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## "A Synergistic Approach to Labor Analgesia: Bupivacaine Alone Versus Its Combination with Clonidine"

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### **Abstract:**

**Background:** Epidural labour analgesia is the gold standard for providing effective pain relief during childbirth. While bupivacaine is commonly used, adjuvants like clonidine may enhance its efficacy without the side effects of opioids. This study compares the efficacy and safety of 0.125% bupivacaine alone versus in combination with 60 mcg clonidine for epidural labour analgesia.

**Methods:** In this prospective, randomized comparative study, 100 term parturients (ASA I/II) were divided into two equal groups. Group A received 0.125% bupivacaine alone, while Group B received 0.125% bupivacaine with 60 mcg clonidine. Parameters evaluated included onset and duration of analgesia, number of top-up doses, hemodynamic changes, sedation, ambulation, mode of delivery, maternal satisfaction, neonatal Apgar scores, and side effects. **Results:** The onset of analgesia was similar between Group A ( $9.94 \pm 1.01$  min) and Group B ( $9.7 \pm 8.14$  min) ( $p = 0.196$ ). Duration of analgesia was significantly longer in Group B ( $102.88 \pm 12.4$  min) compared to Group A ( $46.36 \pm 11.92$  min) ( $p < 0.05$ ). Group B also required fewer top-ups (only 2% needed 3 top-ups) versus Group A (48%) ( $p < 0.05$ ). Two-segment regression time was longer in Group B ( $108.86 \pm 12.3$  min) than Group A ( $50.92 \pm 12.62$  min). Mild sedation was observed in 40% of Group B. Hemodynamic parameters were stable, with some significant differences in systolic BP and heart rate favoring Group A. Apgar scores at 1 and 5 minutes were comparable. Maternal satisfaction was higher in Group B (44% rated "excellent") versus Group A (22%) ( $p < 0.05$ ). **Conclusion:** Clonidine as an adjuvant to bupivacaine provides prolonged analgesia, reduces top-up needs, and improves maternal satisfaction without adverse maternal or neonatal effects.

**Keywords:** Epidural analgesia, bupivacaine, clonidine, labour pain, maternal satisfaction, neonatal outcome, hemodynamic stability.

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### **Introduction:**

"The delivery of the infant into the arms of a conscious and pain-free mother is one of the most exciting and rewarding moments in medicine."— *Moir* [1]

Labour is a universally painful process, shaped by neurological transmission and a woman's cognitive-emotional response to stimuli. As Sir James Young Simpson

described in 1848, the suffering during childbirth often exceeds what is tolerable under ordinary circumstances [2]. For centuries, various pain-relieving methods were attempted, but the use of labour analgesia was restricted until the late 19th century due to religious and medical opposition. Pain was thought to be biologically valuable. This view changed as the physiological harms of unrelieved labour pain became evident [3]. A major turning point occurred when Queen Victoria received chloroform during the birth of Prince Leopold in 1853, bringing obstetric analgesia into broader acceptance [4].

Many techniques, such as opioids and inhalational agents, have been trialed but showed limited efficacy and safety. Spinal anaesthesia, though effective, was associated with significant hypotension and motor block, while caudal blocks eventually gave way to epidural analgesia, now considered the gold standard [5,6]. To improve mobility and reduce side effects, dilute concentrations of local anaesthetics with adjuvants are being explored. Opioids like fentanyl and sufentanil are commonly added but can cause sedation, pruritus, shivering, and reduced neonatal APGAR scores [5,7]. Clonidine, a non-opioid alpha-2 agonist, offers analgesia and local anaesthetic-sparing benefits when combined with Bupivacaine [8–11]. A 60-µg clonidine dose was selected in this study, as lower doses are less effective [11], while higher doses may cause bradycardia, sedation, and fetal heart rate disturbances [7,8,12]. Bupivacaine 0.125% was chosen to balance analgesia with minimal motor blockade—an optimal concentration between 0.0625% and 0.25% [13,14]. This study evaluates the efficacy and safety of adding clonidine (60 µg) to 0.125% Bupivacaine in epidural labour analgesia, focusing on analgesia quality, labour progression, ambulation, delivery mode, fetal outcomes, satisfaction, and side effects.

