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Background Infusion Is Not Beneficial during Labor Patient-controlled Analgesia with 0.1% Ropivacaine plus 0.5 μg/ml Sufentanil

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Background: **Although patient-controlled epidural analgesia (PCEA) during labor has been extensively studied in recent clinical trials, the role of a background infusion associated with self-administered boluses is still debated. The authors designed a study to assess whether the use of PCEA with or without background infusion could improve the comfort of parturients and their satisfaction during labor and delivery without affecting the total consumption of local anesthetics.**

Methods: **One hundred thirty-three laboring parturients requesting epidural analgesia administered *via* PCEA with a solution of 0.1% ropivacaine plus 0.5 μg/ml sufentanil were randomly assigned to four groups, according to the rate of background infusion used (0, 3, 6, and 9 ml/h). Local anesthetic requirements, maternal satisfaction, verbal pain scores, incidence of side effects, and outcome of labor were compared among groups.**

Results: **Patient demographics, labor characteristics, side effects, and Apgar scores were similar in each group. No significant differences were observed between groups in verbal pain scores during labor, number of supplemental boluses, or maternal satisfaction. A significantly greater overall total drug consumption with a 6-ml/h or a 9-ml/h background infusion (74 and 78 ml, respectively) was observed in comparison with PCEA without a background infusion (55 ml). A similar relation was observed for hourly use during both the first and the second stage of labor.**

Conclusion: **The results of this study suggest that the use of a background infusion with PCEA during labor leads to a greater consumption of anesthetic solution without improving comfort and satisfaction of parturients. Moreover, not using a background infusion does not provide an increased incidence of supplemental boluses (which might cause problems in a busy unit) and allows for a substantial reduction in the cost of analgesia.**

SINCE its first description during labor in 1988 by Gambling *et al.*,[1] patient-controlled epidural analgesia (PCEA) has been extensively studied in many clinical trials. PCEA for labor analgesia has been advocated as efficient and safe, with several advantages when compared with continuous epidural infusion, such as a reduction in local anesthetic requirements, motor blockade, or unscheduled clinician top-ups.[2] Many studies comparing different anesthetic solutions and different PCEA settings have tried to establish the ideal administration regimen, providing adequate analgesia during labor and high maternal satisfaction with minimum side effects and local anesthetic requirements.[2] Hence, a trend toward the use of low concentrations of local anesthetics has been observed in recent studies.[3–7] However, many questions regarding the administration regimen are still debated, such as the optimal bolus size and lockout interval or the desirability of a background infusion.[8–10]

To date, only two studies have compared efficacy and local anesthetic consumption during labor using PCEA with or without background infusion.[8,9] However, the role of a background infusion was not clearly established in these studies. Therefore, we designed a study to assess whether the use of PCEA with or without a background infusion could improve the comfort of parturients and their satisfaction during labor and delivery without affecting the total consumption of anesthetic solution.

Materials and Methods

After approval by the local ethics committee (Lyon, France) and written consent was obtained, nulliparous or primiparous adult parturients with American Society of Anesthesiologists physical status I or II who requested epidural analgesia during the first stage of labor were enrolled in this prospective, randomized, double-blind study. Women with severe medical or obstetric complications, multiple gestations, prostaglandin-induced labor,[11] contraindication to epidural analgesia, weight greater than 100 kg, or height less than 155 cm or greater than 185 cm and those who were unable to use the PCEA pump were excluded. No parturient received any analgesic agent before participation in the study.

Instruction in the use of the PCEA pump took place before the insertion of the epidural catheter. Parturients were told to press the demand button whenever pain occurred and to expect some relief within a few minutes. Before placement of the anesthetic, parturients were asked to assess their pain with a verbal pain score (VPS), using a numeric rating scale (0 = no pain, 10 = worst pain imaginable). An 18-gauge epidural catheter was then inserted 3 cm into the epidural space at the L3–L4 or L4–L5 interspace, with the parturient in the sitting position. Catheters were aspirated gently for return of blood or cerebrospinal fluid, and no test dose was administered.[12,13]

Parturients were then randomly assigned by a computer-generated list to one of the following groups: group 0

