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ORIGINAL ARTICLE

A randomized comparison of a five-minute versus fifteen-minute lockout interval for PCEA during labor

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Background: The best combination of bolus size and lockout interval for patient-controlled epidural analgesia (PCEA) is not known. This study compared a 5-min with a 15-min lockout interval.

Methods: Parturients were randomly assigned to receive PCEA with either a 5-min or a 15-min interval. All had a 15-mL loading dose, continuous background infusion 6 mL/h of 0.125% bupivacaine plus fentanyl 2 μg/mL, PCEA bolus volume 5 mL, maximum hourly dose 26 mL. Visual analogue scores for pain, nausea and pruritus, sensory levels to ice, sacral analgesia, motor power, blood pressure and fetal heart rate were assessed pre-epidural and regularly thereafter until delivery. The numbers of boluses and attempts and patient satisfaction were recorded.

Results: 29 patients were assigned to the 5-min group and 31 to the 15-min group, but the 15-min group contained twice as many nulliparous women. Side-effect and complication rates did not differ between groups. VAS pain scores were reduced from a median of 79 in the 15-min group and 82 in the 5-min group to a median of zero 30 min after epidural insertion. Bolus/attempt ratio was 0.88 in the 5-min vs. 0.70 in the 15-min group. The numbers of requests for physician intervention were similar. No differences in pain scores, side-effects, drug use or patient satisfaction were demonstrated.

Conclusion: The 5-min lockout interval appears the more efficient and has been used safely in our practice for 15 000 parturients, although a larger study is required to confirm the relative efficacy, efficiency and safety of this regimen.

Keywords: Anesthesia: Obstetric; Epidural; Patient controlled analgesia; Anesthetics, local: bupivacaine; Opioids: fentanyl; Measurements: visual analogue scale, bolus-to-attempt-ratio

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INTRODUCTION

Patient-controlled epidural analgesia (PCEA) during labor has become increasingly popular with patients, nurses and physicians alike. It provides advantages over continuous infusion epidural analgesia, which include patient-control, dose-sparing, immediate availability of a bolus dose, and possibly greater efficiency.[1] A number of studies have evaluated the effects of different dosing schedules on the effectiveness of labor analgesia using PCEA.[2–10] Lockout intervals between 5[11] and 30 min[2] have all been used. In theory, a shorter lockout interval might improve labor analgesia by reducing the time before a patient can self-administer another dose if needed, while improving patient satisfaction. In addition, a shorter lockout interval might reduce manpower needs associated with top-ups for inadequate labor analgesia. This study compares a PCEA bolus of 5 mL plus a 5-min lockout interval, (a more aggressive dose regimen than

previously studied), with a PCEA bolus of 5 mL plus a 15-min lockout interval, a more commonly used recipe. The hypothesis that the 5-min lockout is superior to the 15-min lockout was tested with the primary outcome variables being analgesic efficacy as assessed by visual analogue (VAS) pain scores. Secondary outcome variables included sensory levels, drug use, ratio of boluses/attempted boluses (b/a), number of physician interventions, patient satisfaction, and the incidence of side effects.

METHODS

Following approval by the Sharp Healthcare Institutional Review Board, 65 patients gave written consent to participate in the study. American Society of Anesthesiology (ASA) class I-II, English-speaking parturients, in active labor with an uncomplicated singleton pregnancy, were recruited early during labor and before they requested epidural analgesia. Exclusion criteria included presence of medical or obstetric complications, contraindications to epidural analgesia and allergy to local anesthetic or fentanyl. Each parturient received 500-1000 mL of intravenous crystalloid solution before epidural catheter insertion at the L 2/3 or L3/4 interspace. All patients received a 15-mL epidural loading dose and a 6-mL/h background infusion of 0.125% bupivacaine plus fentanyl 100 μg and had access to 5-mL bolus doses by PCEA of the same solution. Patients were assigned to one of two PCEA groups using a computerized randomization schedule: in the "15-min group" the lockout interval was 15 min, while in the "5-min group" it was 5 min. The maximum allowable hourly dose was 26 mL (32.5 mg of bupivacaine and 52 μg of fentanyl) for both groups. A study nurse not involved in the care of the patient used a computer-generated randomization sheet to program the PCA pump. This study nurse was the only person not blinded to group assignment and pump settings. All patients were instructed to use the demand button when pain returned and to expect some relief within 10 min. Patients were encouraged to have the anesthesiologist called if they felt that analgesia was inadequate. The data collectors were not involved in the clinical management of the patient. The following data were collected before, 30 and 60 min after epidural insertion and hourly thereafter until delivery: VAS scores using a 100-mm scale for pain, nausea and pruritus, sensory levels to ice, sacral analgesia as assessed by sensation to ice at the S2 dermatome bilaterally (popliteal fossa) and motor power as measured on a 1-4 scale modified from Bromage:[12] (1: unable to move legs or feet, 2: able to move feet, 3: able to flex knees, 4: able to flex hips). Bilateral sensory levels were tested by moving an ice cube across the patient's skin, starting in blocked segments and proceeding cephalad towards unblocked segments. The heart rate, systolic and mean arterial pressure, need for treatment of hypotension (<100 mmHg systolic or <20% of baseline), fetal heart rate and the number of PCEA boluses and attempts were also recorded. The ratio of self-administered boluses to attempts (b/a) was calculated and the number of requests per patient for unscheduled visits by the anesthesiologist was recorded.

Other data included total and hourly PCEA volumes used, mode of delivery and neonatal outcome including Apgar scores and birth weight. Within one hour of delivery, patients were asked to rate their satisfaction with the analgesic regimen on a four-point scale (1: poor, 2: satisfactory, 3: good, 4: excellent) for the periods before epidural insertion (i.v. analgesia) and for three periods after epidural catheter insertion: the first and second stages of labor, and delivery.

For the purpose of this study, the first stage of labor was defined as the time between epidural insertion until full cervical dilatation. The second stage was defined as the time between full cervical dilatation and delivery.

Statistical analysis

Power analysis was carried out using PASS statistical software (Number Cruncher Statistical System, NCSS). The primary outcome variable for sample size determination was VAS pain score. The sample size was computed using information from previous studies and an assessment of clinical relevance. In order to detect a 20% difference in mean VAS scores, assuming a standard deviation of 25% of the magnitude of the mean (that is, a moderate effect size of 0.25), and to achieve 80% power and 5% level of significance, 30 subjects per group were required. Normally distributed data were expressed as means ± standard deviation; other data were expressed as medians and interquartile ranges. PCEA data-use patterns and VAS for pain were analyzed both as a function of time after epidural insertion as well as time before delivery. This approach served to synchronize the dataset, so that for a given event of interest (either administration of the loading dose or delivery) at any given time-point, women were at the same stage relative to the event of interest. Baseline and 30-min data were excluded when pain data were expressed as time before delivery in order to exclude the effect of baseline pain and the initial loading dose on the pain curve. Data pertaining to the side effect profile (nausea, pruritus, hypotension, need for ephedrine, motor scores) were analyzed as a function of time after epidural insertion/administration of the loading dose with the rationale that the loading dose represented the largest single dose of drug and thus was more likely to cause side effects than use of the PCEA itself.