### **Aim & Objectives:**

The primary aim of this study is to provide effective and continuous analgesia during childbirth while ensuring maternal comfort and safety. It seeks to reduce the stress of labour, maintain hemodynamic stability, and avoid respiratory depression or complications associated with analgesic techniques. Additionally, the goal is to preserve maternal consciousness throughout labour and ensure the delivery of a healthy, crying new-born.

The objectives of the study are to compare the efficacy of epidural Bupivacaine alone versus Bupivacaine with Clonidine, assess maternal acceptability and satisfaction with the analgesic method, and evaluate both maternal and fetal outcomes.

**Material and methods:**

Study was conducted over a two-year period, from January 2022 to December 2023, at the Dr DY Patil Medical college, Pune, Maharashtra.

**Study Design and Participants:** This randomized comparative study included 100 healthy term parturients (ASA physical status I or II), aged 20–35 years, admitted in active labour with singleton pregnancies and cephalic presentation. All participants had cervical dilatation of at least 3 cm and were eligible for epidural labour analgesia. Patients were randomly allocated into two equal groups (n=50 each):

- **Group A:** Received 10 mL of 0.125% Bupivacaine alone.
- **Group B:** Received 10 mL of 0.125% Bupivacaine combined with 60 µg Clonidine.

Top-up doses of 5–7 mL was administered upon maternal complaint of pain or when visual analogue scale (VAS) score exceeded 4. **Inclusion and Exclusion Criteria:** All included parturients were in active labour with term gestation, singleton pregnancy, and cephalic presentation. Exclusion criteria were as follows:

- **Anaesthetic contraindications:** Patient refusal, infection at the injection site, known hypersensitivity to anaesthetic agents, or bleeding disorders.
- **Obstetric contraindications:** Cephalopelvic disproportion, eclampsia, and diabetes mellitus.

**Pre-procedural Assessment:** On admission, a detailed medical, obstetric, and anaesthetic history was taken, followed by physical and obstetric examinations. Baseline investigations included haemoglobin estimation, blood grouping and typing, and urine analysis. The procedure was explained in the local language, and informed written consent was obtained from the parturient and a responsible attendant.

**Equipments and Drugs**

The following were used:

- **Epidural equipment:** 18G Tuohy needle and sterile catheter set.
- **Syringes and needles:** 2 mL, 5 mL, and 10 mL syringes; 18G, 22G, and 24G hypodermic needles.
- **Sterilization and disposables:** Autoclaved instruments; gamma-sterilized epidural set; sterile swabs, gloves, and antiseptic solutions.
- **Drugs:** 0.125% Bupivacaine, Clonidine (60 µg), Ranitidine (1 mg/kg), and Metoclopramide (0.2 mg/kg).

- **Emergency setup:** Airway equipment (ET tubes, laryngoscope, Ambu bag, oxygen, suction) and resuscitation drugs were available throughout.

#### Procedure

Patients were preloaded with Ringer lactate (20 mL/kg) and premedicated with intravenous Ranitidine and Metoclopramide. Standard monitors including non-invasive blood pressure (NIBP), electrocardiography (ECG), and pulse oximetry were applied.

In the left lateral flexed position, the lumbar area was prepared using antiseptic technique. The epidural space was identified at the L3–L4 or L4–L5 interspace using the loss of resistance technique via an 18G Tuohy needle. A catheter was threaded 4 cm into the epidural space, and the needle was withdrawn.

The assigned drug solution (either Bupivacaine 0.125% alone or with Clonidine 60 µg) was administered in a 10 mL dose. Top-ups were administered as needed based on pain scores, without an initial test dose. Vital signs and pain levels were closely monitored following each dose.

#### Monitoring and Outcome Assessment

Patients were observed for:

- **Onset of analgesia:** Time from drug administration to first painless contraction ( $VAS \leq 3$ ).
- **Duration of analgesia:** Time from analgesia onset to the first top-up.
- **Pain score monitoring:** VAS and hemodynamic parameters were recorded at 1, 5, 10, 15, 30, 45, 60, 90, 120, 150, 180, 210, and 240 minutes.
- **Labour progress:** Total duration was calculated from catheter placement (3 cm dilatation) to delivery.
- **Ambulation ability:** Graded as independent with assistance, partial difficulty, or inability to walk.
- **Sedation:** Evaluated using the Ramsay Sedation Scale.
- **Fetal well-being:** Assessed by cardiotocography and Apgar scores at 1 and 5 minutes.
- **Side effects:** Maternal hypotension ( $>20\%$  drop in systolic BP), bradycardia ( $HR < 60$  bpm), sedation, respiratory depression, pruritus, nausea, and vomiting.

