

Continuous Epidural Infusion of 0.0625% Bupivacaine-0.0002% Fentanyl during the Second Stage of Labor

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A randomized, double-blind, placebo-controlled study was performed to evaluate the analgesic efficacy and influence of continuing an epidural infusion of 0.0625% bupivacaine-0.0002% fentanyl during the second stage of labor in nulliparous women. When the cervix was fully dilated, coded study solution was substituted for the known bupivacaine-fentanyl solution. The study solution for 29 patients was 0.0625% bupivacaine-0.0002% fentanyl; 34 patients received saline placebo. The two groups had similar pain scores during the first stage of labor. During the second stage, pain scores were significantly higher in the saline-placebo group at each 30-min interval between 60 and 150 min after the diagnosis of full cervical dilation. Similarly, there was a significant difference between the two groups in global assessment of analgesia quality during the second stage, but the difference occurred in those patients with a second-stage duration of ≥ 60 min. Among the women who delivered vaginally, eleven of 28 (39%) women in the bupivacaine-fentanyl group, versus five of 34 (15%) in the saline-placebo group, had surgical perineal anesthesia for vaginal delivery ($P < .05$). Six of 28 (21%) women in the bupivacaine-fentanyl group, and five of 34 (15%) in the saline-placebo group, underwent instrumental vaginal delivery ($P = \text{NS}$). The median duration of the second stage of labor was 53 min (range = 5-283) in the bupivacaine-fentanyl group, and 63 min (range = 16-181) in the saline-placebo group ($P = \text{NS}$). There were no significant differences between groups in Apgar scores or umbilical cord blood gas and acid-base values. The authors conclude that maintenance of an epidural infusion of 0.0625% bupivacaine/0.0002% fentanyl until delivery provided better second-stage analgesia than did replacement of the bupivacaine-fentanyl solution with saline placebo. Second, epidural infusion of bupivacaine-fentanyl until delivery did not significantly increase the incidence of instrumental delivery. (Key words: Analgesics, opioids: fentanyl. Anesthesia: obstetric. Anesthesia techniques: epidural. Anesthetics, local: bupivacaine.)

THERE is controversy regarding the management of epidural analgesia during the second stage of labor. Specifically, there is disagreement whether effective second-stage analgesia necessarily increases the incidence of instrumental delivery. In an earlier study,¹ we observed that

the continuous epidural infusion of 0.75% lidocaine beyond a cervical dilation of 8 cm did not prolong the second stage of labor or increase the incidence of instrumental delivery in nulliparous women, but it also did not reliably provide second-stage analgesia. In a second study,² we noted that the continuous epidural infusion of 0.125% bupivacaine beyond a cervical dilation of 8 cm resulted in second-stage analgesia that was clearly superior to that provided by replacement of the bupivacaine with saline placebo. However, epidural bupivacaine infusion until delivery prolonged the second stage of labor and increased the incidence of instrumental delivery.

The addition of opioid to local anesthetic allows a reduction in the dosage of local anesthetic and results in less-intense motor block.^{3,4} In an earlier study,³ we observed that the continuous epidural infusion of 0.0625% bupivacaine-0.0002% fentanyl produced first-stage analgesia similar to that provided by the infusion of 0.125% bupivacaine alone. Women who received bupivacaine-fentanyl experienced less-intense motor block, but they did not have a significantly shorter second stage or a lower incidence of instrumental delivery than women who received bupivacaine alone. A legitimate criticism of that study is that the epidural infusion was discontinued at full cervical dilation in both groups. We hypothesized that the less-intense motor block provided by 0.0625% bupivacaine-0.0002% fentanyl might allow the anesthesiologist to maintain epidural analgesia until delivery without increasing the likelihood of instrumental delivery. Therefore, the purpose of the present study was to determine if continuous epidural infusion of 0.0625% bupivacaine-0.0002% fentanyl during the second stage of labor: 1) provides effective second-stage analgesia; and 2) increases the incidence of instrumental delivery in nulliparous women.

Methods

The protocol was approved by the University of Iowa Institutional Review Board for research involving human subjects. Written informed consent was obtained from healthy, nulliparous women with term (≥ 36 weeks) singleton fetuses in vertex presentation. Women with pre-eclampsia or insulin-dependent diabetes were excluded. Each fetus had a normal heart rate pattern before induction of epidural analgesia.

