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ORIGINAL ARTICLE

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Programmed intermittent epidural boluses for maintenance of labor analgesia: an impact study

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ABSTRACT

Introduction: The aim of this impact study was to compare the analgesic efficacy and side effect profile of programmed intermittent epidural boluses (PIEB) + patient-controlled epidural analgesia (PCEA) to continuous epidural infusion (CEI) + PCEA for maintenance labor analgesia after the introduction of PIEB at our institution.

Methods: We conducted a retrospective analysis after replacing the background CEI with PIEB for our labor PCEA. Pre-change pump settings were CEI 12 mL/h with PCEA (12 mL bolus, lockout 15 min); PIEB settings were a 9 mL bolus every 45 min with PCEA (10 mL bolus, lockout 10 min). We compared medical records of all women receiving epidural or combined spinal-epidural labor analgesia for vaginal delivery for two months before PIEB implementation to a two-month period of PIEB utilization following a five-month introductory familiarization period. The primary outcome was the proportion of women requiring rescue clinician boluses.

Results: Fewer patients in the PIEB group required rescue clinician boluses compared to the CEI group (12% vs. 19%, P=0.012). Time to first rescue bolus request and total bolus dose were not different. Peak (median [IQR]) pain scores were 2[0–5] with CEI and 0[0–4] with PIEB. There was no difference in instrumental delivery rates.

Conclusions: Using PIEB compared to CEI as the background maintenance epidural analgesia method in conjunction with PCEA reduced the number of women requiring clinician rescue boluses while providing comparable labor analgesia. The findings of this clinical care impact study confirm the results of randomized controlled studies and suggest PIEB may be a preferable technique to CEI for the maintenance of labor analgesia.

Keywords: Epidural; Labor analgesia; Programmed intermittent epidural bolus; Automated epidural boluses

Introduction

Epidural analgesia is the most effective technique to treat labor pain.[1] Maintenance regimens have evolved from manual boluses to continuous infusions to patient-controlled boluses. Patient-controlled epidural analgesia (PCEA) with or without a background continuous epidural infusion (CEI) is a commonly utilized technique to maintain labor analgesia.[2,3] Compared to CEI, PCEA regimens reduce local anesthetic consumption, decrease the need for clinician boluses and minimize motor blockade.[4] Adding a continuous background infusion to a PCEA regimen reduces the need for clinician boluses and may improve analgesia.[5] However, these techniques do not eliminate the need for clinician boluses for inadequate labor analgesia.

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Programmed intermittent epidural bolus (PIEB) is an automated method of administering epidural local anesthetic with or without opioids. The technique provides fixed boluses at scheduled intervals. Programmed intermittent epidural bolus can be utilized as an alternative to a CEI alone or as a background administration with a PCEA technique. A number of randomized controlled trials (RCT) have compared PIEB ± PCEA to CEI ± PCEA.[6–13] Findings were mixed, but overall, results suggest a benefit to PIEB compared to CEI. A meta-analysis of these comparative studies found a statistically significant reduction in local anesthetic use and increased maternal satisfaction with PIEB.[14] However, all studies used non-commercial PIEB devices or provided intermittent epidural boluses manually. An epidural pump with PIEB plus PCEA capability became available in the UK in September 2012 and in the USA in March 2014 (CADD Solis Epidural Pump, Smiths Medical, St. Paul, MN, USA).

The aim of this study was to compare PIEB + PCEA to CEI + PCEA for labor analgesia following the

introduction of PIEB at our institution. The primary outcome of this clinical impact study was the proportion of women needing a rescue clinician epidural bolus for inadequate analgesia. We hypothesized that PIEB would decrease the number of women needing clinician boluses compared to CEI while providing comparable labor analgesia.

Methods

We conducted a retrospective review of electronic medical records for vaginal deliveries with neuraxial analgesia before and after the introduction of PIEB. Stanford University Institutional Review Board approval was obtained for this quality assurance review and analysis. We included records of all vaginal deliveries with either epidural or combined spinal-epidural (CSE) analgesia. Exclusion criteria included: block failure (defined as a block requiring replacement or documentation of the anesthesia team offering a replacement with patient refusal); delivery or need for clinician bolus within 60 min of epidural/CSE placement; incidental dural puncture; epidural equipment failures; and any significant deviation from our standard protocol (e.g. loading the epidural with lidocaine compared to our standard bupivacaine solution) for labor analgesia maintenance during the study period.

