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Does Early Administration of Epidural Analgesia Affect Obstetric Outcome in Nulliparous Women Who Are Receiving Intravenous Oxytocin?

David H. Chestnut, M.D., Robert D. Vincent, Jr., M.D.,† Joan M. McGrath, M.D.,‡ Won W. Choi, M.D.,§ James N. Bates, M.D., Ph.D.‖*

Background: **Some studies suggest that epidural analgesia prolongs labor and increases the incidence of cesarean section, especially if it is administered before 5 cm cervical dilation. The purpose of the current study was to determine whether early administration of epidural analgesia affects obstetric outcome in nulliparous women who are receiving intravenous oxytocin.**

Methods: **Informed consent was obtained from healthy nulliparous women with a singleton fetus in a vertex presentation, who requested epidural analgesia while receiving intravenous oxytocin at at least 36 weeks' gestation. Each patient was randomized to receive either early or late epidural analgesia. Randomization occurred only after the following conditions were met: (1) the patient requested pain relief at that moment, (2) a lumbar epidural catheter had been placed, and (3) the cervix was at least 3 but less than 5 cm dilated. Patients in the early group immediately received epidural bupivacaine analgesia. Patients in the late group received 10 mg nalbuphine intravenously. Late-group patients did not receive epidural analgesia until they achieved a cervical dilation of at least 5 cm or until at least 1 h had elapsed after a second dose of nalbuphine.**

Results: **Early administration of epidural analgesia did not prolong the interval between randomization and the diagnosis of complete cervical dilation, and it did not increase the incidence of malposition of the vertex at delivery. Also, early administration of epidural analgesia did not result in an increased incidence of cesarean section or instrumental vaginal delivery. Thirteen (18%) of 74 women in the early group and 14 (19%) of 75 women in the late group underwent cesarean section (relative risk for the early group 0.94; 95% confidence interval 0.48–1.84). Patients in the early group had lower pain scores between 30 and 120 min after randomization, and were more likely to experience transient hypotension. Infants in the late group had lower umbilical arterial and venous blood *p*H and higher umbilical arterial and venous blood carbon dioxide tension measurements at delivery.**

Conclusions: **Early administration of epidural analgesia did not prolong labor or increase the incidence of operative delivery, when compared with intravenous nalbuphine followed by late administration of epidural analgesia, in nulliparous women who were receiving intravenous oxytocin. (Key words: Anesthetic techniques: epidural. Anesthetics, local: bupivacaine. Opioids: nalbuphine. Pregnancy.)**

This article is accompanied by an editorial. Please see: Dewan DM, Cohen SE: Epidural analgesia and the incidence of cesarean section: Time for a closer look. ANESTHESIOLOGY 80:1189–1192, 1994.

EPIDURAL analgesia during labor is associated with an increased risk of prolonged labor and operative delivery (*i.e.*, cesarean section or instrumental vaginal delivery). There remains controversy as to whether there is a cause-and-effect relationship between the use of epidural analgesia and prolonged labor or operative delivery. Some physicians have long argued that epidural analgesia prolongs the first stage of labor, especially if it is administered during the latent phase.[1–3] Two studies suggested that administration of epidural analgesia before 5 cm cervical dilation increases the risk of cesarean section in nulliparous women.[4,5] Unfortunately, some women—especially those who receive intravenous oxytocin for induction or augmentation of labor—experience severe pain during early labor. The purpose of the current study was to determine whether early administration of epidural analgesia affects obstetric outcome in nulliparous women who are receiving intravenous oxytocin.

* Professor of Anesthesia and of Obstetrics and Gynecology.

† Assistant Professor of Anesthesia.

‡ Associate in Anesthesia.

§ Professor of Anesthesia.

‖ Associate Professor of Anesthesia.

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Reprints will not be available. Address correspondence to Dr. Chestnut: Department of Anesthesiology, University of Alabama at Birmingham, 619 South 19th Street, Birmingham, Alabama 35233.

Methods

The protocol was approved by the University of Iowa institutional review board for research involving human subjects. Informed consent was obtained from healthy nulliparous women with a singleton fetus in a vertex presentation, who were receiving intravenous oxytocin for induction or augmentation of labor at at least 36 weeks' gestation, between January 1, 1990 and May 31, 1992. Exclusion criteria included: (1) preeclampsia; (2) insulin-dependent diabetes mellitus; (3) estimated fetal weight of at least 4,500 g; and (4) a cervical dilation of at least 5 cm.

