



# Application of 0.15% ropivacaine in labor analgesia for primiparous women with severe pain

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## Highlights

- Explored the delivery analgesia mode for the special population of first-time mothers with severe pain.
- Explored the effectiveness and safety of high-concentration ropivacaine in epidural labor analgesia.
- Focused on providing humanistic care for the emotional well-being of postpartum women, extending beyond mere pain relief.

## Abstract

**Objective:** To compare the efficacy and adverse reactions between 0.15% ropivacaine combined with sufentanil and 0.1% ropivacaine combined with sufentanil for labor analgesia in primiparous women with severe pain. **Method:** 195 full-term singleton primiparous women with severe pain (visual pain assessment [VAS]  $\geq 6$ ) were randomly allocated to two epidural analgesia groups using different drug formulations. One group received 0.1% ropivacaine + 0.3  $\mu\text{g/mL}$  sufentanil (control group,  $n=98$ ). The other group was treated with 0.15% ropivacaine and 0.3  $\mu\text{g/mL}$  sufentanil (experiment group,  $n=97$ ). The following parameters were recorded: analgesia onset time; maximum VAS scores before analgesia, at 20 min after epidural administration, and during labor; number of analgesic pump presses; number of rescue analgesia events; total analgesic drug consumption; modified Bromage score; maternal satisfaction; duration of labor stages; mode of delivery; neonatal Apgar scores at 1 min and 5 min; and incidence of adverse reactions during labor analgesia, such as skin itching, nausea and vomiting, urinary retention, and fever. **Result:** The onset time of analgesia in the experimental group was significantly shorter than that in the control group ( $P<0.05$ ). While the maximum VAS scores in both groups were significantly lower at 20 minutes post-epidural administration and during labor than before delivery analgesia ( $P<0.05$ ), no statistically significant inter-group differences were observed in VAS scores or in the number of pump compressions, rescue analgesia events, dosage of anesthetic drugs, modified Bromage score, or satisfaction ratings. Similarly, no significant differences were found between the two groups in the duration of labor, mode of delivery, and Apgar scores of newborns at 1 and 5 minutes, or the incidence of pruritus, nausea/vomiting, urinary retention, or intrapartum fever. **Conclusion:** For primiparous women with severe labor pain, initial use of 0.15% ropivacaine combined with sufentanil significantly shortens the onset time, provides more comprehensive analgesic effects, achieves higher satisfaction, and does not increase short-term adverse reactions (including motor block) compared to the conventional 0.1% concentration regimen.

**Keywords:** Labor analgesia, ropivacaine, severe labor pain, primipara

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## Introduction

During the long process of childbirth, the mothers will inevitably experience severe pain, triggering extensive physiological stress reactions that affect respiration, circulation, metabolism, uterine contractions, and placental perfusion, potentially endangering the condition of the fetus [1, 2]. Timely and effective labor analgesia is crucial for ensuring the safety of both mother and baby. At present, epidural analgesia is the “gold standard” for labor analgesia, and ropivacaine has become the preferred drug due to its lower cardiac and central neurotoxicity [3, 4]. However, the recommended concentration range of ropivacaine in international guidelines (0.0625%-0.15%) is relatively broad, and evidence regarding its dose-response relationship—particularly among individuals with severe labor pain—remains insufficient [5]. Therefore, optimizing the concentration of ropivacaine is of great clinical necessity, especially for mothers with severe pain and higher analgesic needs. The author found in previous research that appropriately increasing the concentration of ropivacaine can shorten the onset time of analgesia without increasing drug consumption or adverse reactions, while also receiving positive feedback from mothers. Through literature review, the author found that similar clinical studies are not abundant, and the optimal concentration of ropivacaine has not been confirmed. This study aims to evaluate the clinical value of ropivacaine at a concentration of 0.15% in this population by comparing two different concentration regimens.

## Materials and methods

### *Subjects and ethics*

After the institutional review board approval, primiparous women carrying a single, live, term fetus and requesting epidural labor analgesia were asked to participate in the study immediately after entering the delivery room. All of the eligible parturients signed an individual informed consent. Prior to analgesia, each parturient was given a detailed explanation of the epidural puncture and catheterization, analgesics used for epidural analgesia, possible accidents such as failed epidural catheterization and inadvertent epidural puncture, and alternative rescues available.

