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Original Article

Efficacy and side effects comparison of bupivacaine and ropivacaine with fentanyl for labor analgesia under combined spinal and epidural analgesia

Qinzheng Zhao[1*], Changting Yan[1*], Baojun Fang[1*], Xiang Wei[2], Qingjuan Wang[1], Yuhuan Bai[1], Yuanli Chen[3], Jinxia Gao[4]

[1]Department of Anesthesiology, Liaocheng Dongchangfu District Maternal and Child Health Hospital, Liaocheng, Shandong Province, China; [2]Department of Anesthesiology, Shanghai Changzheng Hospital, Shanghai City, China; [3]Department of Anesthesiology, Shanghai Pulmonary Hospital, Tongji University School of Medicine, Shanghai City, China; [4]Department of Anesthesiology, The Second Hospital of Dalian Medical University, Dalian, Liaoning Province, China. [*]Equal contributors and co-first authors.

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Abstract: Objective: With the universal two-child policy in China, scar uterine ruptures have increased maternal mortality. Reducing the rate of cesarean sections by increasing the rate of vaginal deliveries in nulliparous parturients is an urgent task. To compare the efficacy and side effects of bupivacaine and ropivacaine with fentanyl in parturients delivering vaginally, this randomized double-blind clinical trial was performed. Methods: A total of 94 nulliparous parturients were enrolled in early labor and randomized to receive bupivacaine or ropivacaine for labor analgesia under combined spinal and epidural analgesia. A total of 79 parturients delivering vaginally were included for subsequent analysis. Spinal anesthesia was initiated with 2 mL of 0.125% bupivacaine or ropivacaine plus 5 μg fentanyl, then patient-controlled epidural analgesia (PCEA) was used for pain relief (a loading dose of 5 mL of 0.125% bupivacaine or ropivacaine with 2 μg/mL fentanyl, then an intermittent bolus of 5 mL with a background infusion of 8 mL/hour). Pain and myodynamia were measured before anesthesia (T0), at the beginning of PCEA (T1), at full cervical dilatation (T2), and 5 minutes after delivery (T3). Results: Duration of spinal analgesia was shorter in the ropivacaine group (P=0.035) with lower sensory levels (P=0.014). Press frequency of PECA pump was a little higher in the bupivacaine group (P=0.025). VAS scores were similar in the two groups, while myodynamia scores during T2 (P=0.003) and T3 (P<0.0001) were higher in ropivacaine group than the bupivacaine group. No other differences were found between the groups. Conclusion: Ropivacaine is just as safe as bupivacaine. There were no differences in neonatal outcomes or postpartum complications. Better myodynamia highlights the clinical application of ropivacaine.

Keywords: Bupivacaine, ropivacaine, labor analgesia, combined spinal and epidural analgesia

Introduction

With the universal two-child policy in China, scar uterine ruptures have increased maternal mortality. Reducing the rate of cesarean sections by increasing the rate of vaginal deliveries in nulliparous parturients is an urgent task. Labor pain may be the worst pain ever experienced by women, causing negative effects on respiratory, cardiovascular, neuroendocrine, and limbic systems [1]. To block such severe pain, neuraxial analgesia is frequently administered to women in labor for pain relief [2, 3]. Safer methods of labor analgesia, with fewer side effects, still need to be explored due to the demerits of local anesthetics such as maternal motor blockade and hypotension. Bupivacaine has been used for many years because of its long duration of action, limited placental transfer, and minimal neonatal effects [4, 5]. Another widely used amino acid local anesthetic, ropivacaine, has been declared to be of less cardiac toxicity than bupivacaine [6, 7]. Although both ropivacaine and bupivacaine produce motor block, preclinical animal and clinical studies have suggested that ropivacaine produces less motor block than bupivacaine [8-11]. It remains controversial, however, whe-

ther ropivacaine is associated with any clinical benefits, as some studies have found the drugs to be indistinguishable [12-14].

Previous studies have demonstrated that fentanyl reduces local anesthetic requirements by approximately 25% [14-16]. More and more doctors have realized that dilute solutions of local anesthetics combined with opioids can minimize unwanted motor block. Moreover, combined spinal and epidural analgesia (CSEA), combining the advantages of spinal and epidural anesthesia, has been widely employed for labor analgesia [17-20]. Thus, to explore a safer and more effective approach, this study compared the efficacy and side effects of 0.125% bupivacaine and ropivacaine solutions under CSEA, with fentanyl added to reduce the local anesthetic requirement.