Each patient was receiving intravenous oxytocin for induction or augmentation of labor *at the time of randomization.* The oxytocin infusion was begun at a rate of 1.0 mU/min, and the rate was increased by 1.0 mU/min, every 30 min, until an adequate labor pattern was achieved.

A patient was randomized to one of two groups by opening a sealed, opaque envelope that contained the identity of the group assignment. The envelopes were numbered, and the group assignments were made according to a computer-generated table of random numbers.

Each patient was randomized to receive either early or late epidural analgesia. A patient was randomized only *after* all of the following conditions were met: (1) the patient requested pain relief at that moment; (2) a 20-G epidural catheter had been placed via the L3–L4 interspace; and (3) the cervix was at least 3 but less than 5 cm dilated, according to a vaginal examination performed during the 30 min before opening the randomization envelope. Time zero was the time that the randomization envelope was opened.

At time zero, patients in the early group received a 500-ml bolus of Ringer's lactate intravenously. Five minutes after time zero, patients in the early group received 3 ml 1.5% lidocaine with epinephrine, via the epidural catheter. At 10 min, patients in the early group received 5 ml 0.25% bupivacaine via the epidural catheter. Subsequently, these patients received additional boluses of 0.25% bupivacaine, as needed to maintain analgesia, and to maintain a sensory level of at least T10. When the cervix was at least 5 cm dilated, each patient received a continuous epidural infusion of 0.125% bupivacaine, at an initial rate of 12 ml/h. The cephalad dermatomal level of anesthesia was determined by pinprick at 30-min intervals. The epidural infusion rate was adjusted to maintain satisfactory analgesia while minimizing motor block and optimizing expulsive efforts during the second stage of labor.

Five minutes after time zero, patients in the late group received nalbuphine 10 mg intravenously. Late-group patients could receive a second dose of nalbuphine, on request, at least 1 h after the first dose. Late-group patients did not receive epidural analgesia until they achieved a cervical dilation of at least 5 cm, or until at least 1 h had elapsed after the second postrandomization dose of nalbuphine. (The latter criterion was included as a rescue alternative.) At that time, late-group patients received a 500-ml bolus of Ringer's lactate intravenously. Subsequently, epidural analgesia was achieved and maintained, using a protocol identical to that used for the early-group patients.

Vaginal examinations were performed for obstetric indications and/or at any time that a patient requested analgesia. The cervical dilation was assessed using 0.5-cm increments (*i.e.*, a cervical dilation of 3–4 cm was considered to be 3.5 cm). The fetal heart rate was monitored continuously before, during, and after administration of nalbuphine or epidural analgesia in every patient. Adequate left uterine displacement was maintained at all times. An automated blood pressure monitor was used to determine maternal blood pressure every 2 min for the first 20 min after a bolus injection of local anesthetic. Subsequently, maternal blood pressure was measured every 15 min. Maternal hypotension was defined as a systolic blood pressure less than 100 mmHg, or a decrease of at least 20% in the systolic blood pressure. Hypotension was treated by intravenous administration of 5 or 10 mg of ephedrine, followed by administration of a bolus of Ringer's lactate.

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 time zero, and at 30-min intervals during the first stage of labor. Also, each patient was asked two additional questions at 60, 120, and 180 min after randomization. The first question was as follows: "How would you rate the quality of analgesia during the last hour—excellent, good, fair, or poor?" The second question was as follows: "How satisfied are you with your analgesia during the last hour—very satisfied, satisfied, unsatisfied, or very unsatisfied?"

