

Patient-controlled Epidural Analgesia during Labor: A Comparison of Three Solutions with a Continuous Infusion Control

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This study examined the efficacy of patient-controlled epidural analgesia (PCEA) during labor and compared the suitability of three different PCEA solutions. After establishing effective epidural analgesia with 12 ml of 0.25% bupivacaine, 72 parturients in active labor were randomly assigned to one of four groups: physician-controlled continuous epidural infusion using 0.125% bupivacaine (CEI); PCEA using 0.125% bupivacaine (B); PCEA using 0.125% bupivacaine with fentanyl 1 µg/ml (BF); and PCEA using 0.125% bupivacaine with fentanyl 1 µg/ml and 1:400,000 epinephrine (BFE). The CEI infusion was begun at 12–16 ml/h and adjusted to maintain a T10 sensory level and adequate pain relief. PCEA pumps were programmed to deliver a 6 ml/h basal infusion, 4 ml on-demand boluses, 10-min lockout intervals between doses, and a 20 ml hourly limit. Hemodynamic parameters, sensory level, quality of analgesia, duration of labor, overall satisfaction, and Apgar scores did not differ among groups. Compared with CEI, PCEA with plain bupivacaine did not decrease total local anesthetic usage or average hourly infusion rates during labor. However, addition of fentanyl (groups BF and BFE) decreased hourly infusion requirements. Average hourly infusion rates were 13.0 ± 1.1 ml/h (B), 10.6 ± 0.6 ml/h (BF), and 9.6 ± 0.5 ml/h (BFE); group B differs from others ($P < 0.05$). No instance of respiratory depression or complication secondary to PCEA was observed. Mild pruritus occurred only with fentanyl-containing solutions, whereas dense motor block developed more frequently with the epinephrine-containing solution. These data suggest that PCEA is a safe and effective method for labor analgesia but that it does not reduce anesthetic requirements or improve analgesia compared with a closely titrated infusion. Of the solutions tested, 0.125% bupivacaine plus fentanyl, 1 µg/ml, appears the most suitable for PCEA use. (Key words: Analgesia: patient-controlled. Anesthesia: obstetric. Anesthetic technique: epidural.)

PROVIDING EFFECTIVE AND SAFE pain relief during labor requires titration of analgesics to treat a pain stimulus that varies greatly both between individuals and, within each individual, as labor progresses. Patient-controlled analgesia (PCA) allows individual titration of drug delivery, minimizing periods of overmedication or inadequate analgesia, and PCA with iv opioids can successfully provide labor analgesia.¹⁻³ However, systemically administered

opioids may alter fetal heart rate patterns and produce maternal sedation or neonatal respiratory depression.⁴ Epidural infusion of local anesthetic and/or opioids provides selective, segmental analgesia, and can produce perineal anesthesia for delivery and postpartum surgical repairs. A preliminary report⁵ suggested that patient-controlled epidural analgesia (PCEA) during labor minimizes periods of pain and provides analgesia using less local anesthetic than continuous epidural infusion (CEI). However, the slow onset of analgesia following each patient-administered dose of epidural local anesthetic could lead to transient inappropriately increased patient demands, extensive neural blockade, and hemodynamic instability. Although addition of epinephrine or fentanyl to bupivacaine speeds onset of analgesia, such combinations have not been examined for use in PCEA during labor. To address these issues, this study compares side effects, pain control, and drug requirements, not only between PCEA and continuous bupivacaine infusion but also between PCEA with bupivacaine alone and bupivacaine in combination with “enhancers” (fentanyl, epinephrine).

Materials and Methods

The Clinical Research Practices Committee approved the study and informed consent was obtained from all participants. We limited participation to ASA Physical Status 1 or 2 parturients with term singleton fetuses in vertex presentation and no history of fetal compromise. Patients with evidence of fetal distress prior to epidural catheter insertion or history of adverse reactions to opioids or local anesthetics were excluded.