Methods

This prospective, double-blind, and randomized study protocol was performed after approval from the Institutional Ethics Committee (The Second Hospital of Dalian Medical University). Written informed consent was also provided. This study was registered at the China Clinical Trial Registry (ChiCTR ID: ChiCTR-IOR-17011151). A total of 94 ASA physical status I and II parturients, in active labor, with a cervical dilation of 2-3 cm were enrolled and randomized using a computer-generated table of random numbers. This study included nulliparous parturients at greater than 37 weeks of gestation and full-term pregnancy without any contraindications for regional anesthesia. Patients were excluded if they were less than 18 years old or allergic to any study drugs. They were also excluded with preeclampsia, neurological disease, or previous cesarean delivery. Patients were randomly allocated into either the ropivacaine group or bupivacaine group. The study solution was prepared by the same anesthesiologist, not directly involved in the implementation of CSEA or data collection. Investigators and patients were both blinded to the solution type. Age, weight, height, gestation, oxytocin use, and mode of delivery were recorded.

Lactated Ringer's solution 500 mL was infused after reaching the operating room. Electrocardiogram, non-invasive blood pressure, and pulse oximetry were monitored and recorded. All neuraxial blocks were implemented following a strict aseptic technique with the patients awake, in a right lateral position. Midline approach and loss of resistance-to-air techniques were used in both groups.

Tuohy needles CSE kit (Tuoren Medical Device Co., Ltd. Henan, China) were used to perform CSE in the L3-4 interspaces. After confirming the epidural space, the spinal needle was inserted slowly and stopped after the dural click. After confirming correct spinal needle placement by aspiration of cerebrospinal fluid, 2 mL of 0.125% bupivacaine (bupivacaine group) or ropivacaine (ropivacaine group) plus 5 μg fentanyl was injected. After spinal needle removal, the epidural catheter was inserted 4 cm into the epidural space and fastened after removing the epidural needle. Patients received 0.125% bupivacaine or ropivacaine with 2 μg/mL fentanyl by PCEA (loading dose of 5 mL study solution, then an intermittent bolus of 5 mL with a background infusion of 8 mL/hour and 20-minutes lockout) if they complained of labor pain (VAS score ≥2). Sensory levels were measured by pinprick 5 minutes after subarachnoid injection. Patients transferred for cesarean deliveries were excluded from subsequent data-analysis.

Measurements

Total volume of study solution, press frequency of PCEA pump, and duration of analgesia were recorded at complete cervical dilation by an independent investigator. Non-invasive blood pressure and heart rate (HR) were continuously measured and recorded before anesthesia (T0), at the beginning of PCEA (T1), at full cervical dilatation (T2), and 5 minutes after delivery (T3). A 0-10 visual analogue scale (VAS) was used to evaluate labor pain. A score of "0" indicated no pain while "10" indicated the worst pain imaginable. Myodynamia was assessed using a 0-5 scale (0= no contraction, 1= visible/palpable muscle contraction but no movement, 2= movement with gravity eliminated, 3= movement against gravity only, 4= movement against gravity with some resistance, and 5= movement against gravity with full resistance) for manual muscle testing (MMT). Duration of second stage labor and Apgar scores of newborns were measured at 1 minute, 5 minutes, and 10 minutes after birth. Postpartum complications, including postpartum hemorrhage,

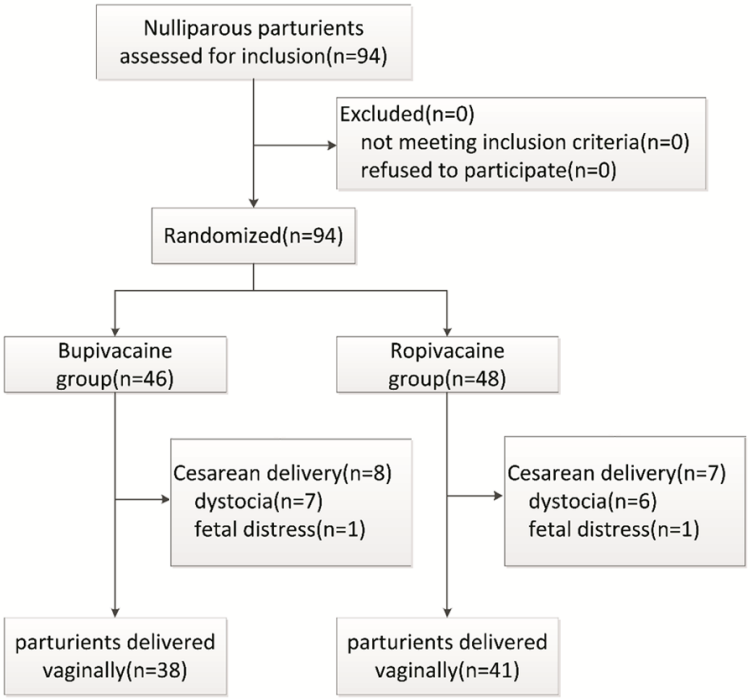

Figure 1. Participant flow and randomization process.

