

COMPARISON OF 0.125% ROPIVACAINE – DEXMEDETOMIDINE VERSUS 0.125% LEVOBUPIVACAINE – DEXMEDETOMIDINE FOR EPIDURAL LABOUR ANALGESIA

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ABSTRACT

Background: Epidural analgesia is widely used for labour pain relief, and adjuvants such as dexmedetomidine are added to local anaesthetics to improve analgesic quality while minimizing motor blockade. This study compared 0.125% ropivacaine and 0.125% levobupivacaine, both with dexmedetomidine, for epidural labour analgesia with respect to onset, quality and duration of analgesia, motor blockade, and labour outcome. **Materials and Methods:** This prospective, randomized, double-blinded comparative study included 50 parturients randomized into two groups of 25 each. Group A received epidural 0.125% ropivacaine with dexmedetomidine (0.5 mcg/kg), and Group B received 0.125% levobupivacaine with dexmedetomidine (0.5 mcg/kg), as initial and top-up doses. Onset and duration of analgesia, VAS score, motor blockade, labour duration, mode of delivery, maternal haemodynamics, and neonatal outcome were compared. **Result:** Group A had a significantly faster onset of analgesia than Group B (11.36 vs. 15.44 min; $p < 0.001$), while Group B had a significantly longer duration of analgesia (180 vs. 160 min; $p < 0.001$). More participants in Group B required three top-up doses (68% vs. 44%; $p = 0.049$), although cumulative top-up dose was comparable. VAS scores were similar between groups at all assessed time points. Labour duration and mode of delivery were comparable. Group A showed significantly higher MAP at 5 and 30 minutes, while Group B had higher HR at 60 minutes. Maternal and neonatal outcomes were otherwise comparable. **Conclusion:** Ropivacaine-dexmedetomidine provided faster onset, while levobupivacaine-dexmedetomidine offered longer analgesia with fewer top-ups; both combinations were safe and effective for labour epidural analgesia, with comparable quality of analgesia and labour outcome.

INTRODUCTION

The act of childbirth is still considered to be one of the major miracles yet to be cracked by mankind. The inevitable part of childbirth which is the labour pain and its challenges are one of the areas where human beings still interfere for a painless miracle. The labour which starts with the onset of contractions to the delivery of foetus produces the stimulation of a lot of mechanoreceptors and sensory receptors. Pain is visceral in character, gets started gradually, weakly restricted, first and foremost in the lower abdomen, also transmitted to lumbosacral area, gluteal region and thighs.^[1]

The pain which is obviously a part and parcel of the labour if exceeds leads to any adverse effects for both mother and baby. For mother it can lead to hypocarbia, vasoconstriction of uterine arteries, increasing maternal oxygen supply, increased release

of stress hormones and thus leads to reduced uterine perfusion. For baby, the shift towards the mother leads to reduced foetal oxygen supply and reduced blood circulation to the placenta which leads to serious condition for the baby. An ideal labour analgesia should be safe for both the sides; administrative ease should have a rapid and consistent action. Even there should not be any compromise for the mother or baby in terms of oxygen supply, perfusion or blockade levels.^[1]

Epidural labour analgesia improves cardiovascular, pulmonary functions in respiratory and cardiovascular compromise. During epidural labour analgesia mother is awake, cooperative, and actively participate in labour processes. Compared with other methods of pain relief, epidural labour analgesia is associated with the highest level of maternal satisfaction.^[2-4]

Epidural analgesia satisfy the fundamental needs of labour analgesia by satisfying the purpose of lessening the pains of labour without affecting other sensations such as a yearning to push and to permit usual walking while preserving the tone of pelvic floor muscles as well as retaining the feeling of the baby's head in the vagina thus letting labour to proceed unrestricted.^[5] The foundation of block lies in giving utmost analgesia with least amount of motor block as ambulation of patient is linked with better start and succession of active labour. Many anaesthetic drugs and adjuvant are there for the purpose of epidural analgesia. Many studies are there which involve the usage of multiple drugs in various combinations and concentrations to assess which is more efficacious.