## *Research object*

This study enrolled postpartum women who gave birth in Suzhou BenQ Medical Center from January 2024 to December 2024. Inclusion criteria: full-term (gestational age  $\geq 37$  weeks) singleton primiparous women, aged 20-35 years, with a body mass index of 21-29 kg/m<sup>2</sup>, American Society of Anesthesiologists physical status I or II, and assessed by an anesthesiologist using a visual pain assessment (VAS) as having severe pain (score  $\geq 6$ ) before labor analgesia. Exclusion criteria: pre-eclampsia, contraindications to neuraxial anesthesia, allergy to opioids or ropivacaine, failure to achieve a sensory block level of T10 within 30 min after epidural administration, accidental dural puncture during the procedure, local anesthetic systemic toxicity, pump malfunction during labor analgesia, and epidural catheter blockage or dislodgement [6].

### *Randomization assignment*

After initial screening, eligible subjects were assigned to either the sole local anesthetic group or the combination group through a randomization sequence generated via the online software QuickCalcs# (Graphad, San Diego, CA). The allocation list was sealed and kept by an independent staff member not involved in the study. Immediately after epidural labor analgesia requested by the parturient, the corresponding allocation number was disclosed to determine the analgesic medication to be given [7]. Except for the parturients and caregivers, the data-collecting and data-analyzing members were blinded to the group assignment.

### *Grouping and handling*

The parturients were divided into Group C (control group) and Group E (experimental group) using a random number table. Study solutions were specially prepared by a researcher who did not participate in subsequent anesthesia procedures or follow-up. The analgesic drugs for Group C and Group E were 0.1% ropivacaine plus 0.3 µg/mL sufentanil and 0.15% ropivacaine plus 0.3 µg/mL sufentanil, respectively [7, 8]. All operations and follow-up were performed by anesthesiologists who were unaware of the grouping situation.

### Anesthesia plan

Upon entering the delivery room, all parturients received intravenous access and continuous monitoring of heart rate, blood pressure, peripheral capillary oxygen saturation, fetal heart rate and uterine contraction intensity. When uterine contractions remained inadequate, it was up to the midwife to determine whether to use oxytocin for infusion [8, 9]. With the parturient in the left lateral position, epidural puncture was performed at the L2-3 interspace. After confirming absence of cerebrospinal fluid or blood return, a catheter was inserted and secured. A 5 mL test dose of 1% lidocaine was administered; following a 5-minute observation period with no signs of local anesthetic systemic toxicity or lower-limb motor block, the catheter was fixed. The parturient was then turned to a left-tilt position and given a 10 mL initial bolus of the study analgesic solution. Sensory block level was assessed 15 minutes later. If the block reached T10 or above, a patient-controlled epidural analgesia pump was connected, set to a background infusion of 8 mL/h, a bolus dose of 8 mL, and a lockout interval of 15 minutes. If there was sudden pain during labor (VAS>4), the anesthesiologist would check the position of the epidural catheter and administer 10 mL of 0.2% ropivacaine as remedial analgesia. If the pain did not improve satisfactorily after 15 minutes, it was considered a failure of analgesia. In such cases, the anesthesiologist examined the anesthesia plane and re-punctured the catheter, and the case was withdrawn from this study [10, 11].

### Observation indicators

- ① The onset time of analgesia was recorded as the interval from the first epidural injection to the occurrence of effective analgesia (VAS score <4 points during uterine contractions).
- ② The maximum VAS score was recorded before delivery analgesia, at 20 minutes after epidural administration, and during labor. Pain scores were assessed immediately after each uterine contraction, and the expectant mother recalled the contraction to report the most severe pain experienced during that period.
- ③ Analgesic efficacy during childbirth was assessed by recording: the number of analgesic pump demands, the dosage of analgesic

drugs used, frequency of rescue analgesia, modified Bromage score after analgesia onset (0 points, no motion block, full flexion of hip, knee, and ankle possible; 1 point, unable to flex hip or raise straight leg, but full knee and ankle flexion possible; 2 points, unable to flex knee joint, only ankle flexion possible; 3 points, unable to flex ankle joint or move lower limbs), and the satisfaction rate of analgesia [8, 13]. The modified Bromage score was tested every hour from analgesia initiation until the end of delivery, and the maximum value would be recorded.

