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PCEA compared to continuous epidural infusion in an ultra-low-dose regimen for labor pain relief: a randomized study

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Background: Patient-controlled epidural analgesia, PCEA, has been introduced in obstetric analgesia during the past decade. Many studies have shown that the consumption of analgesic is reduced when the parturient requests her own doses. This study investigates whether this is also true when using an ultra-low-dose regimen.
Methods: Eighty parturients were prospectively randomized to have either continuous epidural infusion (CEI) with ropivacaine $1\,mg\,ml^{-1}$ and sufentanil $0.5\,\mu g\,ml^{-1}$, $6\,ml\,h^{-1}$, *or* patient-controlled epidural analgesia (PCEA) with 4 ml demand doses with 20 min' lockout. The epidural start dose was the same for the two groups, 8 ml of the study solution. Rescue bolus doses were given when needed and the continuous infusion could be increased, which gave the two groups the same maximum possible dose. The consumption of local ropivacaine in combination with sufentanil during labor was registered. Hourly assessments made throughout labor included pain intensity documented with visual analog score, VAS, the patient's opinion on epidural efficacy, motor block, pruritus and need for nitrous oxide.
Results: The PCEA group consumed 33% less of the study solution than the CEI group. Mean total consumption was 35 ml (SD 18.0) and 52 ml (SD 19.6), respectively. Mean hourly consumption was $5.2\,ml\,h^{-1}$ (SD 2.54) in the PCEA group and $6.9\,ml\,h^{-1}$ (SD 1.31) in the CEI group. There were no significant differences between the two groups in pain relief, epidural efficacy, side-effects or obstetric outcome.
Conclusion: PCEA reduces doses compared to continuous infusion even when ultra-low-dose local anesthetic with opioid is used. The PCEA technique provides individual titration of doses to an acceptable degree of pain relief.

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Key words: Epidural; labor; obstetric analgesia; PCEA.

PATIENT-CONTROLLED epidural analgesia, PCEA, for labor pain relief has been introduced during the past decade (1–3). Many studies have shown a decrease in drug consumption when compared to continuous epidural infusion, CEI (3, 4). In these studies the epidural block was established with high-dose local anesthetic and then maintained with low-dose local anesthetic with opioid. The present aim was to investigate whether an ultra-low-dose local anesthetic with opioid regimen could be used throughout and still decrease drug consumption with PCEA compared to continuous infusion.

Ropivacaine is a local anesthetic which has been gradually introduced in obstetric anesthesia (5–7). The present study also aimed to try the drug combination ropivacaine $1\,mg\,ml^{-1}$ with sufentanil $0.5\,\mu g\,ml^{-1}$ in an ultra-low-dose protocol.

Methods and material

This prospective randomized non-blinded study was approved by the Ethics Committee of Uppsala University and Huddinge Hospital. It was a multicenter study performed in Gävle County Hospital and Söder Hospital in Stockholm. The parturients had received verbal and written information about the study during their antenatal visits. A power calculation showed that a total sample size of 80 parturients would discover a 25% reduction in analgesic requirement with a power of 81%.

Studied consecutively, the parturients were all healthy with singleton pregnancies, ASA classification I-II. None had received systemic opioids for 6 h before entering the study. Exclusion criteria were ASA classification III–IV, breech presentation and existing language barrier that would have precluded instruction

on the use of the pump. Epidurals were decided at the parturient's request. Randomization was done using urn model with 80 tickets. Each ticket was drawn without replacement. The parturients were grouped, by sealed envelope assignment, to receive epidural analgesia with PCEA or CEI. An intravenous infusion with crystalloid acetated Ringer's solution was started. The study solution was prepared by the anesthetist in charge. Eleven ml of sodium chloride 0.9% was withdrawn from a bag of 100 ml. Ten ml of ropivacaine 10 mg ml^{-1} and 1 ml of sufentanil 50 μg ml^{-1} were then added to the bag, giving 100 ml of ropivacaine 1 mg ml^{-1} and sufentanil 0.5 μg ml^{-1}. An epidural catheter was placed at the L2-L3 or L1-L2 interspace and a test dose of 3 ml was followed 3 min later by a main dose of 5 ml of the study solution. Subsequently, according to the randomization, a pump was connected to the epidural catheter.

