Comparison of Intrathecal Bupivacaine, Levobupivacaine for Cesarean Section

Petchara Sundarathiti MD*,
Nakkanan Sangdee MD*, Inthuon Sangasilpa MD*,
Waraporn Prayoonhong MD*, Supitcha Papoun RN*

** Department of Anesthesiology, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand*

Background: *Some investigators found a greater incidence of hypotension in patients receiving intrathecal hyperbaric solution than in patients receiving plain solution for cesarean section.*

Objective: *Compare the effects of intrathecal hyperbaric bupivacaine 10 mg with intrathecal bupivacaine 11 mg and intrathecal levobupivacaine 11 mg, all with 10 µg of fentanyl, for cesarean section.*

Material and Method: *This prospective, randomized, double-blinded study was approved by the Ethics Committee. Ninety ASA I-II parturients undergoing elective cesarean section were enrolled. Group H received 10 mg of 0.5% hyperbaric bupivacaine plus fentanyl 10 g, Group B received 11 mg of 0.5% bupivacaine plus fentanyl 10 g, and Group L received 11 mg of 0.5% levobupivacaine plus fentanyl 10 g. Spinal anesthesia (SA) was undertaken in right lateral position and spinal solutions were injected approximately 30 to 40 seconds. Sensory and motor block were assessed at 5-minute intervals. Side-effects such as hypotension, nausea, pruritus, shivering, and headache were recorded.*

Results: *Demographic data were similar in all groups. The level of an absence of cold sensation, the level of pinprick analgesia, and time to achieve sensory block to T4 level of Group H was significantly higher than Group B and Group L. The degree of motor block was comparable in all groups. The incidence of visceral pain was minimal, rated as mild pain and only found in Group B. The incidence of hypotension was comparable with Group H = 67%, Group B = 56%, and Group L = 50%. Other side effects such as nausea, vomiting, pruritus, shivering, and headache were not statistically significant. Patient's satisfaction rated as very good and was not different between the three groups.*

Conclusion: *The level of absence of cold sensation, level of pinprick analgesia, and time to achieve sensory block to T4 level were statistically higher in patients receiving hyperbaric bupivacaine than in patients receiving plain bupivacaine and plain levobupivacaine, while the differences were not statistically significant in all groups regarding effective surgical anesthesia, postoperative analgesia, and side effects. Therefore, Levobupivacaine can be an alternative to bupivacaine.*

Keywords: *Spinal anesthesia, Cesarean section, Levobupivacaine, Bupivacaine*

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Spinal anesthesia (SA) is very popular for cesarean section because it offers a profound and symmetrical sensory and motor block of high quality[1]. The goal of spinal anesthesia for cesarean section is the provision of effective surgical anesthesia and postoperative analgesia, with minimal maternal and neonatal side effects. Specifically, this includes the preservation of maternal cardiac output and uteroplacental blood flow[2]. Maternal pain is the most common reason for patient's dissatisfaction, particularly if the uterus is exteriorized. The anesthetist's interest has focused on the optimal local anesthetic/opioid combination and dose to achieve these goals.

Bupivacaine is widely used for SA, mainly as a hyperbaric solution. Some investigators found a greater incidence of hypotension in patients receiving hyperbaric solution than in patients receiving plain solution because of the higher spread of the hyperbaric solution[3].

Levobupivacaine, the pure S(-) enantiomer of racemic bupivacaine, has recently been introduced for obstetric spinal and epidural anesthesia[4,5]. Recent reports compared intrathecal levobupivacaine with bupivacaine and found less incidence of hypotension with levobupivacaine[6]. Hyperbaric levobupivacaine for cesarean section has been found to be 38% less potent than hyperbaric bupivacaine[7].

In the present study, we compared the effects of intrathecal hyperbaric bupivacaine 10 mg

Correspondence to:
Sundarathiti P, Department of Anesthesiology, Faculty of Medicine, Ramathibodi Hospital, Main Building 5th floor, 270 Rama VI Road, Toong Phayathai, Ratchathewi, Bangkok 10400, Thailand.
Phone: 0-2201-1513
E-mail: petcharas@gmail.com

with intrathecal bupivacaine 11 mg and intrathecal levobupivacaine 11 mg, all with 10 μg of fentanyl, for cesarean section.

