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Dexmedetomidine; Ropivacaine; Epidural Analgesia; Labour Analgesia; Parturient; Neuraxial Analgesia; Randomized Controlled Trial

COMPARATIVE EFFICACY AND SAFETY OF TWO CONCENTRATION OF DEXMEDETOMIDINE (0.2 μG/ML & 0.5 μG/ML) AS AN ADJUVANT TO 0.2% INJ. ROPIVACAINE FOR EPIDURAL LABOR ANALGESIA: A PROSPECTIVE RANDOMIZED DOUBLE BLIND CONTROLLED STUDY

Dr. Harsh Mehta MD, Assistant Professor, Department of Anaesthesiology, Government Medical College, Bhavnagar, Gujarat.

Dr. Sagar Kanani MD, Senior resident, Department of Anaesthesiology, Government Medical College, Bhavnagar, Gujarat.

Dr. Komal Shah MD, Associate Professor, Department of Anaesthesiology, Government Medical College, Bhavnagar, Gujarat.

Dr. Arpit Patel Resident Doctor, Department of Anaesthesiology, Government Medical College, Bhavnagar, Gujarat.

ABSTRACT

Background: Epidural analgesia is an effective neuraxial technique for labour pain relief. Low-concentration ropivacaine minimizes motor blockade, while dexmedetomidine may enhance analgesia and prolong block duration. This study compared two concentrations of dexmedetomidine added to 0.2% ropivacaine for epidural labour analgesia. **Methods:** This prospective, randomized, double-blind controlled study was conducted after institutional ethics approval and Clinical Trials Registry–India registration (CTRI/2024/10/075255). Thirty primigravida parturients aged 18–30 years with term singleton cephalic pregnancies in active labour were randomized equally to receive 10 mL of 0.2% ropivacaine with dexmedetomidine 0.2 μg/mL (Group D1) or 0.5 μg/mL (Group D2). Pain, sensory and motor block, maternal haemodynamics, oxygen saturation, labour progression, drug requirements, fetal heart rate, mode of delivery, sedation, neonatal Apgar scores and satisfaction were assessed. **Results:** Baseline demographic characteristics were comparable. VAS scores decreased rapidly in both groups. At 20 minutes, mean VAS was 0.71 ± 0.76 in D1 and 0.33 ± 0.52 in D2 (p=0.32), with no statistically significant between-group differences at subsequent recorded intervals. Sensory block onset was 10.6 ± 0.98 versus 13.7 ± 3.01 minutes (p=0.46), while duration to first top-up was 122.1 ± 27.97 versus 150.0 ± 21.21 minutes (p=0.09) in D1 and D2, respectively. Maternal pulse, mean arterial pressure and SpO_2 remained comparable. Ropivacaine requirement was 35.71 ± 7.87 mg in D1 versus 31.67 ± 7.53 mg in D2 (p=0.37). The number of top-ups was 1.57 ± 0.79 versus 1.17 ± 0.75 (p=0.37). Fetal heart rate and neonatal Apgar scores were comparable. No hypotension, bradycardia, pruritus or respiratory depression was reported. **Conclusion:** Both dexmedetomidine concentrations combined with 0.2% ropivacaine provided effective epidural labour analgesia with stable maternal and neonatal outcomes. The higher concentration showed a numerically longer duration of analgesia and fewer top-ups, but differences were not statistically significant.

INTRODUCTION

Labour pain is a complex physiological and psychological experience. Severe pain and anxiety may increase maternal sympathetic activity and catecholamine release and can influence maternal haemodynamics and uterine activity. Effective analgesia therefore aims not only to reduce pain but also to preserve maternal cooperation, motor function and physiological stability.

Epidural analgesia is widely used for labour because it can provide effective segmental analgesia while permitting progression of labour and maternal participation. Ropivacaine is particularly useful at low concentrations because it provides predominantly sensory blockade with less motor impairment than higher-concentration local anaesthetics. However, reducing local anaesthetic concentration may increase the need for rescue doses.

Adjuvants can improve the quality and duration of neuraxial analgesia and potentially reduce local anaesthetic requirements. Dexmedetomidine, a selective α2-adrenergic agonist, has analgesic and sedative properties and has been investigated as a neuraxial adjuvant. Previous studies cited in the dissertation have suggested useful analgesic effects across concentrations ranging from approximately 0.2 to 1.0 μg/mL, with higher concentrations potentially associated with more sedation or motor effects.

The present study was designed to compare two relatively low concentrations of dexmedetomidine, 0.2 and 0.5 μg/mL, when combined with 0.2% ropivacaine for epidural labour analgesia in primigravida parturients. The primary outcome was pain relief assessed using the Visual Analogue Scale (VAS).