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Each patient received an iv infusion of 750 ml lactated Ringer's solution over 10–15 min before induction of epidural analgesia. When the cervix was 3–7 cm dilated, an epidural catheter was inserted *via* the L3-4 interspace and advanced 3–4 cm. Each patient received, in sequence:

- 1) at time-zero, 3 ml of 1.5% lidocaine with 1:200,000 epinephrine;
- 2) at 5 min, 6 ml of 0.125% bupivacaine-0.0008% fentanyl;†
- 3) at 10 min, a continuous epidural infusion of 0.0625% bupivacaine-0.0002% fentanyl** at 12.5 ml/h *via* a syringe pump.

Uterine displacement was maintained continuously and each patient was encouraged to turn from side to side at 30-min intervals. The cephalad dermatomal level of anesthesia was determined by pinprick at 30-min intervals. The infusion rate was increased or decreased to maintain a sensory level of T10. If it was necessary to increase the rate of infusion, the patient first received an additional 5-ml bolus of 0.0625% bupivacaine-0.0002% fentanyl.

When the cervix was fully dilated, the syringe containing known bupivacaine-fentanyl solution was replaced by a 60-ml syringe of coded study solution, freshly prepared by a hospital pharmacist according to a table of random numbers. The study solution was administered in a double-blind manner. The study solution for one group of patients was 0.0625% bupivacaine-0.0002% fentanyl. Patients in the other group received saline placebo. The connecting tubing was disconnected from the epidural catheter and flushed with study solution before the infusion of study solution was begun. The rate of study solution infusion was equal to the previous rate of known bupivacaine-fentanyl infusion. Two 5-ml boluses of study solution were given to patients in whom perineal anesthesia was absent. Each patient was then encouraged to push with contractions.

The obstetric staff had agreed that the infusion of study solution would be continued until delivery in all patients unless there was a lack of progression in descent of the vertex after at least 2 h of the second stage. The obstetric staff had also agreed that operative delivery would be performed for obstetric indications only, and that they would not perform instrumental delivery for failure to progress until at least 3 h of the second stage.

Supplemental anesthesia was not administered to any patient until delivery. An epidural bolus of known local anesthetic was administered only if the obstetrician had decided to perform operative delivery. Otherwise, pudendal block and/or perineal infiltration with 1% lidocaine were performed as indicated.

The anesthesiologist asked each patient to indicate her pain score on an unmarked 100-mm visual analog pain scale (0 = no pain, 100 = worst possible pain) at 30-min intervals. Further, the anesthesiologist asked each patient to assess the quality of her analgesia during the first and second stages of labor. The first assessment ("How would you describe the quality of your pain relief since epidural anesthesia was begun: excellent, good, fair, poor, very poor?") was performed at the diagnosis of full cervical dilation. The second assessment ("How would you describe the quality of your pain relief during the time that you were pushing: excellent, good, fair, poor, very poor?") was performed immediately after delivery. If an epidural bolus of known local anesthetic was administered for operative delivery, the second assessment of analgesia quality was performed before administration of the epidural bolus.

Maternal blood pressure was determined at 1-min intervals for 20 min, and subsequently at 15-min intervals with an automated blood pressure monitor. Maternal hypotension was defined as a decrease in systolic blood pressure of $\geq 20\%$, or a systolic blood pressure < 100 mmHg. Hypotension was treated promptly by increasing the rate of iv fluid administration and by administering 5–10 mg of ephedrine intravenously.

The duration of the active phase of the first stage of labor was defined as the interval between cervical dilation of 4 and 10 cm. The duration of the second stage of labor was defined as the interval between the diagnosis of complete cervical dilation and delivery. Instrumental deliveries were classified according to the recent classification of the American College of Obstetricians and Gynecologists.†† Motor block was assessed according to the method of Bromage⁵ (none, partial, almost complete, complete). Neonatal assessment was by Apgar scores and umbilical venous and arterial blood gas and acid-base analysis.

Statistical analysis was by Student's *t* test, Wilcoxon test, chi-square, and Fisher exact test as indicated. The Kruskal-Wallis test was used to compare the two groups regarding patient assessment of analgesia quality. A split-plot analysis of variance for nonparametric data was used to test for divergence of ranked pain scores over time. $P < 0.05$ was considered statistically significant.

Results

Seventy-five women consented to participate in the study between July 1, 1988 and June 30, 1989. Eight women were excluded because they underwent cesarean delivery for dystocia after induction of epidural analgesia

† Fentanyl 8.33 $\mu\text{g/ml}$, or fentanyl 50 μg in 6 ml.