Statistical analysis was by chi-square analysis, Fisher's exact test, Student's t test, and the Mann–Whitney U

Table 1. Maternal Characteristics

	Early (n = 74)	Late (n = 75)	P
Age (yr)*	26 ± 6	24 ± 6	NS
Race			
White	66 (89%)	65 (87%)	NS
Other	8 (11%)	10 (13%)	
Socioeconomic status			
Private	39 (53%)	40 (53%)	NS
Indigent	35 (47%)	35 (47%)	
Attended prepared childbirth class			
Lamaze	29 (39%)	25 (33%)	NS
Other	12 (16%)	15 (20%)	
None	33 (45%)	35 (47%)	
Gestational age (wk)*	39.7 ± 1.8	39.9 ± 1.5	NS
Weight (kg)*	81 ± 17	84 ± 16	NS
Height (cm)*	164 ± 6	164 ± 7	NS
Cervix at start of oxytocin (cm)†	2 (0.75)	2 (0.75)	NS
Reason for oxytocin			
Induction	24 (32%)	29 (39%)	NS
Augmentation of labor	50 (68%)	46 (61%)	
Membranes ruptured before randomization	73 (99%)	72 (96%)	NS

* Mean ± SD.

† Median (quartile deviation).

test as indicated. The Bonferroni test was used to correct for multiple comparisons of pain scores. $P < 0.05$ was considered significant, except for the analysis of pain scores, for which a P value < 0.005 was required for significance.

Results

One-hundred fifty patients were randomized to receive either early or late epidural analgesia. One patient in the early group was excluded after randomization, because the obstetrician discovered that the initial assessment of the fetal presentation was incorrect, and that the fetus had a breech presentation. That patient then underwent cesarean section because of breech presentation and an estimated fetal weight of 4,000 g.

The two groups were similar with regard to maternal characteristics (table 1). The most common indication for administration of oxytocin was induction or augmentation of labor after spontaneous rupture of membranes.

Table 2 summarizes data for the progress of labor. Early administration of epidural analgesia did not prolong the interval between randomization and the diagnosis of complete cervical dilation. Also, early administration of epidural analgesia did not increase the incidence of malposition of the vertex at delivery.

Early administration of epidural analgesia did not result in an increased incidence of instrumental vaginal delivery or cesarean section (table 3). Thirteen (18%) of 74 women in the early group, and 14 (19%) of 75

Table 2. Progress of Labor

	Early (n = 74)	Late (n = 75)	P
Interval between start of oxytocin and randomization (min)*	330 ± 254	306 ± 229	NS
Cervix at randomization (cm)†	3.5 (0.5)	3.5 (0.5)	NS
Cervix at time of epidural test dose (cm)†‡	3.5 (0.5)	5 (0.5)	<0.0001
Interval between randomization and epidural test dose (min)*	5 ± 2	122 ± 56	<0.0001
Interval between randomization and complete cervical dilation (min)*§	318 ± 197	273 ± 140	NS
Second stage of labor (min)*	91 ± 60	77 ± 69	NS
Position of vertex at delivery			
Occiput anterior	60 (81%)	59 (79%)	NS
Occiput posterior or transverse	14 (19%)	16 (21%)	
	(n = 61)	(n = 61)	
Position of vertex at vaginal delivery			
Occiput anterior	53 (87%)	57 (93%)	NS
Occiput posterior or transverse	8 (13%)	4 (7%)	

* Mean ± SD.

† Median (quartile deviation).

‡ Twenty-six women in the late group received epidural analgesia ≥1 h after their second postrandomization dose of nalbuphine, before they achieved a cervical dilation of 5 cm.

§ Excludes 8 patients in the early group and 12 patients in the late group who underwent cesarean section before complete cervical dilation.

Table 3. Method of Delivery

	Early (n = 74)	Late (n = 75)	*P*
Spontaneous vaginal	29 (39%)	24 (32%)	NS
Instrumental vaginal	32 (43%)	37 (49%)	NS
Cesarean section	13 (18%)	14 (19%)	NS
Indication for instrumental vaginal delivery			
Elective	19 (26%)	17 (23%)	NS
Nonreassuring FHR tracing	8 (11%)	15 (20%)	
Prolonged second staeg (≥3 h)	5 (7%)	5 (7%)	
Indication for cesarean section			
Dystocia	9 (12%)	12 (16%)	NS
Nonreassuring FHR tracing	4 (5%)	2 (3%)	

FHR = fetal heart rate.

women in the late group underwent cesarean section (relative risk for the early group = 0.94; 95% confidence interval = 0.48–1.84). Likewise, early administration of epidural analgesia did not increase the incidence of cesarean section for dystocia, and it did not increase the incidence of a prolonged second stage of labor (*i.e.*, ≥ 3 h).