Single distal orifice epidural catheters were inserted at the L2–3, L3–4, or L4–5 interspace in parturients when the cervix was dilated 3–7 cm. Incremental injection of 0.25% bupivacaine (2 ml, followed in 5 min by 5 ml, followed in 3 min by 5 ml) established at least a bilateral T10 pinprick sensory block ensuring proper epidural placement. Patients with inadequate analgesia following these injections were excluded from the study.

Patients were randomly assigned to one of four groups (table 1). The CEI group received a 0.125% bupivacaine infusion initiated at 12–16 ml/h and titrated hourly by adjusting infusion rate in 2 ml/h increments to maintain sensory blockade to at least the T10 dermatome and adequate analgesia. The three PCEA groups received

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TABLE 1. Composition of Study Syringes

Group	N	Bupivacaine 0.25% (ml)	Saline (ml)	Fentanyl (μ g)	Epinephrine (μ g)
CEI	18	25	25	0	0
B	16	25	25	0	0
BF	21	25	24	50	0
BFE	17	25	23.875	50	125

0.125% bupivacaine alone (B) or in combination with fentanyl 1 μ g/ml (BF) or fentanyl 1 μ g/ml and epinephrine 1:400,000 (BFE). PCA pumps were programmed to deliver a 6 ml/h base infusion, 4 ml patient triggered boluses, 10 min lockout periods between doses, and a 20 ml hourly limit. Each participant was limited to 100 ml of a study solution and thereafter received plain 0.125% bupivacaine. All patients could receive up to three additional physician-administered 5 ml doses of 0.125% bupivacaine for inadequate analgesia. Patients with inadequate analgesia after three doses were removed from the protocol (one patient in the CEI group, one patient in the BF group). Physicians were blinded to PCEA content and injected 0.25% bupivacaine epidurally as required for perineal analgesia prior to delivery. Patients receiving less than 2 h of infusion were excluded from data analysis. Seventy-two parturients satisfied these study criteria.

PCEA participants used Bard™ programmable PCA infusion pumps with handheld trigger devices. We loaded infusion pumps with 50 ml of solution per syringe and attached the PCA delivery tubing directly to the epidural catheters. Three digit entrance codes and case locks prevented inadvertent reprogramming or tampering. A memory module recorded all patient demands and volume delivered.

Parturients reported pain intensity on a 0 to 10 verbal scale (0 = no pain, 10 = worst conceivable pain) prior to epidural catheter insertion, at the initiation of the epidural infusion, and every hour until delivery. Fetal heart rate was continuously monitored throughout the study period. Maternal heart rate and blood pressure were measured with a Dinamap™ vital signs monitor with each initial dose, and then every 5 min for 15 additional min. Blood pressure, heart rate, sensory level to pin testing, motor strength, and the presence of pruritus, nausea, or respiratory depression were noted at hourly intervals during the infusion. Hypotension, defined as a decrease in systolic blood pressure by 30% from baseline or to a value less than 100 mmHg, was treated by iv fluid administration and incremental doses of ephedrine. Motor blockade was scored on a 0–3 scale (0 = free movement of legs and feet; 1 = free movement of feet, decreased ability to flex knees; 2 = unable to flex knees, able to move toes; 3 = unable to move knees or feet) based on the grading system of Bromage *et al.*⁶ The respiratory rate of all PCEA

patients was monitored for 6 h after discontinuing a study infusion. On the first postpartum day all patients assessed their overall satisfaction with labor analgesia on a 4-point scale (0 = unsatisfactory, 1 = fair, 2 = good, 3 = excellent). Maternal height, weight, age, gravidity, parity, method of delivery, 1- and 5-min Apgar scores, and use of neonatal naloxone were recorded.

Noncontinuous variables were compared using chi-square analysis. Continuous variables were compared using one- and two-way analysis of variance (ANOVA) as appropriate, with post hoc *t* tests using a Bonferonni correction. *P* < 0.05 was considered significant.

Results

The groups did not differ in demographic or labor characteristics (table 2). The overall cesarean section rate observed in this study (19%) is identical to that observed in a previous study of epidural anesthesia for labor at our institution.⁷ No neonates received naloxone, and only one infant (in the CEI group with congenital heart disease) had a 5-min Apgar score less than 7.