- ④ The duration of labor and the delivery method were documented.
- ⑤ The Apgar scores of newborns at 1, 5, and 10 minutes after birth were recorded, along with the number of cases in which the Apgar score was  $\leq 7$ .
- ⑥ Adverse reactions in parturients were recorded, such as skin itching, nausea and vomiting, urinary retention, lethargy, and intrapartum fever (body temperature  $\geq 37.5$  °C during labor).
- ⑦ The number of cases using oxytocin was recorded.

### Sample size calculation

In this study, the sample size was determined based on the onset time of analgesia during labor. According to preliminary research, the time to achieve a pain score below <3 was  $12 \pm 1.8$  minutes with 0.1% ropivacaine and  $10 \pm 1.1$  minutes with 0.15% ropivacaine. Assuming  $\alpha=0.05$  and  $\beta=0.1$ , a total of 164 parturients were needed. To account for potential dropouts and data loss, an increase of about 20% in the number of cases was required, resulting in a total of 200 cases being collected.

### Statistical analysis

SPSS 19.0 statistical software was used for analysis. Normal distribution measurement data are expressed as mean $\pm$ standard deviation ( $\bar{X} \pm s$ ), and one-way analysis of variance was used for inter-group comparison; Non-normal distribution metric data are represented by median and interquartile range, and between-group comparisons were conducted using the Mann Whitney U test. Count data

Table 1. Comparison of baseline characteristics

| Group | Cases | Age (year) | Height (cm) | Weight (kg) | Pregnancy (w) | Cervical opening size (cm) |
|-------|-------|------------|-------------|-------------|---------------|----------------------------|
| CG    | 98    | 27.9±3.8   | 158.3±4.2   | 68.5±7.8    | 39.8±1.1      | 1.5±0.6                    |
| EG    | 97    | 27.5±4.2   | 159.1±3.9   | 67.2±6.9    | 39.6±1.0      | 1.6±0.6                    |

Note: CG, control group; EG, experiment group.

Table 2. Comparison of analgesia onset time

| Group     | Onset (min) |
|-----------|-------------|
| CG (n=98) | 17.8±2.0    |
| EG (n=97) | 10.9±1.2    |
| P         | <0.001      |

Note: P<0.05, the onset time of analgesia in the EG group was significantly shorter than that in the CG group.

Table 3. Comparison of VAS scores at different time points

| Group     | Before analgesia | 20 minutes after administration | During labor process | P      |
|-----------|------------------|---------------------------------|----------------------|--------|
| CG (n=98) | 8 (7-8)          | 1 (1-2) <sup>a</sup>            | 2 (2-3) <sup>a</sup> | <0.001 |
| EG (n=97) | 8 (6-9)          | 1 (1-2) <sup>a</sup>            | 2 (1-2) <sup>a</sup> | <0.001 |
| P         | 0.74             | 0.97                            | 0.82                 |        |

Note: <sup>a</sup>P<0.05, compared with before analgesia, the VAS scores of 20 minutes after administration and during labor process has significantly decreased.

are presented as an number (percentage), and comparisons between groups were performed using the chi-square test or Fisher's exact test. P<0.05 indicates a statistically significant difference.

## Result

During the study period, 200 pregnant women met the inclusion criteria. One patient in group E withdrew from the study due to analgesic pump malfunction, and two patients in each group were excluded following accidental rupture of the dura mater. In the end, a total of 195 patients completed the study. There were no statistically significant differences between the two groups in age, height, weight, gestational age, or size of the cervix during analgesia (Table 1).

The onset time of analgesia in group E was significantly shorter than that in group C, and the difference was statistically significant (P<0.001; Table 2).

Before analgesia, there was no statistically significant difference in VAS scores between the two groups. After 20 minutes of epidural admin-

istration, the VAS scores of both groups were significantly lower than the pre-analgesia values (P<0.001). Similarly, the maximum VAS scores during labor were significantly reduced compared with pre-analgesia levels (P<0.001), but the difference between the two groups was not statistically significant (Table 3).

