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Original Research Article

Effect of Patient Controlled Epidural Analgesia with Ropivacaine and Fentanyl on Labour With and Without Mandatory Bolus: A Randomized Controlled Trial

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Abstract

Background: Epidural analgesia is among the most effective methods for intrapartum pain relief. Patient-controlled epidural analgesia (PCEA) has become increasingly popular technique for this, especially after advent of ropivacaine, with ongoing debate regarding the role of background or mandatory bolus infusions in optimizing analgesia and maternal satisfaction.

Methods: A prospective randomized double-blinded intervention study was conducted on ninety parturients in active labour which were randomized into 2 groups to receive either PCEA alone or PCEA with an hourly mandatory bolus using 0.125% ropivacaine with fentanyl (2 µg/mL). The primary outcomes were analgesia quality (measured by VAS) and total drug consumption. Secondary outcomes included maternal satisfaction, mode of delivery, neonatal Apgar scores, and incidence of motor block. Data were analysed using Student's t-test and chi-square test, with $p < 0.05$ considered significant.

Results: Both groups achieved effective labour analgesia. The mean number of demand boluses was significantly lower in Group PCEA+MB (0.33 ± 0.47) compared to Group PCEA (3.08 ± 0.73; $p < 0.001$). Mean total epidural drug consumed in group PCEA+MB was 26.91± 4.23 ml and in group PCEA was 25.62± 2.71 ml which was not significantly different ($p = 0.089$). Maternal satisfaction was significantly higher in Group PCEA+MB. Obstetric and neonatal outcomes, including Apgar scores and motor block incidence, were similar.

Conclusion: Addition of mandatory bolus to PCEA with ropivacaine and fentanyl resulted in more efficient pain relief with less demand of rescue top ups and increased maternal satisfaction without any significant side effects among parturients.

Keywords: Labour analgesia, patient-controlled epidural analgesia, ropivacaine, fentanyl, maternal satisfaction.

Introduction

Labour pain is among the most intense forms of physiological pain experienced by women, resulting from complex interactions between physiological, psychological, and social factors.[1] Epidural analgesia has long been known to effectively attenuate labour pain. It is administered as a continuous infusion via a catheter placed in the epidural space, with or without the option for the patient to self-administer supplemental doses through a programmable pump—known as patient-controlled epidural analgesia (PCEA).

PCEA is a safe and effective technique that improves maternal satisfaction, reduces delays in drug delivery, and decreases nursing intervention. It also enhances the self-esteem of parturients by giving them greater control over their pain. [2,3] However, the potential benefit of adding mandatory boluses (MB) to PCEA is still under evaluation. The addition of epidural opioids to local anaesthetics reduces the required dose of local anaesthetic, thereby decreasing the incidence of maternal hypotension and motor blockade while prolonging the duration of labour analgesia. [4,5]

This benefit is most commonly demonstrated when fentanyl is added to ropivacaine for labour analgesia. Ropivacaine, when combined with fentanyl, provides effective analgesia with minimal motor blockade and fewer maternal or foetal side

effects compared to bupivacaine. Despite the proven efficacy of PCEA in providing labour analgesia, breakthrough pain remains a concern, particularly during the later stages of labour when contractions intensify. This may necessitate repeated on-demand boluses, increasing maternal discomfort and workload for caregivers. The addition of mandatory (programmed) boluses at fixed intervals may help maintain a more uniform block, improve drug spread in the epidural space, prevent breakthrough pain, and enhance the overall quality of analgesia without increasing total drug consumption. [6,7] However, limited published data exist comparing PCEA alone versus PCEA with mandatory boluses using a ropivacaine–fentanyl combination in Indian parturients. [8]

Therefore, this study was undertaken with an objective to evaluate whether the addition of mandatory boluses to PCEA improves the quality and duration of labour analgesia, reduces the need for additional top-up doses, and enhance maternal satisfaction while maintaining maternal and neonatal safety.

Material and Method

This prospective, randomized, controlled study was conducted after obtaining approval from the Institutional Ethics Committee (Approval No. F1/Acad/MC/JU/17/17559) and written informed consent from all participants.

Ninety ASA II parturients, aged more than 18 years, weight less than 100 kg and height 150 cm or more, in active labour with singleton pregnancies at term, primigravida or second gravida (previously normal vaginal delivery) and who were able to use the PCEA pump were included in the study. The parturients with any obstetric complications, opioid dependence, local infection at site of injection, allergy to local anaesthetics, foetal anomalies and history of coagulation disorders were excluded from the study.