Labor analgesia was equivalent for all groups, and pain scores in all groups tended to increase during the later periods of labor (fig. 1). Only one patient (in group BF) used more than 100 ml of study solution. The percentage of patients requiring additional 0.25% bupivacaine to provide dense perineal anesthesia sufficient for pain-free episiotomy prior to delivery did not differ among groups (CEI, 15/17; B, 10/15; BF, 12/14; and BFE, 12/14). Overall satisfaction with labor analgesia was similar for all groups (proportion of patients with excellent satisfaction was 94% in CEI, 76% in PCEA-B, 82% in PCEA-BF, and 94% in PCEA-BFE). No patient in any group reported a satisfaction score less than 2.

TABLE 2. Demographic and Labor Characteristics

	CEI (n = 18)	B (n = 16)	BF (n = 21)	BFE (n = 17)
Age (yr)	25 ± 1	26 ± 1	25 ± 1	27 ± 2
Weight (kg)	74 ± 2	81 ± 3	71 ± 2	81 ± 2
Height (cm)	164 ± 1	165 ± 1	164 ± 1	165 ± 2
No. of nullipara	15	10	16	11
Cervical (cm) dilatation	4.4	4.3	4.1	4.4
Duration 1st stage (min)	536 ± 43	577 ± 55	534 ± 69	632 ± 70
Duration 2nd stage (min)	111 ± 15	115 ± 25	93 ± 17	107 ± 17
No. of C/S	1	1	7	5
Proportion of vaginal deliveries by forceps	7/17	4/15	5/14	5/12
Apgar <7				
1 min	2	1	1	0
5 min	1	0	0	0

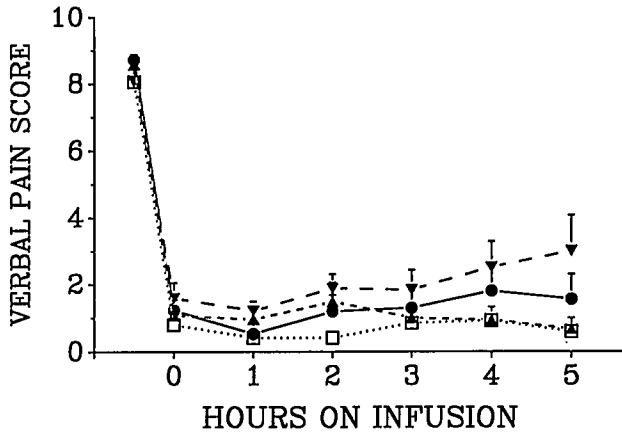


FIG. 1. Verbal pain scores prior to and immediately following institution of epidural anesthesia, and for 5 h during epidural infusion in patients receiving CEI (●), PCEA-B (▼), PCEA-BF (▲), and PCEA-BFE (□). Each point represents the mean \pm SEM of 8–22 patients. No difference among groups by two-way ANOVA.

Mean levels of pinprick analgesia did not differ among groups (fig. 2). Despite hourly evaluations of the CEI infusion rates and low PCEA basal rates, a bilateral sensory block more cephalad than T9 occurred in a significant percentage of hourly observations in all groups (CEI, 23%; B, 16%; BF, 28%; and BFE, 30%). Three PCEA patients, despite excellent analgesia and reported understanding of PCA technique, developed a sensory block more cephalad than T6 without hemodynamic compromise.