There were no statistically significant differences in the number of analgesic pump demands, modified Bromage score, or the need for rescue analgesia between the two groups of parturients. No analgesia failure occurred in either group during the study. Satisfaction with pain relief was significantly higher in Group E than in

Group C (P<0.001; Table 4), and the dosage of ropivacaine used in Group C was significantly higher than that in Group E (P<0.001; Table 4).

There was no statistically significant difference in the delivery methods between the two groups (Table 5). Neonatal Apgar scores of both groups were above 9 points, and the difference was not statistically significant.

One case (1%) of skin itching occurred in Group C, and the parturient complained of mild itching that could be tolerated and was not treated. However, Group E did not experience any skin itching, and the difference between the two groups was not statistically significant. The incidence of nausea/vomiting, urinary retention, and intrapartum fever did not differ significantly between the two groups (Table 6). Both groups did not experience drowsiness.

## Discussion

Some parturients experience severe pain in the early stages of labor, for which conventional concentrations of ropivacaine often provide inadequate analgesia. Increasing the concentration of local anesthetics is an effective and

Table 4. Comparison of analgesic efficacy during childbirth

|                                       |        | CG (n=98)           | EG (n=97)                          | P      | X <sup>2</sup> |
|---------------------------------------|--------|---------------------|------------------------------------|--------|----------------|
| PCA time (n)                          |        | 3 (2-3)             | 3 (2-4)                            | 0.75   |                |
| Dosage of analgesic drugs (ml)        |        | 76.43 (58.62-96.87) | 72.35 (52.43-92.58)                | 0.64   |                |
| Dosage of Ropivacaine (mg)            |        | 76.43 (58.62-96.87) | 108.53 (78.65-138.87) <sup>a</sup> | <0.001 |                |
| Dosage of Sufentanil (μg)             |        | 22.93 (17.59-29.06) | 21.71 (15.73-27.77)                | 0.82   |                |
| Bromage score [n (%)]                 | 0      | 97 (99)             | 95 (98)                            | 0.92   |                |
|                                       | 1      | 1 (1)               | 2 (2)                              | 0.86   |                |
| Remedy [n (%)]                        | 0 time | 24 (24.5)           | 32 (33.0)                          | 0.09   | 2.16           |
|                                       | 1 time | 42 (42.9)           | 38 (39.2)                          | 0.62   | 0.86           |
|                                       | 2 time | 18 (18.4)           | 16 (16.5)                          | 0.32   | 0.25           |
|                                       | 3 time | 14 (14.2)           | 11 (11.3)                          | 0.58   | 0.98           |
| Satisfaction with pain relief [n (%)] |        | 74 (76)             | 92 (95) <sup>a</sup>               | <0.001 |                |

Note: <sup>a</sup>P<0.05, the dosage of ropivacaine used in the EG group was significantly lower than that in the CG group, and the satisfaction with pain relief of the EG group was significantly higher than that of the CG group.

Table 5. Comparison of delivery outcomes

|                            |                   | CG (n=98)  | EG (n=97)  | P    | F    |
|----------------------------|-------------------|------------|------------|------|------|
| Delivery method [n (%)]    | Natural birth     | 91 (93)    | 90 (93)    | 0.92 |      |
|                            | Caesarean section | 7 (7)      | 7 (7)      | 0.98 |      |
| Total volume of blood (ml) |                   | 268.4±32.5 | 263.5±42.3 | 0.86 |      |
| Apgar scores               | 1 min             | 9.7±0.4    | 9.8±0.3    | 0.65 | 1.01 |
|                            | 5 min             | 9.5±0.4    | 9.3±0.5    | 0.68 | 1.25 |
|                            | 10 min            | 9.8±0.3    | 9.9±0.2    | 0.71 | 1.03 |
| Usage of oxytocin (n)      |                   | 75         | 68         | 0.78 |      |

Table 6. Comparison of adverse reactions [n (%)]

|                         | CG (n=98) | EG (n=97) | P    |
|-------------------------|-----------|-----------|------|
| Pruritus                | 1 (1)     | 0 (0)     | 0.43 |
| Nausea and vomiting     | 4 (4)     | 4 (4)     | 0.93 |
| Urinary retention       | 5 (5)     | 4 (4)     | 0.86 |
| Fever during childbirth | 14 (14)   | 12 (12)   | 0.45 |

easy-to-use strategy in such cases [9, 12]. Since the diffusion rate of local anesthetics is logarithmically related to concentration, doubling the concentration of ropivacaine, for example, can shorten the onset time by about one-third [5, 13, 14]. Therefore, initiating analgesia with a higher concentration (0.15%) can significantly shorten the onset of action and improve maternal satisfaction. This clinical practice has confirmed that the use of 0.15% ropivacaine solution throughout the entire process not only has a good analgesic effect, but also does not increase related adverse reactions.