In the *CEI-group* an 'IVAC P1000 Syringe Pump' (Alaris Medical Systems, UK) with a continuous infusion of 6 ml h^{-1} of the study solution was started. A rescue bolus dose of 5 ml study solution could be administered by the midwife or anesthetist if VAS exceeded 5 or if the parturient experienced inadequate analgesia. This could be repeated three times up to 15 ml of rescue bolus doses. For each bolus dose the infusion rate was increased by 2 ml h^{-1} up to a maximum of 12 ml h^{-1}.

In the *PCEA-group* an 'Abbott Pain Manager' (Abbott Laboratories) was programmed to give bolus doses of 4 ml on demand, with 20 min lock-out time and no 1- or 4-h limit.

A rescue bolus dose of 5 ml study solution could be given by the midwife or anesthetist if VAS exceeded 5 or if the parturient experienced inadequate analgesia. This could be repeated three times up to 15 ml of rescue bolus doses. The resulting maximum dose was 12 ml h^{-1} and up to 15 ml of rescue bolus doses. The PCEA parturients were instructed to press the button as soon as they felt uncomfortable with the pain relief, not to wait until the pain became severe. The function and meaning of lock-out time were explained to them.

The study design permitted the same possible maximum doses to the two groups.

Both groups were told they could have extra rescue bolus doses if their analgesia was unsatisfactory.

Pain was scored on a Visual Analog Scale (VAS) with zero representing no pain and 10 representing the worst pain imaginable. The parturient was asked to rate the pain she felt during the latest contraction.

Pain score was registered before receiving epidural block and 20 min after the bolus dose; subsequently with hourly assessments until delivery was complete. This included VAS and parturient's subjective ratings of the quality of the block as excellent, good, fair or poor. Any use of nitrous oxide was registered. The parturient was also asked whether she felt she was given sufficient analgesia. The hourly assessments included registration of existing motor block with straight-leg-raise test. The occurrence and severity of pruritus and hypotension were registered. Obstetric parameters such as need for Cesarean section or vacuum extraction were noted, as were bladder catheterization and the use of oxytocin. Neonatal condition was assessed with Apgar score and umbilical artery or vein pH.

Within 2 h of delivery each parturient was asked if she thought the epidural had given her the pain relief she had expected. The parturients who had had the PCEA pump were asked three more questions: was it good to 'press' your own doses? Did you feel safe with the treatment? If you were to give birth again, would you choose the same method of pain relief?

The statistical analysis was performed using the SPSS statistical computer software, version 11.0 for Windows NT. Data are reported as means and standard deviations or medians together with minimum and maximum values. Boxplots show the distributions as median 10/90 percentiles and range. Student's *t*-test, the Mann–Whitney *U*-test, the χ^2-test with Yate's correction factor and Fisher's exact test were used when appropriate. In all instances a *P*-value of <0.05 was considered as significant. All the tests were two-tailed.

Results

Demographics

In the two hospitals 97 parturients were included in the study. Of these 17 were unable to fulfill the protocol: eight because of technical problems with the pump or the epidural, eight because of delivery within an h and one because of existing exclusion criteria.

Thus 80 parturients were studied, 40 in each group, completing the protocol.

The two groups were equal in all respects, except that labor was induced in five patients in the PCEA group and in none in the CEI group (Table 1).

Pain assessments and analgesic requirements

The hourly assessment of pain intensity (VAS) is shown in Figure 1.

The parturients' subjective assessments of pain relief were similar in the groups (Fig. 2).

