Epidural analgesia with a bupivacaine-fentanyl mixture in obstetrics: comparison of repeated injections and continuous infusion

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We compared the efficacy and side-effects of continuous infusion versus repeated injections of epidural bupivacaine-fentanyl during labour. Forty-four parturients were randomly distributed into two groups balanced for population size, morphology and parity. Analgesia was begun at the same stage of labour with a mixture of 20 ml 0.25 per cent plain bupivacaine and 2 ml (100 µg) fentanyl. In Group I the initial dose ranged from 8–12 ml as a function of height; an injection of the same dose was repeated immediately upon recurrence of pain. In Group II, after an initial dose of 5–7 ml, a continuous infusion of 3 ml·h⁻¹ was begun, and continued until full dilatation. Analgesia was rated using a pain scale; effects on maternal blood pressure, respiratory rate and neonatal status were noted. Bupivacaine and fentanyl assays were carried out on maternal venous blood in 30 parturients during the course of labour. There was a longer latency to onset of analgesia in Group II (approximately five minutes), followed by a more constant degree of analgesia. This better analgesia cannot be accounted for by a difference in dosage: doses were significantly lower in Group II, despite the fact that labour was of the same duration. The course of labour, and maternal and neonatal status were

comparable in the two groups. Assays showed no difference in bupivacaine blood concentrations between the two groups nor signs of drug accumulation. The constant infusion technique is advantageous since it provides a more regular degree of analgesia with lower doses than those required for patients having repeated injections.

Key words

ANAESTHESIA: obstetric; ANAESTHETIC TECHNIQUES: epidural; ANESTHETICS, LOCAL: bupivacaine; ANALGESICS: fentanyl.

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Epidural obstetric analgesia requires repeated injections of local anaesthetics even when a long-acting agent such as bupivacaine is used. Addition of fentanyl to the local anaesthetic increases the duration of analgesia; however it does not eliminate the need for reinjections.¹ Since scheduling of reinjections is a function of recurrence of pain, a sufficient level of analgesia cannot be continuously maintained. Numerous studies have shown the efficacy of continuous infusions for obstetrical analgesia.^{2,3} Along with development of a stable degree of analgesia, the reports stress the limited degree of hypotension and decreased risk of technical accidents (intrathecal or intravascular injection, contamination during manipulations).

Since both bupivacaine and fentanyl cross the placental barrier it is important to determine blood levels of these two agents. Glover,⁴ Evans and Carrie,⁵ Matouskova and Hanson,⁶ Rosenblatt *et al.*,⁷ for bupivacaine, and Cousin *et al.*⁸ for fentanyl, showed that blood levels were far below the threshold values considered to be toxic. Nevertheless, in a recent editorial, Morison and Smedstad⁹ noted that for comparison of the two techniques, it was necessary to present series carried out under comparable conditions. For example, in the study by Nadeau and Elliott¹⁰ dosages were very different with the two administration methods, possibly explaining the better results with the continuous infusion.

The purpose of this study is to compare the quality of analgesia, maternal side-effects, effects on the neonate, and maternal blood levels with repeated injections or continuous infusion of bupivacaine and fentanyl.

TABLE I Pain rating scale proposed by Cathelin *et al.*²⁸

Score/Description	Features
5 / Intolerable pain	Accompanied by shouting, crying, moaning, psychomotor agitation
4 / Severe pain	While the patient maintains self-control he feels sufficiently threatened to demand immediate relief
3 / Tolerable pain	Continuous pain of which the patient is constantly aware
2 / Mild pain	Sensation perceived as painful, but which is occasionally forgotten
1 / Very mild pain	Sensation perceived more as a discomfort than as actual pain
0 / No pain	No sensation of discomfort

Methods

After having given informed consent, 44 parturients were assigned to two groups of 22 via a random number draw. Group I was given repeated injections and Group II continuous infusion of the epidural analgesic mixture. Epidural analgesia was required for patient comfort during labour because of dystocia for trial labour. Maternal characteristics recorded included age, height, weight and parity. After about 100 ml of lactated Ringer's solution was infused, a lumbar epidural blockade was performed with the patient in the sitting position, once the patient was in active labour and the cervix was 3.5 to 4 cm dilated. Injections were made through a catheter threaded via the L₂-L₃ interspace. The patient then assumed the supine position, without a tilted position as a rule, to assure the homogeneous spread of local anaesthetic solution. If a sensory level of T₁₀ was not achieved, the patient was tilted head down. After full dilatation, the patient was placed in a semirecumbent position.