Material and Method

The protocol approved by the Ethics Committee, and written informed consent was obtained from each patient. Ninety ASA I-II parturients ≥37 weeks of gestation undergoing elective cesarean section were enrolled into this prospective randomized, controlled trial. Uncomplicated primigravida pregnancy, body weight <90 kg and normal fetal heart rate at the time of admission were mandatory inclusion criteria.

Our sample size was 90, calculated for an analysis of variance (ANOVA) which was designed to detect the difference in time taken to reach highest level of cold sensation among three study groups. Assuming the maximum difference of such time between Group B and both Group H and Group L were two minutes, and the common SD was 2.5 minutes based on the pilot study, the sample size needed was 24 per group at an alpha level of 0.05 with 80% of power. An additional 20% of number was added for the prevention of data loss, so totally the trial enrolled 90 patients who were prospectively divided into three groups.

The patients were randomly assigned into three groups for SA according to a table of random numbers. Group H received 10 mg of 0.5% hyperbaric bupivacaine plus fentanyl 10 g, Group B received 11 mg of 0.5% bupivacaine plus fentanyl 10 g, and Group L received 11 mg of 0.5% levobupivacaine plus fentanyl 10 g.

Monitoring included pulse oximetry, ECG and noninvasive blood pressure. These parameters were recorded before intrathecal injection, and at 1-minute intervals until delivery, then every five minutes throughout surgery. Oxygen 3 L/minute was administered via a cannula. An intravenous crystalloid infusion of 10 ml/kg was administered over 15 to 20 minutes before intrathecal injection. SA was undertaken in right lateral position, using a 27-G Quincke needle at the lumbar L3-L4 interspace. After confirming free flow of cerebrospinal fluid (CSF), spinal solutions were injected for approximately 30 to 40 seconds. Subsequently, patients were turned to a 15° left lateral supine position on the operating table, which was kept horizontal.

Maternal hypotension was defined as a 20% reduction in systolic arterial pressure from baseline values and was treated with intravenous ephedrine 5 mg at 3-minute intervals. Severity of hypotension was graded as mild (≤10 mg ephedrine), moderate (15-20 mg ephedrine), and severe (>20 mg ephedrine). Bradycardia was defined as a pulse rate of 50 bpm and was treated with intravenous atropine 0.5 mg.

Absence of cold sensation was tested with an alcohol swab as a change from cold sensation compared with that of the chest. The level of pinprick analgesia was tested with a 20-G needle as a change from a dull sensation to a sharp sensation. The surgical technique was uniform for all patients and included exteriorization. Occurrences and severity of visceral pain throughout the entire operation, as indicated by the patient were observed and recorded on a 10 cm visual analog scale (VAS). A value of 3 or higher was considered to indicate moderate to severe pain. Intravenous ketamine 0.5 mg/kg was used during surgery as a rescue analgesic.

The degree of motor block was assessed using modified Bromage scale (MBS; 0 = able to lift legs; 1 = ability to flex knees but not the hip; 2 = unable to flex knees, but no problems with ankle movement; and 3 = no movement possible in any lower extremity joint). Sensory and motor blocks were assessed at 5-minute intervals until the block level reached T4. A sensory block level of T4 was required to initiate the surgery.

An hour after the surgery, patients were taken to the recovery room where HR, MAP and Pulse oximetry were monitored. Side-effects such as hypotension, nausea (0 = none, 1 = nausea, 2 = vomiting) and pruritus (0 = none, 1 = some pruritus, 2 = disturbing pruritus), shivering, and headache were recorded. Sensory and motor blockade were also evaluated every 10 minutes. Apgar score was assessed at the ages of 1- and 10-minute.

The patients were visited during the first postoperative day. Assessment of patient satisfaction was evaluated using the following scoring system: 0 = not satisfied, 1 = moderate, 2 = good, 3 = very good. All assessments after surgery were made by a nurse anesthetist who was not involved in the patient's care and was blinded to the group assignment as well as to the drug injected.

