

## ORIGINAL ARTICLE

# A randomized comparison of a five-minute versus fifteen-minute lockout interval for PCEA during labor

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**Background:** The best combination of bolus size and lockout interval for patient-controlled epidural analgesia (PCEA) is not known. This study compared a 5-min with a 15-min lockout interval.

**Methods:** Parturients were randomly assigned to receive PCEA with either a 5-min or a 15-min interval. All had a 15-mL loading dose, continuous background infusion 6 mL/h of 0.125% bupivacaine plus fentanyl 2 µg/mL, PCEA bolus volume 5 mL, maximum hourly dose 26 mL. Visual analogue scores for pain, nausea and pruritus, sensory levels to ice, sacral analgesia, motor power, blood pressure and fetal heart rate were assessed pre-epidural and regularly thereafter until delivery. The numbers of boluses and attempts and patient satisfaction were recorded.

**Results:** 29 patients were assigned to the 5-min group and 31 to the 15-min group, but the 15-min group contained twice as many nulliparous women. Side-effect and complication rates did not differ between groups. VAS pain scores were reduced from a median of 79 in the 15-min group and 82 in the 5-min group to a median of zero 30 min after epidural insertion. Bolus/attempt ratio was 0.88 in the 5-min vs. 0.70 in the 15-min group. The numbers of requests for physician intervention were similar. No differences in pain scores, side-effects, drug use or patient satisfaction were demonstrated.

**Conclusion:** The 5-min lockout interval appears the more efficient and has been used safely in our practice for 15 000 parturients, although a larger study is required to confirm the relative efficacy, efficiency and safety of this regimen.

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## INTRODUCTION

Patient-controlled epidural analgesia (PCEA) during labor has become increasingly popular with patients, nurses and physicians alike. It provides advantages over continuous infusion epidural analgesia, which include patient-control, dose-sparing, immediate availability of a bolus dose, and possibly greater efficiency.<sup>1</sup> A number of studies have evaluated the effects of different dosing schedules on the effectiveness of labor analgesia using PCEA.<sup>2–10</sup> Lockout intervals between 5<sup>11</sup> and 30 min<sup>2</sup> have all been used. In theory, a shorter lockout interval might improve labor analgesia by reducing the time before a patient can self-administer another dose if needed, while improving patient satisfaction. In addition, a shorter lockout interval might reduce manpower needs associated with top-ups for inadequate labor analgesia. This study compares a PCEA bolus of 5 mL plus a 5-min lockout interval, (a more aggressive dose regimen than

previously studied), with a PCEA bolus of 5 mL plus a 15-min lockout interval, a more commonly used recipe. The hypothesis that the 5-min lockout is superior to the 15-min lockout was tested with the primary outcome variables being analgesic efficacy as assessed by visual analogue (VAS) pain scores. Secondary outcome variables included sensory levels, drug use, ratio of boluses/attempted boluses (b/a), number of physician interventions, patient satisfaction, and the incidence of side effects.

