, Jain M. Intrathecal 0.75% Isobaric ropivacaine versus 0.5% heavy bupivacaine for elective caesarean delivery: A randomized controlled trial. Journal of Pakistan medical students. 2012; 2(2):75-80.

DOI: 10.14260/jemds/2014/2220

16. McDonald SB, Liu SS, Kopacz DJ. Hyperbaric spinal ropivacaine: A comparison to bupivacaine in volunteers. Anaesthesiology. 1999; 90(4):971-7.
17. Boztug N, Bigat Z, Karsli B. Comparison of ropivacaine and bupivacaine for intrathecal anaesthesia during outpatient arthroscopic surgery. J clin anaesth. 2006; 18(7):521-5.
18. Gautier PE, De Kock, Van Steenberge A. Intrathecal ropivacaine for ambulatory surgery. Anesthesiology 1999; 91 (5):1239-45.
19. Whiteside JB, Burke D, Wildsmith J. Comparison of ropivacaine 0.5% (in glucose 5%) with bupivacaine 0.5% (in glucose 8%) for spinal anaesthesia for elective surgery. British J Anaesthesia. 2003; 90(3):304-308.

AUTHORS:

1. C. Radhika Rani
2. N. S. V. Rama Krishna
3. V. Harinath Babu
4. A. S. Kameswara Rao

PARTICULARS OF CONTRIBUTORS:

1. Post Graduate, Department of Anaesthesia, Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, East Godawary Dist., A. P.
2. Assistant Professor, Department of Anaesthesia, Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, East Godawary Dist., A. P.
3. Professor, Department of Anaesthesia, Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, East Godawary Dist., A. P.
4. Professor, Department of Anaesthesia, Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, East Godawary Dist., A. P.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. C. Radhika Rani,
W/o Dr. K. Sunil Kumar,
Plat No. 202, 3rd Floor,
Vijaya Mohan Residency,
6/1, Kannavarithota,
Guntur – 522004, A. P.
E-mail: radhikakilari@gmail.com

Date of Submission: 08/03/2014.
Date of Peer Review: 10/03/2014.
Date of Acceptance: 12/03/2014.
Date of Publishing: 14/03/2014.