Comparison Of Intrathecal Hyperbaric Ropivacaine And Bupivacaine For Caesarean Delivery

U Srivastava, K Joshi, A Gupta, Y Dwivedi, H Anand, A Kannaujia, S Pilendram

Citation

U Srivastava, K Joshi, A Gupta, Y Dwivedi, H Anand, A Kannaujia, S Pilendram. *Comparison Of Intrathecal Hyperbaric Ropivacaine And Bupivacaine For Caesarean Delivery*. The Internet Journal of Anesthesiology. 2012 Volume 30 Number 4.

Abstract

Background: Ropivacaine a recently introduced local anaesthetic with lesser cardiotoxicity and shorter duration of anaesthesia may be of value in obstetrics. Aim of this study was to evaluate efficacy of spinal anaesthesia with 0.5% hyperbaric ropivacaine during caesarean section and to compare with that of hyperbaric bupivacaine. Methods: In this double blind prospective randomized study, block characteristics of hyperbaric ropivacaine were compared with that of hyperbaric bupivacaine in patients receiving single shot spinal anaesthesia for caesarean delivery. Eighty parturients were randomly allocated to two groups. Group R (n=39) received 15 mg of 0.5% hyperbaric ropivacaine in 8.3% dextrose and group B (n=41) received 11 mg of 0.5% hyperbaric bupivacaine (commercially available preparation).Result: Onset of sensory block was slightly slower in group R but the speed of onset of motor block was similar in both groups. Regression of sensory and motor block was faster in group R. The incidence of hypotension and other side effects was similar in the two groups. Quality of surgical anaesthesia in group R was indistinguishable from that of group B. Conclusion: It was concluded that 15 mg of ropivacaine in 8.3% dextrose provided satisfactory anaesthesia for caesarean delivery similar to that with 11 mg of 0.5% hyperbaric bupivacaine.

INTRODUCTION

Hyperbaric bupivacaine is the standard local anaesthetic for providing spinal anaesthesia for caesarean delivery. Ropivacaine is a relatively new local anaesthetic of amino-amide class which is structurally closely related to bupivacaine. It is less cardiotoxic on overdose or accidental intravenous injection, has shorter duration of motor block and is less potent than bupivacaine. Although cardiotoxicity is not an issue after spinal anaesthesia as it involves very small doses, block characteristics especially shorter duration of motor block and haemodynamic stability are of value in obstetric practice.

As optimal dose of hyperbaric ropivacaine for caesarean delivery is not known investigators have used variable doses ranging between 10 –25 mg [1-5] . A dose response study of hyperbaric ropivacaine for caesarean delivery[6], determined ED50 (95% confidence interval) to be 10.37 (5.23-11.59) mg and ED95 (95% confidence interval) to be 15.39 (13.8-25.59) mg. Based on this, other studies[7,8] and our own preliminary study data, we selected 15 mg dose of ropivacaine for single shot spinal anaesthesia for parturients requiring caesarean delivery and compared it with that of 11 mg hyperbaric bupivacaine, the standard anaesthetic for this surgery. The purpose of the study was to investigate if 15 mg of hyperbaric ropivacaine provided satisfactory surgical anaesthesia for caesarean delivery similar to 11 mg of hyperbaric bupivacaine. We also compared block characteristics and safety profile of the two drugs.

METHOD

After approval from Institutional Review Board and informed written consent, 80 women of ASA I & II status requiring non-urgent caesarean delivery with single live fetus were recruited in this prospective, randomized double blind study. Exclusion criteria were those with hypertension, fetal distress, with systemic disease and with any contraindication to spinal anaesthesia. The study was double blind and the randomization plan was based on computer generated code that was maintained in sequentially numbered opaque envelops until just before use. The anaesthesia resident who accomplished the spinal block prepared the spinal solution and was not subsequently involved in data collection and the person who recorded the

observations was not present at the time of spinal. They received intrathecal injection of either 11 mg of 0.5% hyperbaric bupivacaine in 8% dextrose (Group B) or 15 mg of 0.5% hyperbaric ropivacaine in 8.3% dextrose (Group R). Hyperbaric ropivacaine solution was prepared just before injection with 2 ml of 0.75% ropivacaine and 1 ml of 25% dextrose. To facilitate blinding 0.8 ml saline was added to bupivacaine thus making injectate volume to be 3 ml in each group. The specific gravity of the prepared solutions were 1.031 (ropivacaine) and 1.030 (bupivacaine) at 23 degree C.