Ropivacaine, an usual local anaesthetic drug which is less cardio toxic in animals, over and above it may also be more discriminatory for sensory fibres when compared to other local anaesthetics, producing fewer motor block. Its small lipid solubility leads to superior sensory motor differentiation by jamming sensory nerve fibres more eagerly than motor fibre. This allows for amplified maternal ambulation and also allows for normal progression of labour, which leads into fewer instrumental deliveries and more vaginal deliveries.^[6,7]

Levobupivacaine, a usual local anaesthetic, which showed an outline close to bupivacaine in terms of commencement, eminence, and period of sensory block, but with slighter cardiac and neurotoxin adverse effects. The clinical data showed its effectiveness and security for regional anaesthetic techniques with negligible hemodynamic fluctuations.^[8]

The adding up of adjuvants like Opioids or α -2agonist offer a dose spare effect of local anaesthetics and would speed up the onset of sensory blockade of epidural anaesthesia and reduce the efficient dose of local anaesthetic. Sedation, steady hemodynamic and skill to give long-lasting postoperative analgesia are the chief attractive qualities of an epidural adjuvant. Dexmedetomidine acts on pre and post synaptic sympathetic nerve terminal and central nervous system to reduce the sympathetic outflow and nor epinephrine release causing sedation, analgesia, sympatholytic and hemodynamic effects. Motor blockade tends to be denser with dexmedetomidine at higher doses and concentrations. Dexmedetomidine is also devoid of respiratory depression, pruritus, nausea, and vomiting.^[9]

This study aimed at comparing the Ropivacaine and Levobupivacaine with Dexmedetomidine as adjuvant for epidural analgesia in labour regarding onset, quality and duration of analgesia, motor blockade, labour outcome.

Aim and Objectives: To compare 0.125% Ropivacaine and 0.125% Levobupivacaine with dexmedetomidine as adjuvant for epidural analgesia in labour regarding onset, quality and duration of analgesia, motor blockade, labour outcome.

MATERIALS AND METHODS

This prospective randomized double-blinded comparative study was conducted in the Department of Obstetrics and Gynaecology, Government Medical College, Theni. Eligible parturients admitted for delivery were enrolled and followed up according to the study protocol. The study protocol was approved by the Institutional Ethical Committee (2544/ME1/18). Written informed consent was obtained from all participants prior to enrolment.

Sample Size: A total of 50 patients were included in the study and randomized into two groups of 25 each:

- Group A: 10 ml of 0.125% Ropivacaine with Dexmedetomidine (0.5 mcg/kg body weight) as the initial dose, and 8 ml of 0.125% Ropivacaine with 0.5 mcg/kg body weight Dexmedetomidine as top-up doses as and when required.
- Group B: 10 ml of 0.125% Levobupivacaine with Dexmedetomidine (0.5 mcg/kg body weight) as the initial dose, and 8 ml of 0.125% Levobupivacaine with 0.5 mcg/kg body weight Dexmedetomidine as top-up doses as and when required.

Inclusion Criteria: Primigravida in labour, ASA grade 1 and 2, with a singleton pregnancy of 35 weeks gestation or more, cephalic presentation, and in the active stage of labour with cervical dilatation of 3–5 cm, were included in the study.

Exclusion Criteria: Patients with breech presentation, antepartum haemorrhage, severe pre-eclampsia, aortic stenosis, cephalopelvic disproportion, coagulation defects, anticoagulant therapy, vertebral deformity, or local sepsis were excluded from the study.

Randomization: Subjects included in the study were randomized into the two groups using the lottery method.

Data Collection: Baseline demographic and obstetric characteristics, including age, weight, height, Body mass index (BMI), gestational age, and cervical dilatation at epidural placement, were recorded. Maternal haemodynamic parameters, mean arterial pressure (MAP) and heart rate (HR) and Visual Analogue Scale (VAS) pain scores were assessed at 5, 15, and 30 minutes after drug administration, then at 45 and 60 minutes, and every 60 minutes thereafter until delivery.

Participants were monitored throughout labour for onset and duration of analgesia, number and dose of top-up requirements, duration of the first, second, and total stages of labour, mode of delivery, foetal HR, neonatal Apgar scores at 1 and 5 minutes, degree of motor blockade, and any patient complaints or adverse effects following epidural administration.