## METHODS

Following approval by the Sharp Healthcare Institutional Review Board, 65 patients gave written consent to participate in the study. American Society of Anesthesiology (ASA) class I-II, English-speaking parturients, in active labor with an uncomplicated singleton pregnancy, were recruited early during labor and before they requested epidural analgesia. Exclusion criteria included presence of medical or obstetric complications, contraindications to epidural analgesia and allergy to local anesthetic or fentanyl. Each parturient received 500-1000 mL of intravenous crystalloid solution before epidural catheter insertion at the L 2/3 or L3/4 interspace. All patients received a 15-mL epidural loading dose and a 6-mL/h background infusion of 0.125% bupivacaine plus fentanyl 100 µg and had access to 5-mL bolus doses by PCEA of the same solution. Patients were assigned to one of two PCEA groups using a computerized randomization schedule: in the "15-min group" the lockout interval was 15 min, while in the "5-min group" it was 5 min. The maximum allowable hourly dose was 26 mL (32.5 mg of bupivacaine and 52 µg of fentanyl) for both groups. A study nurse not involved in the care of the patient used a computer-generated randomization sheet to program the PCA pump. This study nurse was the only person not blinded to group assignment and pump settings. All patients were instructed to use the demand button when pain returned and to expect some relief within 10 min. Patients were encouraged to have the anesthesiologist called if they felt that analgesia was inadequate. The data collectors were not involved in the clinical management of the patient. The following data were collected before, 30 and 60 min after epidural insertion and hourly thereafter until delivery: VAS scores using a 100-mm scale for pain, nausea and pruritus, sensory levels to ice, sacral analgesia as assessed by sensation to ice at the S2 dermatome bilaterally (popliteal fossa) and motor power as measured on a 1-4 scale modified from Bromage:<sup>12</sup> (1: unable to move legs or feet, 2: able to move feet, 3: able to flex knees, 4: able to flex hips). Bilateral sensory levels were tested by moving an ice cube across the patient's skin, starting in blocked segments and pro-

ceeding cephalad towards unblocked segments. The heart rate, systolic and mean arterial pressure, need for treatment of hypotension (<100 mmHg systolic or <20% of baseline), fetal heart rate and the number of PCEA boluses and attempts were also recorded. The ratio of self-administered boluses to attempts (b/a) was calculated and the number of requests per patient for unscheduled visits by the anesthesiologist was recorded.

Other data included total and hourly PCEA volumes used, mode of delivery and neonatal outcome including Apgar scores and birth weight. Within one hour of delivery, patients were asked to rate their satisfaction with the analgesic regimen on a four-point scale (1: poor, 2: satisfactory, 3: good, 4: excellent) for the periods before epidural insertion (i.v. analgesia) and for three periods after epidural catheter insertion: the first and second stages of labor, and delivery.

For the purpose of this study, the first stage of labor was defined as the time between epidural insertion until full cervical dilatation. The second stage was defined as the time between full cervical dilatation and delivery.

## Statistical analysis

Power analysis was carried out using PASS statistical software (Number Cruncher Statistical System, NCSS). The primary outcome variable for sample size determination was VAS pain score. The sample size was computed using information from previous studies and an assessment of clinical relevance. In order to detect a 20% difference in mean VAS scores, assuming a standard deviation of 25% of the magnitude of the mean (that is, a moderate effect size of 0.25), and to achieve 80% power and 5% level of significance, 30 subjects per group were required. Normally distributed data were expressed as means  $\pm$  standard deviation; other data were expressed as medians and interquartile ranges. PCEA data-use patterns and VAS for pain were analyzed both as a function of time after epidural insertion as well as time before delivery. This approach served to synchronize the dataset, so that for a given event of interest (either administration of the loading dose or delivery) at any given time-point, women were at the same stage relative to the event of interest. Baseline and 30-min data were excluded when pain data were expressed as time before delivery in order to exclude the effect of baseline pain and the initial loading dose on the pain curve. Data pertaining to the side effect profile (nausea, pruritus, hypotension, need for ephedrine, motor scores) were analyzed as a function of time after epidural insertion/administration of the loading dose with the rationale that the loading dose represented the largest single dose of drug and thus was more likely to cause side effects than use of the PCEA itself.

Differences within groups over time were analyzed with the Kruskal Wallis test. Differences between groups were analyzed using the Mann Whitney U test and  $\chi^2$  analysis. To test for consistency over time of a difference in the upper quartile pain scores, the sign test was used. Statistical significance was assumed at a *P* value of <0.05.

## RESULTS

A total of 65 patients were recruited into the study, but data from five patients, two from the 15-min and three from the 5-min group, were excluded from the analysis because the PCEA button was not used before delivery (*n*=3), protocol violation (*n*=1) or failure of the initial epidural catheter with subsequent epidural replacement (*n*=1).