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received no background infusion, and groups 3, 6, and 9 received 3-, 6-, and 9-ml/h background infusions, respectively. All parturients received a mixture of 0.1% ropivacaine and 0.5 μg/ml sufentanil, which is the standard anesthetic solution in our institution,[6] administered *via* an IVAC® PCAM® pump (Alaris Medical Systems Inc., San Diego, CA), set by an anesthesiologist not directly involved in the patient's care or data collection. All groups received a 12-ml initial bolus of the anesthetic solution, followed after 30 min by the corresponding background infusion, *i.e.*, 0, 3, 6, or 9 ml/h. Additional 5-ml boluses with a 5-min restrictive period and a dose limit of 22 ml/h (including the background infusion) were authorized in all groups. Parturients who experienced inadequate analgesia during labor (VPS > 4) irrespective of PCEA use could receive additional 5-ml boluses of the study solution. Parturients were excluded from data analysis if they had persistent inadequate analgesia (requiring more than two supplemental boluses per hour) or delivery within 2 h after epidural catheter insertion. All observations were made by another anesthesiologist who was unaware of the PCEA settings.

The VPS during labor and common side effects such as nausea, somnolence, and pruritus were evaluated by using a 0–10 scale before epidural placement at 30 min and then at every hour after study drug administration, as well as motor block (modified Bromage scale: 0 = bilateral sustained straightening of leg, 1 = unable to straighten leg, 2 = just able to flex knees, 3 = foot movement only). The total and hourly volumes of the solution required and the number of boluses (demanded, delivered, and supplemental) were recorded at delivery (or at the time of decision for cesarean delivery). Calculations of first-stage hourly volumes of anesthetic solution were performed with both inclusion and exclusion of the initial 12-ml bolus.

Maternal and fetal heart rates were monitored continuously, and maternal noninvasive blood pressure was measured at regular intervals. Maternal hypotension, defined as systolic blood pressure of less than 100 mmHg or a decrease of more than 25%, was treated by intravenous doses of ephedrine as needed and by assumption of the left lateral decubitus position and administration of oxygen *via* a facemask. Each fetal and maternal event, therapeutic interventions, outcome of labor, and Apgar scores at 1 and 5 min were recorded. Maternal satisfaction with labor analgesia was evaluated 2 h after the delivery using a 0–10 scale (0 = not satisfied at all, 10 = fully satisfied).

Statistical Analysis

Assuming an SD of 25 ml in the mean total volume of 0.1% ropivacaine plus 0.5 μg/ml sufentanil administered *via* PCEA during labor (as reported in a previous study performed at our institution),[6] the power of the one-way analysis of variance with a total sample of at least 120 subjects (30 parturients/group) reached 90% at a significance level of 0.05 with a goal of 20% difference in the total volume of anesthetic solution among the four groups (SamplePower 1.02; SPSS Inc., Chicago, IL).

Statistical analyses were performed with StatView 5.0 software (SAS Institute, Cary, NC). Data are presented as mean (95% confidence interval) for continuous variables and percentage for discrete variables. Statistical analyses of demographic data, amount of anesthetic solution administered, duration of labor, and maternal satisfaction were performed using one-way analysis of variance, with the Bonferroni test for *post hoc* comparisons when significance was determined by analysis of variance. The incidence of oxytocin use, side effects or motor blockade, Apgar scores less than 7 at 1 and 5 min, the mode of delivery, and the need for supplemental boluses were analyzed using the chi-square test. Verbal pain scores during labor were analyzed using two-way analysis of variance for repeated measures. A P value less than 0.05 was considered statistically significant.

Results

Of the 140 parturients enrolled in this study, 7 were excluded (1 in group 0, 1 in group 3, 3 in group 6, and 2 in group 9) because of deviations in the protocol standard, incomplete data collection, or delivery within 2 h after epidural catheter insertion. No parturient required epidural boluses in addition to the initial bolus to establish analgesia, and none was excluded because of persistent inadequate analgesia during labor. One hundred thirty-three parturients completed the study: 34 in group 0, 34 in group 3, 32 in group 6, and 33 in group 9. Demographic data and labor characteristics are presented in table 1 and did not differ between groups. The durations of first stage of labor (defined as the time between epidural blockade and full cervical dilation) and of second stage (defined as the time between full cervical dilation and the completion of vaginal delivery or the decision to proceed with cesarean delivery) were similar in each group (table 1).