The mixture included 20 ml of 0.25 per cent plain bupivacaine and 2 ml fentanyl (100 µg). Following a test dose of 2 ml, parturients in Group I received a dose of the analgesic mixture determined as a function of their height: 8 ml between 150 and 160 cm and 10 ml for those taller than 160 cm. A dose identical to the initial one was reinjected upon recurrence of pain. Administration was stopped after full dilatation. In Group II, after injection of a 2 ml test dose, patients received a bolus injection half that administered to the preceding group (i.e., 4 or 5 ml). An infusion of the same mixture was started immediately thereafter at a constant flow rate (3 ml·h⁻¹), previously shown to produce satisfactory analgesia. Administration of the mixture was stopped upon full dilatation.

Quality of analgesia was evaluated using the rating scale proposed by Cathelin (Table I) with a score of 0 equal to complete analgesia (100 per cent) and 5 representing no analgesia (0 per cent). Duration of labour was measured between the beginning of the epidural injection and either full dilatation or decision to carry out a Caesarean section. The frequency of uterine contractions was determined in both groups from three measures performed in each parturient. The amount of oxytocin required was evaluated by determining the number of drops·min⁻¹ required for an infusion solution containing 10 µ syntocinon in 500 ml five per cent glucose. The number of forceps extractions and Caesarean sections was noted.

Blood pressure, heart rate and respiratory rate were measured at 5 and then 15 min intervals. Adverse effects, including vomiting, dizziness, pruritus and respiratory depression (a rate less than 10/min) were documented. After delivery, the condition of the newborn was assessed at 1 and 5 min, using Apgar scores, and at 30 min using a neuro-sensorial evaluation reported by Amiel-Tison.¹¹

Total dosages of bupivacaine and fentanyl used in the two groups were calculated. Venous blood samples were taken from 15 parturients of each group for assay of bupivacaine and fentanyl. In Group I, samples were taken 20, 40 and 60 minutes after each injection and upon complete dilatation. In Group II, they were taken 20, 40, 60, 120 and 180 minutes following the initial bolus, and again upon complete dilatation.

Bupivacaine was assayed by a high-pressure liquid chromatography assay with a threshold of 0.10 µg·ml⁻¹. Fentanyl was assayed by radioimmunoassay with a Fen. RIA.200 kit supplied by the Belgium National Institute (acceptable precision for levels above 0.1 ng·ml⁻¹), providing a detection threshold of 0.02 ng·ml⁻¹ plasma. Statistical analysis was carried out using Student's *t* test for small groups and by analysis of variance. Dunnett's test¹² was used to assess the Apgar scores.

Results

The two groups were similar in terms of age (24.77 ± 0.92 years for Group I, 26.82 ± 1.22 years for group II), height (160.77 ± 1.08 and 161.23 ± 1.11 cm), weight (66.68 ± 2.63 and 69.95 ± 2.25 kg) and parity (1.14 ± 0.75 and 1.14 ± 0.99). Epidural anaesthesia was begun at the same degree of dilatation in the two groups (respectively 3.88 ± 0.18 cm and 3.77 ± 0.21 cm).

Analgesia developed more rapidly in Group I (7.30 ± 0.30 minutes) than in Group II (12.57 ± 0.32 minutes) (*p* < 0.001). Development of analgesia is given in the Figure. In both groups analgesia was excellent, without significant differences at T = 15, T = 30 and T = 60. A

FIGURE Development of analgesia in the two groups (per cent calculated with pain rating scale). Number of patients is given at the top of each column.

difference between the two groups appeared at $T = 90$ and became highly significant ($p < 0.001$) at $T = 180$. Analgesia was better and more constant in Group II than in Group I. In Group I, analgesia upon full dilatation was rated 3.06 ± 0.82 after the first injection (delivery of less than 90 minutes duration) and 2.60 ± 0.41 after one reinjection (delivery in between 90 to 180 minutes). In Group II, analgesia was rated 1.85 ± 0.37 for short labour (4 hours) and 1.77 ± 0.26 for longer labour. The difference between analgesia scores with the two techniques was significant ($p < 0.05$) for short labor and highly significant ($p < 0.001$) for longer labor.

