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CLINICAL INVESTIGATIONS

The Effects of the Addition of Sufentanil to 0.125% Bupivacaine on the Quality of Analgesia during Labor and on the Incidence of Instrumental Deliveries

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In a double-blinded, randomized, prospective multi-center study of 695 women, we investigated whether epidural injection of sufentanil added to 0.125% bupivacaine with epinephrine (1:800,000) reduces the total amount of local anesthetic required, resulting in less motor blockade and reduced incidence of instrumental deliveries, and improves the quality of analgesia provided by this low concentration of local anesthetic without jeopardizing the safety of the baby. In addition, other potential benefits of sufentanil (such as decrease in the incidence of shivering) and side effects were examined. It was found that adding incremental doses of 10 μg sufentanil up to a maximum of 30 μg reduced the incidence of instrumental deliveries from 36 to 24% ($P < 0.01$) and significantly improved quality and duration of analgesia without depressing the neurobehavioral status of the baby. No other benefits from adding sufentanil were found. The only side effect that occurred more frequently after sufentanil was pruritus. We conclude that epidural injection of 10–30 μg sufentanil added to 0.125% bupivacaine with epinephrine (1:800,000) improved the quality of analgesia during labor and reduced the incidence of instrumental deliveries without jeopardizing the safety of the baby. (Key words: Analgesics, opioid: sufentanil. Anesthesia, obstetric: instrumental delivery. Anesthetic techniques: epidural. Anesthetics, local: bupivacaine. Fetus: neurobehavioral score.)

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EPIDURAL ANALGESIA for labor and delivery has been accepted in most obstetric centers because of its effectiveness and safety. Nevertheless, epidural analgesia during labor is blamed for an increased incidence of instrumental deliveries,[1,2] the motor blockade being partially responsible. After the epidural administration of 0.125% bupivacaine, motor blockade is minor, but this low concentration is still effective in providing labor analgesia.[3] Minimizing the degree of motor blockade to decrease the incidence of instrumental deliveries without decreasing analgesic quality can be achieved by a further reduction in the total amount of bupivacaine by adding an opioid to the local anesthetic.[4] However, to our knowledge, no study has shown a decrease in the incidence of instrumental deliveries by this method.

This study was therefore undertaken to determine whether epidural injection of sufentanil added to 0.125% bupivacaine with epinephrine (1:800,000) would reduce the total amount of local anesthetic, resulting in less motor blockade and a reduction in the incidence of instrumental deliveries. Sufentanil was chosen because other studies have shown that sufentanil in doses of up to 30 μg added to bupivacaine does not result in neonatal depression, as ascertained by low Apgar scores.[5,6] In addition, because sufentanil is a potent opioid characterized by high lipid solubility and high affinity for the opiate μ-receptor,[7] it should have a rapid onset of action and minimal side effects.[8]

The study also allowed us to investigate whether epidural injection of sufentanil added to 0.125% bupivacaine with epinephrine (1:800,000) improves the quality of an-

algesia without jeopardizing the safety of the baby, and to determine the effect of this combination on the speed of onset and duration of analgesia, duration of labor, and incidence of side effects.

Materials and Methods

This prospective, randomized, double-blinded, multicenter study was established in five Belgian hospitals after approval by their committees on human research. Informed consent was obtained from all patients. Patients, anesthesiologists, obstetricians, and neonatologists all were unaware of the local anesthetic mixture.

The study included 695 pregnant women at term (ASA physical status 1 or 2) in spontaneous or induced labor, all of whom requested epidural analgesia for labor. Only women who had not received sedatives, analgesics, or any medication other than oxytocin or prostaglandin E_2 and who had singleton fetuses in the vertex presentation were included.

The 695 women were randomly divided into two groups, receiving either 0.125% bupivacaine with epinephrine (1:800,000) (control group) or 0.125% bupivacaine with epinephrine (1:800,000) plus sufentanil (sufentanil group).

After hydration by intravenous infusion of 1,000 ml lactated Ringer's solution, the epidural puncture was performed at either the L2–L3 or L3–L4 interspace while the woman was in the left lateral decubitus position. The epidural space was identified by loss of resistance to saline using an 18-G Tuohy needle, and a Portex multi-orifice catheter was inserted into the epidural space.