** Fentanyl 2 $\mu\text{g/ml}$, or 25 $\mu\text{g/h}$.

†† American College of Obstetricians and Gynecologists Committee Opinion: Obstetric forceps, #59, 1988.

but before full cervical dilation. Two women in each group were excluded because of a protocol violation during the second stage.

Among the remaining 63 patients, there were 29 patients in the bupivacaine-fentanyl group and 34 in the saline-placebo group. The two groups were similar with regard to maternal characteristics (table 1).

CONDUCT OF LABOR AND DELIVERY

Eleven patients in the bupivacaine-fentanyl group and nine in the saline-placebo group were receiving iv oxytocin before induction of epidural analgesia. Six patients in the bupivacaine-fentanyl group and four in the saline-placebo group had iv oxytocin started after induction of epidural analgesia.

There were no significant differences between groups in duration of the active phase of the first stage of labor, duration of infusion of known bupivacaine-fentanyl, or dosage of bupivacaine and fentanyl before the start of the study solution (table 2). Twenty-eight of 29 (97%) patients in the bupivacaine-fentanyl group and 33 of 34 (97%) in the saline-placebo group had no detectable motor block at the beginning of the second stage. Similarly, 27 of 29 (94%) patients in the bupivacaine-fentanyl group and 34 of 34 (100%) in the saline-placebo group had no detectable motor block just before delivery. The two groups were also similar with regard to position of the vertex immediately before delivery (table 2).

The epidural infusion of study solution was continued until delivery in all patients. One woman in the bupivacaine-fentanyl group and none in the saline-placebo group underwent cesarean section during the second stage for apparent cephalopelvic disproportion. (At surgery it was

TABLE 1. Maternal Characteristics

	Bupivacaine-Fentanyl (n = 29)	Saline-Placebo (n = 34)
Age (yr)*	21 ± 5	21 ± 4
Race		
Caucasian	28 (97%)	32 (94%)
Black	1 (3%)	2 (6%)
Socioeconomic status		
Indigent	22 (76%)	27 (79%)
Private	7 (24%)	7 (21%)
Childbirth preparation class		
None	16 (55%)	20 (59%)
Lamaze	9 (31%)	11 (32%)
Health Department/University	4 (14%)	3 (9%)
Gestational age (weeks)*	39.7 ± 1.6	40.1 ± 1.6
Weight (kg)*	76 ± 13	80 ± 16
Height (cm)*	164 ± 5	164 ± 7
Cervical dilation before epidural (cm)*	4.8 ± 1.0	5.1 ± 0.9

P was not significant.
* Mean ± SD.

TABLE 2. Conduct of Labor

	Bupivacaine-Fentanyl (n = 29)	Saline-Placebo (n = 34)
Duration of active phase of first stage (min)*	316 ± 188	317 ± 199
Duration of known bupivacaine-fentanyl infusion (min)*	227 ± 159	215 ± 164
Bupivacaine dosage before start of study solution (mg)*	47 ± 30	44 ± 29
Bupivacaine dosage after start of study solution (mg)*	16 ± 13	0
Fentanyl dosage before start of study solution (µg)*	169 ± 80	161 ± 84
Fentanyl dosage after start of study solution (µg)*	50 ± 41	0
Duration of second stage (min)†	53 (5-283)	63 (16-181)
Position of vertex immediately before delivery		
Occiput anterior	27 (93%)	31 (91%)
Occiput posterior	1 (3%)	3 (9%)
Occiput transverse	1 (3%)	0 (0%)

P was not significant.

* Mean ± SD.

† Median (range) (excluding one woman in the bupivacaine-fentanyl group who underwent cesarean section after full cervical dilation).

noted that an ovarian tumor seemed to have caused obstruction of fetal descent.) Among the remaining women who delivered vaginally, the median duration of the second stage of labor was 53 min (range = 5-283) in the bupivacaine-fentanyl group, and 63 min (range = 16-181) in the saline-placebo group (P = NS). Five of 28 (18%) women in the bupivacaine-fentanyl group versus one of 34 (3%) in the saline-placebo group had a second-stage duration of ≥180 min (P = 0.08). Six of 28 (21%) women in the bupivacaine-fentanyl group versus five of 34 (15%) in the saline-placebo group underwent instrumental vaginal delivery (P = .52) (table 3). Indications for the instrumental deliveries were: 1) failure to progress (four patients in the bupivacaine-fentanyl group, one in the saline-placebo group, P = NS); and 2) fetal distress (two patients in the bupivacaine-fentanyl group, four in the saline-placebo group, P = NS). Each patient with a diagnosis of failure to progress had had a second stage of at least 180 min.