Although total bupivacaine usage (initial test dose + infusion + sitting dose) for vaginal delivery was similar among groups (133 ± 9 , 119 ± 10 , 111 ± 8 , and 113 ± 8 mg for groups CEI, PCEA-B, BF, and BFE, respectively), the groups differed in average hourly infusion require-

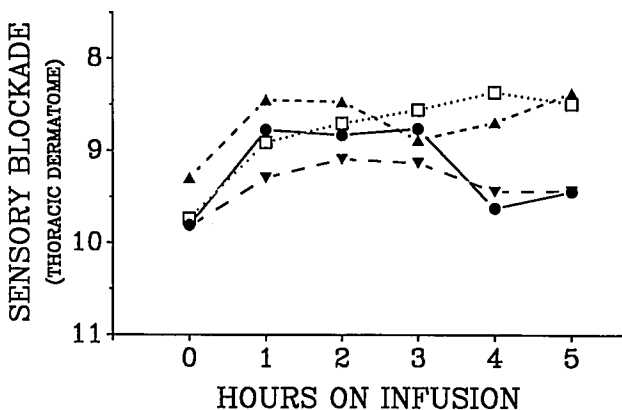


FIG. 2. Average of left and right cephalad dermatome of sensory blockade to pinprick following institution of epidural anesthesia and for 5 h during epidural infusion in patients receiving CEI (●), PCEA-B (▼), PCEA-BF (▲), and PCEA-BFE (□). Each point represents the mean of 8–22 patients. No difference among groups by two-way ANOVA.

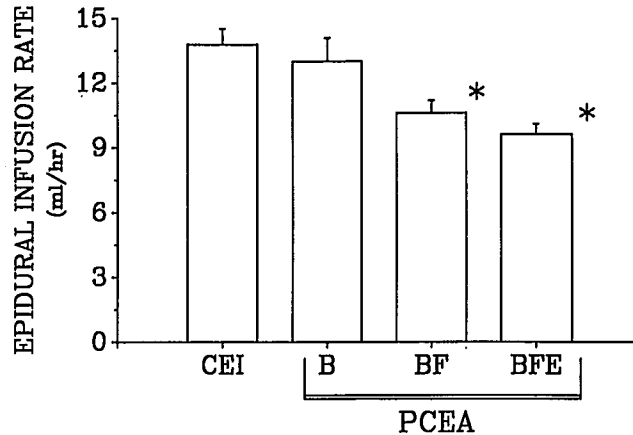


FIG. 3. Average solution infusion rate, including incremental doses, but excluding initiation and "sitting" doses, for patients in the CEI and PCEA groups. Error bars represent one SEM. * $P < 0.05$ versus PCEA-B.

ments (fig. 3). Within each group, patients who delivered vaginally or by cesarean section had similar infusion rates during labor.

Incidence of side effects differed among groups (table 3). Mild pruritus, not requiring treatment, occurred only in patients receiving fentanyl-containing solutions. No patient complained of pruritus but answered positively after direct questioning. Dense, grade 2 or 3 motor block, was most frequently observed in the group receiving the epinephrine-containing solution (table 3) and developed predominantly following prolonged infusions (fig. 4). Maternal heart rate and blood pressure during labor did not vary among groups. No participant had a respiratory rate < 12 breaths/min either during or for 6 h following epidural infusion.

Discussion

This study compares the efficacy of PCEA versus carefully titrated CEI during labor, examines the suitability of different solutions for PCEA, and provides preliminary information on PCEA safety.

EFFICACY

According to the parameters measured in this study, PCEA shows no advantages over CEI. In contrast to a

TABLE 3. Percentage of Hourly Observations with Side Effects

Group	Nausea	Pruritus	Grade 2–3 Motor Block
CEI	13	0	7
PCEA B	4	0	9
PCEA BF	4	6	2
PCEA BFE	3	2	26*

* $P < 0.05$ versus all other groups.