Catheters were removed after episiotomy repair and inspected for intactness. Maternal satisfaction with analgesia was assessed on the next day using a 4-point scale: Excellent, Good, Fair, or Poor.

**Pain Assessment Tool:** Pain relief was measured using a 10-cm Visual Analogue Scale (VAS), ranging from 0 (no pain) to 10 (worst imaginable pain), explained to patients using color-coded ends for clarity. **Statistical Analysis:** Data were expressed as mean  $\pm$  standard deviation (SD). Group comparisons were performed using Student's *t*-test for continuous variables and Chi-square test for categorical data. A *p*-value  $<0.05$  was considered statistically significant.

### Results and observations:

This prospective, comparative study was conducted on 100 healthy term parturients (ASA Grade I and II), randomly divided into two groups:

- **Group A** received 0.125% Bupivacaine alone
- **Group B** received 0.125% Bupivacaine + 60 mcg Clonidine

Demographic variables, onset and duration of analgesia, need for top-up doses, side effects, maternal satisfaction, and neonatal outcomes were compared.

**Table 1: Demographic Characteristics**

Parameter	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	P value
Age (years)	23.82 $\pm$ 2.42	23.16 $\pm$ 2.16	0.15 (NS)
Weight (kg)	56.12 $\pm$ 2.98	56.04 $\pm$ 2.98	0.89 (NS)
Height (cm)	154.86 $\pm$ 3.98	154.70 $\pm$ 4.11	0.86 (NS)

Both groups were demographically comparable. The mean age in Group A was 23.82  $\pm$  2.42 years, while in Group B it was 23.16  $\pm$  2.16 years. The average body weight and height were similar across both groups, with no statistically significant differences ( $p > 0.05$ ). This indicates that the two groups were homogenous in terms of baseline characteristics, ensuring a fair comparison of outcomes.

**Table 2: Onset of Analgesia**

Groups	Mean $\pm$ SD (min)	P value
Group A	9.94 $\pm$ 1.01	0.196 (NS)
Group B	9.7 $\pm$ 8.14	

The mean onset of analgesia, measured from drug administration to the first painless contraction (VAS  $\leq 3$ ), was slightly shorter in Group B (9.7  $\pm$  8.14 min) compared to Group A (9.94  $\pm$  1.01 min). However, this difference was not statistically significant ( $p = 0.196$ ), suggesting that the addition of clonidine did not markedly alter the time of onset.

**Table 3: Duration of Analgesia**

Group	Mean $\pm$ SD (min)	P value
Group A	46.36 $\pm$ 11.92	< 0.05 (HS)
Group B	102.88 $\pm$ 12.40	

A significant difference was noted in the duration of analgesia between the two groups. Group A had a mean analgesia duration of 46.36  $\pm$  11.92 minutes, whereas Group B showed a markedly prolonged duration of 102.88  $\pm$  12.40 minutes. This was statistically highly significant ( $p < 0.05$ ), indicating a synergistic effect of clonidine in enhancing and prolonging pain relief.

**Table 4: Number of Top-Up Doses**

Number of Top-Ups	Group A (n=50)	Group B (n=50)	P value
1	5 (10%)	19 (38%)	< 0.05 (S)
2	21 (42%)	30 (60%)	< 0.05 (S)
3	24 (48%)	1 (2%)	< 0.05 (S)

The requirement for top-up doses was notably different between the groups. Group A had a higher percentage of patients (48%) needing 3 top-ups, while only 2% in Group B required the same. Conversely, a larger proportion of patients in Group B (38%) achieved satisfactory analgesia with a single top-up compared to just 10% in Group A. These differences were statistically significant ( $p < 0.05$ ), highlighting the efficiency of clonidine in reducing the need for additional dosing.