TABLE 3. Method of Vaginal Delivery

	Bupivacaine-Fentanyl (n = 28)	Saline-Placebo (n = 34)
Spontaneous	22 (79%)	29 (85%)
Outlet forceps	0 (0%)	0 (0%)
Low forceps	2 (7%)	4 (12%)
Midforceps	2 (7%)	1 (3%)
Midvacuum followed by low forceps	2 (7%)	0 (0%)

P was not significant.

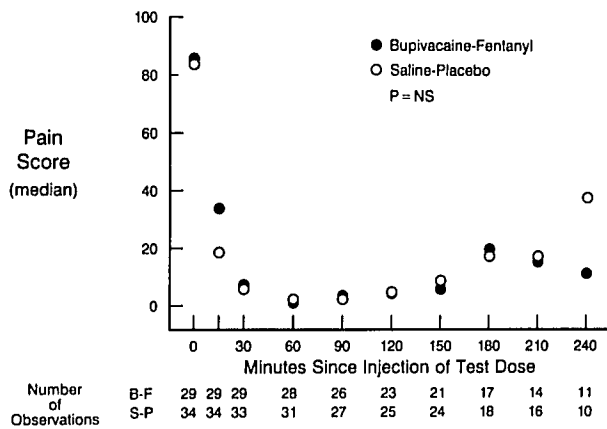


FIG. 1. Median pain scores during the first stage of labor.

ANALGESIA QUALITY

Eight of 29 (28%) patients in the bupivacaine-fentanyl group and 11 of 34 (32%) in the saline-placebo group had received an iv injection of nalbuphine before epidural analgesia ($P = NS$). No patient in either group received a systemic injection of opioid after induction of epidural analgesia.

Eighteen of 29 (62%) patients in the bupivacaine-fentanyl group and 24 of 34 (71%) in the saline-placebo group required at least one 5-ml bolus of known bupivacaine-fentanyl solution during the first stage of labor. At full cervical dilation, five patients in each group had an infusion rate > 15 ml/h. Eighteen of 29 (62%) patients in the bupivacaine-fentanyl group and 22 of 34 (65%) in the saline-placebo group did not have perineal anesthesia at full cervical dilation and received an epidural bolus of study solution.

The two groups had similar pain scores during the first stage of labor (fig. 1). Similarly, there was no difference

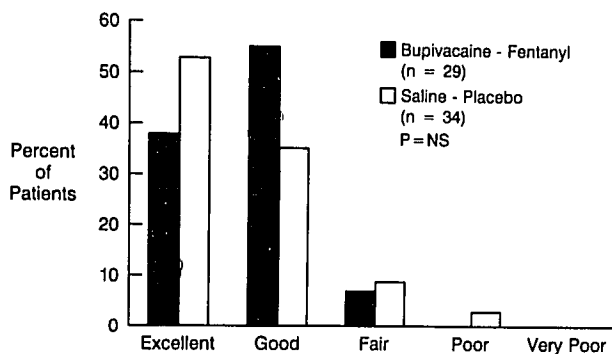


FIG. 2. Patient assessment of analgesia quality during the first stage of labor.

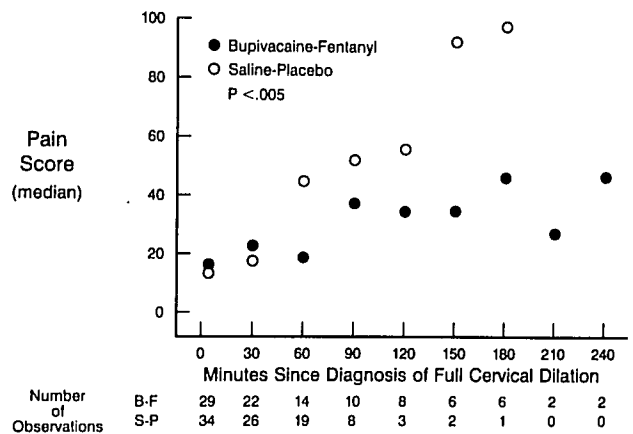


FIG. 3. Median pain scores during the second stage of labor. Pain scores were significantly higher in the saline-placebo group at each 30-min interval between 60 and 150 min.

between groups in patient assessment of analgesia quality during the first stage (fig. 2).