All data were analyzed using the program SPSS for Windows version 11.5. Descriptive statistics were expressed as mean, SD, median and range. Comparison of variables between the 3-patient-groups were made using an Analysis of variance (ANOVA) followed by Scheffe's, or Kruskal-Wallis test followed by Mann-Whitney U test, appropriately. Comparisons

between and among categorical variables were made using Chi-square tests. A p-value <0.05 was considered statistically significant.

Results

Demographic data and the mean duration of surgery were similar in every group (Table 1). All patients had satisfactory anesthesia and operation without intraoperative complications.

The level of an absence of cold sensation and the level of pinprick analgesia of Group H was significantly higher than Group B and Group L, while the level of an absence of cold sensation and the level of pinprick analgesia of Group B was similar to Group L. The time to achieve sensory block to T4 level of Group H was significantly faster than Group B and Group L, while the time to achieve sensory block to T4 level of Group B was similar to Group L (Table 2).

The degree of motor block was comparable in all groups as MBS = 3 and the time to maximum degree of motor block of Group H was significantly faster than Group B and Group L (Table 2). The incidence of visceral pain was negligible, rated as mild pain, and only found in Group B with no statistical difference. The incidence of hypotension was higher in Group H but was not statistically different as the following, Group H = 67%, Group B = 56%, and Group L = 50% while the severity of hypotension was comparable in all groups. Other side effects such as nausea, vomiting, pruritus, shivering, and headache were minimal and were not statistically significant

Table 1. Patients' characteristics

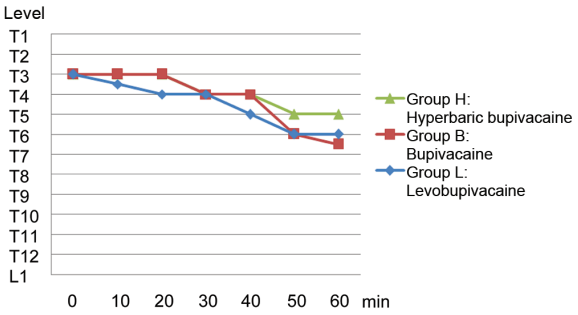
	Group H (n = 30)	Group B (n = 30)	Group L (n = 30)	p-value
Age (year)	30.37±4.04	31.87±4.26	33.07±5.19	0.070
Pulse rate (bpm)	80.57±9.30	81.77±6.90	85.67±14.46	0.161
SBP (mmHg)	117.33±8.65	115.47±11.88	120.07±10.83	0.241
DBP (mmHg)	73.73±8.06	71.50±8.31	73.60±8.38	0.504
Weight (kg)	67.18±9.91	66.37±7.52	67.93±9.62	0.802
Height (cm)	160.32±6.19	155.67±10.83	157.97±4.92	0.072
BMI (kg/m^2)	26.14±3.41	27.86±6.18	27.21±3.65	0.345

SBP = systolic blood pressure; DBP = diastolic blood pressure; BMI = body mass index
Data are mean ± SD

Table 2. Block characteristics at intraoperative period

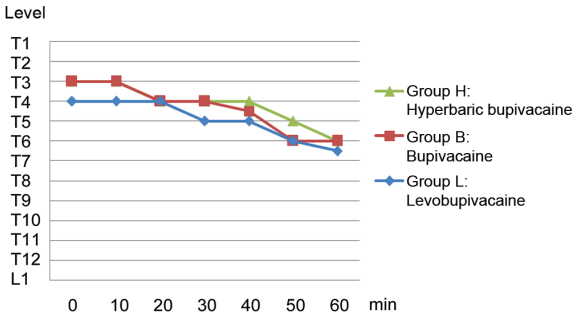
	Group H (n = 30)	Group B (n = 30)	Group L (n = 30)	p-value
Sensory block				
Highest level of absence of cold sensation, median (range)	T3 (T2-T5)	T4 (T2-T5)	T4 (T2-T5)	0.012*
Time to highest level of cold sensation, mean ± SD (min)	5.50±1.53	10.33±5.07	8.50±3.97	<0.001*
Highest level of pinprick analgesia, median (range)	T4 (T2-T5)	T4 (T2-T6)	T4 (T2-T6)	0.015*
Time to highest level of pinprick analgesia, mean ± SD (min)	5.67±1.73	10.33±5.07	8.67±4.14	<0.001*
Motor block				
Highest degree of motor block: MBS, median (range)	3 (2-3)	3 (2-3)	3 (1-3)	0.854
Time to maximum degree of motor block, mean ± SD (min)	5.33±1.27	10.33±5.07	8.00±3.85	<0.001*
OP-time, mean ± SD (min)	59.83±13.93	58.17±11.56	59.00±13.35	0.884
Total iv fluid, mean ± SD (ml)	1,874.00±442.33	1,700.00±320.29	1,869.00±414.52	0.159