For each woman a set of three coded ampules containing 10 ml was prepared. The ampules with the study solution were provided by the Janssen Pharmaceutica laboratories, Beerse, Belgium. For the women in the control group, each ampule contained 12.5 mg bupivacaine (0.125%) and 12.5 μg epinephrine in physiologic saline (1:800,000), and for those in the sufentanil group 12.5 mg bupivacaine, 12.5 μg epinephrine, and 10 μg sufentanil. As soon as the contractions became painful, a first epidural injection of 10 ml was made over 60 s. During the injection and for the following 10 min the patient was placed in the supine position with left lateral tilt. During the remainder of labor she could either remain in this position or lie completely on her side.

The spread of analgesia was tested every 5 min by cold (ether swab) and pain (pin-prick) stimuli until maximum spread was achieved. If analgesia was not satisfactory after the first bolus an identical bolus was given. When additional injections were required the same solution was given. If, after use of the three coded ampules, further analgesia was requested, the woman, in either group, received 10 ml injections of 0.125% bupivacaine with epinephrine (1:800,000) without sufentanil. Thus, the maximum dose of sufentanil a woman received was 30 μg. The last injection before delivery was given with the woman in the sitting position to maximize analgesia of the sacral nerves. If analgesia still was insufficient after the first injection and persisted after the second injection, more concentrated solutions of bupivacaine were administered, and the patient was withdrawn from further analysis.

A systolic arterial blood pressure less than 100 mmHg or a decrease of 30% from the initial blood pressure was considered hypotension and was treated immediately with intravenous injections of 5–10 mg ephedrine. The fetal heart rate was recorded continuously by a cardiotocographic monitor.

The women were asked to rate the quality of analgesia using a four-point scale: excellent (no pain), good (only short periods of pain), moderate (longer periods of pain) or insufficient, before and 10 and 20 min after each injection. Furthermore, the women were asked to report immediately when pain relief started. The onset of analgesia (the time interval between each injection and the first notion of pain relief by the patient) and duration of analgesia (the time between two injections) were recorded.

The type of delivery (spontaneous, forceps, vacuum extraction or cesarean section) and duration of labor after induction of the epidural also were noted.

Motor blockade was assessed in two ways. The abdominal muscles were evaluated before the first epidural injection and immediately before delivery by the rectus abdominis muscle test (RAM test).[9] In addition, in 150 women, randomly distributed in the two groups, the muscles of the lower limbs were evaluated immediately before delivery by the modified Bromage scoring system (full range of motion = 0; moves feet and knees = 1; moves feet only = 2; and unable to move feet or knees = 3).[10]

All of the babies were evaluated at 1 and 5 min after birth by Apgar scores, and 143 babies born in one of the five centers (University hospital, Katholieke Universiteit Leuven) also were evaluated 60 min after birth by the Neurological and Adaptive Capacity Scoring System.[11]

The women were questioned and observed through labor and delivery for the following side effects: pruritus, somnolence, nausea, vomiting, shivering, and hypotension.

The quality of analgesia, the incidence of instrumental deliveries, the occurrence of side effects, and the Neurological and Adaptive Capacity Scores were compared using the chi-squared test. Data for mother's age, weight, and height, gestational age, cervical dilation, contraction rate, onset of analgesia, duration of analgesia, duration of labor, total dose of bupivacaine, and motor blockade were analyzed using the Mann-Whitney U test. To analyze the intragroup blood pressure changes, the Wilcoxon

TABLE 1. Maternal and Neonatal Characteristics

Variable	Control (n = 347)	Sufentanil (n = 348)
Age (yr)	27 ± 4	29 ± 4
Weight (kg)	73 ± 11	73 ± 12
Height (cm)	165 ± 7	165 ± 7
Gestational age (weeks)	39 ± 1	40 ± 1
Cervical dilation before epidural (cm)	4 ± 1	4 ± 1
Time between contractions before epidural (min)	3 ± 2	3 ± 2
Parity		
Nulliparous	62%	59%
Parous	38%	41%
Labor		
Spontaneous	31%	32%
Induced	69%	68%
Weight of baby (kg)	3.4 ± 0.3	3.4 ± 0.3

Data are means ± SD.
No significant differences between the two groups.

signed-rank test was used. A P value < 0.05 was considered to be statistically significant. All data are presented as mean ± standard deviation (SD).

Results

The total study population consisted of 695 women, 347 in the control group, and 348 in the sufentanil group. The mother's age, weight, height, parity, ASA physical status, cervical dilation at the start of the epidural analgesia, contraction rate, and the baby's gestational age and weight did not differ significantly between the two groups (table 1). Labor was induced in a similar number of women in each group, and the parity also was comparable between the two groups.

