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Epidural Labor Analgesia: Continuous Infusion Versus Patient-Controlled Epidural Analgesia With Background Infusion Versus Without a Background Infusion

Manuel C. Vallejo,* Vimala Ramesh,* Amy L. Phelps,† and Neera Sah*

*Department of Anesthesiology, Magee-Womens Hospital of UPMC, University of Pittsburgh, Pittsburgh, Pennsylvania.
†A.J. Palumbo School of Business Administration, Duquesne University, Pittsburgh, Pennsylvania.

Abstract: **The purpose of this study was to compare the total epidural dose of 3 commonly used labor epidural modalities. After local institutional review board approval, 195 laboring parturients received an epidural catheter for labor analgesia. All patients received an initial bolus of 0.1% ropivacaine (10 mL) and fentanyl (100 μg). Maintenance of labor analgesia consisted of ropivacaine 0.1% with fentanyl 2 μg/mL. Patients were then randomly assigned into 3 groups: Group 1 (continuous epidural infusion [CEI]), continuous infusion at 10 mL/h; group 2 (CEI + patient-controlled epidural analgesia [PCEA]), CEI at 5 mL/h with a demand dose of 5 mL allowed every 20 minutes with a 20 mL/h maximum dose; group 3 (PCEA), demand doses only of 5 mL every 15 minutes with a 20 mL/h maximum dose. Measured variables included total epidural dose, total bolus requests and boluses delivered, number of staff interventions, pain Visual Analog Scale (VAS; 0–100), modified Bromage scores, stage I and II labor duration, delivery outcome, and maternal satisfaction after delivery. No differences were noted with respect to pain VAS, modified Bromage scores, stage I and II labor duration, number of staff interventions, delivery outcome, and maternal satisfaction score. Total infusion dose was lower in demand dose only PCEA compared with CEI and CEI + PCEA groups ($P = < .01$). Demand dose–only PCEA results in less total epidural dose compared with CEI and CEI + PCEA without affecting labor duration, motor block, pain VAS, maternal and neonatal outcomes, and maternal satisfaction.**

Perspective: ***This article compares 3 commonly used labor epidural delivery modalities (traditional continuous epidural infusion, patient-controlled epidural analgesia with a background infusion, and demand dose–only patient-controlled epidural analgesia). Benefits in epidural dose reduction with demand dose only PCEA does not translate into improved maternal and neonatal outcome.***

Key words: *Labor analgesia, continuous epidural, patient-controlled epidural analgesia, maternal outcome.*

Epidural analgesia is the most effective way of providing pain relief in labor.[16] Continuous epidural infusion (CEI) has become the most popular form of providing labor analgesia because it has the advantage of providing continuous analgesia.[15] However, CEI can result in progressive regression in the block requiring reactivation (administration of a bolus dose), with resultant increase in the anesthesiologist's workload.[2,7,10] On the other hand, a high CEI delivery rate (>15 mL/h) can result in a dense motor block requiring the infusion to be stopped.[2,4,10]

Patient-controlled epidural analgesia (PCEA) was first described by Gambling in 1988 and has increased in popularity.[3,8] As labor pain patterns change throughout labor, PCEA allows the patient to self-manage her labor pain, with the advantage of eliminating the problems of overdosing and underdosing commonly associated with CEI.[8]

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Supported by the Department of Anesthesiology, University of Pittsburgh.
Address reprint requests to Dr. Manuel C. Vallejo, Magee-Womens Hospital of UPMC, Department of Anesthesiology, 300 Halket Street, Pittsburgh, PA 15213. E-mail: vallejomc@anes.upmc.edu
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PCEA can be provided as demand dose only or in combination with a continuous background infusion. The purpose of this study is to determine whether continuous epidural infusion or patient-controlled epidural analgesia with or without a continuous background infusion is most advantageous in reducing labor pain with minimal motor block and staff intervention, while using the least amount of medication.

Methods

With local investigation review board (IRB) approval, this prospective, randomized, double-blinded study enrolled 195 parturients who requested labor epidural analgesia. All study subjects provided written consent. Patients were randomly assigned by computer program into 1 of the 3 treatment groups: Group 1, CEI; group 2, CEI + PCEA; and group 3, PCEA.