Table 1

Demographics			
	CEI ($n=40$)	PCEA ($n=40$)	
Parturient height (cm)[a]	166 (5.39)	166 (6.3)	NS
Parturient weight (kg)[a]	80.6 (9.83)	78.8 (12.2)	NS
Gestational length (weeks)[a]	40.2 (1.17)	40.3 (1.24)	NS
Cervical dilation (cm)[a]	5.1 (1.11)	4.9 (1.4)	NS
Primiparae (*n* and %)	34 (85%)	33 (82.5%)	NS
Induction of labor (*n* and %)	0 (0%)	5 (12.5%)	0.027

[a]Mean (SD).

In the PCEA group total consumption was 33% lower and hourly consumption 25% lower than in the CEI group (Table 2). The initial bolus dose of 8 ml is not included in the hourly consumption. The hourly doses in the PCEA group ranged from 0 to 10.63 ml h^{-1} compared to 6–11.6 ml h^{-1} in the CEI group. Mean total sufentanil consumption was 17.5 μg (SD 9.0) in the PCEA group and 26 μg (SD 9.8) in the CEI group. In the PCEA group 65% demanded less than 6 ml h^{-1} and 30% more than 6 ml h^{-1}.

After delivery, 82.5% of the PCEA group parturients felt that the epidural had given the pain relief expected. The corresponding figure in the CEI group was 85%. The main reason in both groups for not being completely satisfied was insufficient relief from pressure felt during the second stage.

In the PCEA group 97.5% felt safe with the treatment, 92.5% thought that it was good to be in control of their own doses and would choose the same method of pain relief if they were to give birth again.

The need for nitrous oxide is shown in Figure. 3.

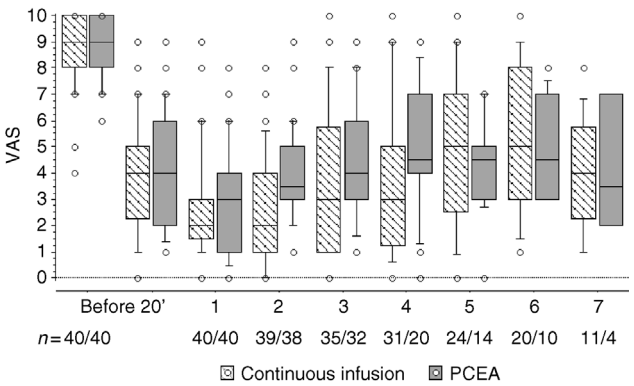

Fig. 1. VAS scores before block, after 20 min and every hour. There were no significant differences between the two groups. Data are presented as median and 25th/75th percentile in boxes. Whiskers are 10th/90th percentiles. Circles represent outliers. Numbers in each group are reduced every hour due to deliveries.

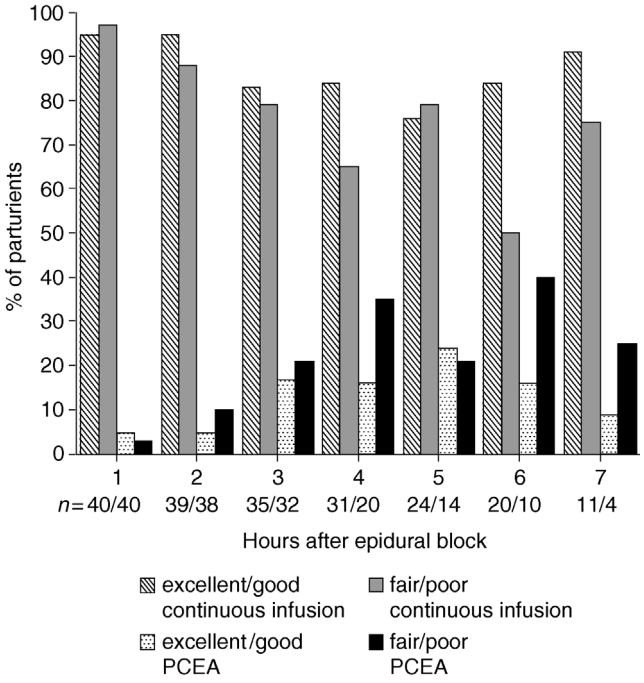

Fig. 2. Parturients' subjective hourly assessments of pain relief. The differences seen in the figure are not significant. Numbers in each group are reduced every hour due to deliveries.

