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A randomized comparative study of patient-controlled epidural analgesia with manual standard intermittent bolus for labor analgesia

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ABSTRACT

Background: Patient-controlled epidural analgesia (PCEA) pump has proven to reduce the incidence of unscheduled clinician interventions and total dose of local anesthetic administered for labor pain. **Aims and Objectives:** The aim of the study was to compare the quality of analgesia, maternal satisfaction, amount of rescue analgesia needed, and neonatal outcome between clinician delivered manual bolus doses and PCEA pumps for epidural labor analgesia. **Materials and Methods:** 60 parturients of the American Society of Anesthesiologists II scheduled for normal vaginal delivery were randomly divided into two groups, Group A (PCEA) and Group B (Manual bolus). Both groups received an initial epidural bolus of 10 mL of 0.125% Inj. Bupivacaine + 20 mcg injection fentanyl. Group A (PCEA) patients received a basal infusion of 5 mL/h with self-administered bolus of 2 mL with a lockout interval of 15 min. Group B patients were provided with a bolus of 10 mL of the same solution manually after every hour. Patients of both groups were given manual rescue boluses for distressing pain (visual analog scale [VAS] >5). **Results:** Mean VAS score in Group A was 2.97 ± 0.73; and in Group B, it was 3.03 ± 0.56 (P > 0.05). Total bupivacaine use and mean duration of second stage of labor in both groups was found comparable. Mean top-up requirement of local anesthetics was significantly high in Group B. Maternal satisfaction was also higher in PCEA group. **Conclusion:** As PCEA pump provides continuous infusion of local anesthetics, there was lesser requirement of top ups of bupivacaine and higher maternal satisfaction score in PCEA group than manual bolus group.

Key words: Labor analgesia; Patient-controlled epidural analgesia; Visual analog scale

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INTRODUCTION

Pain relief is an important issue for women in labor. Women experience varying degrees of pain in labor and exhibit an equally varying range of responses to it.[1] The ideal labor analgesic should be easy to administer, should provide predictable and rapid onset of analgesia, should be devoid of motor block, and expulsive efforts should be preserved during the second stage of labor. Epidural analgesia is the gold standard for reducing pain during labor.[2] It leads to higher maternal satisfaction levels and good maternal and fetal safety profiles.

Epidural analgesia is usually maintained manually as intermittent boluses or continuously by electronic syringe pumps, elastomeric pumps, or using computerized infusion pumps. Continuous infusion of analgesics through an infusion pump reduces the variability of analgesia during labor by reducing the incidence of breakthrough pain and is associated with higher maternal satisfaction.[3]

Recent practice guidelines for obstetric anesthesia advise that basal infusion improves analgesia when provided as a part of a patient-controlled epidural analgesia (PCEA) regimen.[4,5] It has proven to reduce the incidence of unscheduled clinician interventions and the total dose of local anesthetic administered. It also reduces the incidence of lower extremity motor block.[6] As labor pain has highly variable intensity, and the character of the pain often

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changes as it progresses. Administration of PCEA allows for some self-titration at this level by the mother.

Aims and objectives

The purpose of the present study was to compare the quality of analgesia and material satisfaction between clinician delivered manual bolus doses and PCEA pumps during labor. We also intended to compare the dose of analgesic drug, amount of rescue analgesia, maternal hemodynamic changes, and neonatal Apgar scores between the two groups and also complications and side effects of both the techniques, if any.

MATERIALS AND METHODS

This randomized comparative study was conducted in Mahatma Gandhi Memorial Medical College and Maharaja Yashwantrao Hospital and MTH Hospital, Indore, in a duration of 1 year from 13 July 2021 to 12 June 2022 after taking approval from the Institutional Ethics and Scientific Review Committee. The study was conducted on 60 full-term parturient women of the American Society of Anesthesiologists II scheduled for normal vaginal delivery, who were willing for epidural analgesia during labor, after taking written informed consent. The women included in the study had singleton pregnancy with vertex presentation with normal fetal heart rate. They had no contradiction for epidural labor analgesia. The patients were randomly allocated into two groups by closed envelope method (simple random sampling).

Upon arriving in the labor room and consulting the attending obstetrician, written informed consent was taken and vital parameters were noted. An intravenous cannula of 20G was inserted in a peripheral vein and 15 mL/kg of ringer lactate was started. Baseline parameters such as pulse rate, systolic blood pressure, diastolic blood pressure, mean blood pressure, and oxygen saturation were recorded. Epidural block was given after consulting with the attending obstetrician at 3–4 cm cervical dilatation in left lateral position in L2-3 interspinous space with 18 G Tuohy's epidural needle. Loss of resistance to air was used for correct localization of the epidural space. The catheter was fixed leaving 6 cm into the epidural space. An epidural test dose of 3 mL of lidocaine 2% with epinephrine 1:200,000 was given followed by continuous monitoring of the heart rate and blood pressure to confirm correct placement.