All parturients had received ranitidine 50 mg intravenously 60 minutes before surgery and 500 ml of Hartman's solution as preload, 15 minutes prior to spinal. On arrival in the operation room, continuous monitoring with Electocardiogram (ECG), Pulse Oximetry (SPO_2) and non-invasive arterial pressure was done.Spinal anaesthesia was given in L3-L4 or L4-L5 interspace in left lateral position with 25 G Quincke needle. The position of the needle was confirmed by aspiration of CSF , study solution injected over 45 seconds and the patients were turned supine with pillow placed under the right hip. As is our routine Oxygen (O_2) 4 L min^{-1} was given by a face mask until the delivery of infant. Non-invasive arterial blood pressure was measured every 2 minutes until delivery and subsequently at 10 minutes interval while SpO2 and ECG were monitored continuously.

The sensory block assessments were done bilaterally with 27 G short-bewel needle and degree of lower limb motor block was assessed according to modified Bromage scale (0 = full movement, 1 = inability to raise extended leg, can bend knees, 2 = inability to bend knee, but can flex ankle, 3 = no movement in limb). Assessments were done at 0, 2, 5, 10, 15, 20 and 30 minutes and then at 20 minutes interval as soon as possible after surgery by an anaesthetist who was not present at the time of spinal anaesthesia, so was unaware of the group allocation. The observations were done until sensory block regressed to L4 level and motor block regressed to Modified Bromage scale = 0 (complete recovery). The surgeon was asked to rate the quality of muscle relaxation during surgery as excellent, good or poor.

Intraoperatively, hypotension (defined as systolic BP <100 mm Hg or a reduction in mean arterial pressure of more than 20% from baseline) was treated with 6 mg boluses of intravenous ephedrine and IV fluids. Bradycardia (heart rate < 60 beats per min.) was treated with atropine. Surgery was allowed as soon as the upper sensory level was at or above T5. If the patient complained of pain during surgery it was treated with 25 g intravenous fentanyl. Anaesthesia was defined as successful when the surgery was completed without any supplementary analgesia. Nausea/vomiting were treated with 4 mg of intravenous ondansetron.

Based on the data of previous study ,[1] mean ± SD of duration of motor block and time to sensory regression to T10 level was used for power analysis. To detect a difference of 30 minutes for both the variables between two groups, a minimum of 39 patients per group was necessary with type 1 error of 0.01 and a power of 90%. One way ANOVA was used for repeated variables and unpaired t test was used for other variables.

RESULTS

The two groups were not different regarding demographic characteristics. Neonatal Apgar scores measured at one and five minutes were also similar. Time elapsed between spinal injection and skin incision was also the same (table I). Sensory and motor block characteristics are depicted in table II. Maximal sensory level in group R was T3 whereas in group B, it was T4. Time taken to reach to T10 level and maximal level was slightly longer in group R than in group B ($p<0.05$). Regression of sensory block to T10 and L4 level was prolonged in group B compared to group R ($p < 0.05$) suggesting faster recovery of sensory block in group R. Speed of development of motor block in lower limbs was similar in the two groups but , the time of complete motor recovery was significantly shorter in group R in comparison to group B (127±20.42 vs 182.9±30.83 minutes, $p=0.026$).

Surgery was completed without any need for analgesic supplementation in about 90% patients in both groups (successful anaesthesia). Four patients in each group required analgesia supplementation at the skin incision ($p>0.05$), (table III). According to the obstetrician, the muscular relaxation was excellent in majority of the patients in both groups. Mean time of first request for analgesia was significantly longer in group B than group R (226 ±48.6 vs 188 ±23.6 mins, $p = 0.021$) (table III). Hypotension was noted in 54% (group R) and 59% (group B) of patients. Lowest mean arterial pressure (MAP) and maximal reduction in MAP was comparable among the groups (Table IV). Transient neurological symptoms were not seen in any patient. The incidence of other side effects was low in both the groups.