Table 1. Patient characteristics

	Bupivacaine group (n=46)	Ropivacaine group (n=48)	*t* or X^2 value	*P* value
Age (year)	24.15±2.84	25.38±4.18	-1.653	0.102
Height (cm)	161.35±3.88	160.31±4.09	1.259	0.211
Weight (kg)	70.09±8.82	73.36±7.68	-1.924	0.057
Gestation (weeks)	39.96±1.15	39.85±1.20	0.421	0.675
Mode of delivery, n (%)			0.138	0.710
Eutocia	38 (82.61%)	41 (85.42%)		
Cesarean delivery	8 (17.39%)	7 (14.58%)		
Oxytocin use, n (%)	14 (30.43%)	21 (43.75%)	1.782	0.182
Eutocia	12 (31.58%)	18 (43.90%)	1.272	0.259
Cesarean delivery	2 (25.00%)	3 (42.86%)	-	0.608[a]

Note: Values are mean ± SD or number (%). [a]Data compared by Fisher's exact test.

pruritus, urinary retention, and nausea/vomiting, were recorded the day after delivery.

Statistical analysis

Student's t-test was used to compare continuous variables. Categorical data were assessed using Chi-squared test or Fisher's exact test, as appropriate. Comparison of myodynamia grades and VAS scores was performed by using Mann-Whitney rank sum test. P<0.05 indicated statistical significance. Statistical analyses were performed using SPSS 17.0 (SPSS Inc).

Results

Ninety-four parturients were initially enrolled in this study, with 79 of them delivering vaginally (38 received bupivacaine/fentanyl and 41 received ropivacaine/fentanyl) (**Figure 1**). Baseline characteristics of the patients were similar in each group, including age, height, weight, and gestation. There were no significant differences between the groups in requirements for oxytocin and mode of delivery as shown in **Table 1**.

Of patients delivering vaginally, the mean total volume of ropivacaine/fentanyl administration was 40.41±29.25 mL versus 45.18±23.38 mL for bupivacaine/fentanyl, without any differences between groups. Press frequency of PECA pump was a little higher in the bupivacaine group (P=0.025). Maximum sensory levels in each group were almost the same. Duration of spinal analgesia was shorter in the ropivacaine group (P=0.035) with lower sensory levels (P=0.014), while total time and time spent on epidural analgesia were similar between the groups as shown in **Table 2**.

Systolic blood pressure (SBP), diastolic blood pressure (DBP), and HR were about the same between the groups at T0, T1, T2 and T3 (**Figures 2** and **3**).

Duration of the second stage of labor was similar in the ropivacaine group (63.78±41.01 min) compared with the bupivacaine group (70.55±43.33 min; P=0.478), as were the Apgar scores of newborns at 1 minute, 5 minutes, and 10 minutes after birth (**Table 3**).

There were no statistically significant differences in postpartum complications between the

Table 2. Characteristics of anesthesia and block performance (parturients delivered vaginally)

	Bupivacaine group (n=38)	Ropivacaine group (n=41)	*t* or *u* value	*P* value
Total volume of study solution (ml)	45.18±23.38	40.41±29.25	0.796	0.428
Press frequency of PCEA pump	3 (0-10)	2 (0-9)	554.500	0.025*
Sensory level	T8 (T6-T10)	T10 (T6-T10)	556.000	0.014*
Duration of analgesia (min)				
Spinal[1]	89.34±33.09	74.12±30.02	2.144	0.035*
Epidural[2]	197.05±127.66	189.76±147.15	0.331	0.742
Overall	286.39±141.21	260.88±162.82	0.742	0.461

Note: Values are mean ± SD or median (range). [1]From injection of spinal anesthesia to requirement of epidural analgesia (PCEA); [2]From requirement of epidural analgesia (PECA) to full dilatation of cervix. *Compared with the bupivacaine group, P<0.05.