The labor analgesia maintenance technique at our institution was changed from CEI to PIEB in October 2014. We trialed one other PIEB regimen (8 mL every 45 min) for a month before changing to the regimen utilized in the study (9 mL every 45 min). Consecutive electronic anesthetic records for vaginal deliveries at the Lucile Packard Children's Hospital, Stanford, California were retrieved from the two months (August–October 2014) before the change. Similarly, electronic anesthetic records for all consecutive vaginal deliveries during a two-month period in March to May 2015 were reviewed. The data collection interval was chosen to allow a several month familiarization period after the change to a PIEB regimen.

At our institution, labor analgesia is initiated with either epidural 0.125% bupivacaine + sufentanil 10 μg 15 mL or a CSE with intrathecal bupivacaine 2.5 mg + sufentanil 5 μg. Our epidural catheters are 19-gauge spring-wound single-orifice catheters (BBraun, Bethlehem, PA, USA) and are inserted using a 17-gauge Tuohy needle. If a CSE technique is used, the dural puncture is made with a 27-gauge Gertie Marx spinal needle (IMD Inc., Huntsville, UT, USA). Before the protocol change, labor analgesia was maintained with a background CEI of 0.0625% bupivacaine + sufentanil 0.4 μg/mL at 12 mL/h with PCEA (12 mL bolus, lockout 15 min). The PIEB regimen used during the study period was a PIEB of 9 mL every 45 min starting 30 min after pump initiation combined with a PCEA (10 mL bolus, lockout 10 min). The neuraxial techniques and solutions did not change with the introduction of PIEB.

Demographic and obstetric data, epidural placement time, delivery time, time of the first clinician bolus, total number and dosage of clinician boluses, numerical verbal pain scores (VPS, 0=no pain and 10=worst pain imaginable) before and after epidural/CSE placement, highest VPS after epidural placement until delivery, and mode of delivery were all recorded. Additionally, side effects or complications such as one-sided pain or sensory level, the need to adjust the epidural medication regimen due to a dense block, or hypotension requiring anesthesia intervention were extracted from electronic records (EPIC, Verona, WI, USA). All clinician bolus data recorded in the medical records were double-checked by one investigator (CPM).

At our institution, the anesthesia provider (resident or fellow with direct attending supervision) explains the epidural maintenance protocol before and after insertion of the epidural catheter. Women are instructed to administer a PCEA dose for pain above their desired threshold, and to call the anesthesia provider if severe pain occurs or pain is not managed with PCEA doses. Nursing staff help women manage the epidural pumps and record VPS every hour. The anesthesia residents and fellows are instructed to use bupivacaine 0.125–0.25% in 5–10 mL increments to treat pain not controlled by PCEA use.

Statistical analysis

The primary outcome was the proportion of women requiring a clinician rescue bolus during labor. Secondary outcomes included mean and highest VPS during labor, number of clinician boluses needed, total clinician bolus dose (mg of bupivacaine), incidence of unilateral pain or sensory level, hypotension requiring anesthetic intervention, and mode of delivery. An a priori power calculation based on previous quality assurance data found that we required 200 patients per group (power 0.80, alpha 0.05) to show a 50% difference in the proportion of women requiring clinician boluses before and after the introduction of PIEB. Based on clinical workload at our institution, two months of data collection would ensure an adequate sample size. Histograms for each variable were created and data graphed to assess normality of data distribution. Outcome measures between groups were compared using the Student's t test for normally distributed variables, and Rank-sum test for non-parametric comparisons. Categorical variables were investigated using Pearson's chi-squared test. Patients with missing data were included in the analysis. Data are presented as mean ± standard deviation (SD), median [interquartile range (IQR)] or number (percentage) as appropriate. For the primary outcome, $P<0.05$ was considered statistically significant. For secondary