**Table 5: Two-Segment Recession Time**

Groups	Mean $\pm$ SD (min)	P value
Group A	50.92 $\pm$ 12.62	< 0.05 (HS)
Group B	108.86 $\pm$ 12.30	

The mean time for two-segment sensory level recession was significantly longer in Group B (108.86  $\pm$  12.30 min) than in Group A (50.92  $\pm$  12.62 min), with  $p < 0.05$ . This finding supports the extended duration of sensory blockade with clonidine, thereby contributing to prolonged analgesia.

**Table 6: Total Duration of Labour**

Group	Mean $\pm$ SD (min)	P value
Group A	247.5 $\pm$ 58.11	0.0506 (NS)
Group B	228.4 $\pm$ 35.76	

The total labour duration from epidural insertion to delivery was slightly shorter in Group B ( $228.4 \pm 35.76$  min) compared to Group A ( $247.5 \pm 58.11$  min). Although this difference approached significance, it was not statistically significant ( $p = 0.0506$ ). Nonetheless, the trend suggests that improved analgesia might facilitate smoother labour progression.

**Table 7: Sedation Score (Ramsay Score)**

Sedation Level	Group A (n=50)	Group B (n=50)
Score 2	50 (100%)	30 (60%)
Score 3	0	19 (38%)
Score 4	0	1 (2%)

All parturients in Group A had a Ramsay sedation score of 2, indicating they were calm and cooperative. In contrast, 60% of Group B patients had a score of 2, 38% scored 3 (responding only to commands), and 2% reached score 4 (brisk response to stimulus). This shows that clonidine caused mild sedation in some patients without deep sedation or respiratory compromise.

**Table 8: Ambulation Ability**

Ambulation Grade	Group A (n=50)	Group B (n=50)
Could walk with difficulty with support	50 (100%)	48 (96%)
Could walk with difficulty (without support)	0	2 (4%)
Could not walk	0	0

All patients in Group A could ambulate with difficulty and required support. In Group B, while 96% needed support, 4% could ambulate with difficulty without assistance. No patient in either group was unable to walk, indicating preservation of motor function with both regimens.

**Table 9: Mode of Delivery**

Mode of Delivery	Group A (n=50)	Group B (n=50)	P value
Spontaneous	50 (100%)	49 (98%)	> 0.05 (NS)
LSCS / Instrumental	0	1 (2%)	

Spontaneous vaginal delivery was achieved in all patients in Group A and in 98% of Group B. One patient in Group B required instrumental or caesarean delivery. The difference was not statistically significant ( $p > 0.05$ ), implying that addition of clonidine did not negatively influence labour outcomes.



**Table 10: Neonatal APGAR Score**

Time Point	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	P value
1 minute	8.34 $\pm$ 0.86	7.98 $\pm$ 0.76	0.053 (NS)
5 minutes	10	10	NS

The mean APGAR scores at 1 and 5 minutes were similar in both groups. Group A had a slightly higher 1-minute score (8.34  $\pm$  0.86) compared to Group B (7.98  $\pm$  0.76), but this was not statistically significant ( $p = 0.053$ ). At 5 minutes, all neonates in both groups had a perfect score of 10, indicating no adverse neonatal effects.

**Table 11: Side Effects**

Side Effect	Group A (n=50)	Group B (n=50)
Nausea	4 (8%)	5 (10%)
Vomiting	2 (4%)	1 (2%)
Shivering	1 (2%)	1 (2%)
Others (pruritus, respiratory depression, etc.)	0	0

Minor side effects such as nausea, vomiting, and shivering were observed at low and comparable frequencies in both groups. Nausea occurred in 8% of Group A and 10% of Group B, while vomiting and shivering were rare and evenly distributed. No major complications like pruritus, sedation-related respiratory depression, or hypotension were noted.

**Table 12: Maternal Satisfaction**

Satisfaction Score	Group A (n=50)	Group B (n=50)	P value
Excellent	11 (22%)	22 (44%)	< 0.05 (S)
Good	38 (76%)	28 (56%)	< 0.05 (S)
Fair	0	0	
Poor	1 (2%)	0	

Maternal satisfaction was notably higher in Group B, where 44% rated their experience as “excellent” compared to 22% in Group A. “Good” ratings were more common in Group A (76%) than in Group B (56%). Only 1 patient in Group A rated the experience as “poor,” while none in Group B did. This difference was statistically significant ( $p < 0.05$ ), affirming better subjective pain control with the Bupivacaine - Clonidine combination.

