

HYPERBARIC SPINAL FOR ELECTIVE CESAREAN SECTION

- Ropivacaine vs Bupivacaine -

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Abstract

Purpose: To compare hyperbaric spinal ropivacaine to hyperbaric spinal bupivacaine for elective cesarean delivery in a prospective, randomized, double blinded study.

Methods: With the University Ethics Committee approval, 66 parturients for elective cesarean deliveries received either 15 mg of hyperbaric ropivacaine (N = 33) or 11.25 mg of hyperbaric bupivacaine (N = 33) with 0.1 mg of preservative-free morphine and 0.01 mg fentanyl. The sensory and motor blockades were assessed at 3, 6, and 9 min after injection. The APGAR scores, umbilical cord gases, intra-operative side effects and the total duration of motor and sensory blockade, were recorded.

Results: The two groups had similar demographics, and similar times for sensory block to T6 and Bromage score 3 motor blockade. The median levels of sensory blockade were T3 and T2 for the ropivacaine and bupivacaine groups respectively. Duration of sensory block was shorter in the ropivacaine group (174 ± 24 min vs 217 ± 46 min; $P < 0.001$). Duration of motor block was shorter in the ropivacaine group (85 ± 26 vs 159 ± 56

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min; $P < 0.001$). The obstetricians rated intra-operative anesthesia as excellent in both groups. None of neonates had Apgar scores less than 7. There was no difference in cord gases between the two groups. Side effects did not differ between the two groups. The ropivacaine patients expressed significantly higher satisfaction levels ($P < 0.016$).

Discussion: 15 mg of hyperbaric ropivacaine with 0.1 mg morphine and 0.01 mg fentanyl provided excellent anesthesia for cesarean delivery. The advantages of hyperbaric ropivacaine consist of faster regression of the block and higher patient satisfaction.

Keywords: spinal anesthesia, cesarean section, bupivacaine, ropivacaine.

Introduction

Hyperbaric 0.75% spinal bupivacaine is a commonly used local anesthetic for elective cesarean deliveries. This agent has a long duration of sensory blockade with delayed return of motor activity. That long duration of action delays recovery of motor function and prolongs postanesthesia care unit stay after delivery.

Ropivacaine is a local anesthetic with structural and pharmacodynamic properties similar to bupivacaine^{1,2}. Several studies have compared ropivacaine and bupivacaine for spinal anesthesia in obstetric patients for cesarean deliveries³⁻⁵. Although the doses of ropivacaine, bupivacaine and morphine were different in the three studies, all reported good intraoperative anesthetic conditions. While Danelli *et al*³, found that sensory blockade was shorter with ropivacaine, Ogun *et al*⁴, did not observe any difference in time for recession of sensory blockade between isobaric ropivacaine and bupivacaine solutions.

Chung *et al*⁶ reported that addition of intrathecal fentanyl can improve the quality of intraoperative analgesia, and the duration of complete and effective analgesia for cesarean delivery under ropivacaine spinal anesthesia. None of the previous studies that compared ropivacaine and bupivacaine spinal anesthetics for cesarean deliveries have included intrathecal fentanyl.

In this study we compared hyperbaric ropivacaine and bupivacaine with the addition of 0.1 mg of preservative-free morphine and 0.01 mg fentanyl. We assessed the quality of intraoperative anesthesia, efficacy and the duration of sensory and motor blockades as well as evaluations by the surgeons and patients.

Methods and Materials

The University of Manitoba Ethics Committee approved this study. Sixty-six parturients gave informed written consent. Sample size of the study was determined by our biostatistician. The study was conducted in a prospective, randomized, double blinded fashion.

Inclusion criteria were parturients scheduled for elective cesarean section with a singleton fetus, pregnancy at term, who were between 150 cm – 180 cm tall, between 18 years and 40 years of age and weighted between 60 kg – 120 kg. Exclusion criteria were patient refusal, inability to communicate in English, and any other contra-indication to regional block. Patients were recruited at our preoperative cesarean section clinic. A pharmacist prepared all the spinal solutions.

Patients were randomly assigned to two groups of 33 patients each to receive either an intrathecal injection of 15 mg of hyperbaric ropivacaine or 11.25 mg of hyperbaric bupivacaine. Hyperbaric ropivacaine solutions were made with 1.5 ml of 1% ropivacaine and 1 ml of 20% dextrose. We added 0.1 mg preservative-free morphine and 0.01 mg fentanyl to the local anesthetic as in our usual practice. The total volume and dextrose concentration of both spinal anesthetic solutions were equal. Patients, obstetrician, anesthesia residents, staff anesthesiologists, nurses, and all health care personal in the cesarean section room, were blinded to group assignment.

