VOLUME-6 | ISSUE-3 | MARCH - 2017 • ISSN No 2277 - 8179 | IF : 4.176 | IC Value : 78.46

Hyperbaric Spinal Ropivacaine for Elective Cesarean Section: A Comparison to Hyperbaric Bupivacaine

Anaesthesiology

KEYWORDS: Ropivacaine, Bupivacaine, Hyperbaric, Spinal, Cesarean.

Dr. YOGESH CHAND MODI — ASSISTANT PROFESSOR DEPARTMENT OF ANAESTHESIA SMS MEDICAL COLLEGE JAIPUR (RAJASTHAN)

Dr. REEMA MEENA — PROFESSOR DEPARTMENT OF ANAESTHESIA SMS MEDICAL COLLEGE JAIPUR (RAJASTHAN)

ABSTRACT

Background : We evaluated the clinical efficacy and safety of spinal anesthesia with 0.5% hyperbaric ropivacaine compared with 0.5% hyperbaric bupivacaine for elective cesarean section.

Methodology: Eighty healthy, full-term parturients were randomly assigned to receive either 10 mg of 0.5% hyperbaric bupivacaine or 15 mg of 0.5% hyperbaric ropivacaine intrathecally.

Results: There were no significant differences in demographic or surgical variables or neonatal outcomes between groups. Onset time of sensory block upto T10 and upto peak level was more in the Ropivacaine group (P< 0.05). The median peak level of analgesia was T6 (T5-7) in both groups. Duration of sensory block was shorter in the ropivacaine group (128±6.34min vs. 107.6±6.33min; p<0.01). Complete motor block of the lower extremities was obtained in all patients. Onset of motor block was earlier in bupivacaine group (6.9±1.43min) in comparison to ropivacaine group (8.45±1.06 min).Ropivacaine produced a shorter duration of motor blockade than bupivacaine (102.75±12.03 min vs. 146±18.4min; P<0.001).

The intraoperative quality of muscle relaxation was similar in both groups. Side effects did not differ between groups.

Conclusion: 15mgs. of 0.5% hyperbaric ropivacaine provided effective spinal anesthesia with shorter duration of sensory and motor block, compared with 10 mg of 0.5% hyperbaric bupivacaine when administered intrathecally for cesarean section

Introduction Ropivacaine is a long-acting local anaesthetic amide which has almost same clinical properties as bupivacaine in terms of onset, duration and quality of block but has certain advantages over bupivacaine in that it has less potential for both CVS and CNS toxicity(1-4) and it causes preferential more blockade of sensory nerve fibres(9).

Ropivacaine is less potent than bupivacaine but it has been proved in various studies that it is equally efficacious at equivalent doses(7).

The efficacy and dosage of spinal ropivacaine for cesarean section is unknown. Based on several previous studies (7, 8, and 9) we determined that 15 mg of 0.5% hyperbaric ropivacaine was comparable to 10 mg of 0.5% hyperbaric bupivacaine for spinal anaesthesia in cesarean section.

Aim of the study To compare the efficacy and safety of hyperbaric ropivacaine with hyperbaric bupivacaine in spinal anaesthesia for elective cesarean section.

Study design Hospital based, randomized controlled, single blind interventional study.

Methodology This study was approved by the research and review board of our hospital. An informed written consent was obtained from all patients.

All patients were of ASA grade I or II, 150–165 cms. in height, age group of 25-35 years, 50-70 Kgs. of weight and were scheduled for elective cesarean section under spinal anaesthesia. Parturients who had obstetric complications or evidence of fetal compromise were excluded.

Assuming the mean difference in onset of sensory block between bupivacaine and ropivacaine 0.7 minutes with standard deviation ± 1.1, the sample size (n) was estimated 40 patients in each group.

Group1 [Controll group] (n=40) consist of patients received 0.5% hyperbaric bupivacaine (2 ml),

Group2 [Study group] (n=40) consist of patients received 0.5% hyperbaric Ropivacaine (3ml).

The patients were randomly assigned into either group. Hyperbaric ropivacaine solutions was made with 2 mL of 0.75% ropivacaine and 1 mL of 20% dextrose. All solutions were prepared and injected by a resident. Patients, surgeons, and another resident, who was involved in the patient's clinical assessment and treatment, were blinded to group assignment. Lactated Ringer's solution 10 mL/kg was infused before the initiation of the spinal block.