There were no significant differences in terms of the course of delivery in the two groups. The mean intervals between two contractions were respectively 175 ± 2.29 seconds and 175 ± 2.25 seconds, and the rate of infusion of syntocinon was respectively 15 ± 0.3 and 15 ± 0.23 drops $\cdot \text{min}^{-1}$. Duration of labour was 139.0 ± 63.50 minutes in group I and 133.63 ± 54.55 minutes in group

II. The frequency of forceps extractions was the same in the two groups: forceps were required for three patients in group I and four in group II, Caesarean sections for six in group I and five in group II. The high frequency of forceps and Caesarean sections can be explained by indications of peridural analgesia: only anticipated difficult labour. Blood pressure, heart rate and respiratory rate show no significant differences. No side effects occurred.

TABLE II Apgar scores at the first and fifth minute

Time	Apgar score	Group I	Group II	P
1 minute	>9	14 (64%)	15 (68%)	NS
	5-9	7 (31.8%)	7 (31.8%)	NS
	<5	1 (4.5%)	0 (0%)	NS
5 minutes	>9	21 (95.4%)	22 (100%)	NS
	5-9	1 (4.5%)	0 (0%)	NS
	<5	0	0	

TABLE III Maternal bupivacaine and fentanyl blood levels measured after each injection and at complete dilation in Group I

Time (min)	Initial bolus			Second injection			Third injection			Complete dilation
	20	40	60	20	40	60	20	40	60	
Bupivacaine $\mu\text{g}\cdot\text{ml}^{-1}$										
Mean	0.352	0.257	0.236	0.30	0.282	0.262	0.19	0.18		0.238
S.D.	± 0.092	± 0.054	± 0.053	± 0.048	± 0.058	± 0.045				± 0.049
n	8	8	8	4	4	4	1	1		7
Fentanyl $\text{ng}\cdot\text{ml}^{-1}$										
Mean	0.290	0.290	0.261	0.317	0.327	0.277	0.25	0.24		0.278
S.D.	± 0.041	± 0.022	± 0.031	± 0.069	± 0.055	± 0.054				± 0.042
n	7	6	78	4	4	4	1	1		6

Consumption of the analgesic mixture was calculated as a function of duration of epidural analgesia: $7.70 \pm 1.35 \text{ ml}\cdot\text{h}^{-1}$ in Group I and $5.32 \pm 0.95 \text{ ml}\cdot\text{h}^{-1}$ in Group II. It was significantly shorter in group II than in group I ($p < 0.001$). There were no significant differences between the two groups in terms of the Apgar scores (Table II) or of the Amiel test (27 ± 0.33 and 27 ± 0.36 , respectively for a total score of 30).

Results of assays are shown in Tables III and IV. Assays for bupivacaine and fentanyl during continuous infusion (20, 40, 60, 120 and 180 minutes after the bolus) did not show any significant differences. Upon complete dilatation, in Group I the mean bupivacaine blood concentration was $0.238 \pm 0.049 \mu\text{g}\cdot\text{ml}^{-1}$, versus $0.245 \pm 0.049 \mu\text{g}\cdot\text{ml}^{-1}$ in Group II; the difference between the two groups was not significant. The mean blood fentanyl concentration was $0.278 \pm 0.42 \text{ ng}\cdot\text{ml}^{-1}$ in Group I and $0.258 \pm 0.038 \text{ ng}\cdot\text{ml}^{-1}$ in Group II. The difference between the two groups was also not significant.

Discussion

Time to onset of analgesia is shortened when fentanyl is combined with bupivacaine,^{1,13} possibly due to rapid

uptake of the morphine derivative into the blood¹⁴ and also as fentanyl penetrates into the substantia gelatinosa better than either meperidine or morphine.¹⁵ In the present study, time to onset of analgesia in Group I was similar to that recorded by other authors: between five and ten minutes. The longer latency in Group II can be explained by the fact that the volume of the initial bolus was smaller than that administered to Group I, or in other studies. The delay was moderate (approximately five minutes) and cannot be considered to be a major drawback. In spite of the absence of a double blind design, after the first ten minutes quality of analgesia was better in Group II than in Group I. With the repeated injection technique, it would seem better to give repeat doses prior to the recurrence of pain, resulting in more steady analgesia, and avoidance of tachyphylaxis.¹⁶ But because of the unexpected duration of action of the precedent injection, it could procure too frequent injections and excessively high plasma concentrations.