Patients in the early group received a greater total dose of bupivacaine, as expected from the study design (table 4). Patients in the early group had significantly lower pain scores between 30 and 120 min after randomization (fig. 1). Likewise, patients in the early group had analgesia of better quality, and were more satisfied with their analgesia, at 60 and 120 min after randomization (fig. 2). There was no significant difference between groups in analgesia quality or patient satisfaction at 180 min (data not shown). Patients in the late group had slightly lower pain scores between 210 and 270 min after randomization ($P < 0.005$) (fig. 1). Among those patients who delivered vaginally, 44 (72%) of 61 women in the early group, and 39 (64%) of 61 women in the late group had satisfactory anesthesia immediately before delivery, and did not require a supplemental injection of local anesthetic.

Patients in the early group were more likely to experience transient hypotension during the 1st h after administration of epidural analgesia (table 5). There was no significant difference between groups in the incidence of nausea, emesis, or urinary retention.

Patients in the early group were more likely to have meconium-stained amniotic fluid (table 6). However, most cases of meconium-stained amniotic fluid were detected before randomization, and there was no difference between groups in the onset of meconium-stained amniotic fluid after randomization. There was no significant difference between groups in infant weight or 1- or 5-min Apgar scores. Also, there was no significant difference between groups in the incidence of fetal scalp blood *p*H determination after randomization, or in the incidence of naloxone administration after delivery. Infants in the late group had lower umbilical arterial and venous blood *p*H and higher umbilical arterial and venous blood carbon dioxide tension measurements at delivery. There was no significant difference between groups in umbilical arterial or venous blood oxygen tension or base deficit.

Discussion

Some obstetricians contend that epidural analgesia prolongs the first stage of labor primarily if it is administered during the latent phase.[1–3] Read *et al.*[3] assessed obstetric outcome in 1,355 consecutive patients who had a vaginal delivery at their hospital. Approximately 405 patients received lumbar epidural analgesia with either 0.25% or 0.375% bupivacaine. The remaining patients received either meperidine or no analgesia. The authors did not describe the method of group assignment, and there is no evidence that they randomly assigned either the method or the timing of analgesia. The authors concluded:

> In spontaneous, augmented or induced labors, both in primigravid and parous women, mean cervical dilation rates were slower in women given epidurals

Table 4. Management of Analgesia

	Early (n = 74)	Late (n = 75)	*P*
Doses of nalbuphine before randomization*			
None	44 (59%)	54 (72%)	NS
One	17 (23%)	13 (17%)	
Two	10 (14%)	8 (11%)	
Three	3 (4%)	0 (0%)	
Doses of nalbuphine after randomization			
None	74 (100%)	0 (0%)	<0.0001
One	0 (0%)	31 (41%)	
Two	0 (0%)	44 (59%)	
Total dose of bupivacaine (mg)†	116 ± 71	75 ± 47	<0.0001

* If a patient received one or more doses of nalbuphine before randomization, those doses did not count toward the two-dose limit after randomization.

† Mean ± SD.