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, double-blind controlled study was conducted in the Department of Anaesthesiology, Government Medical College and Sir T. General Hospital, Bhavnagar, Gujarat, India. Institutional Review Board approval was obtained (IRB No. 1354/2024). Written informed consent was obtained from all participants in the local language. The trial was registered with the Clinical Trials Registry–India (CTRI/2024/10/075255).

Participants

Thirty primigravida women aged 18–30 years, ASA physical status I or II, with term singleton cephalic pregnancy and active labour were enrolled. Eligibility included cervical dilatation up to 4 cm, uterine contractions at least once every five minutes and absence of contraindications to regional anaesthesia or the study drugs.

Patients with local anaesthetic allergy, preterm labour, pre-eclampsia/eclampsia, thyroid disease, cardiomyopathy, multiple pregnancy, previous caesarean delivery, abnormal lie, antepartum haemorrhage, morbid obesity, severe anaemia, haemodynamic instability, psychiatric or neurological disorders, or altered mental status were excluded.

Randomization and Intervention

Participants were randomized using a computer-generated random-number sequence into two equal groups (n=15 each). Group D1 received 10 mL of 0.2% ropivacaine with dexmedetomidine 0.2 μg/mL; Group D2 received 10 mL of 0.2% ropivacaine with dexmedetomidine 0.5 μg/mL.

Epidural technique

After intravenous access and routine monitoring, lumbar epidural space was identified by the loss-of-resistance technique at L2–L3 or L3–L4 using an 18-G Tuohy needle. A 20-G multi-orifice epidural catheter was advanced 5 cm into the epidural space. After a test dose of 3 mL of 1.5% lignocaine with adrenaline 1:200,000 and a 10-minute observation period, the assigned study solution was administered. Blinding was maintained by preparation of the syringes by a team member who was not involved in patient assessment; the assessor was unaware of group allocation.

Outcome Assessment

VAS, sensory block, modified Bromage motor assessment, heart rate, blood pressure, SpO_2 and Ramsay Sedation Score were assessed at 10, 20 and 30 minutes and subsequently at 30-minute intervals according to the study protocol. A 5-mL top-up of the assigned solution was administered when VAS was ≥4. An additional 5-mL top-up could be given at delivery for episiotomy pain if the previous top-up had been administered more than 60 minutes earlier. Total ropivacaine and dexmedetomidine requirements and the number of top-ups were recorded. Labour progression was monitored by the obstetric team with four-hourly vaginal examinations. Fetal heart sounds were recorded hourly. Mode of delivery, neonatal Apgar scores at one and five minutes, maternal satisfaction and obstetrician satisfaction were recorded.

RESULTS

Table 1: Demographic Data

Variable	Group D1 (n=15)	Group D2 (n=15)	p value
Age (years)	24.9 ± 2.41	23.8 ± 1.17	0.36
Height (cm)	149.0 ± 4.97	150.7 ± 4.27	0.53
Weight (kg)	57.0 ± 4.08	58.3 ± 2.80	0.51

The groups were comparable with respect to age, height and weight.

Table 2: Comparison of VAS Score Between Two Groups

Time	D1	D2	p value
Baseline	8.86 ± 0.38	9.00 ± 0.00	0.38
10 min	4.00 ± 0.58	3.83 ± 0.75	0.66
20 min	0.71 ± 0.76	0.33 ± 0.52	0.32
30 min	0.57 ± 0.54	0.33 ± 0.52	0.43
1 h	0.57 ± 0.54	0.33 ± 0.52	0.43
1.5 h	2.57 ± 3.74	0.33 ± 0.52	0.18
2 h	3.57 ± 3.55	1.67 ± 3.62	0.36
2.5 h	1.80 ± 2.79	4.00 ± 3.68	0.26
3 h	2.14 ± 3.13	1.68 ± 3.14	0.79
3.5 h	2.57 ± 3.41	0.20 ± 0.45	0.16
4 h	0.75 ± 0.50	1.80 ± 4.03	0.63
4.5 h	0.68 ± 0.58	0.50 ± 0.71	0.79
5 h	4.00 ± 4.24	3.00	0.88
Sensory block variable	D1	D2	p value
Onset of sensory block (min)	10.6 ± 0.98	13.7 ± 3.01	0.46
Time to peak level (min)	24.9 ± 3.39	23.8 ± 2.71	0.57
Duration to first top-up (min)	122.1 ± 27.97	150.0 ± 21.21	0.09

Pain scores decreased rapidly in both groups, with all participants reported in the dissertation to be pain-free within 20 minutes. No statistically significant between-group difference was demonstrated at the recorded time points. The duration to first top-up was numerically longer with 0.5 µg/mL dexmedetomidine, although the difference did not reach statistical significance.