MBS = modified Bromage scale; Op-time = operative time; Total iv fluid = total intravenous fluid
* p-value <0.05



PACU = post-anesthesia care unit

Fig. 1 Level of absence of cold sensation at PACU.



PACU = post-anesthesia care unit

Fig. 2 Level of pinprick analgesia at PACU.

(Table 3). At Post-Anesthesia Care Unit (PACU), the highest level of absence of cold sensation (Fig. 1), the highest level of pinprick analgesia (Fig. 2), time to two-segment regression were similar in all groups. The degree of motor block of Group B, at 60 minutes, was significantly greater than Group H and Group L (Fig. 3) as demonstrated in Table 4. There was no difference in the neonatal outcome and time to first dose IV analgesia in all groups (Group H = 236.17±61.08 min, Group B = 243.23±74.55 min, and Group L = 262.83±77.44 min; *p*-value 0.33). Patient satisfaction was rated as very good and was not different between the groups.

Discussion

Controversial results have been presented concerning the predictability of the level of SA, probably a result of the wide differences in the type of patients (parturient or non-parturient), drugs and dosages, the method used such as speed of local

Table 3. Side effects at intraoperative period

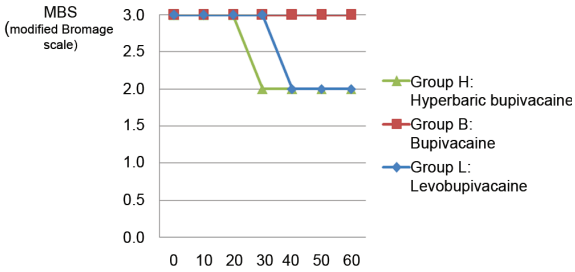
	Group H (n = 30)	Group B (n = 30)	Group L (n = 30)	*p*-value
Hypotension	20 (0.67)	17 (0.57)	15 (0.50)	0.421
Nausea	14 (0.47)	8 (0.27)	6 (0.2)	0.067
Vomiting	4 (0.13)	2 (0.07)	0	0.117
Shivering	0	0	1 (0.03)	0.364
Visceral pain	1 (0.03)	4 (0.13)	0	0.064

Data are number (%)

Table 4. Block characteristics at post-anesthesia care unit

	Group H (n = 30)	Group B (n = 30)	Group L (n = 30)	*p*-value
Sensory block				
Highest level of absence of cold sensation, median (range)	T5 (T3-T12)	T7 (T2-T10)	T6 (T3-T9)	0.861
Time to two-segment regression, mean ± SD (min)	49.67±14.50	44.67±17.56	46.67±13.73	0.450
Highest level of pinprick analgesia, median (range)	T6 (T2-T12)	T6 (T3-T10)	T7 (T3-T11)	0.592
Time to two-segment regression, mean ± SD (min)	50.00±13.65	47.33±14.37	46.00±13.54	0.526
Motor block				
Degree of motor block at 60 min (MBS 60 min), median (range)	2 (0-3)	3 (1-3)	2 (0-3)	<0.001*

MBS = modified Bromage scale (MBS; 0 = able to lift legs; 1 = ability to flex knees but not the hip; 2 = unable to flex knees, but no problems with ankle movement; and 3 = no movement possible in any lower extremity joint)
* *p*-value <0.05



PACU = post-anesthesia care unit
MBS = modified Bromage scale

Fig. 3 The degree of motor block at PACU.

anesthetic injection, and how to measure the level of the block.

Hyperbaric bupivacaine, at 10 mg or less, has been shown to carry a risk of inadequate block[8,9]. Cesarean deliveries require traction of peritoneum and handling of intraperitoneal organs, resulting in intraoperative visceral pain. For this reason, many anesthetists routinely use higher doses of bupivacaine in cesarean deliveries to improve patient comfort. However, higher doses are associated with higher blocks[10-12], seemed to produce more hypotension, and delay recoveries[13,14].