The spread of analgesia was comparable between the two groups, with a mean cephalad dermatome level for sensory anesthesia of T10. Delivery was performed by cesarean section in 14 (4.0%) women in the control group and 20 (5.7%) women in the sufentanil group (not statistically significant). Among the nulliparous women, 11 of 215 (5.1%) in the control group and 17 of 205 (8.3%) in the sufentanil group underwent cesarean section (not statistically significant). Among the parous women, cesarean section was performed in 3 of 132 (2.3%) in the control group and 3 of 143 (2.1%) in the sufentanil group (not statistically significant).

The quality of analgesia was significantly better when sufentanil was added to the bupivacaine than when no sufentanil was added. In the sufentanil group only 4 of the 348 (1.1%) women complained of insufficient analgesia, whereas in the control group 29 of the 347 (8.4%) women complained of insufficient analgesia ($P < 0.001$). Therefore, the latter women required administration of higher concentrations of bupivacaine and were excluded from further analysis. Of the women who received sufentanil, 94% experienced no or only short periods of pain during the first stage of labor, whereas of those who did not receive sufentanil, only 76% had no or only short periods of pain ($P < 0.001$). However, no difference was found in the quality of analgesia during the second stage of labor or during episiotomy and suturing.

Although the onset of analgesia was almost simultaneous in both groups after the first epidural injection, analgesia started significantly faster in the sufentanil group after the second and third injection ($P < 0.001$) (table 2). In addition, the analgesia lasted longer in the women who received sufentanil than in the women who received no sufentanil. This difference in the duration of analgesia was more pronounced after the first and second injection ($P < 0.001$) than after the third injection ($P < 0.01$).

A mean total dose of 34.3 ± 17.1 mg bupivacaine was administered to the women in the sufentanil group, whereas 42.2 ± 19.4 mg was necessary for the women in the control group ($P < 0.001$). The duration of labor after induction of the epidural was 3.6 ± 2.6 h in the control group and 3.7 ± 2.7 h in the sufentanil group (not statistically significant). The duration of the second stage was 27 ± 21 min in the control group and 33 ± 24 min in the sufentanil group (not statistically significant).

The incidence of instrumental deliveries in the women who delivered vaginally was 24% in the sufentanil group,

TABLE 2. Time of Onset and Duration of Analgesia

Injection	Control		Sufentanil	
	n	Time (min)	n	Time (min)
Onset				
1	318	9.8 ± 5.4	344	8.7 ± 4.3
2	301	8.4 ± 3.8	274	6.3 ± 3.9*
3	212	8.3 ± 5.2	168	6.4 ± 4.1*
Duration				
1	299	60 ± 42	270	90 ± 42*
2	208	72 ± 36	163	96 ± 84*
3	147	60 ± 30	83	78 ± 54†

Data are means ± SD.
* $P < 0.001$ *versus* control.
† $P < 0.01$ *versus* control.

TABLE 3. Incidence of Instrumental Deliveries (Forceps or Vacuum)

Type of Delivery	Parity	Incidence (%)* Control (n = 304)	Incidence (%)* Sufentanil (n = 324)
Spontaneous	Nulliparous	55	66*
	Parous	78	88*
	Total	64	76*
Instrumental	Nulliparous	45	34*
	Parous	22	12*
	Total	36	24*

* The percent of women having either spontaneous or instrumental delivery after exclusion of the women who underwent cesarean section or who required higher concentrations of bupivacaine because of insufficient analgesia (see text).
* $P < 0.01$ *versus* control.

whereas the incidence in the control group was 36% ($P < 0.01$) (table 3).

Motor blockade was less pronounced in the women who received sufentanil than in the women who received no sufentanil, according both to the RAM test ($P < 0.01$) (table 4) and to the Bromage score ($P < 0.01$) (table 5). The degree of motor blockade in the abdominal muscles associated with the epidural analgesia, or the difference between the RAM tests before the induction of the epidural and immediately before delivery was 14.1 ± 18.9% in the control group and 11.3 ± 17.3% in the sufentanil group ($P < 0.05$). For the 150 women whose motor blockade was tested by the Bromage score, full range of motion was present in 51 of the 81 women (63%) who received sufentanil and in 29 of the 69 women (42%) who received no sufentanil.

There was no significant difference in the Apgar scores of the babies in the two groups. For the women who received sufentanil, 90.7 and 99.4% of the babies scored 7 or higher at 1 and 5 min, respectively, after birth. For the women who received no sufentanil, these figures were 92.7 and 98.3%.