Epidural analgesia is the gold standard for labor pain relief, and ropivacaine has become the preferred choice due to its low cardiac and central nervous system toxicity [15, 16]. The

recommended conventional dose is 0.08%-0.15%, so the control group (Group C) used the hospital's standard formula (0.1% ropivacaine + 0.3 μg/mL sufentanil) [17]. The experimental group (Group E) was administered 0.15% ropivacaine combined with a small dose of sufentanil.

This concentration was selected based on the finding by Xing et al. that the lowest effective concentration of ropivacaine for labor analgesia is 0.154% [18]. Therefore, selecting a concentration close to the minimum effective concentration is aimed at providing more sufficient baseline analgesia for severely painful mothers, which is theoretically reasonable and clinically targeted.

Both groups in this study showed good analgesic effects during the late stage of labor, with little need for remedial measures. For those in need of remedial analgesia, a single dose of 0.2% ropivacaine was administered. Sng et al. have demonstrated that this concentration acts rapidly and effectively without increasing adverse reactions [19]. In this study, rescue

analgesia was significant (the vast majority only required one attempt without failed withdrawal). Most importantly, even when the concentration was increased to 0.2%, no significant motor block or other related adverse reactions were observed, fully verifying the safety of this remedial plan.

Both groups of mothers achieved good analgesic effects, but the control group gained higher satisfaction scores, which seems to be related to its shorter onset time of analgesia. When pregnant women experience frequent uterine contractions for the first time, they often feel anxious and tense, which may lead to irritability toward surrounding people and situations [20]. When the pain is suppressed, the anxious emotions are often relieved, making the mother more optimistic about the entire delivery process, which can be easily seen from the comparison of the mothers' expressions. Deng et al. evaluated the relationship between intraspinal delivery analgesia and postpartum depression, and the results showed that the incidence of postpartum depression in women who received intraspinal delivery analgesia was significantly lower than that in women who did not [21]. This also indicates that sufficient analgesia can reduce the incidence of depression in women.

Although increasing the concentration of ropivacaine can shorten the onset time of analgesia and improve satisfaction with postpartum analgesia, higher drug concentrations will also be accompanied with more adverse reactions, such as uterine atony, weakened lower limb strength, and severe liver and kidney load [22, 23]. Therefore, the use of higher-concentration ropivacaine has certain limitations. It is primarily suitable for postpartum women who experience severe pain immediately at the beginning of delivery, those who have already experienced severe pain and cannot undergo single-shot spinal anesthesia, or those who have more stringent requirements regarding the onset time of analgesia. The safety and effectiveness of high-concentration ropivacaine in labor analgesia need further verification.

This study is a single-center study that only includes term singleton primiparous women, and the extrapolation of results is limited, especially with respect to other common populations experiencing severe labor pain (such as multiparous women). In the future, multi-center,

large-sample studies are needed to verify the effectiveness and safety of the 0.15% concentration in this population. In addition, the observation period is relatively short, recording only short-term adverse reactions (such as motor block and hypotension), without systematic evaluation of potential long-term outcomes (such as postpartum depression and chronic low back pain). Further follow-up is needed, and a more comprehensive study should be designed to clarify the long-term safety of different concentrations of ropivacaine.

## Conclusion

In summary, for primiparous women with severe labor pain, the initial use of 0.15% ropivacaine combined with sufentanil for epidural analgesia significantly shortens the onset time, provides more effective analgesia, and does not increase short-term adverse reactions (including motor block), compared to the conventional 0.1% concentration regimen. This clinical protocol effectively meets the pain relief needs of mothers with severe pain, improves satisfaction with the delivery experience, and has favorable clinical applicability.

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