Intervention: All patients were preloaded with 500 ml of Ringer Lactate prior to the block. Under strict aseptic precautions, with the patient in the right lateral position, 1–2 ml of 2% Lignocaine was infiltrated at the L2/L3 or L3/L4 interspace. The epidural space was identified using the loss-of-

resistance technique with a Tuohy's needle, and an 18-G epidural catheter was inserted so that 3–4 cm remained within the space. The Tuohy's needle was withdrawn slowly and the catheter secured. Patients in Group A received epidural 0.125% Ropivacaine with Dexmedetomidine as the initial and top-up doses. Patients in Group B received epidural 0.125% Levobupivacaine with Dexmedetomidine as the initial and top-up doses. Doses were administered once the patient reached the active stage of labour with cervical dilatation of 3–5 cm. Onset of analgesia was defined as the time from drug administration to a VAS score <3. A top-up dose of 8 ml was administered when the VAS score exceeded 4.10 The level of analgesia was assessed using pin-prick sensation, and motor blockade was assessed using the Modified Bromage Scale.¹¹ The study procedure was considered complete upon spontaneous vertex delivery or assisted vaginal delivery.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using SPSS version 24. Continuous variables were expressed as mean $\pm$ standard deviation for normally distributed data or median with interquartile range for non-normally distributed data, while categorical variables were presented as frequencies and percentages. Categorical variables were compared using the Chi-square test or Fisher's exact test, as appropriate. Normally distributed continuous variables were compared using the independent-samples t-test, whereas the Mann–Whitney U test was used for non-normally distributed variables. A p-value <0.05 was considered statistically significant.

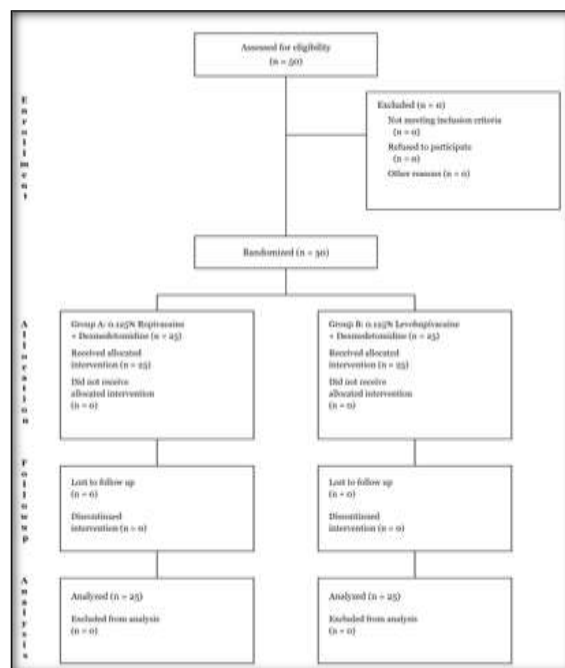


Figure 1: CONSORT flow diagram

RESULTS

Mean age was 22.00 ± 2.26 years in Group A and 21.48 ± 2.12 years in Group B, and mean gestational age was 38.72 ± 0.79 and 38.96 ± 0.89 weeks, respectively. Baseline VAS scores were 8.88 ± 0.93 and 8.80 ± 0.87 . All baseline variables had p values greater than 0.05 [Table 1].

Table 1: Baseline maternal and obstetric characteristics

Variable	Group A	Group B	p value
Age, years	22.00 ± 2.26	21.48 ± 2.12	0.86
BMI, kg/m ²	22.74 ± 2.44	23.27 ± 2.09	0.81
Gestational age, weeks	38.72 ± 0.79	38.96 ± 0.89	0.79
Cervical dilatation at epidural placement, cm	3.88 ± 0.67	4.16 ± 0.75	0.36
Baseline VAS score	8.88 ± 0.93	8.80 ± 0.87	0.89
Baseline MAP, mmHg	85.04 ± 4.36	84.96 ± 7.00	0.14
Baseline HR, beats/min	90.88 ± 12.28	88.04 ± 6.36	0.31
Fetal HR, beats/min	134.48 ± 8.40	135.84 ± 8.39	0.92

Values are expressed as mean $\pm$ standard deviation. Independent-samples t-test was used.

The mean onset time of analgesia was 11.36 ± 1.35 min in Group A and 15.44 ± 1.39 min in Group B ($p < 0.001$). The median duration of analgesia was 160 min in Group A and 180 min in Group B ($p < 0.001$). Three top-up doses were required by 11 participants

(44.0%) in Group A and 17 participants (68.0%) in Group B ($p = 0.049$). The cumulative top-up dose was 24.40 ± 5.07 mg in Group A and 26.80 ± 4.76 mg in Group B ($p = 0.09$) [Table 2].

