EPIDURAL ANALGESIA COMPARED WITH COMBINED SPINAL–EPIDURAL ANALGESIA DURING LABOR IN NULLIPAROUS WOMEN

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ABSTRACT

Background Among nulliparous women, there appears to be an association between the use of epidural analgesia during labor and an increased risk of dystocia. We tested the hypothesis that combined spinal–epidural analgesia, which permits ambulation during labor, is associated with a lower incidence of dystocia than continuous lumbar epidural analgesia.

Methods Between July 1995 and September 1996, we randomly assigned 761 nulliparous women in spontaneous labor at term who requested epidural analgesia to receive either continuous lumbar epidural analgesia or a combination of spinal and epidural analgesia. Among the women who received combined spinal–epidural analgesia, some were discouraged from walking and others were encouraged to walk. Maternal and neonatal outcomes, the incidence of dystocia necessitating cesarean section, and measures of patients' satisfaction were compared in the two groups.

Results There were no significant differences in the overall rate of cesarean section, the incidence of dystocia, the frequency of maternal or fetal complications, the patients' or nursing staff's assessment of the adequacy of analgesia, or the degree of overall satisfaction between the two groups. Significantly more women receiving combined spinal–epidural analgesia had pruritus ($P<0.001$) and requested additional epidural bolus doses of local anesthetic ($P=0.01$). For all the women, dystocia necessitating cesarean section was significantly more likely when analgesia was administered with the fetal vertex at a negative station (odds ratio, 2.5; $P<0.001$) or at less than 4 cm of cervical dilatation (odds ratio, 2.2; $P<0.001$).

Conclusions As compared with continuous lumbar epidural analgesia, the combination of spinal and epidural analgesia is not associated with an overall decrease in the incidence of cesarean delivery. (N Engl J Med 1997;337:1715-9.)

LUMBAR epidural analgesia is the most commonly used form of regional blockade for pain relief during labor. With the increasing availability of this safe and effective form of analgesia, there has been an increase in the number of women who receive epidural analgesia, either alone or in conjunction with systemic narcotics, during labor and delivery.[1,2]

Intrapartum epidural analgesia is most commonly induced by placement of a catheter within the epidural space in the lower lumbar spine. Solutions of a local anesthetic, a narcotic, or both are given either as intermittent bolus doses or as a continuous infusion. Although segmental analgesia is excellent, substantial sensory and motor blockade commonly results. Consequently, women are unable to walk during epidural analgesia and are usually confined to bed.

An alternative but less commonly used form of intrapartum analgesia is the combination of spinal and epidural analgesia. This method combines a single intrathecal injection of a lipid-soluble opioid with an epidural infusion of a solution containing both a local anesthetic and a narcotic. Satisfactory analgesia without motor blockade results, preserving a full range of motion and the ability to walk.

Controversy continues about the benefits, risks, and costs of intrapartum epidural analgesia.[3-11] Studies of women delivering their babies at term have suggested an association between the use of conventional lumbar epidural analgesia for pain relief during labor and an increased rate of operative delivery.[4-8] Particularly for nulliparous women, the timing of the epidural analgesia, as measured by the degree of cervical dilatation, has been identified as a factor in the association between epidural analgesia and the diagnosis of dystocia.[2,4]

The effect of ambulation on labor is unclear. Various reports have suggested an association between an upright position and shorter labor.[12-14] Pregnant women often prefer to walk while in labor and may be more comfortable when upright. Intrapartum ambulation has no known detrimental effects and may be as valuable as oxytocin augmentation in managing dysfunctional labor.[15] Although women in labor are able to walk after the spinal or epidural administration of a narcotic agent, the safety and potential benefits of this form of analgesia as compared with those of conventional intrapartum epidural analgesia have not been reported.[16-21]

We performed a prospective, randomized study

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comparing continuous lumbar epidural analgesia with the combination of spinal and epidural analgesia in nulliparous women in spontaneous labor at term. The purpose of the study was to compare these types of intrapartum conduction analgesia with respect to safety, efficacy, and patients' satisfaction and to assess the relation of the timing of epidural analgesia to the need for operative delivery.

