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Continuous Epidural Infusion vs. Programmed Intermittent Epidural Boluses with Patient Controlled Epidural Analgesia Among Parturients with a Laboring Epidural: A Retrospective Chart Review

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Abstract

Background: The objective of this study was to retrospectively analyze several maternal outcomes following a laboring epidural practice change from Continuous Epidural Infusion (CEI) without Patient-Controlled Epidural Analgesia (PCEA) to Programmed Intermittent Epidural Boluses (PIEB) with PCEA on a 12-bed obstetric unit at a large, urban teaching hospital.

Methods: A retrospective chart review was conducted comparing two groups of patients who received a Continuous Epidural Infusion (CEI) versus Programmed Intermittent Epidural Boluses (PIEB) with Patient-Controlled Epidural Analgesia (PCEA). Three hundred fifty-one patient records were included in the study. The records were evaluated to assess for differences in three primary outcomes: the incidence of breakthrough pain requiring manual epidural boluses, the incidence of hypotensive events requiring vasopressors, and the length of second-stage labor. Additionally, the records were evaluated to assess differences in two secondary outcomes: the rate of instrument-assisted vaginal delivery and unplanned cesarean sections (c-section).

Results: The average number of manual provider boluses for breakthrough pain in all patients decreased significantly, from 1.37 in group one (CEI) to 0.13 in group two (PIEB+PCEA), $t(349) = 6.29$, $P<.001$. The average number of hypotensive events requiring vasopressors also dropped significantly from 0.13 (CEI) to 0.03 (PIEB+PCEA), $t(349) = 2.24$, $P=.013$. There were no significant differences when comparing the length of second-stage labor or the rates of instrumented-assisted vaginal or cesarean delivery.

Conclusions: PIEB+PCEA decreased the incidence of manual provider boluses for breakthrough pain and the incidence of hypotension requiring vasopressors when compared with CEI alone. PIEB+PCEA may decrease anesthesia provider workload, improve the hemodynamic stability of laboring parturients, and increase patient satisfaction. Future research is needed to better understand the effect of PIEB+PCEA on laboring outcomes and to determine the ideal epidural settings to optimize the obstetric patient's labor experience.

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Introduction

Labor pain consistently ranks among the most severe pain a person experiences in their lifetime [1]. Presently, epidurals are considered the gold standard for pain control in labor and 71.3% of laboring parturients elect to receive an epidural for pain management during childbirth in the United States [1,2]. Programmed Intermittent Epidural Boluses (PIEB) is one of the latest technologies in epidural pain management. Unlike Continuous Epidural Infusions (CEI), PIEBs deliver automated doses of medication at specified time intervals. This results in increased segmental spread within the epidural space compared to CEIs and may provide more uniform pain control [3,4].

With new evidence and advancements in delivery pump technology, some obstetric centers have transitioned away from CEIs to varying combinations of programmed intermittent epidural boluses with patient-controlled epidural anesthesia (PCEA). Currently, most literature focuses on the transition from CEI to PIEB or the addition of PCEA to CEI. Few studies compare the differences in outcomes of CEI without PCEA versus PIEB+PCEA. The purpose of this study is to retrospectively analyze patient outcomes after modifying the labor epidural practice from CEI to PIEB+PCEA on a 12-bed obstetric unit at a large urban teaching hospital. The study primarily aimed to determine if a difference exists in the number of manual provider boluses for breakthrough pain, hypotensive events requiring vasopressors, or the duration of second-stage labor when comparing CEI to PIEB+PCEA. Additionally, the study explored if a difference existed in the rate of instrument-assisted vaginal deliveries and unplanned cesarean sections between these two treatment groups.

Methods

The retrospective chart review was conducted utilizing data in the Electronic Medical Record (EMR). The study was approved by Georgetown University's Institutional Review Board, ID# STUDY00006051. The requirement for informed written consent was waived, as all patient data was deidentified. This manuscript adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [5].