Table 2: Analgesic characteristics and top-up requirements

Variable	Group A	Group B	p value
Onset of analgesia, min	11.36 ± 1.35	15.44 ± 1.39	<0.001*
Duration of analgesia, min; median (IQR)	160 (150–170)	180 (167.5–193)	<0.001*
Participants requiring two top-ups, n (%)	14 (56.0%)	8 (32.0%)	0.049*
Participants requiring three top-ups, n (%)	11 (44.0%)	17 (68.0%)	
Cumulative top-up dose required, mg	24.40 ± 5.07	26.80 ± 4.76	0.09

Values are expressed as mean $\pm$ standard deviation unless otherwise stated. Independent-samples t-test was used for onset time and cumulative top-up dose; Mann–Whitney U test was used for duration of analgesia; chi-square test was used for number of top-ups. *p < 0.05 indicates statistical significance.

At 5 min, the mean VAS score was 4.84 ± 0.80 in Group A and 4.68 ± 0.75 in Group B ($p=0.47$). At 15 min, the median VAS score was 1 (IQR: 0–1) in Group A and 1 (IQR: 0–1.5) in Group B ($p=0.63$). At 30 min, the median VAS score was 0 (IQR: 0–1) in both groups ($p=0.24$).

At 45 min, the median VAS score was 1 (IQR: 1–1) in both groups ($p=0.47$). At 60 min, median VAS was 1 (IQR: 1–2) in both groups ($p=0.79$). At 120 min, median VAS was 1 (IQR: 1–1) in both groups ($p=0.64$). At 180 min, median VAS was 1 (IQR: 1–2) in Group A and 1 (IQR: 1–1) in Group B ($p=0.62$) [Figure 1].

The mean total duration of labour was 202.20 ± 43.69 min in Group A and 202.84 ± 44.73 min in Group B

($p=0.85$). Normal vaginal delivery occurred in 23 participants (92.0%) in Group A and 22 participants (88.0%) in Group B [Table 3].

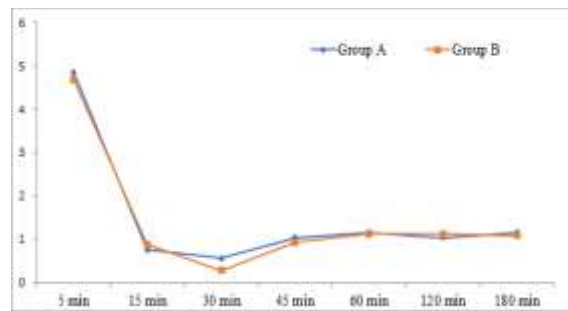


Figure 1: VAS score over time.

Table 3: Motor blockade and labour outcomes

Variable	Group A	Group B	p value
Motor blockade, n (%)	0 (0)	0 (0)	—
First-stage duration of labour, min	156.80 ± 33.72	155.60 ± 34.42	0.82
Second-stage duration of labour, min	45.40 ± 11.45	47.24 ± 12.37	0.67
Total duration of labour, min	202.20 ± 43.69	202.84 ± 44.73	0.85
Normal vaginal delivery, n (%)	23 (92.0%)	22 (88.0%)	—
Caesarean delivery, n (%)	1 (4.0%)	1 (4.0%)	—
Instrumental (forceps) delivery, n (%)	1 (4.0%)	2 (8.0%)	—

Values are expressed as mean $\pm$ standard deviation or frequency (%). Independent-samples t-test was used for labour duration.

MAP at 5 min was 94.08 ± 4.83 mmHg in Group A and 90.68 ± 4.34 mmHg in Group B ($p=0.012$); at 30 min, the corresponding values were 96.08 ± 4.83 mmHg and 92.32 ± 3.98 mmHg ($p=0.004$) (Figure 2). HR at 60 min was 86.04 ± 6.48 beats/min in Group A and 90.64 ± 6.53 beats/min in Group B ($p=0.016$). Other MAP and heart-rate comparisons had p values greater than 0.05.