Sample size was calculated on basis of previous study by Bullingham A et al [9] and 45 patients in each group were needed to detect an inter-group difference with 5% error and 80% power at 95% confidence interval.

Before insertion of epidural for labour analgesia demographic data, parity, gestational age, condition of membrane, cervical dilatation, vital parameters, baseline VAS (Visual analogue scale) and foetal heart rate were noted.

Randomization and Blinding: Participants were randomized into two groups (n = 45 each) using a computer-generated randomization sequence. The PCEA pumps were placed inside opaque covers to ensure blinding of the investigator and participants regarding group allocation.

Group PCEA: PCEA without background infusion.

Group PCEA+MB: PCEA with an additional programmed mandatory bolus of 5 mL every 60 minutes.

Epidural Technique

Standard monitors were applied (ECG, non-invasive blood pressure, pulse oximetry). After preloading with 500 mL Ringer's lactate, epidural placement was performed at the L2–L3 interspace using an 18G Tuohy needle and catheter. Correct placement was confirmed with a test dose. A loading dose of 10 mL of 0.125% ropivacaine with fentanyl 2 µg/mL was administered to achieve a T8–T10 sensory level.

PCEA settings were standardized:

Bolus dose: 5 mL, Lockout interval: 20 minutes, Maximum dose: 10 mL/h

Both groups used identical epidural solutions (ropivacaine 0.125% + fentanyl 2 µg/mL). All pumps were covered with an opaque portable bag to ensure blinding of investigator.

Participants were trained to press the demand button when VAS ≥ 4.

Outcome Measures

Primary outcomes measured were quality of analgesia (VAS 0–10), total local anaesthetic consumption.

Secondary outcomes measured were maternal satisfaction, mode and duration of delivery, motor block (Bromage score), neonatal Apgar scores, maternal and neonatal side effects.

The onset of analgesia was defined as the time from drug administration to VAS < 3. The level of maternal satisfaction was measured using five-point Likert scale (1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, and 5 = very satisfied)

The investigator assessing outcomes (VAS, satisfaction, motor block, neonatal parameters) was blinded to group allocation

Statistical Analysis: Data were analysed using SPSS v21. Continuous variables were expressed as mean ± SD and compared using Student's t-test. Categorical variables were analysed with chi-square test. A p-value <0.05 was considered significant.

Results

All 90 parturients completed the study. The demographic and obstetric variables—including

age, gestational age, weight, height, cervical dilatation, and cervical effacement—were comparable between the two groups ($p > 0.05$). The mean duration of the first and second stages of labour was also similar across groups ($p > 0.05$) (Table 1).

Both groups achieved adequate analgesia but significantly higher total number of demand boluses were required in PCEA group (3.08 ± 0.73) than PCEA+MB group (0.33 ± 0.47), $p<0.001$. In the PCEA+MB group, 15 parturients required a single bolus at 45 minutes, whereas in the PCEA group, 35 parturients required multiple boluses (3–4 boluses) at 45-minute intervals (Table 2).

The mean total volume of epidural drug consumed was comparable between the PCEA+MB (26.91 ± 4.23 ml) and PCEA groups (25.62 ± 2.71 ml) ($p = 0.089$). Total doses of ropivacaine and fentanyl administered were also statistically similar (Table 3).

Maternal satisfaction scores were higher in the PCEA+MB group, with most parturients rating their analgesic experience as "excellent" or "very satisfied." Obstetric outcomes—including mode of delivery, duration of labour, and rate of instrumental deliveries—were similar, with more than 90% achieving vaginal delivery ($p = 0.61$). Neonatal outcomes, including Apgar scores at 1 and 5 minutes, showed no significant difference between groups, and no adverse foetal effects were observed (Table 4).

No significant maternal side effects, including hypotension, motor blockade, nausea, vomiting, or pruritus, were reported in either group.