There was also no significant difference between the two groups according to the Neurological and Adaptive Capacity Scores at 60 min after birth (table 6).

The only significant difference in side effects was that 26% of the women who received sufentanil experienced pruritus, which did not require treatment (table 7).

TABLE 4. Motor Blockade (RAM Test)

Time	Control n	Control Power (%)	Sufentanil n	Sufentanil Power (%)
Before first injection	280	73.8 ± 20.3	292	75.2 ± 19.4
Before delivery	272	59.7 ± 18.8	284	63.9 ± 19.4*

Data are means ± SD.
* $P < 0.01$ *versus* control.

TABLE 5. Motor Blockade (Bromage Test)

Score	Women (%)* Control (n = 69)	Women (%)* Sufentanil (n = 81)
0	42	63*
1	49	36
2	9	1
3	0	0

* The percent of women in each category of the Bromage scoring system.
* $P < 0.01$ *versus* control.

Discussion

In this study we found that epidural injection of sufentanil added to 0.125% bupivacaine with epinephrine (1: 800,000) significantly improved the quality of analgesia during labor. In women who did not receive sufentanil, 8.4% complained of insufficient analgesia, a percentage similar to that found by Bleyaert *et al.*,[12] who used an identical concentration of bupivacaine. Addition of sufentanil decreased the percentage of women who complained of insufficient analgesia from 8.4 to 1.1%. Addition of sufentanil to this low concentration of bupivacaine has been proven to be equally as effective as 0.25% bupivacaine[13] and to improve the quality of analgesia during a continuous infusion of 0.125% bupivacaine.[14] Other opioids, such as fentanyl, also have been found to improve the quality of analgesia during labor when added epidurally to low concentrations of local anesthetics.[15,16]

Although the addition of an opioid to the local anesthetic during labor analgesia consistently reduces the total dose of local anesthetic and diminishes the degree of motor blockade, no prior study has demonstrated a decrease in the incidence of instrumental deliveries. However, one must be careful when making comparisons between these studies. In most studies, motor blockade has been assessed by the Bromage scale, which estimates the degree of motor blockade in the muscles of the lower limbs and not in the muscles involved in the birth process. Most studies also have included a smaller number of patients. In addition, obstetric practice concerning management of the second

TABLE 6. Babies (%) with Perfect Scores in Each Category of the Neurologic and Adaptive Capacity Scores

Category	Control (n = 68)	Sufentanil (n = 75)
Adaptive capacity	2	5
Passive tone	40	33
Active tone	22	17
Primary reflexes	27	23
General assessment	89	84

No significant differences between the two groups.

TABLE 7. Occurrence (%) of Side Effects

Side Effect	Control (n = 318)	Sufentanil (n = 344)
Pruritus	1	26*
Somnolence	4	8
Nausea	5	4
Vomiting	4	4
Shivering	4	1
Hypotension	20	18

* $P < 0.05$ *versus* control.

stage of labor differs between the United States and many European countries. In Belgium, most obstetricians terminate the second stage of labor when 1 h has elapsed, rather than allow it to extend to 2 h for parous women and to 3 h for nulliparous women as is practice in the United States.

Bleyaert *et al.*,[12] using the same concentration of bupivacaine without sufentanil, similar to our control group, noted that 44% of the women had an instrumental delivery. Both of our study groups had a lower incidence of instrumental deliveries (36% in the control group and 24% in the sufentanil group). As in our study, the mean duration of the second stage of labor in Bleyaert *et al.*'s study was shorter than 1 h (21 ± 13 min for the nulliparous women and 14 ± 11 min for the parous women). This decrease in instrumental deliveries is related probably to the amounts of bupivacaine used—55 mg in Bleyaert's patients, and 42.2 and 34.3 mg in our two groups (control and sufentanil groups, respectively).

Chestnut *et al.*,[17] comparing a continuous infusion of 0.125% bupivacaine to 0.0625% bupivacaine plus fentanyl, did not find a decrease in the incidence of instrumental deliveries (25 and 31%, respectively, of the women who delivered vaginally) in nulliparous women by adding an opioid to a bupivacaine concentration even lower than that in our study. However, the total doses of bupivacaine infused by Chestnut *et al.* (67 and 99 mg) still were twice as large as the total doses in our study (34.3 and 42.2 mg). When we correct for the duration of labor after the start of the epidural, Chestnut's patients in the fentanyl group received bupivacaine at 12.8 mg/h as compared to 24.5 mg/h in the bupivacaine-only group, whereas our patients in the sufentanil group received a dose of 9.34 mg/h as compared to 11.6 mg/h in the control group. Nevertheless, Chestnut *et al.* found in the women who delivered vaginally an incidence in instrumental deliveries (31% in the fentanyl group and 25% in the bupivacaine-only group) that was smaller than the incidence in our nulliparous patients (34% in the sufentanil group and 45% in the control group), but they found no difference in instrumental deliveries between their two groups.