METHODS

Subjects

The subjects were nulliparous women in spontaneous labor or with spontaneous rupture of membranes at 36 weeks or more of gestation with a fetus in the vertex position. The women were randomly assigned to one of three groups when epidural analgesia was requested by their obstetricians. One group received conventional lumbar epidural analgesia and were unable to walk around. The other two groups received combined spinal–epidural analgesia; in one group, ambulation was discouraged, and in the other it was encouraged. The labor nurse instructed the patient about ambulation and was responsible for compliance with the protocol. This study was approved by the Memorial Health Research Council, and all the women gave written informed consent.

On admission, the women underwent a minimum of 30 minutes of continuous electronic fetal-heart-rate monitoring to assess fetal status. Subsequently, we performed either electronic fetal-heart-rate monitoring or intermittent auscultation every 30 minutes in the first stage of labor and every 15 minutes in the second stage. After the initiation of analgesia, electronic fetal-heart-rate monitoring was continued for at least 30 minutes.

All the women received a minimum of 1000 ml of lactated Ringer's solution intravenously during the 30 minutes preceding the placement of the epidural needle. The women were seated for the placement of the needle and were then placed in the supine position with left uterine displacement. Blood pressure was monitored with an automated sphygmodynamometer (Dynamapp) every 2 minutes for 10 minutes and then every 5 minutes for 20 minutes. Subsequently, blood pressure was measured at least every 30 minutes until delivery.

Hypotension was defined as a decline in systolic blood pressure to below 90 mm Hg or a decrease of more than 20 percent in mean arterial blood pressure, which was calculated by the sphygmodynamometer. Treatment of hypotension included increasing the rate of intravenous fluid administration or the intravenous administration of ephedrine. Periodic changes in the fetal heart rate were treated with repositioning, discontinuation of oxytocin, administration of supplemental oxygen, saline infusion into the uterus, or emergency delivery, when indicated.

Analgesia

For conventional epidural analgesia, an 18-gauge Touhy needle was used to locate the lumbar epidural space by the loss-of-resistance-to-air technique. After the injection of a 5-ml test dose of 0.25 percent bupivacaine, an epidural catheter was advanced through the needle 3 cm into the epidural space. A bolus dose of 6 ml of 0.25 percent bupivacaine plus 1 ml of fentanyl (50 μg) was administered through the catheter, followed by a continuous infusion of 0.125 percent bupivacaine with 2 μg of fentanyl per milliliter, at a rate of 10 ml per hour.

The women in the groups receiving combined spinal–epidural analgesia were given an intrathecal narcotic with a continuous low-dose epidural infusion. After the location of the epidural space with an 18-gauge Touhy needle, a 4 11/16-in. (11.9-cm) 27-gauge Whitacre spinal needle (Becton Dickinson) was passed through the epidural needle into the subarachnoid space. Then, 10 μg of sufentanil in 2 ml of normal saline was infused, and the spinal needle was removed. An epidural catheter was advanced 3 cm into the epidural space, and a continuous infusion of 0.0625 percent bupivacaine with 2 μg of fentanyl per milliliter was given at a rate of 12 ml per hour.

In the women given combined spinal–epidural analgesia who were encouraged to walk, we assessed the degree of motor block 30 minutes after the beginning of the analgesia. Their status was graded from 1 (complete block) to 6 (able to perform a partial knee bend).[20] Ambulation was limited to women who had no detectable weakness of hip flexion (a score of 5 or 6). Ambulation was defined as a minimum of five minutes of walking per hour. The women in the combined-analgesia–ambulation group were encouraged to walk with the nurse or labor coach within or outside their labor rooms.

The decision about the need for conduction analgesia was made by the managing obstetrician in concert with the labor nurse, in response to a request from the patient. Subsequent bolus doses of epidural solution were administered by the anesthesiologist as requested by the patient and her nurse. The women in the epidural-analgesia group received 8 ml of 0.125 percent bupivacaine in the form of bolus doses, and those in the two combined-analgesia groups received 12 ml of 0.0625 percent bupivacaine.