Sampling population

The researchers analyzed the medical records of obstetrical patients who elected to receive a laboring epidural before and after the laboring epidural practice changed from CEI to PIEB+PCEA. The sample included parturient without preexisting cardiac disease, opioid tolerance, history of opioid addiction, or complications of pregnancy. Preexisting cardiac disease was defined as including valvular disease, congenital heart disease, and hypertrophic cardiomyopathy. To meet inclusion criteria, parturients must have received a laboring epidural for a planned vaginal delivery between the dates of January 1, 2021 - May 1st, 2021 or January 1st, 2022 - May 1st, 2022.

The sample was divided into two groups based on the patient's epidural medication delivery technique. Group one included patients who were admitted between January 1, 2021 - May 1st, 2021 and received a CEI of Bupivacaine 0.1% with fentanyl two µg/mL at a rate of eight mLs/h. Group two included patients who were admitted between January 1st, 2022 - May 1st, 2022, and received PIEB+PCEA of the same solution delivered at six or eight mLs every 45 min and PCEA of five mLs every 10 min, with a one-hour lockout limit of 35 mLs. These groups were determined based on the institution's transition from CEI to PIEB + PCEA in June 2021.

To prevent outlier bias, researchers excluded patients who delivered within one hour of epidural insertion, were opioid-tolerant, had gestational age less than 34 weeks, had documented pre-existing cardiac disease, or who received a combined spinal-epidural. The researchers excluded minors under the age of 18 from the study. The study was exempt from patient consent and patient demographic data was not collected to protect patient privacy. Incomplete charts were excluded from the study to prevent information bias. Incomplete charts were defined as charts that lacked an anesthesia record or significant information to establish adequate exclusion criteria.

Variables

To address the primary variables, the records were evaluated for the incidence of breakthrough pain requiring manual epidural boluses, the incidence of hypotensive events requiring vasopressor treatment, and the length of second-stage labor.

Breakthrough pain requiring manual epidural boluses were assessed by the presence of manual provider boluses in the patient's anesthesia record. Breakthrough pain requiring intervention was defined as a parturient's request for additional pain management from an anesthesia provider, despite having an active epidural. Each bolus was documented as one incidence. The initial bolus with epidural insertion ("loading dose") was excluded.

Hypotensive events requiring vasopressor treatment were assessed by the presence of vasopressor administration in the anesthesia record. Vasopressor(s) administered within 30 minutes of the epidural start time were excluded to eliminate bias related to variation in individual provider practices with loading dose epidural boluses. If vasopressors were dosed consecutively within 15 minutes to achieve normotension, this was documented as a single incidence. The length of second-stage labor was determined by calculating the difference in minutes between complete cervical dilation and delivery of the newborn. This information was found in nursing progress notes and physician delivery notes. Many records did not contain the time of complete cervical dilation; these patients were excluded from the statistical analysis pertaining to second-stage labor only. The length of second-stage labor was not collected on those who had an unplanned cesarean section.

The secondary variables were the rate of instrument-assisted vaginal delivery and unplanned cesarean section. The data was collected by the documented use of forceps or ventouse suction in the provider's delivery note or the presence of a c-section in the anesthesia record.

Statistical analysis

A two-tailed t-test of independent samples was conducted to assess for a statistically significant difference in the primary studied outcomes between group One and group Two. The required sample size was determined using G*Power statistics. According to the G*Power calculator, a sample size of 352 was warranted to achieve a confidence level of 95%. A total of 351 patient records were included in the study; however, adequate power was achieved. The length of second-stage labor was significantly skewed; therefore, group one and group two were compared using the Mann-Whitney U-test rather than t-tests. The rate of instrument-assisted vaginal deliveries and cesarean sections, the secondary outcomes, were evaluated using a chi-squared test.

Data analysis was computed using SPSS software version 29. Methods to control for confounding variables included exclusion of patients less than 18 years of age, who were opioid-tolerant, whose fetal gestational age was less than 34 weeks, or who had documented pre-existing cardiac disease.

Results

A total of 1,940 potentially eligible patients over 18 years old who delivered children between January 1, 2021 - May 1st, 2021 or January 1st, 2022 - May 1st, 2022 were sourced from the medical record. Of these, 645 patient records were evaluated for study participation. Data collection ceased when 351 patients met inclusion and exclusion criteria. Group one contained 175 patients who received CEI in 2021 and group two contained 176 patients who received PIEB+PCEA in 2022.