At the start of the active stage of the first stage of labor (cervical dilatation 3 cm), patients of both the groups received an initial bolus dose of a 10 mL solution containing 0.125% injection Bupivacaine+20 mcg of injection fentanyl through the epidural catheter. In Group A (PCEA Pump group) patients, PCEA pump was attached and was programmed to deliver 5 mL continuous infusion of the above solution in 1 h. Whenever needed, 2 mL bolus of the solution were taken by patients with lockout interval of 15 min. In Group B (Manual bolus group), patients were provided manually with a bolus of 10 mL solution of 0.125% bupivacaine+20 mcg fentanyl after every hour by the principal investigator. Analgesia was assessed using visual analog scale (VAS). Additional manual boluses of 2 mL solution were given to patients if analgesia felt unsatisfactory and if pain was distressing (VAS >5).

The number of times rescue analgesia is required, and drug given was noted. Total dose of the analgesic consumed per hour and during the labor was noted. SpO_2, heart rate, and blood pressure were monitored throughout labor. Fetal heart rate was monitored with the help of the attending obstetrician at regular intervals. Neonatal Apgar scores were noted with the help of the attending pediatrician. Motor blockade was assessed by Bromage scale, and sensory blockade was assessed by temperature and touch. Adverse effects, if any were noted and managed as per protocol. Epidural catheter was removed under all aseptic precautions after delivery. Maternal satisfaction was assessed using Likert scale of satisfaction.

Statistical analysis

Statistical analysis was done using G* software. Mini tab version 17.0 was used for calculating the P values. Chi-square test was used for categorical data. To test the normality Kolmogorov–Smirnov test was applied. Comparison of means between the two groups was done using unpaired 't' test and paired 't' test. Descriptive statistics was presented in the form of numbers and percentages. $P<0.05$ was considered statistically significant.

RESULTS

There were total of 60 patients (30 in each group) in our study. Both the groups were comparable in terms of maternal demography and gravidity (Table 1).

The mean VAS score (overall) in Group A was 2.97±0.73; and in Group B, it was 3.03±0.56. The difference was found to be statistically insignificant (P=0.714) (Table 2). The mean total bupivacaine used in Group A was 53.60±1.00 ml, and in Group B, it was 54.27±1.66 ml. The difference was found to be statistically insignificant (P=0.065) (Table 2).

The mean duration of second stage of labor in Group A was 62.83±0.95 min; and in Group B, it was 65.52±1.15 min. The difference was found to be statistically not significant

Table 1: Characteristics of patients

Characteristics of patients	Group A (n=30)	Group B (n=30)	P value
Age in years	25.07±4.05	23.27±3.46	0.069
Gravidity (primipara/multipara)	36.7%/63.3%	35.0%/70.0%	-
Duration of second stage of labor (min)	62.83±0.95	65.52±1.15	0.0765
Incidence of caesarean section	0	1	0.5
Neonatal Apgar score at 5 min	9.97±0.18	9.93±0.25	0.561

Table 2: Study results

Study results	Group A (n=30)	Group B (n=30)	P value
Mean VAS score first stage	3.71±0.97	3.34±1.34	0.225
Mean VAS score second stage	3.67±1.88	3.91±1.17	0.555
Mean VAS score third stage	1.37±0.49	1.48±0.87	0.548
Mean VAS score fourth stage	1.00±0.00	1.00±0.00	-
Mean VAS score (overall)	2.97±0.73	3.03±0.56	0.722
Total bupivacaine use (mL)	53.60±1.00	54.27±1.66	0.065
Top-ups of bupivacaine required (number)	0.60±0.86	1.69±1.19	0.001
Maternal satisfaction score (quite satisfied/very satisfied)	5/25	15/14	0.004
Mean Bromage score	4.00±0.00	4.00±0.00	-

VAS: Visual analog scale

(P=0.0765) (Table 1). The mean top-ups of bupivacaine required in Group A were 0.60±0.86; and in Group B, it was 1.69±1.19. Significantly, a higher number of top-ups of bupivacaine were required in Group B than Group A. The maternal satisfaction was much higher in Group A than Group B (Table 2).

The mean Bromage score in Group A was 4.00±0.00; and in Group-B, it was 4.00±0.00. The test of comparison could not be done as the standard deviations in both groups were zero (Table 2). In Group A, none of the patients underwent cesarean section, while in Group B, 1 (3.3%) patient underwent cesarean section (Table 1). The mean neonatal Apgar at 5 min was also comparable between the two groups (Table 1).

DISCUSSION

Although epidural labor analgesia can be provided by the number of techniques, but intermittent dosing of local anesthetics by clinicians is commonly used one. However, this technique has a number of drawbacks including inconsistent analgesia, potential toxicity, and concerns about sterility each time the clinician opens the system to administer a bolus. PCEA allows the patient to control the dose of epidural medication as labor and pain pattern changes. It also allows for individualization of drug dosage by the patient, allowing her to modify therapeutic effects according to her need, for complete pain relief.

