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Clinical Investigation

CLINICAL INVESTIGATION

Continuous epidural infusion *vs* programmed intermittent epidural bolus for labour analgesia: a prospective, controlled, before-and-after cohort study of labour outcomes

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This project was presented at the annual scientific meeting of the Australian and New Zealand College of Anaesthetists in May 2016. It was also presented as a poster at the Western Sydney Local Health District quality awards 2016 and the Asia Pacific Forum for Quality and Safety in Healthcare 2016.

Abstract

Background: Recent evidence that programmed intermittent epidural bolus (PIEB) improves maternal outcomes encouraged us to change our labour epidural analgesia protocols and investigate if we could achieve similar results in a clinical setting.

Methods: We conducted a prospective, controlled, before-and-after cohort study. Outcomes after labour analgesia delivered by continuous epidural infusion (CEI) with ropivacaine 0.2% and fentanyl 2μg ml^{-1} were compared with PIEB with patient controlled epidural analgesia (PIEB+PCEA) with ropivacaine 0.1% and fentanyl 2 μg ml^{-1}. The primary outcome was lower limb motor block. Secondary outcomes were local anaesthetic and fentanyl dose, duration of the second stage of labour, mode of delivery, and maternal satisfaction. Outcomes were compared using univariate *t*-test, χ^2 test or Fisher's exact test. Significant differences in outcomes were further evaluated by multiple regression analysis.

Results: A total of 397 women completed the study (CEI 188; PIEB+PCEA 209). The PIEB+PCEA group had significantly fewer patients with motor block [CEI 41/188 (21.8%) *vs* PCEA+PIEB 2/209 (1.0%), $P<0.001$], shorter second stage of labour for primiparous women [CEI 108.2 (61.2), mean (standard deviation), min *vs* PIEB+PCA 79.4 (55.1) min, $P<0.001$], and received less ropivacaine [CEI 72.5 (43.0) mg *vs* PIEB+PCEA 40.4 (23.8) mg, $P<0.001$]. There was no significant difference in mode of delivery, fentanyl dose, or maternal satisfaction.

Conclusions: Benefits of PIEB+PCEA over CEI previously demonstrated in small randomised controlled trials were reproducible on a larger scale in a clinical setting.

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Editor's key points

- Reduced motor block and labour duration may result from optimising epidural analgesia.
- This evaluation of changing labour analgesia protocols assessed different dosing schedules and modes.
- Intermittent epidural bolusing plus patient controlled epidural analgesia reduced motor block compared with continuous infusion.
- Second stage of labour duration was reduced, but there was no difference in overall satisfaction.
- This service evaluation reflects differences between randomised controlled trial evidence and clinical practice.

In New South Wales, Australia, 35% of women in public hospitals and 53% in private hospitals elect to have an epidural for labour pain.[1] Until recently, the standard analgesic regimen was a local anaesthetic combined with an opioid delivered by a continuous epidural infusion (CEI)[1,2] or CEI combined with patient controlled epidural analgesia (PCEA).[3] Intermittent boluses of solution at regular intervals can spread more extensively in the epidural space compared with a continuous infusion,[4] possibly enabling greater therapeutic efficacy. Evidence from randomised controlled trials (RCTs) shows that that programmed intermittent epidural bolus (PIEB) can achieve lower rates of motor block and shortened second stage of labour with similar or better patient satisfaction outcomes using a lower total dose of local anaesthetic.[2]

We conducted a prospective, controlled, before-and-after cohort study to evaluate the change from CEI to PIEB+PCEA for providing epidural analgesia during labour in a metropolitan tertiary referral hospital located in Sydney, New South Wales, Australia. Our aims were to translate the best available evidence for a promising intervention into clinical practice, to evaluate its effectiveness based on patient-centred labour outcomes, and to externally validate the evidence from small RCTs in a larger population in the complexities of the 'real world'.

Methods

This article was prepared in accordance with guidelines for Strengthening the Reporting of OBservational studies in Epidemiology (STROBE).[5]

Study design

This is a prospective, controlled, before-and-after cohort study designed to evaluate the effectiveness of PIEB+PCEA *vs* CEI for labour analgesia. This study was approved by the Western Sydney Local Health District Human Research Ethics Committee [HREC2014/11/5.2(4138)]. Written informed consent was not required by the ethics committee as the study related to an evidence-based institutional change of practice.

Setting and participants

Blacktown Hospital is a tertiary referral hospital located in Sydney, New South Wales, Australia. The obstetric unit handles about 3000 deliveries per year with a lower segment Caesarean section (LSCS) rate of 28% and epidural rate of 21%. All women who received epidural analgesia for planned normal vaginal delivery were eligible for inclusion in the study. Exclusion applied to women who received less than 10 ml of the epidural solution.

The study took place between December 2014 and September 2015, allowing a comparison period of 5 months before and after the change in the standard epidural infusion protocol. Before May 2015, our standard epidural infusion protocol for labour analgesia consisted of a continuous infusion of ropivacaine 0.2% with fentanyl 2μg ml^{-1} (5–15 ml h^{-1}) (CEI group). From May 2015, we changed the protocol to ropivacaine 0.1% with fentanyl 2 μg ml^{-1} with an hourly programmed intermittent bolus of 5 ml plus a PCEA programme of 5 ml bolus with a 10 min lockout period (PIEB+PCEA group). The PIEB bolus volume could be increased up to 10 ml if required.

In all cases, the epidural catheter was inserted according to standard protocols by trained anaesthetic staff, and an initial loading dose of bupivacaine 0.125%, 15–20 ml with fentanyl 5 μg ml^{-1} was given. The loading dose was not included in the total dose analysis as it was part of standard protocol for both groups. An epidural infusion was commenced 30–60 min after insertion of the epidural. CEI was turned down to 2 ml h^{-1} when the midwife assessed the woman was ready to start the second stage of labour, while PIEB+PCEA was continued until delivery.

The follow-up and data collection was performed by the acute pain clinical nurse consultant or an anaesthetic registrar.

Data collection

Patient characteristic data collected about the study participants included maternal age, parity, and gestational age.

The primary outcome was the prevalence of lower limb motor block defined as any weakness in the lower limbs according to the Bromage scale (grade II–IV) and was assessed every two hours from the time of insertion by the midwife during labour.

The secondary outcomes were total local anaesthetic dose, total fentanyl dose, duration of the second stage of labour, mode of delivery, hypotension requiring resuscitation, and maternal satisfaction during the first and second stages of labour. Maternal satisfaction was elicited at the epidural review on the day after delivery using a 10-point verbal numeric rating scale.

The epidural solution was administered by a CADD®-Solis epidural pump (Smith Medical, MN, USA). The PIEB and PCEA bolus was administered at a rate of 250 ml h^{-1}. Total local anaesthetic dose was calculated by volume and concentration of local anaesthetic infused which was recorded by the