End Points

The end points of this study included the status of the newborn (as indicated by the five-minute Apgar score), the rate of cesarean section, the rate of instrumental vaginal delivery, the incidence of side effects, and the degree of satisfaction on the part of the patient. All women and their labor nurses recorded their assessments of the pain experienced by the women just before the administration of epidural analgesia, one hour later, at 7 to 8 cm of cervical dilatation, at the beginning of the second stage of labor, and in the immediate postpartum period. Headache or pruritus requiring medical treatment was recorded. Patients' overall degree of satisfaction with analgesia was measured by means of a questionnaire completed on the first day after delivery.

Statistical Analysis

The results in the three groups were compared by analysis of variance for continuous variables and by contingency-table methods for binary outcomes. We conducted an observational analysis to assess the outcomes in the women who walked during labor and those who did not. All statistical tests were two-sided.

RESULTS

We initially enrolled 775 consecutive nulliparous women admitted in labor at term who requested epidural analgesia. Fourteen women were not included in the analysis because of incomplete data. Of the remaining 761 women, 256 were assigned to receive conventional epidural analgesia, 252 to receive the combination of spinal and epidural analgesia with ambulation discouraged, and 253 to combined spinal–epidural analgesia with ambulation encouraged. There were no significant differences in the characteristics of the women or their infants among the three groups (Table 1). There also were no significant differences in the rate of cesarean section, the proportion with dystocia as the indication for cesarean section, or the mean birth weight of infants delivered after a diagnosis of dystocia was made. The women in the two groups that received combined spinal–epidural analgesia tended to have a greater degree of cervical dilatation at the time of cesarean section ($P = 0.07$) (Table 2). Fewer women

receiving combined analgesia required instrumental vaginal delivery ($P = 0.03$), but there were no significant differences in the mean birth weights of the newborns (Table 3).

At the time epidural analgesia was initiated, there were no significant differences among the groups in the percentage of women with the fetal vertex at a positive station or at zero or at a negative station, or with ≥4 cm or <4 cm of cervical dilatation. The percentages of women receiving oxytocin for augmentation of labor both at the time of the initiation of analgesia and at any later time were similar. There were no significant differences in the mean degree of cervical dilatation at the initiation of epidural analgesia (Table 4). More women had dystocia necessitating cesarean section when they received epidural analgesia with the vertex at a negative station (odds ratio, 2.5; 95 percent confidence interval, 1.5 to 4.0; $P<0.001$) or at <4 cm of cervical dilatation (odds ratio, 2.2; 95 percent confidence interval, 1.4 to 3.4; $P<0.001$) than women who received epidural analgesia with the vertex at 0 or a positive station or at ≥4 cm of cervical dilatation. The findings for the study group as a whole were similar to those in the analysis of subgroups defined according to the type of analgesia.

Significantly fewer women who received conventional epidural analgesia had pruritus ($P<0.001$), and there were fewer requests for additional epidural boluses of bupivacaine ($P = 0.01$) than in the other two groups (Table 5). There were no significant differences in pain scores or measures of overall satisfaction. For all groups at each assessment, the mean pain score assigned by the nurse was significantly lower than the mean score assigned by the woman.

Because of multiple confounding variables, the effect of ambulation after the initiation of spinal–epidural analgesia could not be assessed. Among the 300 women who did not walk and the 205 who did (15 percent of the no-ambulation group and 66 percent of the ambulation group), there were no differences in the mean degree of cervical dilatation at the time of epidural analgesia, the need for oxytocin before or after epidural analgesia, or the mean birth weight of the newborns.

We identified three risk factors for cesarean section performed because of dystocia in the study population: epidural analgesia with the fetal vertex at a negative station (relative risk, 2.0; 95 percent confidence interval, 1.3 to 3.9), initiation of epidural analgesia at less than 4 cm of cervical dilatation (relative risk, 1.8; 95 percent confidence interval, 1.1 to 3.7), and the absence of ambulation (relative risk, 1.6; 95 percent confidence interval, 0.9 to 3.3).