**Table 13: Maternal Heart Rate**

Interval (min)	Group A HR (Mean $\pm$ SD)	Group B HR (Mean $\pm$ SD)	P value
0	94.78 $\pm$ 11.96	96.52 $\pm$ 4.59	>0.05 NS
5	92.96 $\pm$ 9.13	93.74 $\pm$ 4.89	>0.05 NS
10	92.16 $\pm$ 6.53	91.30 $\pm$ 4.91	>0.05 NS
15	89.62 $\pm$ 8.35	87.26 $\pm$ 4.57	<0.05 S
30	91.44 $\pm$ 9.86	86.84 $\pm$ 4.58	<0.05 S
60	94.26 $\pm$ 7.37	85.94 $\pm$ 4.53	<0.05 S
90	90.50 $\pm$ 6.53	91.94 $\pm$ 6.05	>0.05 NS
120	90.54 $\pm$ 5.91	93.84 $\pm$ 6.04	>0.05 NS
150	94.30 $\pm$ 4.62	89.46 $\pm$ 5.75	<0.05 S
180	89.87 $\pm$ 6.92	87.43 $\pm$ 4.54	>0.05 NS
210	88.61 $\pm$ 6.08	88.38 $\pm$ 7.10	>0.05 NS
240	89.71 $\pm$ 3.95	86.18 $\pm$ 5.06	>0.05 NS
270	91.61 $\pm$ 5.38	85.66 $\pm$ 1.96	>0.05 NS

This table shows the maternal heart rate variation over time in both study groups. Initially, both groups had comparable baseline heart rates. Group A (Bupivacaine) demonstrated minor fluctuations with no clinically significant bradycardia. In contrast, Group B (Bupivacaine + Clonidine) showed a more pronounced decrease in heart rate, with statistically significant differences observed at 15, 30, 60, and 150 minutes when compared to Group A ( $p < 0.05$ ). However, in all cases, heart rate remained well above 60 bpm, and none of the parturients required pharmacologic or supportive interventions, indicating that the addition of clonidine, while contributing to mild bradycardia, did not compromise maternal safety.

**Table 14: Maternal Systolic Blood Pressure (mmHg)**

Interval (min)	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	P value
Baseline	108.72 $\pm$ 8.07	111.16 $\pm$ 4.70	—
5	110.18 $\pm$ 6.70	107.76 $\pm$ 5.90	>0.05 NS
10	107.68 $\pm$ 4.89	103.84 $\pm$ 2.51	<0.05 S
15	101.60 $\pm$ 4.37	100.74 $\pm$ 3.18	<0.05 S
30	104.88 $\pm$ 5.14	100.76 $\pm$ 2.45	<0.05 S
60	104.84 $\pm$ 7.09	102.68 $\pm$ 3.17	<0.05 S
90	109.12 $\pm$ 7.66	104.08 $\pm$ 2.90	<0.05 S
120	105.60 $\pm$ 5.77	103.16 $\pm$ 4.86	>0.05 NS
150	108.60 $\pm$ 5.24	102.40 $\pm$ 3.28	<0.05 S
180	105.87 $\pm$ 7.31	104.25 $\pm$ 3.21	<0.05 S
210	106.09 $\pm$ 6.24	105.12 $\pm$ 3.86	>0.05 NS
240	107.33 $\pm$ 3.84	105.29 $\pm$ 4.29	>0.05 NS

270	107.00 ± 4.60	104.00 ± 4.16	>0.05 NS
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Systolic blood pressure was closely monitored throughout the procedure, showing a downward trend in both groups post-initiation of analgesia. Group B exhibited a more consistent and greater reduction from baseline than Group A, with statistically significant differences noted from 10 to 180 minutes ( $p < 0.05$ ). Despite this, the reduction in systolic pressure never exceeded 20% of baseline values in either group. This indicates that while the combination of clonidine with bupivacaine may cause a greater hypotensive effect, it remains within a clinically acceptable range without necessitating the use of vasopressors or inotropic agents.