The mean total volume of anesthetic solution administered during the overall study period was significantly less in parturients receiving no background infusion or a 3-ml/h background infusion when compared with the other groups: 55 ml for group 0 and 69 ml for group 3 *versus* 74 ml for group 6 and 78 ml for group 9 (table 2; $P < 0.05$). There was no difference in the mean total volume of anesthetic solution administered during the first stage of labor, but parturients in group 0 received significantly less anesthetic solution during the second stage of labor than parturients in groups 6 and 9 (table 2; $P < 0.05$). Moreover, the mean hourly volume of anesthetic solution administered was significantly less in groups 0 and 3 than in groups 6 and 9 during the first

Table 1. Patient Demographics and Labor Characteristics

	Background Infusion				
	0 ml/h (n = 34)	3 ml/h (n = 34)	6 ml/h (n = 32)	9 ml/h (n = 33)	*P* Value
Age, yr	26 (24–29)	27 (26–29)	29 (27–31)	28 (27–30)	0.174
Height, cm	163 (161–164)	164 (163–166)	164 (162–167)	164 (162–166)	0.313
Weight, kg	69 (66–71)	73 (70–75)	71 (67–75)	74 (71–78)	0.067
Nulliparous	26 (77)	27 (79)	25 (78)	21 (64)	0.429
Oxytocin use during labor	30 (88)	26 (76)	24 (75)	24 (73)	0.417
Cervical dilation at placement, cm	3 (3–4)	4 (3–4)	3 (3–4)	3 (3–4)	0.679
Mode of delivery					0.382
Vaginal	27 (79)	22 (64)	27 (84)	27 (82)	
Instrumental	4 (12)	6 (18)	3 (10)	5 (15)	
Cesarean	3 (9)	6 (18)	2 (6)	1 (3)	
Duration, min					
First stage of labor*	212 (188–242)	270 (246–309)	218 (186–261)	231 (204–274)	0.064
Second stage of labor†	61 (45–77)	82 (65–101)	92 (71–113)	68 (51–86)	0.067
Maternal satisfaction (0–10 scale)	9 (9–10)	9 (9–10)	10 (9–10)	9 (9–10)	0.109

Data are presented as mean (95% confidence interval) or No. (%). No statistically significant differences exist (analysis by one-way analysis of variance or chi-square test).

* From epidural catheter placement until total cervical dilation. † From total cervical dilation until delivery.

stage of labor (with exclusion of the 12-ml initial bolus of the cumulative total) and was significantly less in group 0 than in group 9 during the second stage of labor (table 2; $P < 0.05$).

Maternal satisfaction values were high and similar between groups (table 1), and no difference was observed in the mean VPS at baseline and throughout labor (fig. 1). The mean PCEA ratios of successful and total PCEA demands were similar between groups during both the first and the second stage of labor (table 2). During the first stage of labor, approximately 15–20% of parturients requested nurse-administered supplemental boluses, and less than 10% requested nurse-administered supplemental boluses during the second part of labor, with no difference between groups (table 2).

No differences in side effects were observed between groups. Although one parturient in group 9 had a Bromage score of 2 during labor, no statistically significant difference in motor block was observed in any group, and approximately 90% of parturients had a Bromage score of 0 during the overall study period (table 3). No differences in side effects (nausea, somnolence, and pruritus) or in the use of ephedrine during labor were observed between groups (table 3). The modes of delivery (*i.e.*, vaginal, instrumental, or cesarean) was similar between groups (table 1), as were the Apgar scores at 1 and 5 min (table 3). No case of prolonged hypotension, respiratory depression, or postpartum hemorrhage of more than 500 ml occurred in any study group.

Discussion

Our results show that 0.1% ropivacaine and 0.5 μg/ml sufentanil administered *via* PCEA with or without back-

Table 2. Local Anesthetics Requirements

	Background Infusion				
	0 ml/h (n = 34)	3 ml/h (n = 34)	6 ml/h (n = 32)	9 ml/h (n = 33)	*P* Value
Total volume, ml	55 (48–65)*	69 (60–77)	74 (66–82)	78 (72–91)	0.009
First stage of labor	47 (42–57)	54 (48–63)	55 (49–53)	60 (53–75)	0.119
Second stage of labor	8 (5–11)*	15 (10–19)	19 (13–26)	18 (13–23)	0.048
Hourly volume, ml/h					
First stage of labor					
With initial bolus	14 (12–16)	13 (12–14)†	16 (14–19)	16 (15–17)	0.006
Without initial bolus	9 (8–11)*	10 (9–11)*	13 (11–15)	12 (12–14)	0.0002
Second stage of labor	9 (5–13)‡	10 (7–12)	12 (9–14)	16 (12–21)	0.014
PCEA ratio,§ %					
First stage of labor	80 (68–85)	75 (68–83)	82 (73–87)	71 (64–83)	0.424
Second stage of labor	87 (78–95)	74 (62–86)	82 (70–93)	76 (61–90)	0.395
One or two supplemental boluses					
First stage of labor	5 (15)	6 (19)	5 (16)	5 (16)	0.979
Second stage of labor	1 (3)	3 (10)	0 (0)	1 (3)	0.255

Data are mean (95% confidence interval) or No. (%).