Spinal anaesthesia was performed in left lateral position with either hyperbaric ropivacaine or hyperbaric bupivacaine according to randomization. After the injection of the spinal medication the patients were turned supine.

Vitals Baseline values of blood pressure and heart rate were defined as values before the spinal injection. After spinal injection values were recorded in every 2 minutes for first 10 minutes, in every 10 minutes in first hour and in every 30 min thereafter. Arterial oxygen saturation and ECG were observed continuously.

Hypotension was defined as a fall in systolic blood pressure below 90mm Hg and was treated by incremental doses of Ephedrine 5 mg i.v. and additional lactated Ringer's solution.

Bradycardia was defined as fall in heart rate below 60 beats per min and was treated with incremental doses of atropine 0.4-0.6 mg i.v. Other adverse effect (eg. Nausea, shivering etc.) were noted and treated accordingly.

Results The patients in both the groups were comparable in terms of age, weight, height, time from induction to skin incision and duration of surgery as shown in (Table 1).

Sensory block was determined by the pinprick test bilaterally at midclavicular level by using a short beveled 25-gauge needle. The level of sensory block was assessed in every 30 seconds till the highest level of sensory block was achieved. Time to achieve sensory block up to T 10 level was noted & defined as onset of sensory block. After completion of surgery it was assessed in every 2 minutes till the regression of sensory block upto T10 dermatome.

Degree of **motor block** was assessed in every 2 minute before starting of surgery and in every 15 minutes postoperatively by using Bromage scale. Time to achieve complete motor block (Bromage

score 3) and time to achieve complete motor recovery (Bromage score 0) since intrathecal injection were noted.

The **quality of abdominal muscle relaxation** was evaluated by the surgeon at the end of the surgery as excellent (no disturbing muscle strain), satisfactory (disturbing, but acceptable muscle strain), or unsatisfactory (unacceptable muscle strain).

Pain was assessed by Visual Analogue Score (VAS). VAS was assessed every 30 minutes. Supplemental analgesia was given when VAS score was >6. Time of supplemental analgesia was noted. Time to the first feeling of pain (complete analgesia) and time to first request of analgesics (effective analgesia) were measured.

The qualitative and quantitative data were collected and analyzed. 'Chi square' test, t test and 'Z' test were applied for analysis of the study. P-value less than 0.05 were considered statistically significant in all the studies.

Table 1. Demographic and Surgical Data

	Bupivacaine (n = 40)	Ropivacaine (n = 40)	p- value
Age (yr)	27.2±1.97	27.2±1.25	0.946(NS)
Weight (kg)	55.53±3.13	55.30±2.14	0.702(NS)
Height (cm)	152.3±2.2	152.8±1.89	0.280(NS)
Induction to skin incision (min)	9.95±0.87	10.18±0.62	0.177(NS)
Duration of surgery (min)	50.68±4.19	49.43±3.53	0.153(NS)

Values are mean± sd

Results: Onset of sensory block to T10 and to the maximum level took more time in the ropivacaine group (4.4±0.5min and 11.45±0.46min) than in the Bupivacaine group (3.14±0.58 min and 8.03±0.54 min; p< 0.001).The median maximal level of sensory block was similar in both groups (T6).

Regression of sensory block to two dermatome below the highest level (68.3±2.33 vs. 80.4±3.32; p<0.001) and duration of sensory block (regression upto T10 dermatome) (107.6±6.33 vs. 128±6.34; p<0.001) was significantly earlier in ropivacaine group in comparison to bupivacaine group (Table 2).

Table 2 Characteristics of Spinal Anaesthesia

	Bupivacaine (n = 40)	Ropivacaine (n = 40)	p value
Sensory block (min)			
Onset time to T10	3.14±0.58	4.4±0.5	<0.001(S)
Maximal sensory level	T6 (T5-T7)	T6 (T5-T7)	0.899(NS)
Time to maximal level	8.03±0.54	11.45±0.46	<0.001(S)
Time to two dermatome regression	80.4±3.32	68.3±2.33	<0.001(S)
Time to regression to T10	128±6.34	107.6±6.33	<0.001(S)
Motor block (min)			
Time to achieve complete block	6.9±1.43	8.45±1.06	<0.001(S)
Time to complete recovery	146±18.4	102.75±12.03	<0.001(S)

Values are mean ± sd

Complete motor block of the lower extremities (Bromage score 3) was obtained in all patients. Time to achieve complete motor block was significantly early in bupivacaine group in comparison to ropivacaine (6.9±1.43 vs 8.45±1.06; p<0.001) but duration of motor block (Bromage Score from 3 to 0) was significantly shorter in ropivacaine group (102.75±12.03 vs 146±18.4; p<0.001).