**Table 15: Maternal Diastolic Blood Pressure (mmHg)**

Interval (min)	Group A (Mean ± SD)	Group B (Mean ± SD)	P value
Baseline	77.52 ± 6.44	75.64 ± 4.92	—
5	77.68 ± 4.90	75.84 ± 4.80	>0.05 NS
10	79.60 ± 3.63	74.88 ± 4.68	<0.05 S
15	78.32 ± 5.87	76.52 ± 4.97	>0.05 NS
30	79.56 ± 3.50	78.04 ± 4.80	>0.05 NS
60	79.24 ± 3.24	77.56 ± 5.16	>0.05 NS
90	80.04 ± 2.57	78.84 ± 4.42	>0.05 NS
120	79.36 ± 4.41	77.40 ± 6.86	>0.05 NS
150	76.72 ± 5.80	74.80 ± 4.42	>0.05 NS
180	79.29 ± 4.07	77.53 ± 4.77	>0.05 NS
210	79.31 ± 3.18	75.12 ± 5.06	>0.05 NS
240	71.33 ± 2.67	69.80 ± 0.49	>0.05 NS
270	82.23 ± 2.73	71.42 ± 3.77	>0.05 NS

Diastolic blood pressure values remained largely stable across both groups. A statistically significant reduction was noted at the 10-minute interval, particularly in Group B, but subsequent measurements revealed minimal deviation from baseline. No time point showed a drop exceeding 20% from the initial value. Importantly, all observed changes were hemodynamically well-tolerated by the patients, and no therapeutic interventions were required. These findings suggest that the diastolic component of blood pressure is less affected than systolic pressure by the addition of clonidine.

**Table 16: Foetal Heart Rate (beats/min)**

Interval (min)	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	P value
Baseline	145.00 $\pm$ 4.54	146.42 $\pm$ 2.30	>0.05 NS
5	144.62 $\pm$ 3.59	145.16 $\pm$ 3.10	>0.05 NS
10	143.86 $\pm$ 2.89	143.74 $\pm$ 5.11	>0.05 NS
15	143.12 $\pm$ 3.59	142.54 $\pm$ 7.11	>0.05 NS
30	144.20 $\pm$ 4.17	145.00 $\pm$ 2.69	>0.05 NS
60	143.48 $\pm$ 3.90	144.56 $\pm$ 2.55	>0.05 NS
90	141.80 $\pm$ 3.97	144.34 $\pm$ 4.71	>0.05 NS
120	142.92 $\pm$ 4.58	143.60 $\pm$ 3.80	>0.05 NS
150	145.06 $\pm$ 4.01	144.26 $\pm$ 2.27	>0.05 NS
180	145.04 $\pm$ 4.67	142.71 $\pm$ 2.35	>0.05 NS
210	145.23 $\pm$ 3.30	142.20 $\pm$ 3.29	>0.05 NS
240	145.82 $\pm$ 5.87	145.46 $\pm$ 3.07	>0.05 NS
270	144.07 $\pm$ 4.79	144.00 $\pm$ 0.81	>0.05 NS

Foetal heart rate was maintained within a normal physiological range (140–150 bpm) in both groups throughout labor analgesia. There were no statistically significant differences between Group A and Group B at any recorded interval ( $p > 0.05$ ). The trends suggest stable foetal well-being in both groups. However, one foetus in Group B developed distress necessitating caesarean section; this was associated with meconium-stained liquor and not linked to any maternal hemodynamic instability, implying it may be unrelated to the analgesic technique. Overall, the data affirm the safety of both regimens in terms of foetal cardiac response.

**Discussion:** The present study evaluates the analgesic efficacy, hemodynamic effects, maternal satisfaction, and neonatal outcomes of 0.125% bupivacaine alone versus 0.125% bupivacaine combined with 60  $\mu$ g clonidine in epidural labour analgesia. The findings strongly support that clonidine, as an adjuvant, enhances analgesic duration, reduces the need for top-up doses, and improves maternal satisfaction without compromising maternal or foetal safety.