Lactated Ringer's solution, 10 ml/kg, was infused 10 min before the initiation of the spinal block. Spinal anesthesia was performed in the sitting position with a 25-gauge Whitacre[®] needle, using a midline approach at the L2-3 or L3-4 interspace. The study drug was injected over 1 minute approximately. After the injection of the spinal medication, the patients remained in the sitting position for 1 min and then placed supine

with left uterine displacement.

Maternal heart rate and arterial blood pressure were measured with an automatic, noninvasive device. The values were recorded before induction, every 3 min till surgery end, and then every 10 min until discharge from the recovery room. Arterial oxygen saturation was continuously monitored using pulse oximetry throughout surgery.

Hypotension (defined as systolic blood pressure < 100 mmHg) was treated with either IV ephedrine or phenylephrine at the discretion of the anesthesiologist. Maternal bradycardia (defined as heart rate < 60 bpm) was treated with either IV atropine or glycopyrrolate. The staff anesthesiologists treated other symptoms at their discretion. Oxygen was routinely administered via nasal cannula at the rate of 3L/min until the delivery.

Surgery was started 10 min post spinal injection when the sensory block was at or above the T6. The staff neonatologist evaluated the condition of the neonate. Apgar scores at 1 and 5 min after delivery was recorded and umbilical cord blood gases were analyzed.

In the operating room, all assessments were performed at 3, 6 and 9 minutes. The assessments of sensory block was with ice in the midclavicular line from L1 to T2 and motor block was assessed by using a modified Bromage scale. Motor block in the lower limbs was assessed by using a modified Bromage scale (0 = no paralysis, 1 = unable to raise extended leg, 2 = unable to flex knee, 3 = unable to flex ankle). The assessments of sensory and motor block also were performed every 15 min in PACU until the sensory block had regressed to L4 and the Bromage score = 0.

At the end of the surgery, the obstetrician evaluated the quality of abdominal muscle relaxation as either excellent (no disturbing muscle strain), satisfactory (disturbing, but acceptable muscle strain), unsatisfactory (unacceptable muscle strain).

For post-operative analgesia, all patients received naproxen 500 mg suppository at the end of the procedure and oral naproxen 250 mg every eight hours for 24 hours.

At twenty four hours after the cesarean section, each patient was

asked to evaluate the anesthesia on the following scale: poor, fair, good, very good, and excellent.

Statistical Analysis

Patient demographics, analgesia requirement, and amount of medication to treat hypotension were compared using T-test and Chi-square. Extent of the motor and sensory block was studied using the Wilcoxon test rank. Duration of motor and sensory recovery was studied using median and interquartermal range. Hypotension was analyzed using repeated measures T-test and ANOVA test. APGAR scores and cord gases in both groups were compared by Chi-square. A p-value < 0.05 was considered significant. The results are presented as mean \pm standard deviation or median.

Results

Demographic Data

All 66 patients completed the study. There was no difference in age, weight, height, gestational age, time from induction spinal anesthesia to the surgery and duration of surgery between the two groups (Table 1).

Table 1
Demographic Data

	Ropivacaine (n = 33)	Bupivacaine (n = 33)
Age (yr)	30 \pm 2	33 \pm 2
Weight (kg)	83.5 \pm 4.9	86 \pm 5.5
Height (cm)	165 \pm 2.5	162 \pm 2.5
Gestational age (wk)	38 \pm 1	38.2 \pm 0.8
Duration of surgery (min)	39 \pm 3.5	42 \pm 3.5

Sensory Block

The times for the block to reach T10 and T6 were similar in the two groups (Table 2).

The median maximal levels of sensory block were similar in the two groups. The height of the sensory block at 3, 6, and 9 min were similar in both groups.

Table 2
Sensory Blocks

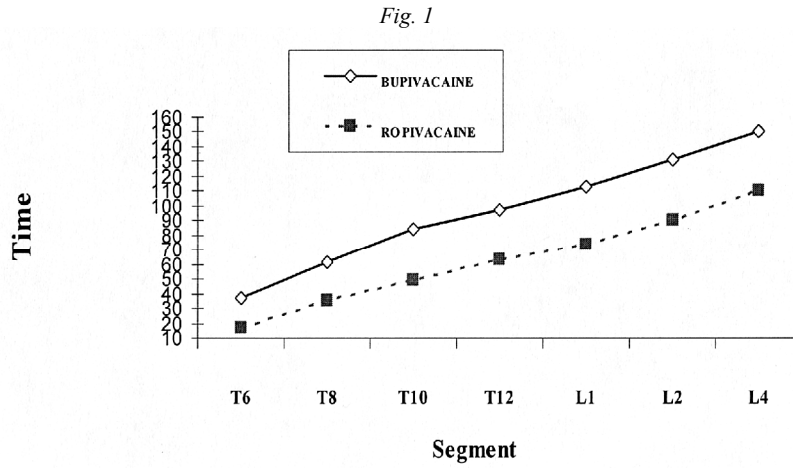
	Ropivacaine (n = 33)	Bupivacaine (n = 33)
Sensory height block		
3 min	T8	T8
6 min	T4	T4
9 min	T3	T2
Maximal sensory level	T3	T2