Figure 1

Table I: Demographic and other data

	Group R n=39	Group B n = 41	p value
Age (years)	26±2.2	27±4.8	0.1769
Wt (kg)	58±3.8	57±4.0	0.0918
Height (cm)	151±7.5	153±2.1	0.3672
Time between Spinal and incision	12.6±2.6	11.2±2.3	0.4999
Duration of surgery	57.5±10.8	54±11.5	0.0692
Apgar score at 1 min 5 min	 7.10±1.34 9.35±0.68	 7.20±0.87 9.20±0.79	

Figure 2

Table II: Comparison of sensory and motor block

Sensory block (minutes)	Group R n=39	Group B n = 41	p value
• Time to reach T10	5.73±0.45	5.19±0.40	0.0432
• Maximal level (Range)	T3 (T2 – T7)	T3 (T4-T7)	0.0444
• Time to reach maximal level	9.7±2.24	7.66±3.0	
• Time to regress to T10 level	110.6 ±12.0	135±26.8	0.041
• Time to regress to L4 level	204.8 ±12.9	264±31.3	0.032
Motor block Time to reach (mins) Bromage I Bromage III	 2.77 ±1.56 6.97 ±2.36	 3.35±3.4 6.40±2.58	 0.1440 0.3666
Time to complete motor recovery (mins) Mean Range	 127.0 ±20.42 (95 – 145)	 182.9±30.83 (98-240)	 0.026

Figure 3

Table III: Surgical Anaesthesia (data presented as number of patients or percentage)

	Group R (n=39)	Group B (n=41)
Successful anaesthesia*	35 (89.7%)	37 (90%)
Analgesic supplement needed	4 (10.3%)	4 (10%)
Conversion to GA	-	-
Quality of muscular relaxation †		
Excellent	34	35
Good	5	5
Poor	-	1
Time of 1st analgesia after surgery (mins)	188±23.6	226±48.8 ‡

*Anaesthesia defined as successful when surgery completed without any supplementary analgesia.

† Muscle relaxation as judged by operating surgeons

‡ $p<0.05$

Figure 4

Table IV : Side Effects

	Group R	Group B
Patients with hypotension	57%	59%
Lowest MAP (mm of Hg)	53±17	55±12
Maximal reduction in MAP	28±6	31±6
Requirement of ephedrine (mg)	11±5	12±3
Bradycardia	4	4
Nausea//vomiting	10	8
Shivering	6	4
Headache	5	5
TNS	-	-

MAP- Mean Arterial Pressure, TNS- Transient Neurological Symptoms, Values are as Mean±SD or number of patients

* $p = 0.01$

DISCUSSION

The results of this study demonstrated that intrathecal 15 mg of ropivacaine in 8.3%dextrone provided effective surgical anaesthesia of similar quality as that by 11 mg of bupivacaine in 8% dextrose. Although the mean time elapsed between spinal injection and skin incision was slightly prolonged in group R in relation to group B, it was neither statistically nor clinically significant. Spinal anaesthesia was successful in almost 90% of patients in each group & in none of the patients, conversion to GA was required.

The time to reach maximal sensory level was slightly longer in group R but time to attain complete motor block of lower limbs was similar to that in group B. But the sensory and motor block regressed faster in group R. The results of this study are in agreement with general conclusion of other studies.[1,2,7,8] Slow onset and faster recovery shows that ropivacaine is less potent than bupivacaine and this is because former is less lypophilic than bupivacaine,[9] but the clinical profile of actions of the two drugs is not different. The duration of full motor recovery of lower limbs in group R ranged between 95-145 minutes with mean duration being 127±20 minutes (range and mean duration in group B ; 94-240 and 182.9±30.83 minutes). Mean duration was approximately 55 minutes less than that in group B. This time may not appear important as the caesarean patients are hospitalized for at least four days. However, faster recovery of motor block may reduce recovery room stay and possibly improve maternal satisfaction.[1,8] Quality of surgical anaesthesia was also comparable among the groups, a finding in agreement with previous reports .[1,8,10] The quality of muscular relaxation as judged by operating obstetrician was good or excellent in majority of the of the patients in both the groups.[1,8] Infact, the operating obstetricians were surprised about any change of spinal drug as the quality of surgical anaesthesia was the same.

Ropivacaine is available only as isobaric solution, which has a specific gravity of 0.9888 at 37° C. This solution is slightly hypobaric, and therefore has more variable and unpredictable block.[11] Evidence from studies suggest that addition of dextrose improves reliability of block.[2,4,12] The present study confirmed that a dextrose containing solution of ropivacaine, hyperbaric to CSF (specific gravity 1.030) can provide consistent and reliable block for caesarean section.

Hypotension was most frequently encountered complication during surgery in both the groups. Although we preloaded all our patients and used wedge pillow in all the patients, the manoeuvres were probably inadequate. The incidence of hypotension and ephedrine usage were similar in both the groups and were comparable to other studies .[1,5,8,10] The incidence of other side effects were low and similar in both the groups. Transient neurological symptoms were not seen in any patient. Neonatal Apgar scores were also similar in each group.