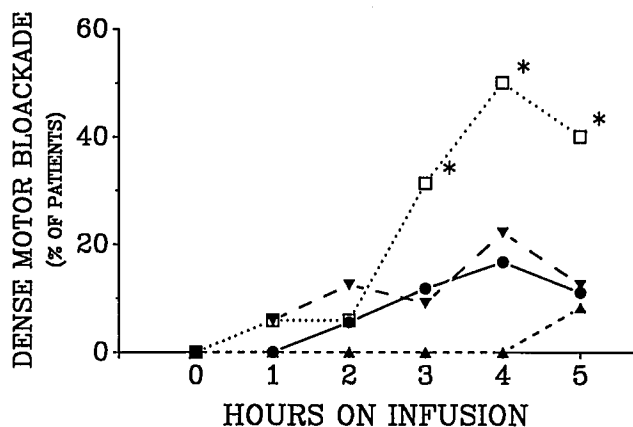


FIG. 4. Percentage of patients with dense (grade 2 or 3) motor block following institution of epidural anesthesia, and for 5 h during epidural infusion in patients receiving CEI (●), PCEA-B (▼), PCEA-BF (▲), and PCEA-BFE (□). Each point represents the mean of 8–22 patients. Group PCEA-BFE differs from others by two-way ANOVA. * $P < 0.05$ versus 0 time point.

previous study,⁵ when compared with CEI, PCEA using 0.125% bupivacaine does not decrease anesthetic requirements or improve analgesia. This discrepancy may occur for several reasons:

1. *Patient management.* In contrast to the fixed dose in the previous study,⁵ the CEI rate was adjusted every hour in this study, and additional bupivacaine administration (5 ml of 0.125% bupivacaine \times 3) was provided at patient request. Also, higher hourly limits (20 ml/h *vs.* 16 ml/h) and shorter lockout intervals (10 *vs.* 20 min) for PCEA were used. These changes enabled gradual decreases in CEI drug use and more rapid drug delivery during PCEA.

2. Closely supervised conventional analgesia with systemically administered opioids can mimic PCA producing equivalent analgesia^{8,9} and in some cases equal drug consumption.‡ In similar fashion, the close physician attendance to our CEI group may have duplicated the on-demand aspects of PCEA.

3. A trend toward less total bupivacaine and lower hourly rates is noted in this study. Establishing statistical significance for this small difference would require a much larger study group ($n = 173$ in each group).

PCEA allows the parturient more direct control over the severity of pain experienced while in labor. Proponents of PCA suggest that increased participation and the feeling of self-control provide psychologic benefits and greater satisfaction.⁸ Despite these theoretic considerations, the CEI and PCEA regimens resulted in equal over-

all satisfaction. The positive interpersonal feedback gained from close physician attention to the CEI group may have produced psychologic rewards equivalent to PCEA. At the 24-h postpartum interview, the four groups reported excellent pain relief and had no complaints about the administration of their epidural analgesia. No woman had difficulty in accepting or implementing the concept of PCEA, and all users were willing to employ PCEA again in future deliveries.

We postulated that rapid analgesic feedback during PCEA would allow women more accurate control of epidural blockade. Sensory level could be closely limited and decreased during the second stage to gain motor strength and facilitate spontaneous delivery. Alternatively, PCEA dosing to develop sacral analgesia in response to pain during the second stage of labor could obviate the need for additional perineal anesthesia at delivery. Neither postulate was supported in this study: CEI and PCEA groups demonstrated equivalent sensory levels throughout labor and delivery. As with drug usage, this lack of difference may reflect close supervision and infusion titration in the CEI group.

SELECTION OF SOLUTION

The ideal PCA agent would be a rapid-acting and highly effective drug without adverse side effects.¹⁰ Rapid onset improves patient feedback and allows close titration of drug requests to changes in pain intensity. Fentanyl–bupivacaine combinations reportedly provide faster and more complete relief of labor pain than that provided by plain bupivacaine^{11,12} with decreased bupivacaine infusion requirements.¹³ Fentanyl presumably increases analgesia *via* stimulation of spinal opiate receptors and systemic absorption.¹⁴ Adding epinephrine to epidural bupivacaine hastens onset⁷ and prolongs effective analgesia,^{7,15} probably by activating spinal α -adrenergic pain processing systems¹⁶ and decreasing vascular absorption of epidural bupivacaine.¹⁷ Our PCEA results substantiate the potentiating effect of fentanyl in reducing hourly bupivacaine use but revealed no additional benefit of adding epinephrine (2.5 $\mu\text{g}/\text{ml}$) to the bupivacaine–fentanyl combination. Epinephrine (3.75 $\mu\text{g}/\text{ml}$) markedly prolongs the duration of analgesia from a bolus injection of a 0.25% bupivacaine–fentanyl mixture during labor.¹⁸ The absence of an epinephrine potentiation in this study may be secondary to different bupivacaine–fentanyl concentrations and delivery methods.