Maternal Haemodynamics and Oxygenation

Maternal pulse rate, mean arterial pressure and SpO_2 remained stable and comparable between groups throughout the observation period. No statistically significant between-group difference was reported for these variables. No episode of hypotension, bradycardia or respiratory depression was recorded in either group.

Table 3: Comparison of Labour Progression and Drug Requirement Between Two Groups

Outcome	D1	D2	p value
Cervical dilatation before bolus (cm)	3.71 ± 0.49	3.83 ± 0.41	0.65
Cervical dilatation at 4 h (cm)	9.57 ± 1.13	10.00	0.38
Ropivacaine requirement (mg)	35.71 ± 7.87	31.67 ± 7.53	0.37
Dexmedetomidine requirement (µg)	4.29 ± 2.56	7.92 ± 1.88	0.07
Number of top-ups	1.57 ± 0.79	1.17 ± 0.75	0.37

Labour progression was comparable. Group D2 required numerically less ropivacaine and fewer top-ups, whereas its dexmedetomidine requirement was higher; none of these differences was statistically significant.

Fetal and Neonatal Outcomes

Fetal heart rate remained comparable at the reported observation points. At one minute, Apgar scores were 8.43 ± 0.54 in D1 and 8.33 ± 0.52 in D2 (p=0.75); at five minutes, the reported mean score was 10 in both groups. No adverse neonatal outcome was reported.

Mode of Delivery, Motor Block, Sedation and Complications

In Group D1, one of 15 participants underwent caesarean delivery for cephalopelvic disproportion. In Group D2, one participant underwent instrumental delivery because of inability to bear down and one underwent caesarean delivery for severe oligohydramnios. The thesis therefore reports 1/15 (6.25%) operative delivery events in D1 and 2/15 (12.5%) in D2, although the D2 category combines instrumental delivery and caesarean delivery.

The thesis reports minimal motor impairment in both groups and Ramsay Sedation Score 2 in all participants. No hypotension, bradycardia, pruritus or respiratory depression was reported. Maternal and obstetrician satisfaction was high in both groups, with no statistically significant difference reported.

DISCUSSION

This randomized double-blind study found that both low-dose dexmedetomidine regimens combined with 0.2% ropivacaine produced effective epidural labour analgesia. VAS scores fell substantially within the first 20 minutes in both groups, supporting the effectiveness of the low-concentration local anaesthetic–dexmedetomidine combination.

The 0.5 µg/mL group showed a numerically longer duration until the first rescue top-up (150 versus 122 minutes) and fewer top-ups (1.17 versus 1.57), although neither difference was statistically significant. Kamble et al[13] reported improved analgesic characteristics with increasing dexmedetomidine concentrations from 0.2 to 0.5 µg/mL, while Zhang et al[16] reported favourable efficacy and tolerability around 0.5 µg/mL.

The onset of sensory block was numerically faster in the 0.2 µg/mL group in this study. This contrasts with some previous work in which higher dexmedetomidine concentrations were associated with faster onset. The difference may reflect the small sample size, variability in onset assessment or differences in local anaesthetic concentration and study protocol.

Maternal haemodynamic stability was observed in both the

groups. This is clinically relevant because α2-adrenergic agonists can produce sympatholysis, bradycardia and hypotension. No clinically important haemodynamic or respiratory adverse event was observed in this study.

Neonatal outcomes were reassuring. Fetal heart rates remained comparable and Apgar scores were similar between groups, with a five-minute score of 10 reported in both groups. The study was not sufficiently large to exclude uncommon neonatal adverse effects, but its findings did not demonstrate an apparent difference in neonatal well-being between the two concentrations.

An important practical finding is that both groups maintained maternal cooperation with minimal motor impairment and Ramsay sedation score 2. Preservation of motor function is a key goal of labour analgesia because excessive motor block may interfere with maternal mobility and bearing down. The low-concentration ropivacaine regimen used in this study may have contributed to this favourable profile.

CONCLUSION

In primigravida parturients undergoing term spontaneous labour, epidural 0.2% ropivacaine combined with dexmedetomidine 0.2 or 0.5 μg/mL provided effective analgesia with stable maternal haemodynamics, minimal motor impairment, preserved maternal alertness and reassuring neonatal outcomes. The 0.5 μg/mL concentration produced a numerically longer duration of analgesia and fewer top-ups, but these differences were not statistically significant. Larger, adequately powered multicentre trials are required to determine whether the higher concentration provides a clinically meaningful benefit.

Conflict of Interest: None.

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