In our study, both the groups were comparable regarding demographic profile and gravidity. Maternal hemodynamic changes were comparable in all four stages of labor in both the groups. We found that before giving the epidural block, the mean VAS in Group A was 7.67±1.21; and in Group-B, was 7.10±1.45 (P=0.106). The mean VAS score after the block in Group A was 2.97±0.73; and in Group B, it was 3.03±0.56 (P=0.106). VAS score at the starting of first stage of labor was more than 5 as patients were experiencing pain. And after few minutes of administration of bolus patients experienced pain relief and VAS score dropped to <5. Although mean VAS score throughout the all four stages of labor was similar (statistically not significant) in both the groups indicating similar analgesia through both the techniques. This finding is in concordance with the study done by Srivastava et al.,[7] as the mean VAS in their study before the administration of epidural was 7.7±1.02 in the PCEA+continuous epidural infusion (CEI) group and 6.9± 0.73 in the intermittent bolus group (P=0.18). After the administration of block, the mean VAS was 1.89 ±1.03 in PCEA + CEI group and 1.96 ±1.08 in the intermittent bolus group (P= 0.32) showing similar analgesia in both the groups. Contrary to this, Roofthooft et al.,[8] in their study found that the patients in the programmed intermittent epidural bolus group had less frequent breakthrough pain compared with the PCEA group, 7 (10.9%) versus 38 (62.3%; P<0.0001), respectively.

We observed that the total bupivacaine used in Group A was slightly less (53.60±1.00 mL) than Group-B (54.27±1.66 mL), but the difference was found to be statistically not significant (P=0.065). Srivastava et al.,[7] in their study found that the total bupivacaine used in both the groups was comparable, i.e., PCEA+CEI group consumed a total volume of 55±9 ml and intermittent bolus group consumed 50±12 mL. (P=0.079).[7] Our findings are also corroborated with the study done by Singh et al.,[9] where

the total bupivacaine consumed was similar in both the groups that is 54.91±9.25 mL in PCEA+BCI group and 49.6±12 mL in intermittent bolus group. Contrary to this, Meena et al.,[10] in their study found that hourly mean drug consumption in the PCEA group was significantly lower as compared with the physician-administered PIEB group (5.46 mL/h, SD=2.01 vs. 6.55 mL/h, SD=1.28; P=0.03).

The mean duration of second stage of labor in Group A was 62.83±0.95 min; and in Group B, it was 65.52±1.15 min (P=0.0765). This finding is similar to the study done by Leo et al.,[11] where the mean duration of second stage of labor was 62.2±37.4 min in the PCEA + AMB group, and in the PCEA+CEI group, it was 76.2±58.2 min (P=0.34).

There was a significantly higher number of top-up requirements of bupivacaine in Group-B (1.69±1.19) than Group A (0.60±0.86), and this finding was similarly observed by Srivastava et al.,[7] where the number of women who asked for rescue boluses in PCEA+CEI group were 2 (8%) and in the intermittent bolus group were 8 (27%) (P<0.05). This is in contrasts with the study done by McKenzie et al.,[12] where the percentage of women requiring rescue boluses was significantly higher in the PIEB+PCEA group.

There was a higher maternal satisfaction score in PCEA group than intermittent bolus group this is in contrast to the study done by Singh et al.,[9] where they found similar levels of maternal satisfaction in both the groups. Whereas Roofthooft et al.,[8] in their study observed that patient satisfaction scores were same in both the groups.

In Group A, none of the patients underwent cesarean section, while in Group B, 1 (3.3%) patient underwent cesarean section after the first stage due to non-effacement of cervix, but the difference was found to be statistically not significant. These findings are in concordance with the finding of a similar study done by Singh et al.[9]

Motor block was comparable in both the group. None of the patient experienced motor block in both the group. Neonatal Apgar score was also comparable in both the groups.

Limitation of the study

We have conducted a single-centered study with a sample size of 30 in each group. To overcome this limitation, multicentric studies with larger sample sizes are needed. The elastomeric patient controlled analgesia pumps are not a cost-effective solution to the CEI technique. Electrical pumps are more cost effective and can be used in multiple patients without affecting sterility, but at the limitation of the patient's mobility and comfort. Time was consumed to program the elastomeric infusion pump according to the needs and explaining the patient about the proper working of the pump.

CONCLUSION

Due to continuous infusion of basal rate of local anesthetic drug through PCEA pump, parturients who received PCEA, required less numbers of rescue analgesics, and reported higher maternal satisfaction levels during labor than the patients who received manual intermittent boluses. Hence, the continuity of pain management was comparatively better in the parturient in the PCEA group than the parturient in the manual intermittent bolus group. The duration of the second stage of labor was not increased in both the groups. The mean VAS score was equivalent in both the groups. The incidence of cesarean section was not increased in any of the groups although there was one incidence reported in the manual bolus group due to non-effacement of cervix in the first stage of labor.

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Authors Contribution:
MB- Concept and design of the study, prepared the first draft of the manuscript and guidance; **AK-** Interpreted the results and reviewed the literature; **DV-** Concept, coordination, preparation of manuscript; **NB-** Statistical analysis and interpretation and revision of the manuscript; **KKA-** Guidance.

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