Vomiting occurred in 1 participant (4.0%) in Group A and 2 participants (8.0%) in Group B. No hypotension, pruritus, urinary retention, or respiratory depression was recorded in either group. Mean Apgar scores at 1 min were 8.16 ± 0.37 in Group A and 8.20 ± 0.41 in Group B ($p=0.72$). At 5 min, mean Apgar scores were 9.44 ± 0.51 and 9.36 ± 0.49 , ($p=0.57$) [Table 4].

Table 4: Maternal haemodynamics, adverse effects, and neonatal outcomes

Variable	Group A	Group B	p value
MAP at 5 min, mmHg	94.08 ± 4.83	90.68 ± 4.34	0.012*
MAP at 30 min, mmHg	96.08 ± 4.83	92.32 ± 3.98	0.004*
HR at 60 min, beats/min	86.04 ± 6.48	90.64 ± 6.53	0.016*
Vomiting, n (%)	1 (4.0%)	2 (8.0%)	—
Apgar score at 1 min	8.16 ± 0.37	8.20 ± 0.41	0.72
Apgar score at 5 min	9.44 ± 0.51	9.36 ± 0.49	0.57

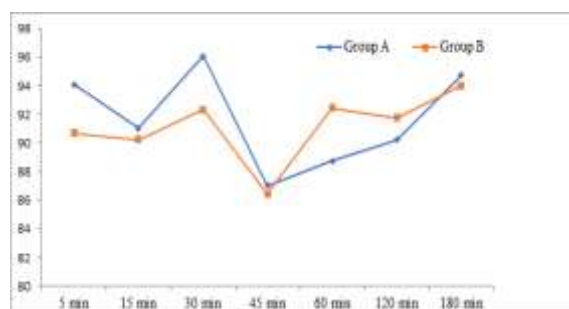


Figure 2: Maternal haemodynamic parameters over time.

DISCUSSION

This study included 50 parturients, with 25 participants in each group. It compared 0.125% ropivacaine–dexmedetomidine with 0.125%

levobupivacaine–dexmedetomidine for epidural labour analgesia. Analgesia started earlier in the ropivacaine group. Mean onset time was 11.36 ± 1.35 min in Group A and 15.44 ± 1.39 min in Group B ($p<0.001$). However, analgesia lasted longer in the levobupivacaine group, with a median duration of 180 min compared with 160 min in the ropivacaine group ($p<0.001$).

Three top-up doses were needed by 17 participants (68.0%) in Group B and 11 participants (44.0%) in Group A ($p=0.049$). The cumulative top-up dose was 24.40 ± 5.07 mg in Group A and 26.80 ± 4.76 mg in Group B, with no significant difference between groups. VAS scores decreased after epidural administration in both groups. At 5 min, mean VAS scores were 4.84 ± 0.80 in Group A and 4.68 ± 0.75 in Group B. VAS scores remained low at later timepoints, with no significant difference between

groups. No motor blockade was observed in either group. The mean total duration of labour was 202.20 ± 43.69 min in Group A and 202.84 ± 44.73 min in Group B. Normal vaginal delivery occurred in 23 participants (92.0%) in Group A and 22 participants (88.0%) in Group B. Caesarean delivery occurred in one participant in each group, while instrumental delivery occurred in one participant in Group A and two participants in Group B.

MAP was higher in Group A at 5 min and 30 min. HR differed at 60 min, with mean values of 86.04 ± 6.48 beats/min in Group A and 90.64 ± 6.53 beats/min in Group B. At other timepoints, MAP and HR were not significantly different. Vomiting occurred in one participant in Group A and two participants in Group B. No hypotension, pruritus, urinary retention, or respiratory depression was recorded. Apgar scores at 1 min and 5 min were similar in both groups.