Fentanyl is well known to improve the intraoperative analgesic potency of local anesthetics and prolongs the postoperative analgesia if administered intrathecally. Bogra et al, reported that the combined effect of fentanyl-bupivacaine is superior to just bupivacaine alone in cesarean section[15]. Therefore, 10 µg of fentanyl was added in all groups in the present study instead of using higher doses.

Levobupivacaine is the isolated S-enantiomer of racemic bupivacaine and is now available commercially as plain solution. On a milligram-per-milligram basis, it is less toxic than bupivacaine because of decreased potency at the sodium channel[16]. Bouvet L et al demonstrated that a sufficient dose of intrathecal levobupivacaine 12 mg added with opioids is required for effective anesthesia for cesarean section[17]. Therefore, we used levobupivacaine 11 mg plus fentanyl 10 µg according to our pilot study.

Khaw K et al found that hyperbaric levobupivacaine was 38% less potent than hyperbaric bupivacaine in cesarean section[7]. Burke D et al suggested that levobupivacaine achieve satisfactory surgical anesthesia for lower limb surgery but with an unpredictable spread of sensory blockade[18]. However, these results were not compared with racemic bupivacaine.

Some studies revealed no detectable differences in sensory or motor block characteristics between hyper- and hypobaric bupivacaine in term-pregnant women[19-21]. Contradictory to the present study, the subarachnoid distribution of hyperbaric solution is significantly greater than plain solution. Baricity differences between spinal anesthetic solutions may produce differences in distribution of anesthetics within the subarachnoid space. The spread of SA with plain solution of levobupivacaine was just as predictable as with bupivacaine[22]. Likewise, we observed considerably shorter onset times for sensory and motor blockade in hyperbaric solution when compared with plain solution (Group B and Group L), and the degree of motor blockade showed a more sustained effect only in plain bupivacaine group. Therefore, our results suggested that the differences in drug distribution existed but did not manifest clinical importance. This is because there were no differences in terms of anesthetic efficiency, hypotension, dyspnea, and time to discharge from PACU.

A strict criterion was used to administer local anesthetic regarding achievement of free flow of CSF and control speed of injection. Regardless of the mechanisms involved and despite the difference in baricity, both subarachnoid solutions used in the present study produced satisfactory anesthesia and postoperative analgesia with similar side effects.

Conclusion

The difference in drug distribution exists between hyperbaric bupivacaine and plain solution, but does not manifest clinical importance due to there are no differences in terms of anesthetic efficiency, hypotension, dyspnea, time to discharge from PACU, and patient satisfaction. Levobupivacaine can be alternative to bupivacaine, so if bupivacaine was not available, levobupivacaine can be used as substitute.

What is already known on this topic?

Bupivacaine is widely used for SA, mainly as a hyperbaric solution. Some investigators found a greater incidence of hypotension in patients receiving hyperbaric solution than plain solution, because of the higher spread of the hyperbaric solution[3]. Levobupivacaine, the pure S(-) enantiomer of racemic bupivacaine, has recently been introduced for obstetric spinal and epidural anesthesia[4,5]. Levobupivacaine is the isolated S-enantiomer of racemic bupivacaine and is now available commercially as plain solution. On a milligram-per-milligram basis, it is less toxic than

bupivacaine because of decreased potency at the sodium channel[16].

What this study adds?

The difference in drug distribution exists between hyperbaric bupivacaine and plain solution, but does not manifest clinical importance due to there are no differences in terms of anesthetic efficiency, hypotension, dyspnea, time to discharge from PACU and patient satisfaction. Levobupivacaine can be alternative to bupivacaine, so if bupivacaine was not available levobupivacaine can be used as substitute.

Potential conflicts of interest

None.