Of the 60 patients completing the study, 31 were assigned to the 15-min group and 29 to the 5-min group. Patient characteristics were similar in the two groups with the exception of parity (Table 1). Despite random allocation, the 15-min group contained twice as many nulliparous women as the 5-min group. Labor outcomes (Table 1), including the rate of spontaneous and operative deliveries, Apgar scores and birth weight were similar in the two groups.

The median VAS pain scores at baseline (Fig. 1a) were similar (79 vs. 82) although the 15-min group contained twice as many nulliparous women. Thirty minutes after epidural insertion, median pain scores were similarly low (0 vs. 0) indicating effective pain relief from the epidural loading dose. When VAS is expressed as a function of hours before delivery (Fig. 1b), pain scores

reflect the clinical experience of increasing pain towards delivery. The 75<sup>th</sup> percentile VAS pain score in the 15-min group were consistently higher than in the 5-min group (*P* < 0.05, sign test). Patients in both groups were equally satisfied with their analgesic management, which was rated mostly as excellent, even before epidural insertion when the only analgesic modality was intravenous opioids and despite high VAS scores during this stage.

PCEA pump use patterns were similar in the two groups (Table 2). The proportion of parturients using the PCEA demand button at each hourly interval ranged from 32 to 71%, with the average number of attempts per patient being 1-2 per hour. PCEA volume, the total number of boluses and the total number of attempts per patient were similar in the two groups (Table 2). The bolus/attempt ratio (b/a), an index of efficiency, was significantly greater in the 5-min group, ( $0.88 \pm 0.18$  vs  $0.70 \pm 0.26$ ; *P* < 0.005,  $\chi^2$  analysis). The proportion of women with b/a = 1, representing perfectly efficient use of the PCEA demand button, was twice as high in the 5-min group (65%) than in the 15-min group (32%) (*P* < 0.005,  $\chi^2$  analysis). Hence, since the number of attempts per patient using the PCEA button is similar in the two groups, and since an attempt more frequently resulted in administration of a bolus in the 5-min group, patients in this group were able to self-administer 10-20% more bupivacaine and fentanyl per hour than patients in the 15-min group (Table 2). However, the proportion of women who requested an extra visit by the anesthesiologist, and the number of requests for extra visits made by each patient did not differ significantly with the nine women in the 15-min group (29%) and five women in the 5-min group (17%) requiring supplemental analgesia.

Sacral anesthesia was present 30 min after epidural insertion in 52% of the 15-min group and 66% of the 5-min group. When expressed as a function of time before delivery, 94% of the 15-min group and 97% of the 5-min group had sacral anesthesia in the hour before delivery. Of those women who had not delivered 4 hours after epidural insertion (*n*=35) all had sacral anesthesia until delivery. Groups were similar regardless of the analytical approach used (time from epidural insertion vs. time before delivery). The median sensory levels were T6-7 as patients approached delivery. The highest overall sensory level achieved was T1 in one woman in the 15-min group just before delivery.

There was no difference between groups in sensory levels (Fig. 2) and side effects, namely nausea, pruritus and hypotension (Table 3). There were two patients in each group with a fall in systolic pressure to <100 mmHg. The lowest systolic pressure recorded was 95 mmHg. All episodes were responsive to fluid bolus.