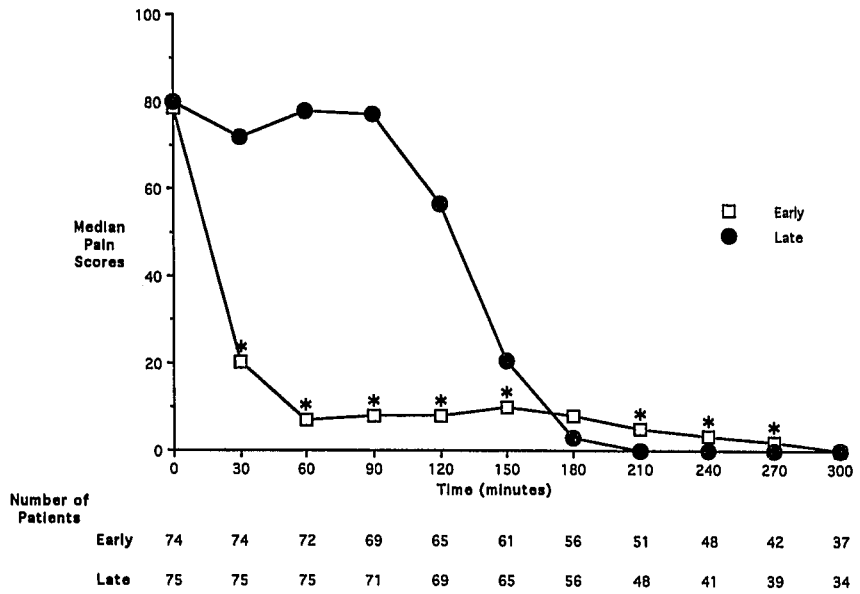

Fig. 1. Median pain scores over time. Patients in the early group had significantly lower pain scores at 30, 60, 90, and 120 min after randomization ($P < 0.005$). Patients in the late group had significantly lower pain scores at 210, 240, and 270 min after randomization ($P < 0.005$). Pain score assessments were discontinued when a patient achieved complete cervical dilation. Thus, the x-axis lists the number of patients who had not achieved complete cervical dilation at each period of assessment.

in the latent phase of labour than in those having epidurals in the active phase, pethidine or no analgesia. . . . There can be no reasonable doubt that epidural analgesia delays the progress of labour, particularly if it is given early, in the latent phase.[3]

Thorp *et al.*[4] retrospectively reviewed obstetric outcome for 500 consecutive nulliparous women who had a spontaneous onset of labor at term, and who delivered at their hospital in 1988. The incidence of cesarean section for dystocia was 11.4% in the epidural group

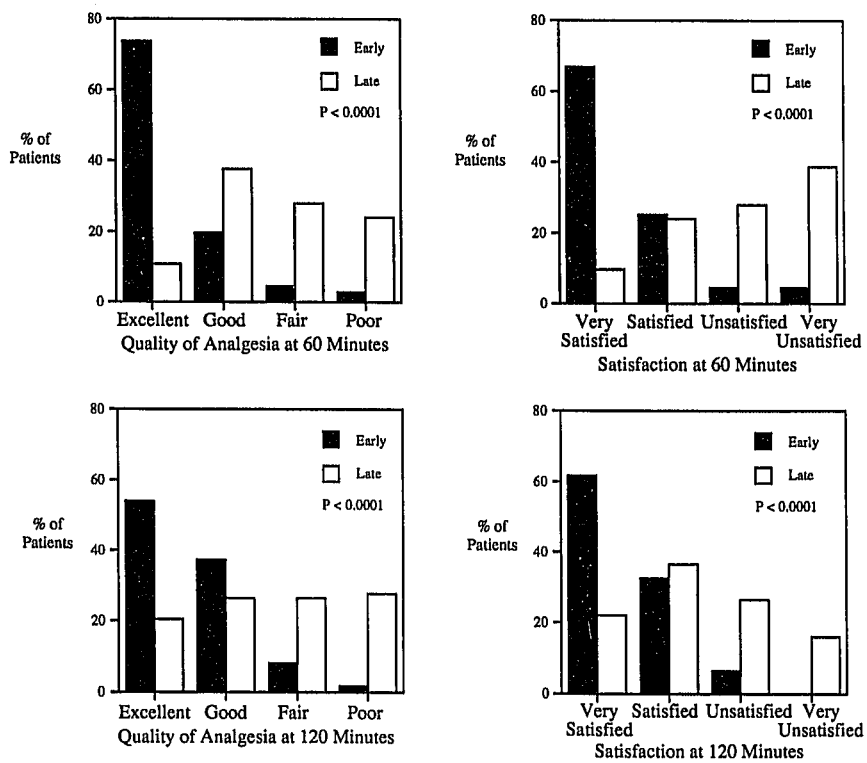

Fig. 2. Assessment of analgesia quality and patient satisfaction at 60 and 120 min after randomization. Patients in the early group had analgesia of better quality than patients in the late group at 60 and 120 min after randomization ($P < 0.0001$). Similarly, patients in the early group were more satisfied with their analgesia than patients in the late group at 60 and 120 min after randomization ($P < 0.0001$).