Evans and Carrie⁵ undertook a prospective comparison of repeated injections versus continuous infusion for epidural anaesthesia with bupivacaine alone. They reported that quality of analgesia was clearly superior with the

TABLE IV Maternal bupivacaine and fentanyl blood levels measured during infusion and upon complete dilation in Group II

Time (min)	20	40	60	120	180	Complete dilation
Bupivacaine $\mu\text{g}\cdot\text{ml}^{-1}$						
Mean	0.199	0.204	0.193	0.320	0.240	0.245
S.D.	± 0.053	± 0.067	± 0.052	± 0.050	± 0.050	± 0.049
n	7	7	7	5	2	7
Fentanyl $\text{ng}\cdot\text{ml}^{-1}$						
Mean	0.24	0.241	0.265	0.276	0.262	0.258
S.D.	± 0.037	± 0.036	± 0.046	± 0.036	± 0.050	± 0.038
n	8	7	8	5	2	8

continuous infusion technique. Nevertheless, the dose infused ($16 \text{ mg} \cdot \text{h}^{-1}$) was considerably greater than that used with repeated injections ($5 \text{ mg} \cdot \text{h}^{-1}$). Lampl *et al.*¹⁷ have recently published a study comparing the two methods of administration of bupivacaine and fentanyl. Results were similar in the two groups, but fentanyl dosages were higher in the infusion group (no fentanyl reinjection was made until dilatation was full in the other group). This higher fentanyl dosage ($131 \pm 43.5 \mu\text{g}$ versus $87 \pm 23.8 \mu\text{g}$) does not seem necessary as Milon *et al.*¹⁸ have shown that increasing fentanyl dosage does not improve analgesia.

The present study suggests the advantage of continuous infusion. Indeed, there was some significant difference in favour of Group II in terms of dosage of the analgesic mixture (5.32 ± 0.95 versus $7.70 \pm 1.35 \text{ ml} \cdot \text{h}^{-1}$). The course of labour was comparable (same interval between two contractions, same duration of delivery), and the number of forceps extractions and Caesarean sections was similar. There were no differences in dosage between the two groups. The assays of bupivacaine and fentanyl blood levels showed no significant difference between the two groups at any time. Nevertheless, it is interesting to note that, administered by continuous infusion, the dose selected was sufficient to provide satisfactory analgesia, did not cause drug-accumulation phenomena, and yielded blood concentrations identical to those for the first group at the end of the second stage of labour. None of the authors who assayed bupivacaine blood levels during continuous rate infusions for this indication^{4,7,19} have reported drug accumulation or tachyphylaxis. Since the majority of published studies concern either comparisons between bupivacaine and bupivacaine-fentanyl administered discontinuously¹⁷⁻¹⁹ or injection of bupivacaine alone at a constant rate^{2,4,5,7,20,21} it is difficult to compare the doses chosen for this study with those reported.

By comparison with 0.25 per cent bupivacaine administered alone by continuous infusion, fentanyl allows a major decrease in dosage. When using bupivacaine alone, Rosenblatt *et al.*⁷ gave an initial bolus of 10 ml followed by $10 \text{ ml} \cdot \text{h}^{-1}$. Evans and Carrie⁵ employed an initial bolus of 7–10 ml followed by $9.48 \text{ ml} \cdot \text{h}^{-1}$ and Glover⁴ used a 10-ml bolus followed by $6\text{--}8 \text{ ml} \cdot \text{h}^{-1}$. Matouskova *et al.*²³ reduced the initial dose to 7 ml, followed by only $5 \text{ ml} \cdot \text{h}^{-1}$. However, a supplementary injection was sometimes required during the course of labour, and delivery required supplementary analgesia by local infiltration or pudendal nerve block. Comparable results were reported by Taylor²⁴ with $6 \text{ ml} \cdot \text{h}^{-1}$ of 0.25 per cent bupivacaine. In the present study, no further injections were required to maintain high-quality analgesia, until the end of delivery.