Number of manual epidural boluses

All 351 patients were assessed for the incidence of manual boluses for breakthrough pain. In group one, 57.1% of patients who received CEI required manual boluses. Of those requiring manual boluses, 39% received one bolus, 25% received two boluses, 18% received three boluses, and 18% required four or more. In group two, only 27.3% of patients who received PIEB+PCEA required manual boluses. Most (64.6%) required only one manual bolus, 18.8% required two, 12.5% required three boluses, and 4.2% required four or more. The average number of boluses among all patients decreased significantly, from 1.37 in group one (CEI) to 0.13 in group two (PIEB+PCEA), $t(349) = 6.29$, $P<.001$ (see Table 1).

Hypotensive events requiring vasopressors

All 351 patients were assessed for the incidence of hypotensive events requiring vasopressor treatment. In group one (CEI), 6.3% of patients required vasopressors, compared with 2.8% in those in group two (PIEB+PCEA). Of those with hypotensive events requiring vasopressors in group one, 45.5% had only one episode, 18.2% had two episodes, 18.2% had three, and 18.2% had four episodes. The patients who required vasopressors in group two had only one episode of treated hypotension. The average number of hypotensive events requiring vasopressors among all patients dropped significantly from 0.13 (CEI) to 0.03 (PIEB+PCEA), t(349) = 2.24, P=.013 (Table 1).

Length of second stage of labor

Group one included 144 vaginal deliveries, and 56 records did not contain adequate information to calculate the length of second-stage labor. Group two included 138 vaginal deliveries, and 105 records did not contain adequate information to calculate the length of second stage labor. The length of second-stage labor was significantly skewed in both groups, therefore groups one and two were compared using a Mann-Whitney U-test rather than t-tests. In group one, the length varied from six to 878 minutes, with a median of 47.5 minutes and a mean of 88.8 minutes (see Table 1). In group two, the length ranged from four to 468 minutes, with a median of 73.0 minutes and a mean of 91.7 minutes. The differences in length by group were not statistically significant, Mann Whitney U=1277.5, P=.14.

Delivery mode

All 351 patients were assessed for delivery mode. Just over three-quarters were vaginal deliveries in both groups (see Table 1). Cesarean deliveries increased after the change to PIEB + PCEA from 17.7% to 21.6%, and assisted vaginal deliveries decreased from 4.6% to 1.7%, but the differences were not statistically significant, $X^2(2)=2.98$, $P=.23$.

Discussion

Key results & interpretation

This study found that the average number of manual provider boluses for breakthrough pain decreased significantly in patients who received PIEB+PCEA. A reduced incidence of pain requiring intervention can lead to less provider strain and an improved labor experience for theparturient [6,7]. The theoretical method that may make PIEB superior to CEI involves fundamental science–speed, pressure, and volume. Two experimental studies analyzed the spread of injectate within the neuraxial space and found a significantly greater segmental spread of injectate using a bolus technique rather than CEI [3,8]. Although not unanimous, most research indicates that PIEB may prevent breakthrough pain in the parturient [6,9-11]. Administrative limitations had previously prevented the conversion from CEI to CEI+PCEA at our institution; once approved for a laboring epidural practice change, the institution opted for a significant change to PIEB+PCEA based on the current evidence illustrating the benefit of PCEA and the superiority of PIEB compared to CEI. Our study strengthens the evidence that PIEB+PCEA may provide superior analgesia during labor and decrease requirements for additional anesthesia provider interventions to treat pain and hypotension. Our institution did not record patient pain scores in the medical record; however, collecting numerical pain score data would be a helpful indicator of maternal satisfaction in future studies.

The average number of hypotensive events requiring vasopressors decreased significantly in patients receiving PIEB+PCEA compared with CEI. Initially, there was concern that bolus dosing may contribute to sympathectomy-related hypotension because of its greater segmental spread in the epidural space [12]; our study found that PIEB+PCEA may have the opposite effect. Hemodynamic stability may contribute to a decrease in provider workload, fetal complications, emergent c-sections, and maternal nausea. The total dose of Local Anesthetic (LA) administered over time is another important factor in patient safety. With greater amounts of LA there are greater risks of toxicity. Eleven randomized control trials compared CEI vs. PIEB and suggested a decreased total consumption of LA when using programmed boluses [6,9-11,13,17]. Our study did not calculate the total dose of LA administered to patients throughout the course of their labor. However, it would be valuable to analyze this number in future studies and to correlate it with the incidence of hemodynamic instability.