Previous studies have explored dexmedetomidine as an epidural adjuvant with local anaesthetics and have reported improved analgesic characteristics in different clinical settings.¹¹⁻¹⁴ Zhang and Li studied 60 full-term primiparous women receiving epidural ropivacaine either alone or with dexmedetomidine $0.5 \mu\text{g/mL}$, and found the median effective concentration of ropivacaine was 0.083% (95% CI: 0.077%–0.089%) alone versus 0.062% (95% CI: 0.058%–0.066%) with dexmedetomidine ($p < 0.05$), with no significant difference in motor blockade, labour stages, mode of delivery, Apgar scores, or adverse effects between groups.¹² Gupta et al. compared dexmedetomidine with fentanyl as an adjuvant to epidural levobupivacaine in women undergoing vaginal hysterectomy. Sensory analgesia began at 7.25 ± 2.3 min with dexmedetomidine and 9.27 ± 2.79 min with fentanyl, and duration of sensory analgesia was longer with dexmedetomidine (187.7 ± 6.9 min) than with fentanyl (146.7 ± 8.3 min; $p = 0.001$).¹³ Although this was not a labour-analgesia study and did not compare ropivacaine with levobupivacaine, it provides indirect background for the use of dexmedetomidine as an epidural adjuvant. Kumar et al. compared 0.1% ropivacaine and 0.1% levobupivacaine with fentanyl for epidural labour analgesia. They reported shorter onset and shorter duration of analgesia with ropivacaine than with levobupivacaine.¹⁵ This pattern is similar to the present study, in which ropivacaine had a faster onset and levobupivacaine had a longer duration. However, their study used fentanyl rather than dexmedetomidine, different local-anaesthetic concentrations, and a different analgesic regimen. Sah et al. compared ropivacaine, bupivacaine, and levobupivacaine with fentanyl for labour epidural analgesia. They found no significant difference in VAS scores or motor scores among the groups during the observation period.¹⁶ Similarly, no significant difference in VAS scores and no motor blockade were observed in the present study. Rani et al. studied 70 nulliparous parturients receiving intermittent epidural boluses of 0.08% levobupivacaine or 0.1%

ropivacaine, both with fentanyl $2 \mu\text{g/mL}$. Onset of analgesia was 22.43 ± 2.6 min with levobupivacaine and 21.00 ± 2.5 min with ropivacaine ($p = 0.37$), while duration of analgesia was 67.2 ± 9.7 min and 66.0 ± 12 min, respectively ($p = 0.66$). Instrumental vaginal delivery was 6.45% with levobupivacaine and 4.54% with ropivacaine ($p = 0.739$); pain relief and neonatal Apgar scores were comparable between groups.¹⁷ Singh et al. randomized 60 parturients to patient-controlled epidural analgesia with 0.1% levobupivacaine or 0.1% ropivacaine, both with fentanyl $2 \mu\text{g/mL}$. Median onset of analgesia was 10 min with levobupivacaine and 11 min with ropivacaine ($p = 0.602$), while mean epidural analgesia duration was 295.50 ± 198.11 min and 343.67 ± 259.92 min, respectively, without a significant difference. Instrumental vaginal delivery occurred in 43.3% of the levobupivacaine group and 30.0% of the ropivacaine group ($p = 0.545$); VAS scores, motor blockade, and Apgar scores were also comparable between groups.¹⁸ This provides context for the descriptively similar delivery outcomes observed in the present study.

Zhao et al. randomized 80 parturients to receive either 0.125% ropivacaine alone or 0.125% ropivacaine with dexmedetomidine $0.5 \mu\text{g/kg}$ for labour epidural analgesia. The dexmedetomidine group had lower VAS scores, systolic and diastolic blood pressure, and HR at most post-epidural timepoints. Duration of labour, instrumental and caesarean delivery rates, Apgar scores, motor-block scores, sedation, and maternal complications did not differ significantly between the groups.¹⁹ Their study supports the relevance of dexmedetomidine in labour epidural analgesia, although it did not directly compare ropivacaine with levobupivacaine.

Overall, both regimens were associated with low VAS scores and no observed motor blockade. Ropivacaine-dexmedetomidine had a faster onset of analgesia, whereas levobupivacaine-dexmedetomidine had a longer duration of analgesia.

Limitations: The mode of delivery and duration of labour varied according to the healthcare practitioner, which may have influenced drug efficacy. The small sample size may have limited the detection of differences in effectiveness between groups. Additionally, pain assessment is subjective and may not have been an optimal measure of drug efficacy.

CONCLUSION

Ropivacaine-dexmedetomidine provided significantly faster onset of analgesia, while levobupivacaine-dexmedetomidine offered longer duration and fewer top-up requirements, for epidural labour analgesia. Quality of analgesia, motor blockade, labour duration, and mode of delivery were comparable between groups, with only transient haemodynamic differences at a few timepoints. Both combinations are safe and effective, with drug choice

guided by whether rapid onset or prolonged analgesia is clinically prioritized.

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