DISCUSSION

We compared continuous lumbar epidural analgesia with combined spinal–epidural analgesia in nul-

TABLE 1. CHARACTERISTICS OF THE STUDY GROUPS.*

CHARACTERISTIC	EPIDURAL ANALGESIA (N=256)	SPINAL–EPIDURAL ANALGESIA, AMBULATION DISCOURAGED (N=252)	SPINAL–EPIDURAL ANALGESIA, AMBULATION ENCOURAGED (N=253)	P VALUE
Age — yr	23±2	23±2	23±2	0.99
Gravidity	1.5±0.8	1.6±0.6	1.5±0.6	0.57
Height — cm	163±6	163±7	163±6	0.87
Estimated week of gestation	39.7±1.2	39.7±1.1	39.7±1.1	0.99
Birth weight of infant — g	3460±466	3436±449	3460±387	0.77
Infant with 5-min Apgar score <7 — no. (%)	2 (0.8)	2 (0.8)	1 (0.4)	0.82

*Plus–minus values are means ±SD.

TABLE 2. CHARACTERISTICS OF DELIVERIES BY CESAREAN SECTION IN THE STUDY GROUPS.*

VARIABLE	EPIDURAL ANALGESIA (N=40)	SPINAL–EPIDURAL ANALGESIA, AMBULATION DISCOURAGED (N=43)	SPINAL–EPIDURAL ANALGESIA, AMBULATION ENCOURAGED (N=41)	P VALUE
Dystocia as indication — no. (% of group)	38 (15)	41 (16)	40 (16)	0.90
Birth weight of infant — g	3658±613	3576±499	3644±443	0.29
Mean cervical dilatation at time of cesarean section — cm	6.5±2.6	7.6±2.5	7.6±2.4	0.07

*Plus–minus values are means ±SD.

TABLE 3. CHARACTERISTICS OF VAGINAL DELIVERIES IN THE STUDY GROUPS.*

VARIABLE	EPIDURAL ANALGESIA (N=216)	SPINAL–EPIDURAL ANALGESIA, AMBULATION DISCOURAGED (N=209)	SPINAL–EPIDURAL ANALGESIA, AMBULATION ENCOURAGED (N=212)	P VALUE†
Spontaneous delivery — no. (%)	130 (60)	150 (72)	142 (67)	0.03
Instrumental delivery — no. (%)	86 (40)	59 (28)	70 (33)	0.03
Birth weight of infant — g	3425±427	3407±434	3444±374	0.65

*Plus–minus values are means ±SD.

†The P values are for the comparison of the two groups receiving spinal–epidural analgesia with the epidural-analgesia group.

liparous women in active labor at term. Despite the greater incidence of pruritus and a greater need for supplemental treatment with bupivacaine among the women who received the combination of spinal and epidural analgesia, there were no significant differences overall in patients' degree of satisfaction, the adequacy of pain relief, or the incidence of side effects among women in the three groups. The women assigned to receive spinal–epidural analgesia had significantly higher rates of spontaneous vaginal delivery and lower rates of instrumental vaginal delivery than the women who received conventional epidural analgesia. There were no significant differences in the rate of cesarean section, yet among the women in whom dystocia necessitated cesarean section, those receiving spinal–epidural analgesia had a greater degree of cervical dilatation when the operation was performed. Although there were no significant differences among the groups in either the total rate of cesarean section or the rate of cesarean section for which dystocia was the indicator, we identified either epidural or spinal–epidural analgesia with the fetal vertex at a negative station, epidural analgesia with cervical dilatation of less than 4 cm, and the absence of ambulation as independent risk factors for dystocia necessitating cesarean delivery.