There was no difference in the length of second-stage labor, the incidence of instrument-assisted vaginal deliveries, or the incidence of unplanned c-sections. The second stage of labor is the most labor-intensive stage for both patients and L&D providers, and its length is heavily influenced by the parturient's ability to push the baby through the pelvis effectively. It is hypothesized that PIEB may reduce the incidence of an undesired motor blockade because the improved distal spread reduces the LA concentration at the spinal cord segment most proximal to the catheter tip [3,7,8]. A study comparing motor blockade incidence using a Bromage score suggested that motor blockade was 13 times more likely in patients who received CEI vs. PIEB [13]. Additionally, the study alluded to a correlation between motor blockade and an increased need for instrument-assisted vaginal delivery, suggesting that decreased motor function may impact

the parturient's ability to push [13]. Current research does not yet indicate that PIEB impacts the mode of delivery or rate of cesarean sections which is consistent with this study's findings [6,18]. In future analysis, assessing motor blockade using a Bromage score and correlating this variable with the incidence of instrument-assisted delivery and c-sections would be valuable.

Limitations & generalizability

With PIEB, as with any emerging technique, there is a lack of standardization in practice. At the time of this publication, neither the American Society of Anesthesiologists nor the Society for Obstetric Anesthesia and Perinatology has practice guidelines regarding PIEB, and there are no published practice recommendations for optimal local anesthetic concentrations, volumes, or infusion settings [19]. The American Association of Nurse Anesthesiology notes the benefits of PIEB in their practice guidelines but suggests following institutional policies when choosing between CEI, PCEA, or PIEB [20]. A review of the published data shows varying epidural solutions, volumes, bolus doses, and bolus interval settings [7,9,10,13,15,21]. Bolus doses ranged from as little as 2.5 mLs of solution every 15 minutes [9] to 10 mLs every hour [13]. Furthermore, most studies utilized varying local anesthetics and adjuncts, making comparisons even murkier. The epidural solution and settings utilized in this study were specific to our institution and thus, our results might have limited external validity when considering the many alternative medication combinations and/or dosages. The generalizability of our results might also be limited by the fact that many institutions currently employ CEI with PCEA. Consequently, they might not experience as large of an effect on the outcomes we measured when switching from CEI+PCEA to PIEB+PCEA. Furthermore, infusion pumps with PIEB capability can be challenging to obtain, hospitals have different availability of medications, and clinical practice changes happen slowly. These limitations provide valuable insights for future research. By conducting a prospective study that addresses these limitations, we can validate and further substantiate the results obtained in our research. This approach will contribute to a more comprehensive understanding of the optimal labor epidural settings and the development of evidence-based protocols.

As a retrospective study, there was no control over record keeping in the sampling window, staff or unit-related changes during the trial period, or individual anesthesia provider variability in treatment of hypotension and pain. Furthermore, meaningful variables like patient pain scores, motor blockade assessment, and the total dose of LA administered were not available in the medical record and could not be included. Lastly, the individual impact of PIEB or PCEA on the studied variables could not be evaluated since they were only assessed in conjunction. These limitations can be addressed in a prospective study by implementing standardized record-keeping procedures, ensuring consistency in staff and unit-related protocols, and establishing clear guidelines for anesthesia provider practices.

Conclusion

Our retrospective study demonstrated significant improvement in clinically meaningful variables for anesthesia providers on labor and delivery units after an institutional change from CEI alone to PIEB+PCEA. This suggests that clinicians could consider implementing the use of PIEB+PCEA as a more effective approach for managing laboring epidurals, potentially leading to improved patient outcomes and less provider workload.

Future research may further validate the benefits of PIEB + PCEA and, ultimately, help clinicians develop evidence-based protocols with optimized labor epidural settings. This approach will contribute to the development of evidence-based protocols and the optimization of labor epidural settings, ultimately enhancing patient care in obstetric units.

Author declarations

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