Table 1: Distribution of obstetric characteristics among study subjects in two groups

Parameter	PCEA + MB (n=45) Mean ± SD	PCEA (n=45) Mean ± SD	P value
Age (in years)	23.22±2.61	22.77±2.68	0.42
Gestational age (in weeks)	37.46±1.74	37.60±0.83	0.64
Weight (in kilograms)	58.68±2.14	58.71±2.09	0.96
Cervical dilatation (in cms)	4.48±0.50	4.44±0.54	0.68
Cervical effacement	80.22±11.17	80.88±10.83	0.77
Mean duration of first stage of labour (in mins)	135.82±14.62	134.44±15.04	0.660
Mean duration of second stage of labour (in mins)	39.55±6.72	40.55±7.24	0.499

Table 2: Number of demand top-up required by parturients in two groups

Top-up	PCEA + MB n (%)	PCEA n (%)	P value
0	30 (66.7)	00 (0.0)	<0.0001
1	15 (33.3)	00 (0.0)	<0.0001
2	00 (0.0)	10 (22.2)	0.001
3	00 (0.0)	21 (46.7)	<0.0001
4	00 (0.0)	14 (31.1)	<0.0001
Mean + SD	0.33±0.47	3.08±0.73	<0.0001

Table 3. Total amount of drug consumed

Total consumption	PCEA + MB	PCEA	P value
Ropivacaine (mg)	33.63 + 5.28	32.02 + 3.38	p>0.05
Fentanyl (mcg)	53.82 + 8.46	51.24+5.42	p>0.05
Mean volume of epidural drug consumed (ml)	26.91± 4.23	25.62± 2.71	0.08

Table 4: Maternal satisfaction score in two groups

Maternal satisfaction score	PCEA + MB n=45 (%)	PCEA n=45 (%)	P value
5	25 (55.5)	24 (53.3)	0.83
4	16 (35.5)	14 (31.1)	0.82
3	04 (8.8)	07 (15.5)	0.51
2/1	0	0	

Discussion

Modern obstetric anesthesia aims not only to relieve pain but also to improve maternal experience, minimize interventions, and ensure foetal safety. Among neuraxial techniques, epidural analgesia provides superior, titratable pain relief while preserving pelvic floor muscle tone.[10]

PCEA offers several advantages, including individualized dosing, reduced anaesthetist intervention, and improved maternal satisfaction.

However, breakthrough pain remains a limitation, especially during the active and late stages of labour. In this study, the addition of an hourly mandatory bolus to PCEA significantly reduced the number of demand boluses and increased satisfaction, without raising total anaesthetic consumption.

These findings are consistent with prior studies. Kalra et al [11] and Tomar et al [12] similarly reported that PCEA combined with background or mandatory boluses decreases breakthrough pain episodes. Lim and Sia [13] found that demand-only PCEA resulted in higher pain scores and lower satisfaction compared with regimens incorporating supplemental boluses. Our results also align with recent randomized controlled trials by Mazda et al [14] and Capogna et al [15], both demonstrating that combining PCEA with basal or programmed boluses improves analgesic stability while maintaining safety.

The total volume of epidural drug consumed was comparable between groups and consistent with previous findings by Tomar et al. [12] This comparable drug consumption suggests that intermittent boluses may facilitate a more uniform epidural spread, enhancing analgesia without increasing total anaesthetic use. Both groups achieved adequate labour analgesia and high maternal satisfaction, as indicated by VAS scores below 3 throughout the study period.

PCEA is inherently subjective and depends on individual pain thresholds, allowing each parturient to use only the required dose of analgesics. [16,17] However, studies have shown that during advanced labour, pain intensity increases despite demand-only PCEA. The addition of mandatory boluses at timed intervals can therefore provide additional comfort during breakthrough pain without compromising obstetric or neonatal safety.[18]

Ocampo et al [19] reported a significant decrease in breakthrough pain and maximum pain scores in patients receiving PCEA with a basal infusion compared to PCEA alone. Similar findings were reported by Srivastava et al [20] and Bremerich et al. [21] Continuous epidural infusion techniques have been associated with higher total local anaesthetic consumption and cost without substantial benefit. [20,21]

A systematic review by Sng et al [22] emphasized that while background infusions may slightly increase instrumental delivery rates, they enhance overall analgesic efficacy. In our cohort, obstetric outcomes remained unaffected, likely due to the use of lower concentration local anaesthetics and carefully titrated bolus intervals. PCEA empowers the parturient to actively participate in her own pain management, promoting a sense of control and autonomy that contributes to higher satisfaction. No serious maternal or foetal side effects were noted during labour in either group. Nevertheless, continuous monitoring of analgesia quality, motor block, hemodynamics, and foetal heart rate remains essential. Both groups demonstrated high maternal satisfaction, with short-lived pain episodes being psychologically acceptable for most women.

Overall, PCEA with an hourly mandatory bolus enhances patient comfort, reduces anaesthetist workload, and provides consistent pain relief throughout labour without compromising maternal or neonatal safety.

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