During the second stage, the two groups differed with regard to pain scores over time (fig. 3). Specifically, pain scores were significantly higher in the saline-placebo group at each 30-min interval between 60 and 150 min after the diagnosis of full cervical dilation (fig. 3). Similarly, there was a small but significant difference between the two groups in global assessment of analgesia quality during the second stage (fig. 4). As with the pain scores, the difference occurred in those patients with a second-stage duration of ≥ 60 min (fig. 5).

Among the women who delivered vaginally, 11 of 28 (39%) women in the bupivacaine-fentanyl group versus five of 34 (15%) in the saline-placebo group had surgical perineal anesthesia at delivery without administration of pudendal block, perineal infiltration, or an epidural bolus of known local anesthetic solution ($P < .05$).

The two groups were similar with regard to maternal side effects (table 4).

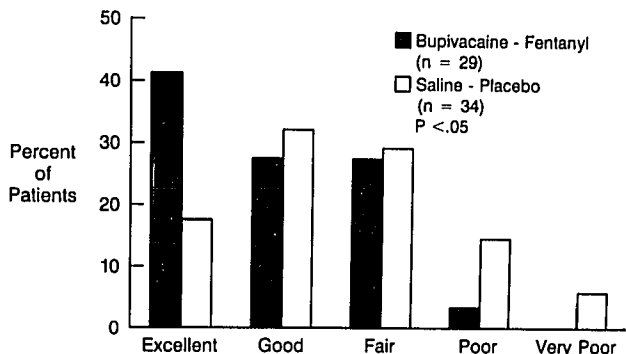


FIG. 4. Patient assessment of analgesia quality during the second stage of labor.

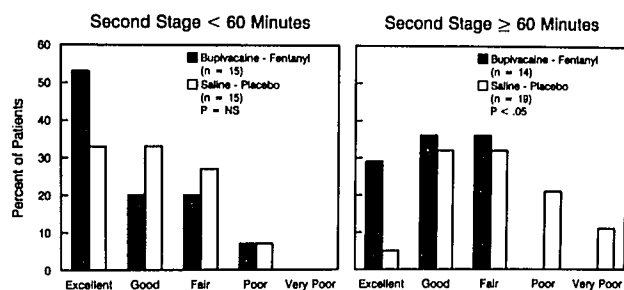


FIG. 5. Patient assessment of second stage analgesia quality according to whether the second stage was <60 min or ≥60 min duration.

EFFECTS ON THE FETUS AND NEONATE

Two of 29 (7%) patients in the bupivacaine-fentanyl group and four of 34 (12%) in the saline-placebo group had transient hypotension during the first hour after induction of epidural analgesia. No patient in the bupivacaine-fentanyl group and three of 34 (9%) patients in the saline-placebo group had transient hypotension thereafter (P = NS). No patient had hypotension during the second stage of labor.

The two groups were similar in infant weight, incidence of meconium-stained amniotic fluid, 1- and 5-min Apgar scores, and umbilical venous, arterial blood gas, and acid-base values (table 5). No infant in the bupivacaine-fentanyl group and one infant in the saline-placebo group received naloxone during the first hour after delivery.

Discussion

There are few data on the analgesic efficacy of epidural infusion of local anesthetic with opioid during the second stage of labor. In the present study, patients in the bupivacaine-fentanyl group had better analgesia in the second stage than women in the saline-placebo group according to all three methods of assessment (i.e., visual analogue pain scores, perineal anesthesia at delivery, and global assessment of analgesia quality), but the difference between groups was relatively small. We do not consider the better analgesia in the bupivacaine-fentanyl group to be self-evident. In an earlier study,¹ women who continued to receive an epidural infusion of 0.75% lidocaine

TABLE 4. Maternal Side Effects

	Bupivacaine-Fentanyl (n = 29)	Saline-Placebo (n = 34)
Pruritus	2 (7%)	4 (12%)
Nausea	4 (14%)	3 (9%)
Emesis	4 (14%)	3 (9%)
Urinary retention	12 (41%)	12 (35%)

P was not significant.