Time for the sensory block to recede to T10 in PACU was significantly shorter in the ropivacaine group compared to the bupivacaine group (50 ± 10 vs 75 ± 15) ($P < 0.0001$). Time for the sensory block to recede to L4 in PACU was significantly shorter in the ropivacaine compared to the bupivacaine (105 ± 15 vs 150 ± 15) ($P < 0.0001$). The duration of sensory block with ropivacaine group was (173 ± 8.6 min) and in the bupivacaine group was (217.6 ± 16.4 min) ($P < 0.0001$) (Fig. 1) and (Table 3).

Table 3
Characteristics of Spinal Anesthesia

	Ropivacaine (n = 33)	Bupivacaine (n = 33)
Sensory block (min)		
Onset time to T10	1.88 ± 0.89	1.96 ± 1.18
Onset time to T6	4.79 ± 1.95	4.81 ± 2.17
Time to regression to T10 in PACU	50 ± 10	$75 \pm 15^*$
Time to regression to L4 in PACU	105 ± 15	$150 \pm 15^*$
Time to complete recovery	173.6 ± 8.6	$217.6 \pm 16.4^*$
Motor block (min)		
Time to Bromage 3 (min)	6.6 ± 0.6	6.4 ± 0.3
Time to complete recovery (min)	85 ± 7.7	$159 \pm 15^*$

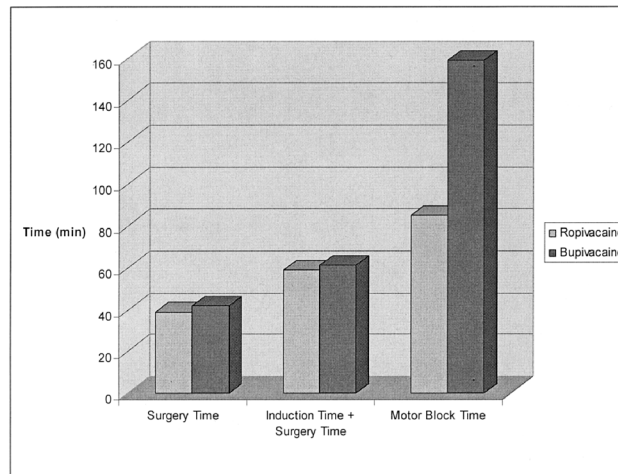
* $P < 0.0001$ compared with ropivacaine group by Chi-square.



Motor Block

Complete motor block of the lower extremities (Gromage score 3) was obtained in all patients except one in the bupivacaine group. The time to complete motor blockade was similar in both groups. The duration of complete motor block was significantly less in the ropivacaine group compared to the bupivacaine group (85 ± 7.7 min vs 159 ± 15 min) ($P < 0.0001$) (Fig. 2).

Fig. 2
Motor Block



Obstetrician Assessment

The quality of intra-operative muscle relaxation was the same as assessed by the obstetrician in both groups (Table 4). No patients, complained of discomfort on skin incision. Two patients in the ropivacaine and three patients in the bupivacaine group experienced discomfort during the closure of the fascia. Those patients required supplementary intravenous analgesics during the last part of the surgery. One patient in the bupivacaine group required morphine in the post-partum period.

APGAR scores did not differ between groups. No neonates had APGAR score of less than 7 at one and five minutes. The umbilical arterial pH did not differ between groups (ropivacaine 7.26 ± 0.03 vs bupivacaine 7.24 ± 0.03). The venous pH did not differ between groups (ropivacaine 7.33 ± 0.02 vs bupivacaine 7.32 ± 0.02). Patient satisfaction was significantly higher in the ropivacaine group than in the bupivacaine group ($P < 0.0016$) (Table 4).

Table 4
Obstetrician's assessment

	Ropivacaine (n = 33)	Bupivacaine (n = 33)
Quality of intra-operative		
Muscle relaxation		
Excellent	33 (100)	31 (94)
Satisfactory	0 (0)	2 (6)
Unsatisfactory	0 (0)	0 (0)
Patient satisfaction		
Poor	0 (0)	0 (0)
Fair	0 (0)	1 (3)
Good	0 (0)	1 (3)
Very good	4 (12)	17 (51)
Excellent	29 (88)	14 (43)*

Values are number of patients (%).