* $P < 0.01$ *vs.* groups 6 and 9 by one-way analysis of variance (Bonferroni *post hoc* test). † $P < 0.01$ *vs.* groups 6 by one-way analysis of variance (Bonferroni *post hoc* test). ‡ $P < 0.01$ *vs.* group 9 by one-way analysis of variance (Bonferroni *post hoc* test). § Ratio of successful and total patient-controlled epidural analgesia (PCEA) demands.

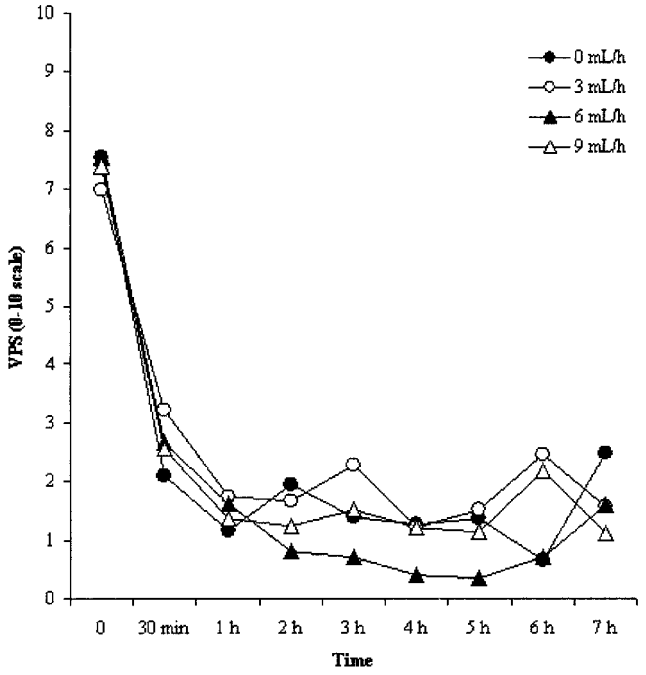

Fig. 1. Mean verbal pain scores (VPSs) during labor. No statistically significant differences exist (by analysis of variance for repeated measures).

ground infusion produce effective pain relief in labor. No significant differences were observed between groups in VPS during labor, number of supplemental boluses, maternal satisfaction, or duration of labor. No difference in the overall total drug consumption was observed between groups 0 and 3; however, pain assessments were similar in the two groups. A significantly greater overall total drug consumption with a 6-ml/h or a 9-ml/h background infusion was observed in comparison with PCEA without background infusion. A similar relation was observed for hourly use during both the first stage (with exclusion of the 12-ml initial bolus) and the second stage of labor. This suggests that the use of a continuous infusion with PCEA does not improve the comfort of parturients or their satisfaction during labor and delivery but leads to a greater consumption of anesthetic solution.

Several reports have indicated that the use of PCEA during labor allows for a lower consumption of local anesthetics when compared with epidural analgesia provided by continuous infusion.[1,2,8] However, although PCEA during labor has been extensively studied in recent clinical trials, the desirability of a background infusion associated with self-administered boluses is still debated.[8,9]

In one of the first reports devoted to this subject, Ferrante *et al.*[8] observed no differences in the total volume of 0.125% bupivacaine plus 2 μg/ml fentanyl administered with PCEA during labor, regardless of the rate of background infusion (0, 3, or 6 ml/h), but a greater need for physician-administered supplemental boluses during the first stage of labor in the PCEA groups receiving no background infusion or a 3-ml/h background infusion when compared with the 6-ml/h group. In our study, no difference in supplemental bolus requirements was observed between groups, but these discrepancies might be explained by differences in the anesthetic solution used in each study (which might affect analgesic requirements) and in the PCEA settings (3-ml boluses allowed every 10 min in the study of Ferrante *et al.* and 5-ml boluses every 5 min in ours).