Obstetric outcome

The duration of labor after epidural was slightly reduced in parturients receiving PCEA compared to those on CEI (Table 3).

Neonatal data

One baby in the PCEA group was born with Apgar score 1-3-3. The diagnosis was E. Coli sepsis. No neonate was treated with naloxone (Table 4).

Side-effects

Pruritus was also experienced in 50% in both groups. The intensity was mild-to-moderate. No parturient had severe pruritus.

Affected motor ability was sporadically seen in four parturients in the CEI group and in two in the PCEA group. One CEI parturient had affected motor ability throughout labor.

One parturient in the CEI group had an episode of hypotension. Her blood pressure was restored promptly with treatment.

Discussion

We found that PCEA gave a lower consumption of analgesic than continuous infusion did, even when

Table 2

Dosage requirements							
	CEI ($n=40$)			PCEA ($n=40$)			
Total consumption (ml)[a]	52 (19.6)			35 (18.0)			$P<0.001$
Hourly consumption (ml h^{-1})[a]	6.9 (1.31)			5.2 (2.54)			$P<0.001$
	1st	2nd	3rd	1st	2nd	3rd	
Need for extra bolus dose (No)	14	2	2	9	3	1	

[a]Mean (SD).

using an ultra-low-dose regimen with ropivacaine 1 mg ml^{-1} and sufentanil 0.5 μg ml^{-1}. This contrasts with the result of another recent study using low-dose local anesthetic and opioid and comparing PCEA to continuous infusion. Those authors saw no difference in analgesic requirements between the two groups (8).

However, earlier studies comparing PCEA and CEI show various degrees of dose reduction (17–47%) with the PCEA technique (1, 3–5, 9–12). In those studies, a rather dense epidural block was established, followed by a dilute solution of local anesthetic, sometimes combined with opioid. Other studies show no dose reduction with PCEA (13–15). This might be because the authors also used continuous background infusion in their PCEA setting.

Pain perceived during labor and delivery varies throughout the course (16) and the idea of self-dosing is logically appealing. PCEA permits titration of doses according to individual need. Parturients that especially benefit from PCEA are those with low drug consumption, who would have been overdosed in a continuous epidural infusion routine. A generally accepted aim in obstetrics is to give only the drugs necessary and no more: an approach that theoretically minimizes the risk of any adverse effect on mother or child.

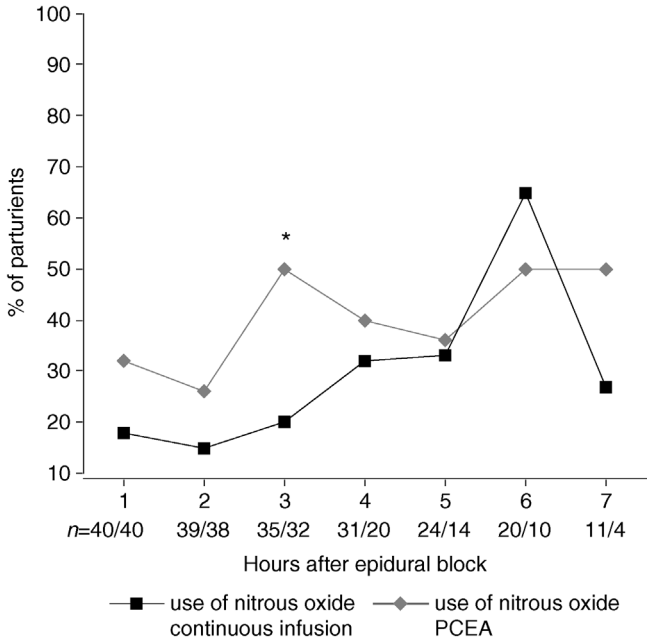

Fig. 3. The use of nitrous oxide. The difference seen at hour 3 is significant ($P<0.01$). Numbers in each group are reduced every hour due to deliveries.