Table 5. Maternal Complications during Labor

	Early (n = 74)	Late (n = 75)	*P*
Hypotension during the 1st hour after administration of epidural analgesia	30 (41%)	15 (20%)	<0.05
Nausea	21 (28%)	21 (28%)	NS
Emesis	17 (23%)	20 (27%)	NS
Urinary retention	53 (72%)	46 (61%)	NS

(n = 294) *versus* 2.4% in the nonepidural group (n = 206) ($P < 0.0001$). There was no difference between groups in the incidence of cesarean section for fetal distress. The authors stated: "The greatest effect of epidural analgesia on the incidence of cesarean section for dystocia was observed in nulliparas who dilated at slower rates (< 1 cm/h) in early labor and who had epidural analgesia placed at 5 cm or less of cervical dilation." The authors concluded that "epidural analgesia in first labors may have contributed significantly to the cesarean epidemic." *Consumer Reports*# cited this study in an article entitled, "Too Many Cesareans."

Some physicians have dismissed the results of these studies, in part, by noting the retrospective study design, with it obvious potential for selection bias. The authors did not consider the possibility that the reasons for administration of epidural analgesia may have reflected an increased risk for prolonged labor and operative delivery. Women who have a prolonged, complicated labor are more likely to request epidural analgesia than women who have a rapid, uncomplicated labor. Wuitchik *et al.*[6] observed a relationship between pain and cognitive activity during early labor and the subsequent progress of labor in 115 healthy nulliparous women. The early onset of severe pain predicted an increased risk of abnormal labor, and it also predicted an increased risk of fetal heart rate abnormalities and operative delivery.

Philipsen and Jensen[7] randomized 111 women of mixed parity to receive either epidural bupivacaine (0.375%) or intramuscular meperidine analgesia during labor. Sixty-five of the 111 subjects were receiving intravenous oxytocin at the time of enrollment in the study. Ten (17%) of 57 women in the epidural group, *versus* six (11%) of 54 women in the meperidine group, underwent cesarean section. Nine (16%) women in the epidural group, *versus* three (6%) women in the meperidine group, underwent cesarean section for dystocia. Unfortunately, the authors did not enroll a sufficient number of patients to exclude the possibility that epidural bupivacaine analgesia causes an increased incidence of cesarean section for dystocia.

Thorp *et al.*[5] recently published the results of a prospective study in which healthy nulliparous women were randomized to receive either epidural bupivacaine or intravenous meperidine analgesia. The authors used an epidural analgesia regimen similar to that used in the current study; namely, women in the epidural group received an initial bolus of 0.25% bupivacaine, followed by a continuous infusion of 0.125% bupivacaine. All subjects had a spontaneous onset of labor, but nine of 48 women in the epidural group, and three of 45 in the meperidine group, were receiving intravenous oxytocin at the time of the first dose of an analgesic drug. The mean ± SD duration of the first stage of labor was 676 ± 394 min in the epidural group, *versus* 519 ± 279 min in the meperidine group. The authors did not report the mean interval between ran-

Table 6. Neonatal Condition

	Early (n = 74)	Late (n = 75)	*P*
Meconium-stained amniotic fluid			
Yes, noted before randomization	11 (15%)	3 (4%)	<0.05
Yes, noted after randomization	8 (11%)	4 (5%)	
No	55 (74%)	68 (91%)	
Scalp *p*H determined after randomization	6 (8%)	3 (4%)	NS
Infant weight (g)*	3,323 ± 572	3,278 ± 528	NS
1-min Apgar score ≥7	57 (77%)	61 (81%)	NS
5-min Apgar score ≥7	72 (97%)	74 (99%)	NS
Naloxone administered to infant	0 (0%)	2 (3%)	NS
Umbilical arterial blood			
*p*H*	7.25 ± 0.06	7.23 ± 0.05	<0.05
P_{CO_2} (mmHg)*	44 ± 9	48 ± 9	<0.05
P_{O_2} (mmHg)*	18 ± 6	18 ± 7	NS
Base deficit (mEq/l)*	6.8 ± 3.1	6.7 ± 3.1	NS
Umbilical venous blood			
*p*H*	7.33 ± 0.05	7.31 ± 0.06	<0.05
P_{CO_2} (mmHg)*	37 ± 6	39 ± 5	<0.05
P_{O_2} (mmHg)*	28 ± 6	28 ± 6	NS
Base deficit (mEq/l)*	5.4 ± 1.9	5.7 ± 2.7	NS

* Mean ± SD.