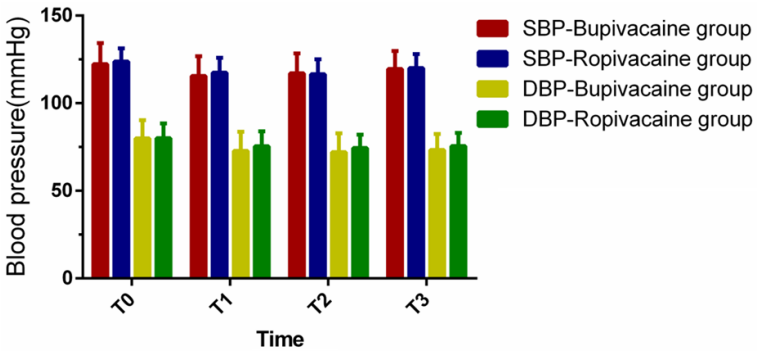

Figure 2. Comparison of systolic blood pressure (SBP) and diastolic blood pressure (DBP) between bupivacaine group and ropivacaine group at T0 (before anesthesia); T1 (beginning of PCEA); T2 (full dilatation of cervix); T3 (5 minutes after delivery). There were no significant differences between the groups.

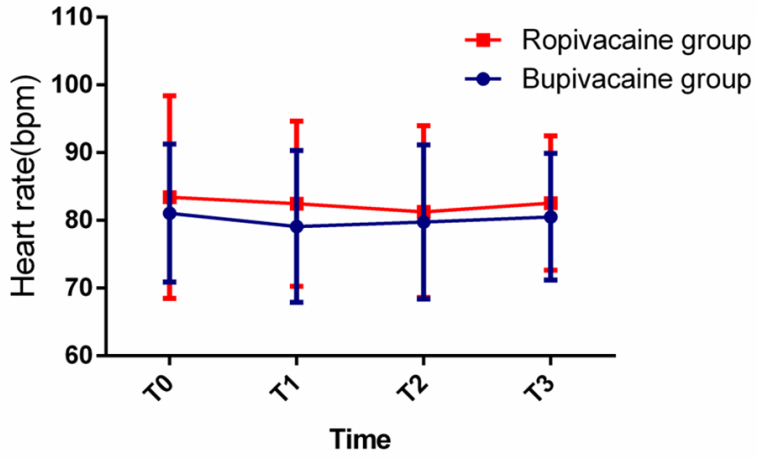

Figure 3. Comparison of heart rate between bupivacaine group and ropivacaine group at T0 (before anesthesia); T1 (beginning of PCEA); T2 (full dilatation of cervix); T3 (5 minutes after delivery). There were no significant differences between the groups.

groups, including postpartum hemorrhage, postpartum pruritus, urinary retention, and nausea/vomiting (**Table 4**).

VAS scores, during labor, were similar between groups at T0, T1, T2 and T3 (**Table 5** and **Figure 4**). Myodynamia scores were comparable at T0 and T1 between the groups, while myodynamia was better in ropivacaine group contrasted with bupivacaine group at T2 (P=0.003) and T3 (P<0.0001) (**Table 5** and **Figure 5**).

Discussion

Lower pain scores and higher maternal satisfaction, with minimal adverse effects on maternal cardiovascular or pulmonary function and fetal physiology, have been reported with the application of neuraxial analgesic techniques during labor and delivery [6, 20]. It has been increasingly believed that opioids, like fentanyl, can reduce local anesthetic requirements and any adverse events that may come along [21]. Whether bupivacaine and ropivacaine are equally effective at lower concentrations and whether ropivacaine should be used instead of bupivacaine for labor relief remains controversial. Many studies have compared the clinical efficacy of ropivacaine and bupivacaine for labor analgesia with or without opioids [1, 10, 13, 14, 21, 22]. Most studies have been comparisons of epidural analgesia. In this present study, the safety and

Table 3. Labor and neonatal outcomes (parturients delivered vaginally)

	Bupivacaine group (n=38)	Ropivacaine group (n=41)	*t* or *u* value	*P* value
Duration of 2nd stage labor (min)	70.55±43.33	63.78±41.01	0.714	0.478
Apgar scores				
1 min	10 (8-10)	10 (8-10)	725.000	0.337
5 min	10 (8-10)	10 (8-10)	776.000	0.949
10 min	10 (8-10)	10 (8-10)	774.500	0.923

Note: Values are mean ± SD or median (range).