### 1. Duration and Onset of Analgesia

The duration of analgesia was significantly longer in Group B (bupivacaine + clonidine) at  $102.88 \pm 12.40$  minutes compared to  $46.36 \pm 11.92$  minutes in Group A ( $p < 0.05$ ), clearly demonstrating the analgesia-prolonging effect of clonidine. The onset of analgesia was comparable between groups ( $p = 0.196$ ), suggesting clonidine does not delay pain relief initiation. These results are in agreement with the study by Syal et al., who also used 60  $\mu$ g clonidine and found a significantly prolonged duration of labour analgesia and reduced requirement for supplemental doses, without delay in onset or adverse neonatal outcomes

[15]. Bajwa et al. also reported similar findings in their comparison of ropivacaine with and without clonidine for labour analgesia, showing prolonged analgesia with fewer top-ups in the clonidine group [16]. Likewise, Mishra et al. observed extended analgesic duration when levobupivacaine was combined with clonidine compared to levobupivacaine-fentanyl combination [17].

## **2. Analgesic Top-Up Requirements**

Our study found a significant reduction in the number of top-up doses required in the clonidine group. Only 2% of patients in Group B needed 3 top-ups compared to 48% in Group A, with a greater proportion requiring only a single top-up (38% vs. 10%). This aligns with results by Ninave and Agarwal, who also reported decreased need for supplemental dosing in the clonidine group receiving ropivacaine–clonidine combination [18].

## **3. Maternal Hemodynamic Parameters**

Maternal heart rate and systolic blood pressure showed statistically significant decreases at multiple time intervals in the clonidine group. However, the reduction never exceeded 20% of baseline, and no intervention was needed, confirming clinical safety. These findings are consistent with studies by Syal et al. and Bajwa et al., both of which reported minor hemodynamic variations with clonidine use that were clinically insignificant and self-limiting [15,16]. Diastolic pressure remained relatively stable, with only transient, non-significant reductions observed, further reinforcing the cardiovascular safety profile of clonidine at the studied dose. Eisenach et al. in their review of  $\alpha_2$ -agonists also highlighted the dose-dependent but generally well-tolerated cardiovascular effects of clonidine in neuraxial anesthesia [19].

## **4. Sedation and Motor Function**

A mild increase in sedation (Ramsay Score 3 or 4) was observed in 40% of patients in Group B, but none had respiratory depression. Similar findings were reported by Bajwa et al. and Mishra et al., where mild sedation was seen without adverse respiratory or neurological outcomes [16,17]. Importantly, motor function was preserved in all cases, with 96% in Group B able to walk with support and 4% unaided, reflecting that the low bupivacaine concentration-maintained ambulation while providing effective analgesia.

## **5. Labour Progress and Delivery Outcome**

The total duration of labour was slightly shorter in the clonidine group ( $228.4 \pm 35.76$  min vs.  $247.5 \pm 58.11$  min), although not statistically significant ( $p = 0.0506$ ). The mode of delivery was predominantly spontaneous in both groups (98–100%), with only one instrumental/LSCS delivery in Group B. These

findings align with results from prior Indian studies, where clonidine use did not alter the course of labour or increase the risk of caesarean delivery [15,16,18].

## 6. Neonatal Outcomes

Apgar scores at 1 and 5 minutes were similar in both groups. While the 1-minute score was marginally lower in Group B, the difference was not statistically significant ( $p = 0.053$ ), and all neonates had a perfect Apgar score of 10 at 5 minutes. Similar neonatal safety outcomes have been consistently reported in multiple Indian and international trials [15,16,18].

## 7. Maternal Satisfaction and Side Effects

Maternal satisfaction was significantly higher in the clonidine group, with 44% rating their experience as “excellent” versus 22% in the bupivacaine-only group ( $p < 0.05$ ). This subjective improvement in analgesic quality without increased complications or labour interference supports clonidine’s use as a beneficial adjuvant. Side effects such as nausea, vomiting, and shivering were infrequent and comparable between groups, echoing previous findings [15–18].

**Conclusion:** This study demonstrates that adding 60 µg clonidine to 0.125% bupivacaine for epidural labour analgesia significantly prolongs the duration of analgesia, reduces the frequency of top-up doses, and enhances maternal satisfaction compared to bupivacaine alone. While mild reductions in maternal heart rate and systolic blood pressure were observed in the clonidine group, they remained within safe limits and required no medical intervention. Motor function and ambulation were well preserved in both groups. Neonatal outcomes, including Apgar scores, were comparable, indicating no adverse effects on the fetus. Mild sedation was noted in some patients with clonidine but without respiratory depression. These findings support the safe and effective use of clonidine as a non-opioid adjuvant in labour epidural analgesia, offering improved analgesic quality and maternal experience.

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