Side effects may limit the usefulness of potential PCEA agents. In agreement with other studies,^{11–13} pruritus following epidurally administered fentanyl is infrequent, mild, and does not require treatment. Using 0.0001% fentanyl and restricting each patient to 100 ml of study solution limits fetal exposure to 100 μg of maternal epi-

‡ Tamsen A: Patient-controlled analgesia: A review of the current state of knowledge. *Seminars in Anesthesia* 5:100–107, 1986

dural fentanyl, a dose shown not to affect Apgar or neurobehavioral scores.^{19,20} As expected,⁶ epinephrine increased the incidence of profound motor block. In addition, because intravascular epinephrine decreases uterine blood flow²¹ and transient tachycardia due to iv epinephrine during PCEA may be overlooked or misinterpreted, inclusion of epinephrine would not appear to increase PCEA safety.

Operative deliveries occurred more frequently in this study in patients who received epidural fentanyl (12 of 38) than in those who did not (2 of 34; $P < 0.05$). However, other studies^{13,19} comparing bupivacaine *versus* bupivacaine-fentanyl epidural solutions in labor populations similar to ours have not reported increased cesarean section rates using bupivacaine-fentanyl combinations. Likewise, Naulty *et al.*²² reported a reduction in cesarean delivery when bupivacaine-fentanyl epidural infusion replaced intermittent lidocaine or bupivacaine injections. The higher percentage of operative deliveries in women receiving epidural fentanyl in this study most likely reflects random variation because the overall 19% rate is identical to a 1987 study group⁷ at our institution receiving routine epidural management, and further studies employing epidural fentanyl at our institution have not shown an increased cesarean section rate compared with control (unpublished observations).

Lower infusion requirements and minimal side effects form a favorable therapeutic profile for the BF solution. Whether slight reductions in bupivacaine usage justify concomitant epidural opioid administration or whether bupivacaine concentration could be further decreased when fentanyl is added are not addressed in this study.

SAFETY

Compared with intermittent injection, continuous epidural infusions may enhance both analgesia and maternal and fetal safety.²³ Continuous infusions avoid potentially dangerous iv or subarachnoid injections of large intermittent boluses through a catheter that has migrated out of the epidural space. However, no single set infusion rate will accommodate the great variation in individual requirements during labor. Using PCEA, our patients safely titrated epidural anesthesia despite a threefold variation in bupivacaine use (6.5–20 mg/h).

Low basal infusion rates, small on-demand boluses, and dilute local anesthetic solutions should enhance PCEA safety. Gradual dissipation or an increase in the sensory level out of proportion to drug delivery would warn of intravascular or subarachnoid catheter migration, respectively, before the development of deleterious effects. Every PCEA bolus functions as a partial subarachnoid test dose²⁴ as the sensory level would increase abruptly. The PCEA program's low hourly limit (20 ml of 0.125%

bupivacaine, 25 mg/h) minimizes the risk of systemic toxicity.

Although PCA technology is extremely reliable, rare mishaps occur,²⁵ usually secondary to human error in programming or loading PCA devices. PCEA is intended to augment rather than supplant medical attention during labor. Anesthetic personnel must be immediately available to recognize and correct the effects of catheter migration. Patient monitoring should be no less vigilant using PCEA than with any other epidural administration technique. Whether use of PCEA can decrease manpower needs on a busy obstetric anesthesia service and justify increased equipment expense is the subject of current study.

In summary, this study suggests that PCEA is a safe and effective method of providing labor analgesia. No complications directly related to PCEA use were encountered. Of solutions tested, low hourly infusion requirements and lack of significant adverse side effects favor use of 0.125% bupivacaine plus fentanyl, 1 μ g/ml, for PCEA during labor. Wider application of PCEA during labor awaits larger scale studies to more fully describe PCEA risks and benefits. As with all epidural analgesia techniques, close patient monitoring is still required.

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