Bupivacaine and fentanyl levels in maternal blood were

always far below those considered to be potentially dangerous: $1.6 \mu\text{g} \cdot \text{ml}^{-1}$ bupivacaine in obstetrics according to Reynolds and Taylor (25) and $1\text{--}2 \text{ ng} \cdot \text{ml}^{-1}$ fentanyl according to Hug and Murphy²⁶ in a study performed in rats. As seen in Table IV, plasma concentrations of bupivacaine peaked 20 min after injection, but fentanyl did not show the same increase. This effect can be explained by differences in pharmacokinetics. The initial volume of distribution is larger for fentanyl than for bupivacaine. While transplacental passage of these two drugs is rapid, the maternal blood levels achieved were not dangerous, in view of published data.⁴⁻⁸ Examination of the neonates at birth did not show any deterioration by comparison with normal test values or any significant difference between the two groups. A complete neuro-sensorial study performed at the 30th minute did not show any difference between the two groups, nor with usual scores. Some authors⁷ consider that the continuous infusion technique increases the safety of epidural analgesia, by limiting the risk of accidental injection of a large bolus into a vein or into the subarachnoid space. The initial bolus is still required (although the volume is smaller), and, as noted by Morison and Smedstad,⁹ this hypothetical advantage has not been substantiated. The risk of bacterial contamination due to repeated injections is probably diminished, and the use of an automatic infusion pump should reduce the difficulty of monitoring the patient for the first signs of recurrence of pain.

Evaluation of side-effects showed no difference between the two techniques; as is usually the case with a combination of bupivacaine-fentanyl, blood pressure remained stable.^{11,18,21,27} No clinical sign of respiratory depression was noted.

Conclusions

Comparison of two techniques for epidural administration of bupivacaine and fentanyl demonstrated a clear advantage for the continuous administration technique in terms of the quality of analgesia obtained: no recurrence of pain during dilation, analgesia sufficient for delivery with the parturient in a semirecumbent position at full dilatation, and no interference with contractions. The duration of labour was not prolonged, and there was no increase in the number of forceps extractions or Caesarean sections. Assay of blood bupivacaine and fentanyl showed no drug-accumulation. While the doses used with the constant infusion protocol were significantly lower, this did not have any apparent clinical consequences other than an increase of approximately five minutes in the latency time. This study thus confirmed the advantage of continuous infusion in obstetric epidural analgesia.

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Résumé

Une analgésie péridurale a été réalisée avec un mélange bupivacaine-fentanyl en cours d'accouchement. Le travail était entrepris dans le but de comparer l'efficacité respective et les effets secondaires possibles de deux techniques d'administration du mélange: injections itératives ou débit constant. Quarante quatre parturientes étaient réparties en deux groupes homogènes quant au nombre, aux données anthropométriques et à la parité. Les analgésies étaient débutées au même stade du travail. Le mélange associait 20 ml de bupivacaine à 0,25 pour cent sans adrénaline et 2 ml (100 µg) de fentanyl. Dans le groupe I la dose de départ allait de 8 ou 10 ml selon la taille, les réinjections se faisant à la réapparition de la douleur avec un volume identique. Dans le groupe II, après une dose initiale de 4 ou 5 ml, une perfusion de 3 ml·h⁻¹ était débutée, et arrêtée à dilatation complète. L'analgésie était quantifiée grâce à une échelle de douleur; la pression artérielle et la fréquence respiratoire chez la mère et l'état des enfants à la naissance étaient notés. Des dosages de bupivacaine et de fentanyl étaient réalisés dans le sang veineux maternel chez 30 parturientes durant le déroulement du travail jusqu'à la fin de la dilatation. Les résultats montrent dans le groupe II: un délai d'action plus long (de 5 min en moyenne), et une analgésie de qualité plus régulière. La meilleure qualité de l'analgésie ne peut pas être expliquée par une différence de posologie: les doses sont significativement inférieures dans ce groupe malgré des accouchements de durée identique. Le déroulement du travail, l'état maternel et celui des nouveaux-nés sont comparables dans les deux groupes. Enfin les dosages révèlent des taux sanguins non significativement différents entre les deux séries et sans signe d'accumulation.

La technique d'administration à débit constant semble donc être intéressante puisqu'elle assure une analgésie de qualité régulière avec des posologies inférieures à celles nécessitées par des injections répétées.