American Society of Anesthesiologists (ASA) Physical Status 1 or 2 parturients who requested labor analgesia at 2–6 cm of cervical dilation at term (37–42 weeks of gestation) with a singleton fetus in the vertex presentation were included into the study. Exclusion criteria included patients who received parenteral analgesics within 1 hour before the epidural block, history of chronic opioid use or chronic pain syndrome, fetal presentation other than vertex, patients with a known history of allergy, sensitivity, or any other reaction to amide local anesthetics, preeclampsia, parturients with any known contraindications to epidural analgesia, and a history of cesarean delivery.

A research coordinator not involved in data collection assigned patients to a study group using a computer-generated randomization table, and set up the epidural pumps in all groups. The patient and the person collecting the data were blinded to the type of epidural delivery modality. The PCEA button was connected to the epidural pump in all patients to blind the data collector and patient as to study group. However, in the CEI group, the pump was unable to indicate when a bolus dose was requested. All epidural catheters were placed in sterile fashion at the L3-4 or L4-5 intervertebral space using the loss of resistance technique to saline. Labor analgesia was initiated in all patients with a bolus of 0.1% ropivacaine (10 mL) and fentanyl (100 μg). Maintenance of labor analgesia consisted of ropivacaine 0.1% with 2 μg/mL fentanyl. Group 1 (CEI) had continuous infusion at 10 mL/h; group 2 (CEI + PCEA), continuous infusion at 5 mL/h with a demand dose of 5 mL allowed every 20 minutes with a 20 mL/h maximum dose; and group 3 (PCEA), demand doses only of 5 mL every 15 minutes with a 20 mL/h maximum dose. All patients were given the same instructions regarding the use of the PCEA button.

Oxytocin was administered at the discretion of the obstetrician. As per study protocol, vital signs (blood pressure, heart rate, pulse oximetry, and fetal heart rate) were recorded at baseline, and every 5 minutes for 15 minutes after the initial bolus and every hour thereafter until delivery.

Treatment for breakthrough pain was defined as pain Visual Analog Scale (VAS) >30 mm (100 mm unmarked line anchored at the left end with no pain and at the right end with worst pain imaginable), and a bolus of 10 mL of epidural medication was administered through the pump. No additional medication was given if the pain VAS <30 mm. If after 15 minutes pain VAS >30, additional 10 mL of the epidural medication was given. If the pain VAS was still >30, a bolus of 5 mL 1.5% lidocaine was administered to rule out a misplaced epidural catheter. If the patient still had a pain VAS >30 despite breakthrough pain intervention, then the patient was assumed to have a misplaced epidural catheter and was excluded from the study, no further data were collected, and the epidural catheter was replaced.

Demographic data included age, height, weight, gravity, parity, cervical dilation was recorded at the time of enrollment. Vital signs, pain VAS, and modified Bromage scores (0 = complete motor block, unable to move feet or knees, 1 = almost complete block, able to move feet only, 2 = partial block, just able to move knees, 3 = detectable weakness of hip flexion, and 4 = no motor weakness with no detectable weakness of hip flexion while supine with full flexion of knees) were collected during the following time periods; baseline (before epidural insertion), 5, 10, and 15 minutes after epidural insertion, and at hourly intervals until delivery. Our primary outcome data was total epidural dose. Secondary outcome data included total bolus requests and boluses delivered, stage I duration (defined as the time from epidural insertion to complete cervical dilatation) and II labor duration (defined as the time from complete cervical dilatation to delivery), number of staff interventions, delivery outcome (vaginal, instrumental vaginal, cesarean), and visual maternal satisfaction (0–100; 0 = totally dissatisfied, 100 = totally satisfied) were recorded after delivery upon removal of the epidural.

Sample Size Calculation

In a study comparing the role of continuous background infusion with PCEA, Ferrante[6] found the total cumulative bupivacaine doses were: 76.3 ± 10.3 mg for CEI, 47.6 ± 6.0 mg for CEI + PCEA, and 40.4 ± 5.8 mg for PCEA. Using a computer-generated statistical program,[9] sample size was determined using ANOVA with 3 treatment groups. At an $\alpha = 0.05$, power of 80%, minimal detectable difference of 6 mg ropivacaine, and a standard deviation of residual of 10.3; the calculated sample size is 57 patients per group for a total of 171 patients. To allow for patients who may not complete the study, a total of 195 patients were studied.

Data Collection and Statistical Considerations

Subjects were excluded from data analysis if there were protocol violations. Data from all the other subjects were analyzed. Normally distributed data are reported as mean ± SD. Variables not following a normal distribution are reported as median with range in parentheses. Normally distributed data were analyzed using ANOVA,