TABLE 4. TIMING OF EPIDURAL ANALGESIA IN THE STUDY GROUPS.*

VARIABLE	EPIDURAL ANALGESIA (N=256)	SPINAL–EPIDURAL ANALGESIA, AMBULATION DISCOURAGED (N=252)	SPINAL–EPIDURAL ANALGESIA, AMBULATION ENCOURAGED (N=253)	P VALUE
Cervical dilatation — no. (%)				
≥4 cm	204 (80)	199 (79)	186 (74)	0.52
<4 cm	52 (20)	53 (21)	67 (26)	0.52
Mean dilatation — cm	4.5±1.3	4.7±1.5	4.6±1.4	0.28
Station — no. (%)				
≥0	96 (38)	98 (39)	83 (33)	0.33
<0	160 (62)	154 (61)	170 (67)	0.33
Timing of oxytocin — no. (%)				
Before epidural analgesia	114 (45)	99 (39)	114 (45)	0.35
After epidural analgesia	158 (62)	171 (68)	173 (68)	0.21

*Plus–minus values are means ±SD.

TABLE 5. SIDE EFFECTS OF ANALGESIA IN THE THREE STUDY GROUPS.

SIDE EFFECT	EPIDURAL ANALGESIA (N=256)	SPINAL–EPIDURAL ANALGESIA, AMBULATION DISCOURAGED (N=252)	SPINAL–EPIDURAL ANALGESIA, AMBULATION ENCOURAGED (N=253)	P VALUE*
	number (percent)			
Pruritus	21 (8)	119 (47)	117 (46)	<0.001
Sedation	2 (1)	2 (1)	3 (1)	0.86
Nausea	3 (1)	6 (2)	5 (2)	0.59
Periodic fetal-heart-rate changes	15 (6)	15 (6)	14 (6)	0.98
Pain requiring additional bolus doses of bupivacaine	68 (27)	96 (38)	85 (34)	0.01
Hypotension	2 (1)	4 (2)	2 (1)	0.59
Headache	1 (<1)	2 (1)	2 (1)	0.81

*The P values are for the comparison of the two groups receiving spinal–epidural analgesia with the epidural-analgesia group.

Factors that affect the incidence of dystocia include fetal weight; maternal height, age, pelvic size, and parity; and the adequacy of uterine contractions.[22-26] In our study, these factors were controlled for (as in the case of parity), did not differ significantly among the groups (fetal weight, maternal age, maternal height, and adequacy of uterine contractions), or were not assessed (pelvic size). The use of epidural analgesia during labor has also been identified as a risk factor by some investigators, particularly in nulliparous women. Decreased uterine activity, longer labor, loss of pelvic muscle tone, and absent or decreased ability to push in the second stage are some effects of epidural analgesia that may play a part in this association.

Three prospective studies and several retrospective reports have found an association between the use of epidural analgesia and an increased risk of dystocia, as compared with that among women receiving systemic narcotics alone.[1-11] This association persists in women in whom labor is actively managed.[27,28] Although epidural analgesia in general has been implicated, its timing may be a critical factor. There is an inverse relation between the degree of cervical dilatation at the time epidural analgesia is initiated in nulliparous women in labor at term and the frequency of cesarean section performed because of dystocia; a similar association between the timing of analgesia and the frequency of cesarean section has not been identified in women receiving systemic narcotics.[1,4] In other studies, there were no significant differences in the rate of cesarean section among nulliparous women receiving epidural analgesia earlier and those receiving it later.[10,11]

Ambulation is commonly believed to be of value in the establishment and progression of active labor. Because of the effects of conventional epidural analgesia on sensation and muscle control, ambulation is not possible after it is given. With the combination of spinal and epidural analgesia, women are usually able and willing to walk during labor. Yet not all women in our study who were encouraged to walk did so. We identified no differences between

the women who walked and those who did not. Nonetheless, as others have reported, the labor-management team has a critical role in determining a woman's level of activity and response to the pain during labor.[29-32]

Combined spinal–epidural analgesia is a safe and satisfactory method of pain relief that does not interfere with muscular control of the lower extremities; it therefore allows women to walk during labor. However, the incidence of dystocia necessitating cesarean delivery among women receiving combined spinal–epidural analgesia does not differ from the rate among those receiving conventional epidural analgesia.

Supported by a grant from the Memorial Medical Center Foundation, Long Beach, Calif.

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