More recently, Petry *et al.*[9] compared the analgesic requirements of parturients receiving 0.125% bupivacaine plus 0.75 μg/ml sufentanil *via* PCEA during labor with or without a background infusion of 3 ml/h after a 10-ml initial bolus, with 3-ml boluses allowed every 12 min and a dose limit of 10 ml/h. Although the total bupivacaine consumption in the group with a 3-ml/h background infusion was greater than in the group with no background infusion (36.4 and 43.6 mg, respectively), this difference did not reach statistical significance. No differences in pain scores were observed between groups. For short-lasting labors (< 3 h), the authors observed a greater consumption of bupivacaine in the group with a 3-ml/h background infusion *versus* the group without a background infusion (32.6 *vs.* 23.9 mg,

Table 3. Side Effects and Apgar Scores

	Background Infusion				
	0 ml/h (n = 34)	3 ml/h (n = 34)	6 ml/h (n = 32)	9 ml/h (n = 33)	*P* Value
Motor block					0.605
Bromage score 0	30 (88)	32 (94)	28 (87)	30 (91)	
Bromage score 1	4 (12)	2 (6)	4 (13)	2 (6)	
Bromage score 2	0 (0)	0 (0)	0 (0)	1 (3)	
Nausea > 4 (0–10 scale)	3 (9)	5 (15)	1 (3)	2 (6)	0.362
Somnolence > 4 (0–10 scale)	22 (65)	17 (50)	15 (47)	17 (52)	0.476
Pruritus > 4 (0–10 scale)	9 (26)	8 (24)	7 (22)	6 (18)	0.877
Ephedrine use	0 (0)	0 (0)	2 (6)	2 (6)	0.229
Apgar scores <7					
At 1 min	1 (3)	3 (9)	3 (9)	2 (6)	0.708
At 5 min	1 (3)	0 (0)	2 (6)	0 (0)	0.269

Data are presented as No. (%). No statistically significant differences exist (analysis by chi-square test).

respectively; $P < 0.05$). However, this difference might be explained by the short duration of labor and the influence of the 10-ml initial bolus on the cumulative total; therefore, the expression of the results as hourly totals might have been more appropriate in that case.

The differences in the findings of Ferrante *et al.* and Petry *et al.* compared with ours may be due to differences in anesthetic solution and PCEA settings. Moreover, no sample size was calculated in either the study of Ferrante *et al.* or the study of Petry *et al.*; hence, the results might have been caused by insufficient power of both studies to detect small differences in local anesthetic requirements during labor. The results of our study suggest that the total volume of anesthetic solution, our primary outcome variable as defined by sample size calculations, increases according to the rate of background infusion, which was not clearly established in the studies of Ferrante *et al.* and Petry *et al.* Moreover, the studies of both Ferrante *et al.* and Petry *et al.* used 0.125% bupivacaine to investigate the issue of background infusions, whereas the current study used a lower concentration (0.1% ropivacaine, probably comparable to approximately 0.075% bupivacaine), which is an increasing trend in obstetric anesthesia and is more in keeping with current practice.[2,6,7,14]

A lower consumption of local anesthetics, however, did not provide in our study a decreased incidence of side effects such as motor block or a decreased incidence of instrumental deliveries. Although the effect of epidural analgesia on the rate of instrumental or cesarean delivery is unclear,[15] it has been shown that motor blockade is reduced when low concentrations of local anesthetics are chosen.[16] In the current study, we chose a concentration of ropivacaine of 0.1% in association with 0.5 μg/ml sufentanil because we have previously described that this concentration was effective during both stages of labor and that the use of lower concentrations might lead to inadequate analgesia during the second stage of labor.[5,6] The low incidence of motor block when decreased concentrations of local anesthetics are chosen—and the overall low incidence of motor block or side effects found in the current study—might therefore explain why no difference was observed in the Bromage scores or instrumental deliveries between groups, which, moreover, were not the primary endpoints of this study.

Besides no increase in the need for supplemental boluses and the apparent lack of clinical benefit, another advantage of PCEA without background infusion is a reduction in the cost of analgesia. As prepared at our institution, three 10-ml bottles of 0.2% ropivacaine are needed to prepare a 60-ml solution of 0.1% ropivacaine. Considering that the mean total volume administered during labor with PCEA with no background infusion is 54.8 ml (which represents one 60-ml syringe) and is 78.0 ml with a 9-ml/h background infusion (which represents two 60-ml syringes), this could represent up to a 50% reduction in cost.

In conclusion, our results suggest that the use of a background infusion with PCEA is not beneficial during labor and leads to a greater consumption of local anesthetic solution without improving the comfort and satisfaction of parturients. Moreover, the use of PCEA without a background infusion does not provide a greater need for supplemental boluses, which might cause logistical problems in a busy unit. Finally, although no decreased incidence in motor block was observed, the use of no background infusion allows for a reduction in the cost of analgesia. Based on these findings, we recommend the use of 0.1% ropivacaine plus 0.5 μg/ml sufentanil administered *via* PCEA without background infusion during labor. Further studies are warranted to determine whether this recommendation would be applicable if other agents such as bupivacaine, levobupivacaine, or fentanyl were administered.

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