Table 4. Postpartum complications (parturients delivered vaginally)

	Bupivacaine group (n=38)	Ropivacaine group (n=41)	*t* or X^2 value	*P* value
Postpartum hemorrhage (ml)	296.05±16.85	290.49±36.74	0.854	0.396
Pruritus, n (%)	16 (42.11%)	16 (39.02%)	0.078	0.780
Urinary retention, n (%)	11 (28.95%)	6 (14.63%)	2.392	0.122
Nausea/vomiting, n (%)	3 (7.89%)	3 (7.32%)	-	1.000[a]

Note: Values are mean ± SD or number (%). [a]Data compared by Fisher's exact test.

Table 5. Evaluation of myodynamia and pain (parturients delivered vaginally)

	Bupivacaine group (n=38)	Ropivacaine group (n=41)	*u* value	*P* value
Myodynamia				
T0	5 (5-5)	5 (5-5)	779.000	1.000
T1	5 (4-5)	5 (4-5)	745.000	0.347
T2	5 (3-5)	5 (4-5)	568.000	0.003**
T3	4 (3-5)	5 (4-5)	331.000	<0.0001****
Pain (VAS score)				
T0	7 (5-10)	7 (4-10)	684.500	0.341
T1	3 (1-5)	3 (2-6)	765.000	0.881
T2	4 (0-10)	3 (0-9)	623.500	0.121
T3	0 (0-3)	0 (0-3)	663.000	0.142

Note: Values are medians (range). T0, before anesthesia; T1, beginning of PCEA; T2, full dilatation of cervix; T3, 5 minutes after delivery. **Compared with the bupivacaine group, P<0.01. ****Compared with the bupivacaine group, P<0.001.

efficacy of bupivacaine and ropivacaine were compared, at a lower concentration (0.125%) with fentanyl, for labor analgesia, using a PCEA technique under another commonly used method, CSEA.

Overall, this present study demonstrated that both 0.125% ropivacaine and 0.125% bupivacaine with fentanyl 2 μg/mL, under CSEA, produced equivalent analgesia with little differences in mode of delivery, oxytocin use, and total volume of local anesthetics. Labor and neonatal outcomes were similar between the groups, including duration of second stage labor and Apgar scores. Postpartum complications were also comparable. There were no significant differences in postpartum hemorrhaging and proportion of patients with pruritus, urinary retention, nausea, or vomiting. These results are in agreement with a previous study and recent meta-analysis [1, 23]. It has been reported that ropivacaine is less potent than bupivacaine [1, 10, 11], which may explained why, in this present study, duration of spinal analgesia was a little shorter in ropivacaine group with lower sensory levels. Interestingly, if ropivacaine is significantly less potent than bupivacaine, press frequency of PECA pump should be higher with ropivacaine/fentanyl than with bupivacaine/fentanyl. In contrast, the present study results showed a higher press frequency in the bupivacaine group, though only by a narrow margin. This may be attributed to shorter duration of analgesia and lower VAS scores in the ropivacaine group, despite having no statistical significance. A similar opposite finding was reported in another study, but it did not give an exact explanation [14].

Some studies have declared that ropivacaine might induce less motor blocks, especially in long labor, decreasing maternal mobility and maternal effort in the second stage. This could lead to inadequate rotation of the fetal presenting part secondary to relaxation of pelvic floor

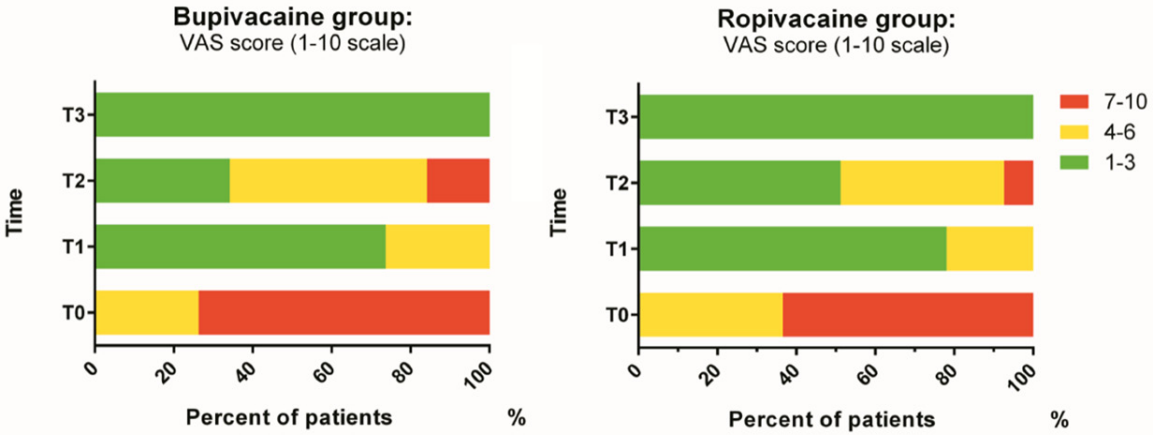

Figure 4. Comparison of VAS scores between bupivacaine group and ropivacaine group at T0 (before anesthesia); T1 (beginning of PCEA); T2 (full dilatation of cervix); T3 (5 minutes after delivery). Percentage of patients with VAS score of 1-3, 4-6, and 7-10 are shown and there were no significant differences between the groups.