The qualities of intraoperative analgesia and abdominal muscle relaxation were similar in both groups (Table 3). No patient, regardless of group, complained of discomfort on skin incision.

There was a significant difference in duration of complete (Time to first feeling of pain) & effective analgesia (Time to first request of analgesics) in between both the groups.

Table 3. Efficacy of Spinal Anesthesia

	Bupivacaine (n = 40)	Ropivacaine (n = 40)	p Value
Quality of intraoperative muscle relaxation			
Excellent	38	33	
Satisfactory	2	7	0.157(NS)
Unsatisfactory	0	0	
Complete analgesia (min)	118±13.7	101.5±9.5	**<0.001(S)**
Effective analgesia (min)	142±14	125.25±10.12	<0.001(S)

Values are number of patients (%) or mean ± sd

Duration of complete & effective analgesia was shorter in Ropivacaine group (101.5±9.5 &125.25±10.12) than in Bupivacaine group (118±13.7 & 142±14).

Apgar scores were similar in both groups. Adverse effects: Hypotension was the most common side effect in both groups. The incidence of hypotension differ non significantly (40% in bupivacaine vs 25% in ropivacaine group; p=0.233).

The incidence of bradycardia (5% vs 2.5%; p=1.00), nausea (10% vs 5%; p=0.671) and shivering (5% vs 5%; p=0.608) also did not differ significantly between groups (Bupivacaine vs ropivacaine).

No other adverse effect or complication were noted.

Discussion We design this study to compare hyperbaric ropivacaine with hyperbaric bupivacaine in spinal anaesthesia for cesarean section in terms of clinical efficacy and safety.

The analgesic spread with isobaric spinal ropivacaine is variable, extending from lumbosacral segments to upper thoracic segments (5–7). Actually, glucose-free ropivacaine and bupivacaine solutions are not isobaric at body temperature. Like glucose-free bupivacaine 0.5% solutions (baricity at 37°C: 0.9990), glucose-free ropivacaine solutions (baricity at 37°C: 0.9988) will behave as slightly hypobaric at body temperature(9). Consequently, the injection of glucose-free ropivacaine solutions may result in a higher spread when the patient is kept in the sitting position for at least 2 min after the injection, as has been demonstrated for bupivacaine.

Plain spinal bupivacaine for cesarean delivery is unreliable and occasionally produces high spinal block (10,11). Therefore, a hyperbaric solution for spinal anesthesia, especially for cesarean section is used.

The optimal dosage of spinal ropivacaine for cesarean section was unknown. The equipotent ratio between bupivacaine and ropivacaine has been 3:2 with isobaric solution for knee arthroscopy(7) or 2:1 with hyperbaric solution in volunteers(8) or 3:2 with hyperbaric solution for elective caesarean section(9).

Based on previous studies (7,8,9), we used 15 mg of 0.5% hyperbaric ropivacaine or 10 mg of 0.5% hyperbaric bupivacaine for spinal anesthesia in cesarean section. The doses are chosen little smaller than in previous study (9) because Indian woman are relatively shorter in height than western woman.

In a study done by Mc Donald et. al (8) hyperbaric bupivacaine 8 mg was compared with hyperbaric ropivacaine 12 mg and no difference in time to peak sensory level and duration of sensory block was found. Our study coincide with Chung CJ et al. Study (9) showing

VOLUME-6 | ISSUE-3 | MARCH - 2017 • ISSN No 2277 - 8179 | IF : 4.176 | IC Value : 78.46

early onset of sensory block to T10 and to the maximum level in case of bupivacaine.

Our study data showed that spinal ropivacaine produced motor blockade of lesser duration in comparison to spinal bupivacaine in equipotent doses. It confirms that spinal ropivacaine is less potent than spinal bupivacaine.

Lesser potency may be because of lesser lipid solubility of ropivacaine which may cause this drug to penetrate the large myelinated A fibers more slowly than the more lipid soluble bupivacaine (12). A difference in the potency between ropivacaine and bupivacaine has been 20%– 40% and 50% in epidural (13,14) and spinal (7,8) studies, respectively.

Studies evaluating the use of intrathecal ropivacaine for ambulatory surgery (7,8) have reported that spinal ropivacaine offers no advantages over bupivacaine for use in outpatients. Spinal ropivacaine 12 mg has produced motor blockade equivalent to bupivacaine 8 mg (8).