* $P < 0.0016$ compared with ropivacaine group.

Side Effects

Hypotension was the most common side effect intraoperatively. The incidence of hypotension in the ropivacaine was 70% and in the bupivacaine was 88%. These results were not clinically significant. The mean dose of ephedrine was 20 mg in the ropivacaine group and 30 mg in the bupivacaine group. The mean phenylephrine dose was 0.120 mg in the ropivacaine group and 0.80 mg in the bupivacaine group. There was one patient in each group who had an episode of bradycardia.

The incidence of vomiting and pruritus were not different intra-operative or post-operative. Significantly fewer patients in the ropivacaine experienced nausea ($P < 0.05$) (Table 5).

Table 5
Side effects

	Ropivacaine (n = 33)	Bupivacaine (n = 33)
Intraoperative		
Pain	2 (6)	3 (9)
Hypotension	23 (70)	29 (88)
Nausea	11 (33)	20 (61)*
Vomiting	3 (9)	3 (9)
Postoperative		
Pain	1 (3)	0 (0)
Pruritis	7 (21)	4 (12)
Nausea	1 (3)	1 (3)
Vomiting	1 (3)	0 (0)

Values are number of patients (%).

* $P < 0.05$ compared with ropivacaine group.

Discussion

In this prospective, randomized, double-blind study, we found that 15 mg of hyperbaric spinal ropivacaine with 0.1 mg morphine and 0.01 mg fentanyl produced good clinical anesthesia with shorter duration of sensory and motor block, compared to 11.25 mg of hyperbaric

bupivacaine with equal opioids, for elective cesarean delivery. The significantly greater levels of satisfaction expressed by patients who received ropivacaine, has not been reported before. The obstetricians rated the quality of intraoperative muscle relaxations as excellent in all patients who had spinal ropivacaine.

In 1993, Chung *et al*⁵ reported that the time to T₁₀ sensory and maximal sensory level blocks in patients who received spinal ropivacaine group were delayed compared to patients who received spinal bupivacaine. Our study, however, revealed that there was no difference in the time to produce T₁₀ sensory block in the two study groups. The time differences reported in Chung *et al*'s study was small. The time to maximal block was 10.6 ± 2.2 min in ropivacaine group compared to 8.1 ± 2.2 min in bupivacaine group. Differences in regression to T₁₀ and L5 in Chung *et al*'s study were 7 min and 26 min respectively. In our study, the differences in regression to T₁₀ and L4 were 25 min and 45 min. The difference might be related to pinprick vs ice testing.

In the present study, intrathecal ropivacaine produced excellent intra-operative analgesia and abdominal muscle relaxation, indistinguishable from spinal bupivacaine. Small supplementary doses of IV fentanyl were administered to two patients in the ropivacaine group during the last part of the surgery. Both the duration of motor and sensory block were less with ropivacaine than with bupivacaine.

In our Institutions, a cesarean section takes an average of 40 min. Spinal ropivacaine produced a block of adequate duration. Adding an opioid to hyperbaric ropivacaine would improve the quality of anesthesia, similar to adding an opioid to hyperbaric bupivacaine⁶. The effective clinical quality of intraoperative anesthesia is consistent with the previous studies of Danelli *et al*³ and Chung *et al*⁵. The dose of spinal ropivacaine was lower in our study, 15 mg, 20 mg and 18 mg respectively were used in the previously mentioned studies. We added morphine and fentanyl to our spinal solution while the previous investigators added only morphine.

The incidence of hypotension was frequent in both groups (70%-88%). Mean doses of ephedrine and phenylephrine, incidence of pruritus

and vomiting did not differ between the groups. The hypotension was easily treated with either ephedrine or phenylephrine and had no maternal or fetal sequels.

The incidence of nausea was different between groups. The conditions of the neonates were good and similar in both groups.

The number of neonates with unsatisfactory APGAR scores or umbilical blood pH values did not differ between groups.

Danelli *et al.*³ reported a significantly greater incidence of itching in patients who received bupivacaine and morphine compared to patients who received ropivacaine and morphine. No significant difference in pruritus among the two groups of our patients was noted.

This prospective, randomized, double-blind study demonstrated that 15 mg of hyperbaric ropivacaine provided similar and effective spinal anesthesia with shorter duration of sensory and motor block, compared with 11.25 mg of hyperbaric bupivacaine for cesarean section. Patients who received ropivacaine expressed significantly higher levels of satisfaction.

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