Too many cesareans. Consumer Reports. February 1991, pp 120–126.

domization and the onset of complete cervical dilation in the two groups. Twelve (25%) of 48 women in the epidural group, *versus* one (2.2%) of 45 women in the meperidine group underwent cesarean section. Eleven of the 12 cesarean sections in the epidural group were performed in women who received epidural analgesia before 5 cm cervical dilation. Nine (19%) of 48 women in the epidural group, *versus* two (4%) of 45 women in the meperidine group had malposition of the vertex.

In the current study, early administration of epidural analgesia did not prolong labor or increase the incidence of malposition of the vertex at delivery. Also, early epidural analgesia did not increase the incidence of cesarean section or instrumental vaginal delivery. The results of the current study are consistent with earlier studies that noted that regional anesthesia does not affect the uterine contractile response to oxytocin.[8,9] Some physicians have suggested that early epidural analgesia results in pelvic floor relaxation, which may interfere with the internal rotation of the fetal head during labor.[4,5,10,11] Other studies have suggested that epidural administration of a dilute solution of local anesthetic results in fewer cases of malposition than administration of a more concentrated solution.[12–15] Some physicians have also expressed concern regarding the adverse effects of epidural analgesia on maternal expulsive efforts during the second stage of labor.[4,5,10] In the current study, we made a conscious effort to maintain analgesia while minimizing the severity of motor block.

Reasons for the discrepancy between the results of the current study and those of the study by Thorp *et al.*[5] are unclear. In the current study, all patients ultimately received epidural analgesia, whereas in the study by Thorp *et al.*,[5] only one of the 45 women in the meperidine group ultimately received epidural analgesia. In the current study, all patients were receiving intravenous oxytocin at the time of randomization, whereas in the study by Thorp *et al.*,[5] the majority of subjects were in spontaneous labor at the time that they received their first dose of bupivacaine or meperidine. Finally, in the study by Thorp *et al.*,[5] the authors assumed responsibility for decisions regarding the method of delivery. The decision to perform a cesarean section is a subjective one, and it was impossible to blind the obstetricians to the group assignment.[16]

The current study does not necessarily confirm that early epidural analgesia does not affect the progress of labor in patients who are receiving intravenous oxytocin. Rather, it suggests that the effect, if any, of early epidural analgesia does not differ from that of intravenous nalbuphine. Indeed, some studies have suggested that opioids may decrease uterine activity and prolong the first stage of labor.[17–22]

We acknowledge that the rates of operative delivery were relatively high in both groups in the current study. However, we underscore the fact that the current study was limited to patients who were receiving intravenous oxytocin at the time of randomization. Patients who require oxytocin for induction or augmentation of early labor are at increased risk for operative delivery, when compared with patients who labor spontaneously. Also, spontaneous rupture of membranes before the onset of labor increases the likelihood of operative delivery.[23] We also acknowledge that the current study did not assess the effect of early administration of epidural analgesia in patients who are in spontaneous labor, and who are not receiving intravenous oxytocin. Such a study is in progress at the University of Iowa.

Infants in the late group had lower umbilical arterial and venous blood *p*H and higher umbilical arterial and venous blood carbon dioxide tension measurements at delivery. This likely reflected higher maternal blood carbon dioxide tension in the late group. We speculate that mild maternal hypercarbia resulted from the administration of nalbuphine, followed by the administration of epidural analgesia. There was no evidence that late-group infants were at increased risk for hypoxemia or metabolic acidosis at delivery.

We conclude that early administration of epidural analgesia did not prolong labor or increase the incidence of operative delivery, when compared with intravenous nalbuphine followed by late administration of epidural analgesia, in nulliparous women who were receiving intravenous oxytocin for induction or augmentation of labor. Patients who received early epidural analgesia were more likely to experience transient hypotension. However, infants in the late group had slightly lower umbilical cord blood *p*H measurements at delivery. Early administration of epidural bupivacaine provided analgesia that was clearly superior to that provided by intravenous nalbuphine. It is unnecessary to await a cervical dilation of 5 cm before administration of epidural analgesia in nulliparous women who are receiving intravenous oxytocin for induction or augmentation of labor.

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