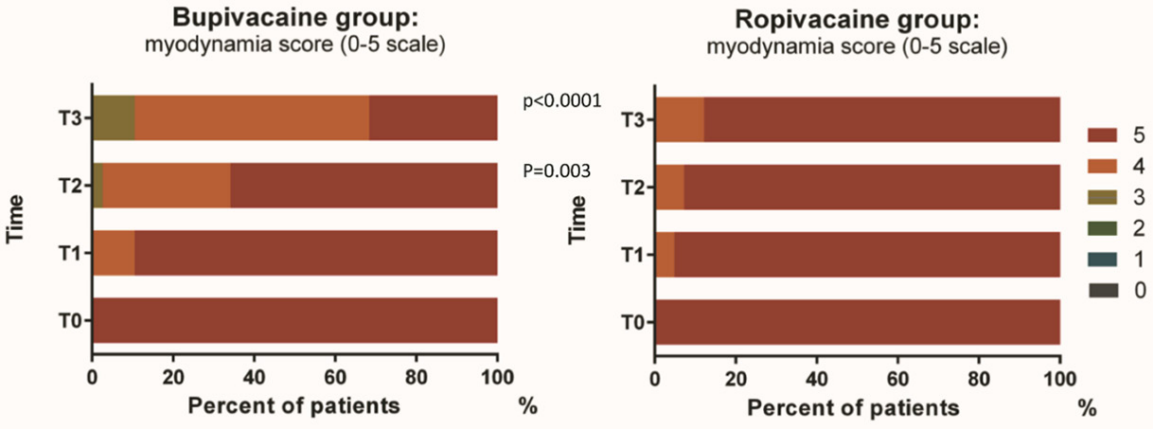

Figure 5. Comparison of myodynamia scores between bupivacaine group and ropivacaine group at T0 (before anesthesia); T1 (beginning of PCEA); T2 (full dilatation of cervix); T3 (5 minutes after delivery). The percentage of patients with motor block (manual muscle testing score of 0-5) are shown and myodynamia scores were higher in ropivacine group contrasted with bupivacaine group at T2 (P=0.003) and T3 (P<0.0001) (Mann-Whitney Rank Sum Test).

muscles [24, 25]. In the present study, a more detailed 0-5 scale MMT was used to assess myodynamia of patients instead of Bromage scores. Myodynamia of all patients was ≥3 during labor, indicating that both methods induced mild motor block. However, patients developed significantly less motor block (higher myodynamia score) with ropivacaine/fentanyl at T2 and T3. The motor block degree in epidural analgesia depends on drug use as well as the cumulative dose of local anesthetics [1]. This may be the reason why a proportion of high myodynamia scores gradually decreased as the delivery went on, with differences showing at T2 and T3 (**Figure 5**).

Compared with bupivacaine, ropivacaine may be less cardiotoxic when administrated with high doses. This, however, is not a problem when applied only in the usual dose range. Therefore, the only consideration is the cost of the drugs, especially in less developed countries. Due to higher costs, it has been difficult to establish the routine use of ropivacaine for labor analgesia.

In summary, both CSEA regimens produced excellent labor analgesia and were equivalent in mode of delivery, oxytocin use, total volume of local anesthetics, duration of second stage labor, pain scores, side effects, and neonatal outcomes, except that patients had higher myodynamia with ropivacaine/fentanyl. Regardless of cost, the ropivacaine/fentanyl CSEA regimen is a better choice. Different methods and dosages should be further tested to

improve safety and satisfaction during delivery.

Disclosure of conflict of interest

None.

Address correspondence to: Jinxia Gao, Department of Anesthesiology, The Second Hospital of Dalian Medical University, No.467 Zhongshan Road, Shahekou District, Dalian 116023, Liaoning Province, China. Tel: +86-0411-84671291; E-mail: Gaojinxia-85r@163.com

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