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การเปรียบเทียบประสิทธิภาพของ levobupivacaine กับ bupivacaine ในการทำ spinal anesthesia สำหรับการผ่าตัดคลอด

เพชรา สุนทรฐิติ, นคนันท์ แสงดี, อินทุอร สง่าศิลป์, วราภรณ์ ประยูรหงส์, สุพิชชา ปาปวน

ภูมิหลัง: จากการศึกษาที่ผ่านมา พบว่าอุบัติการณ์ความดันเลือดต่ำที่เกิดจาก spinal anesthesia สำหรับการผ่าตัดคลอด (cesarean section) ในกลุ่มผู้ป่วยที่ได้รับยา hyperbaric solution มีมากกว่ากลุ่มผู้ป่วยที่ได้รับยา plain solution

วัตถุประสงค์: เปรียบเทียบประสิทธิภาพของยาชาที่ใช้ในการทำ spinal anesthesia ของ hyperbaric bupivacaine 10 mg กับ plain solution ของยา bupivacaine 11 mg และ levobupivacaine 11 mg ที่ให้ร่วมกับ fentanyl 10 μg ในผู้ป่วยผ่าตัดคลอดทุกกลุ่ม

วัสดุและวิธีการ: เป็น prospective randomized double-blinded study โดยผ่านการยินยอมจากหน่วยจริยธรรมการวิจัยในคน สตรีตั้งครรภ์จำนวน 90 ราย ที่มี ASA physical status class I-II และยินยอมเข้าร่วมการศึกษาผ่าตัดคลอดด้วยวิธี spinal anesthesia จะถูกแบ่งเป็น 3 กลุ่ม กลุ่ม H คือกลุ่มที่ได้รับ hyperbaric bupivacaine 0.5% และ fentanyl 10 μg กลุ่ม B คือกลุ่มที่ได้รับ bupivacaine 0.5% และ fentanyl 10 μg และกลุ่ม L ได้รับ levobupivacaine 0.5% และ fentanyl 10 μg โดยทำในท่านอนตะแคงขวาลง และควบคุมเวลาในการเดินยาประมาณ 30-40 วินาที หลังการทำ spinal anesthesia จะมีการประเมิน sensory และ motor block ทุก 5 นาที และผลข้างเคียงอื่น ๆ เช่น ความดันเลือดต่ำ คลื่นไส้ คัน หนาวสั่น และอาการปวดศีรษะจะถูกประเมินร่วมด้วย

ผลการศึกษา: ผู้ป่วยทั้ง 3 กลุ่ม มีลักษณะประชากรไม่แตกต่างกัน ระดับการรับรู้ความเย็นที่สูญเสียไป (absence of cold sensation) และระดับการรับรู้ความเจ็บปวด (pinprick analgesia) รวมถึงระยะเวลาที่ได้การระงับความรู้สึกถึงระดับ T4 ในกลุ่ม H สูงกว่าในกลุ่ม B และ L แต่ระดับของ motor block พบว่าไม่ต่างกันในทุกกลุ่ม ความปวดของอวัยวะภายใน (visceral pain) พบเฉพาะในกลุ่ม B ที่ระดับเล็กน้อยและระดับปานกลาง และพบว่ามีอุบัติการณ์น้อยมาก นอกจากนี้ยังพบว่าอุบัติการณ์ของความดันเลือดต่ำไม่แตกต่างกันอย่างมีนัยสำคัญ ในกลุ่ม H เกิดขึ้นร้อยละ 67 กลุ่ม B ร้อยละ 56 และกลุ่ม L ร้อยละ 50 ส่วนผลข้างเคียงอื่น ๆ เช่น อาการคลื่นไส้ อาเจียน คัน หนาวสั่น ปวดศีรษะก็ไม่แตกต่างกัน สำหรับความพึงพอใจของผู้ป่วยในแต่ละกลุ่มอยู่ในเกณฑ์ดีไม่แตกต่างกัน

สรุป: ระดับ cold sensation และระดับ pinprick analgesia รวมถึงระยะเวลาที่ใช้ในการระงับความรู้สึกถึงระดับ T4 ในผู้ป่วยกลุ่ม hyperbaric solution (bupivacaine) สูงกว่าในผู้ป่วยกลุ่ม plain solution (bupivacaine และ levobupivacaine) แต่ไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติในด้านประสิทธิภาพของการชา การระงับปวดหลังผ่าตัด และผลข้างเคียง ดังนั้น levobupivacaine สามารถใช้ทดแทน bupivacaine ได้ในการทำ spinal anesthesia