Reduced dose of local anesthetic for epidural block favors obstetric outcome by lowering the incidence of Cesarean section and instrumental delivery (17, 18).

Another interesting finding is that the two study groups were satisfied with pain scores of 3–4 instead of complete pain relief. Had our study groups experienced inadequate analgesia, the PCEA group would have used their maximum possible dose, which they did not. A different result was achieved in another PCEA study using ropivacaine 1 mg ml^{-1} with sufentanil 0.5 μg ml^{-1}. In that study an almost three times higher dose was used during the first stage, and a maximum dose of 30 ml h^{-1} during the second (7).

Complete pain relief during labor does not necessarily have to be the therapeutic goal. When women are allowed to tailor their own analgesia they seem to reduce pain score by half, and are satisfied with a moderate VAS. This finding is supported by others (10, 11).

Instructions on how to use the PCEA pump may vary between studies and influence the drug consumption. If the parturient is instructed to demand a bolus dose to achieve complete pain relief she probably uses a higher dose than if she demands only when the contractions feel uncomfortable.

Interestingly, some of the women chose to continue using nitrous oxide even when they were satisfied with the quality of the epidural analgesia. Nitrous oxide is extensively used in labor wards, despite the well-documented weak analgesic effect on labor pain. The resulting sedation may be the purpose of use (19, 20).

An unexpected reason for not entering the study was that some women did not want to 'be in charge'

Table 3

Obstetric outcome			
	CEI ($n=40$)	PCEA ($n=40$)	
Time epidural – partus (min)[a]	357 (128–882)	296 (104–697)	$P<0.001$
Cesarean section[b]	8 20%	5 12.5%	NS
Instrumental delivery[b]	9 22.5%	6 15%	NS
Oxytocin augmentation before epidural[b]	5 12.5%	6 15%	NS
Oxytocin augmentation after epidural[b]	33 (82.5%)	33 (82.5%)	NS
Bladder catheterization during labor	21 (52.5%)	18 (45%)	NS

[a]Median (min-max).
[b]*n* and %.

of dosing the epidural. This is an interesting finding but unfortunately has not been documented in detail.

A shorter duration of labor was found in the PCEA group. Most studies do not have this difference. We found only two studies which demonstrated a significantly shorter duration of labor with PCEA than with continuous infusion (10, 14). The reason for this difference is unclear: many contributing factors determine duration of labor, such as fetal head position and maternal physiognomy for example (21).

Ropivacaine in higher concentrations and volumes than ours gives satisfactory epidural analgesia in labor without significant side-effects, except for some motor block (6, 22). Reducing the local anesthetic is possible when combined with opioid. This gives satisfying analgesic effect and lowers the incidence of motor block, as also shown by others (8).

Using dilute local anesthetic in low doses provides epidural analgesia with stable hemodynamics, a finding which is consistent with those of previous studies (8, 23).

In conclusion, we found that PCEA with ultra-low doses of ropivacaine and sufentanil reduced drug consumption and gave an individual titration of doses, with few and manageable side-effects.

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Table 4

Neonatal data			
	CEI ($n=40$)	PCEA ($n=40$)	
Weight of baby (g)[a]	3708 (565)	3757 (517)	NS
Apgar 1[a]	8.6 (0.87)	8.15 (1.89)	NS
Apgar 5[a]	9.75 (0.49)	9.48 (1.3)	NS
Apgar 10[a]	9.97 (0.16)	9.65 (1.2)	NS
Apgar 1 < 7 (No)	3	6	
Apgar 5 < 7 (No)	0	1	
Umbilical artery pH[a]	7.24 (0.094)	7.23 (0.114)	NS

[a]Mean (SD).

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