However, in our study, like other study in cesarian delivery (9), hyperbaric ropivacaine 15 mg produced a significantly shorter duration of motor blockade than hyperbaric bupivacaine 10 mg. Earlier recovery with spinal ropivacaine may be associated with more patient satisfaction and early mobilisation.

In this study, intrathecal ropivacaine produced excellent intraoperative analgesia and abdominal muscle relaxation, indistinguishable from spinal bupivacaine. The duration of sensory block was shorter and the time to first request of analgesics was earlier with ropivacaine than with bupivacaine in this study.

The incidence of hypotension is frequent but did not differ significantly in both groups. The hypotension was easily treated with ephedrine and did not cause any maternal or fetal sequelae.

Other adverse effects like bradycardia, nausea or shivering occur but did not have significant difference.

In this study, the conditions of the neonates were good and similar in both groups in terms of APGAR score.

Conclusion: 15 mg of 0.5% hyperbaric ropivacaine provided similar and effective spinal anesthesia with shorter duration of sensory and motor block, compared with 10 mg of 0.5% hyperbaric bupivacaine for elective caesarean section.

Early recovery of motor block allows mother to better newborn care including early starting of breastfeeding and shortens the stay of post anaesthesia care unit after the surgery.

References:

1. Akerman B, Hellberg B, Trossvik C. Primary evaluation of the local anaesthetic properties of the amino amide agent ropivacaine (LEA 103). Acta Anaesthesiol Scand 1988;32:571–8.
2. Griffin RP, Reynolds F. Extradural anaesthesia for Caesarean section: a double-blind comparison of 0.5% ropivacaine with 0.5% bupivacaine. Br J Anaesth 1995;74:512–6.
3. Crosby E, Sandler A, Finucane B, et al. Comparison of epidural anaesthesia with ropivacaine 0.5% and bupivacaine 0.5% for Caesarean section. Can J Anaesth 1998;45:1066–71.
4. Bjoyrnestad E, Smedvig JP, Bjerkreim T, et al. Epidural ropivacaine 7.5 mg/ml for elective Caesarean section: a double-blind comparison of efficacy and tolerability with bupivacaine 5 mg/ ml. Acta Anaesthesiol Scand 1999;43:603–8.
5. Van Kleef JW, Veering BT, Burm AGL. Spinal anesthesia with ropivacaine: a double-blind study on the efficacy and safety of 0.5% and 0.75% solution in patients undergoing minor lower limb surgery. Anesth Analg 1994;78:1125–30.
6. Wahedi W, Nolte H, Klein P. Ropivacaine in spinal anaesthesia. Anaesthetist 1996;45:737–44.
7. Gautier PE, De Kock M, Van Steenberge AV, et al. Intrathecal ropivacaine for ambulatory: a comparison between intrathecal bupivacaine and intrathecal ropivacaine for knee arthroscopy. Anesthesiology 1999;91:1239–45.
8. McDonald SB, Liu SS, Kopacz DJ, Stephenson CA. Hyperbaric spinal ropivacaine: a comparison to bupivacaine in volunteers. Anesthesiology 1999;90:971–7.
9. Chung CJ. Hyperbaric spinal ropivacaine for cesarean delivery: a comparison to hyperbaric bupivacaine.[Anesthesia Analgesia 2001 Jul;93(1):157-61],
10. Russell IF. Spinal anaesthesia for Caesarean section: the use of 0.5% bupivacaine. Br J Anaesth 1983;55:309–14.
11. Russell IF. Inadvertent total spinal for Cesarean section. Anaesthesia 1985;40:199–200.
12. Rosenberg PH, Kytta J, Alila A. Absorption of bupivacaine, etidocaine, lignocaine and ropivacaine into N-heptane, rat sciatic nerve and human extradural and subcutaneous fat. Br J Anaesth 1986;58:310–4.
13. Zaric D, Nydahl PA, Philipson L, et al. The effect of continuous lumbar epidural infusion of ropivacaine (0.1%, 0.2%, and 0.3%) and 0.25% bupivacaine on sensory and motor block in volunteers: a double-blind study. Reg Anesth 1996;21:14–25.
14. Polley LS, Columb M, Naughton N, et al. Relative analgesic potencies of ropivacaine and bupivacaine for epidural analgesia in labor: implications for therapeutic indexes. Anesthesiology 1999;90:944–50.