However, it is difficult to compare our results with those of Chestnut *et al.*[17] First, the incidence of cesarean section (control and sufentanil groups, respectively) as compared to Chestnut *et al.*'s 18 and 15% (bupivacaine only and fentanyl groups, respectively). Second, as was stated above, our obstetricians preferred to terminate the second stage of labor after 1 h, whereas in Chestnut *et al.*'s study the mean duration of the second stage in both groups was approximately 2 h. Third, in Chestnut *et al.*'s study, the epidural infusion was discontinued during the second stage of labor, because a previous study by the same investigators had shown an increase in instrumental deliveries from continuing an epidural infusion of 0.125% bupivacaine throughout the second stage.[18] Likewise, Jones *et al.*,[19] when adding fentanyl to 0.08% bupivacaine, did not find a decrease in the incidence of instrumental deliveries. However, the duration of labor was much longer in their study, because only patients in whom a duration of labor longer than 3 h was anticipated were included in their study and because a higher total dose of bupivacaine was administered.

Even if the difference in motor blockade of the abdominal muscles between our two groups as measured by the RAM test may seem clinically unimportant, this difference is perhaps a contributing factor in the incidence of instrumental deliveries. Similarly, there was a difference in motor blockade between our two groups when tested with the Bromage scoring system. To be consistent, we can only conclude that there was indeed a difference in motor blockade between the two groups. The two other differences between the two groups were the total amount of local anesthetic administered and the incidence of instrumental deliveries. In consequence, at least in obstetric practice in Belgium and other European countries where the second stage of labor is not allowed to extend beyond 1 h, there is a connection between these three variables.

Although the criteria for instrumental delivery were not standardized in our study, we suggest that in a patient population consisting of 695 women randomly distributed over the participating hospitals, every possible biasing effect should be minimal or nil.

In addition to improving the quality of analgesia during labor and reducing the incidence of instrumental deliveries, sufentanil in a maximum dose of 30 μg when added to 0.125% bupivacaine with epinephrine (1:800,000) did not cause neonatal depression. These results are in agreement with the results of studies of the effects of the addition of fentanyl[16] and sufentanil.[5,6] However, in the studies in which the effects of sufentanil were examined, the babies were evaluated only by Apgar scores. In our study, the Apgar scores at 1 and 5 min after birth and the Neurological and Adaptive Capacity Scores at 60 min after birth showed no significant differences between the two groups.

Other benefits from adding sufentanil were not revealed. A decrease in the incidence of shivering as re-

ported in two studies[20,21] was not confirmed, but the doses of sufentanil in our study were much lower.

The only side effect that occurred more in the women who received sufentanil was pruritus that did not require treatment. An important factor in using 0.125% bupivacaine with epinephrine (1:800,000) in subsequent doses of 10 ml is that each dose given serves as a test dose. Injected intravascularly, this 10-ml dose does not contain enough bupivacaine (12.5 mg) to be toxic, although it contains a sufficient amount of epinephrine (12.5 μg) to cause an easily detectable, transient maternal tachycardia and hypertension.[22] However, such a small dose of epinephrine injected intravenously may cause a transient reduction in uterine blood flow,[23] and some anesthesiologists prefer not to use epinephrine in obstetric patients. When this same volume (10 ml) is injected intrathecally at lumbar level, a rapidly detected spinal block not exceeding T2 develops.[24] The addition of sufentanil in a concentration of 1 μg/ml to this bupivacaine solution will not change this rationale: accidentally injected into the vascular space, 10 μg sufentanil causes a mild and transient sedation easily reversible by the use of naloxone.[25] Intrathecally, the effects of this small sufentanil dose is minimal because of the short half-life of the drug in the cerebrospinal fluid, which is even shorter than when injected epidurally.[26,***]

In conclusion, the epidural injection of sufentanil added to 0.125% bupivacaine with epinephrine (1:800,000) improved the quality of analgesia during labor and decreased the incidence of instrumental deliveries without jeopardizing the safety of the baby or of the mother.

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