TABLE 5. Newborn Assessment

	Bupivacaine-Fentanyl (n = 29)	Saline-Placebo (n = 34)
Infant weight (g)*	3258 ± 528	3314 ± 390
Meconium-stained amniotic fluid	2 (7%)	5 (15%)
1-min Apgar ≥ 7	25 (86%)	31 (91%)
5-min Apgar ≥ 7	29 (100%)	34 (100%)
Umbilical venous blood analysis*		
pH	7.33 ± 0.08	7.32 ± 0.06
PO ₂ (mmHg)	27 ± 7	25 ± 6
PCO ₂ (mmHg)	37 ± 7	39 ± 5
Base excess (mEq/l)	-4.8 ± 2.7	-4.9 ± 2.4
Umbilical arterial blood analysis*		
pH	7.26 ± 0.07	7.27 ± 0.06
PO ₂ (mmHg)	18 ± 7	18 ± 5
PCO ₂ (mmHg)	46 ± 6	45 ± 7
Base excess (mEq/l)	-5.7 ± 3.3	-5.7 ± 2.8

P was not significant.

* Mean ± SD.

beyond 8-cm cervical dilation did not clearly perceive that they had better analgesia than women whose lidocaine was replaced by saline-placebo. Nonetheless, in the present study we expected a greater difference between groups in second-stage analgesia quality. We suggest four potential reasons why the difference was relatively small. First, substitution of saline-placebo for bupivacaine-fentanyl did not result in immediate diminution of analgesia, and some patients in the saline-placebo group delivered before the level of anesthesia had regressed. Second, the infusion of saline undoubtedly resulted in significant placebo effect in some patients. Third, we consider it difficult to accurately assess pain and analgesia quality during the second stage of labor. Brownridge and Obst⁶ evaluated the analgesic efficacy of epidural administration of 0.125% bupivacaine-0.25% meperidine. They observed that there was a significant correlation between pain scores and patient satisfaction during the first stage of labor, but there was an insignificant correlation between pain scores and patient satisfaction at delivery. Fourth, the low concentration of bupivacaine used in the present study seems inadequate to relieve the intense pain experienced by some patients during the second stage. Like our earlier study¹ of 0.75% lidocaine, the present study illustrates that maintenance of a previously satisfactory epidural infusion until delivery does not guarantee satisfactory second-stage analgesia.

As expected, there was a low incidence of clinically detectable motor block in the present study. Maintenance of the epidural infusion of bupivacaine-fentanyl until delivery did not significantly increase the incidence of instrumental delivery. We acknowledge the low power to detect a small difference between groups in incidence of instrumental delivery. Ideally we would have enrolled additional patients in the study. But an increasing number

of our obstetricians have requested that we provide epidural analgesia during the second stage, and it has become more difficult to identify patients who would accept randomization to active drug or saline-placebo. Further, it would be necessary to enroll approximately 675 patients in each group to confirm that the observed difference in incidence of instrumental delivery (*i.e.*, 21% *vs.* 15%) was statistically significant. However, in an earlier study² with a similar protocol and a similar patient population, epidural infusion of 0.125% bupivacaine until delivery was associated with instrumental delivery in 53% of the patients who delivered vaginally. The present study suggests that epidural infusion of 0.0625% bupivacaine-0.0002% fentanyl until delivery does not significantly increase the incidence of instrumental delivery.

In the present study, there was no significant difference between groups in duration of the second stage of labor. However, among the women who delivered vaginally, five of the six women with a second-stage duration ≥ 180 min were in the bupivacaine-fentanyl group. There is some evidence that effective epidural analgesia may slightly prolong the second stage of labor.^{2,7} But we² and others⁸ noted that a prolonged second stage during epidural analgesia was not associated with an increase in fetal heart rate abnormalities or a decrease in Apgar scores or umbilical cord blood pH. A delay in the second stage is not necessarily harmful to infant or mother, provided there is normal electronic fetal heart rate monitoring and adequate maternal hydration and analgesia.⁸⁻¹⁰ The American College of Obstetricians and Gynecologists^{‡‡} recently defined a prolonged second stage as >3 h in nulliparous patients *with* regional anesthesia, as compared with >2 h in nulliparous patients *without* regional anesthesia.

We conclude that, under the conditions of the present study, maintenance of an epidural infusion of 0.0625% bupivacaine-0.0002% fentanyl until delivery provided better analgesia than did replacement of the bupivacaine-fentanyl solution with saline placebo. The benefit oc-

curred primarily in those patients with a second-stage duration of ≥ 60 min. Second, epidural infusion of bupivacaine-fentanyl until delivery did not significantly increase the incidence of instrumental delivery. Third, epidural infusion of bupivacaine-fentanyl until delivery did not affect the condition of the infant at birth either positively or negatively, as assessed by Apgar scores and umbilical cord blood gas and pH values.

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