Our study demonstrated that single shot spinal anaesthesia with 15 mg of hyperbaric ropivacaine has a definite role in spinal anaesthesia for caesarean delivery. The onset, duration as well as quality of surgical anaesthesia suited well to caesarean delivery and was as effective as produced by 11 mg of hyperbaric bupivacaine. It is safe, reliable and viable alternative to bupivacaine. Shorter duration of motor block may have impact on recovery room stay. However it has few disadvantages. As the hyperbaric solution of ropivacaine is not available commercially, it has to be prepared just before spinal injection and shorter duration of motor block may not always correspond with surgical duration. In general caesarean section is completed in about an hour `however, if surgery is prolonged, recovery of motor block towards end of surgery may necessitate supplementation. Also the early regression of sensory block, results in shorter duration of postoperative analgesia. However, this can be improved by adding opioids to local anaesthetics .[5,7,10]

References

1. Chung CJ, Choi SR, Yeo KH, Park HS, Lee SI, Chin YJ. Hyperbaric spinal ropivacaine for caesarean delivery: a comparison to hyperbaric bupivacaine Anesth Analg. 2001; 93: 157 – 61.
2. Khaw KS, Ngankee WD, Wojng M, Ng F, Lee A. Spinal ropivacaine for caesarean delivery: a comparison of hyperbaric and plain solutions. Anesth. Analg 2002; 94: 680 – 5.
3. Gautier, P De Kock, M, Vanderick, B, Comparison of the effect of intrathecal ropivacaine, levobupuvacaine & bupivacaine for caesarean section. Br J Anaesth 2003; 93: 684 – 89.
4. Chen X, Qian X, Fu F, Lu H, Bein B. Intrathecal sufentanil decreases the median effective dose (ED50) of intrathecal ropivacaine for caesarean delivery. Acta Anesthesiol Scand 2010; 54:284-90
5. Qian XW, Chen XZ, Li DB. Low dose ropivacaine – sufentanil spinal anaesthesia for caesarean delivery: a randomized trial. Int. J. Obstet Anesth. 2008; 17: 309 – 14.
6. Chen X, Chen H, Lou A, Lu CC. Dose response study of spinal hyperbaric ropivacaine for caesarean section. J. Zhejiang Univ Sci. B. 2006; 7: 992 – 997.
7. Sanli S, Yegion A, Kayacan N, Yilmaz M, Coskunfirat N, Karsli B. Effects of hyperbaric spinal ropivacaine for caesarean section: with or without fentanyl Eur J Anaesth 2005; 22: 457 – 461.
8. Al-Abdulhadi O, Biehl D, Ong B, Boker A. Hyperbaric

spinal for elective caesarean section – Ropivacaine vs bupivacaine. MEJ Anesth 2007; 19: 385 – 397.
9. Leone S, Cianni SD, Casati A, Fanelli G, Pharmacology toxicology and clinical use of new long acting local anathetics, ropivacaine and levobupicacaine Acta Biomed 2008; 79: 92 – 105.
10. Ogun Co, Kirgiz EN, Duman A, Okesli S, Akyarek C, Comparison of intrathecal isobaric bupivacaine – morphine and ropivacaine – morphine for caesarean delivery. Br J. Anaesth 2003; 90: 659 – 64.
11. Fettes PDW, Hovking G, Peterson MK, Luck JF, Wildsmith JAW. Comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia Br J Anaesth 2004;94: 107-111
12. Whiteside JB, Burke D, Wildsmith JAW. Spinal anaesthesia with ropivacaine 5 mg ml -1 in glucose 10 mg ml – 1 or 50 mg ml -1. Br J Anaesth 2001; 86: 241 – 4.

Author Information

Uma Srivastava, M D, D A
Professor, Department Of Anaesthesia & Critical Care, S N Medical College

Komal Joshi
postgraduate student, Department Of Anaesthesia & Critical Care, S N Medical College

Amrita Gupta, M D,
lecturer, Department Of Anaesthesia & Critical Care, S N Medical College

Yogita Dwivedi, M D,
lecturer, Department Of Anaesthesia & Critical Care, S N Medical College

Harsh Anand
postgraduate student, Department Of Anaesthesia & Critical Care, S N Medical College

Ashish Kannaujia, M D,
lecturer, Department Of Anaesthesia & Critical Care, S N Medical College

Sathiyanarayanam Pilendram
postgraduate student, Department Of Anaesthesia & Critical Care, S N Medical College