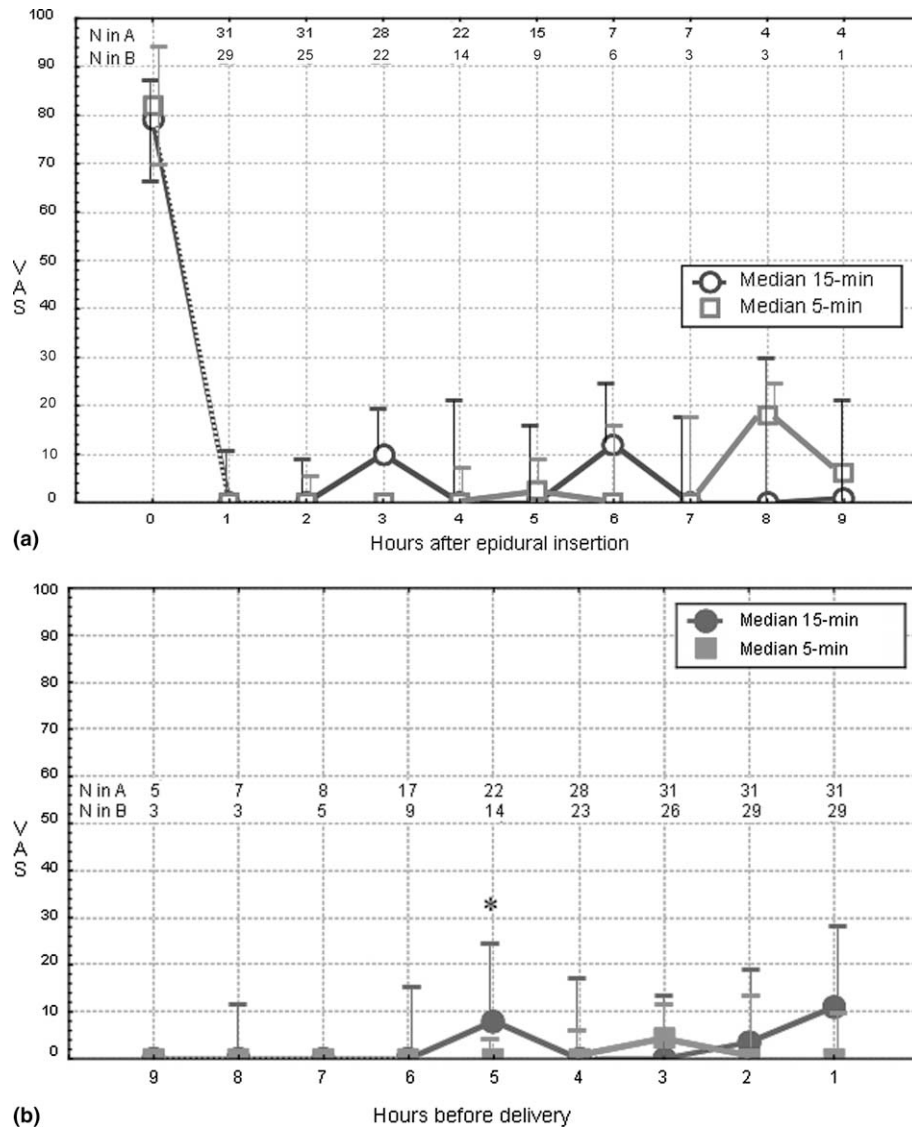
**Table 1. Patient characteristics and labor outcome**

	15-min lockout interval	5-min lockout interval
N	31	29
Age (years)	31 ± 5.6	29 ± 5.8
Height (cm)	164 ± 5	162 ± 8
Weight (kg)	80 ± 14	80 ± 12
Weight gain (kg)	15 ± 5	16 ± 5
Nulliparous	68.0%	34.0%*
Oxytocin	55%	48%
1 <sup>st</sup> stage duration (min)	235 ± 126	210 ± 144
2 <sup>nd</sup> stage duration (min)	80 ± 54	55 ± 43
Spontaneous vaginal delivery	58%	76%
Forceps or vacuum	16%	14%
Cesarean section	26%	10 %
Episiotomy	32%	21 %
Apgar scores	9	9
Birth weight (g)	3481 ± 567	3682 ± 448

Patient characteristics and labor outcome are mean ± SD or percentages per group.

Apgar scores are medians. Differences between groups are not statistically significant, except for parity.

\*(*P* < 0.05).



**Fig. 1** Visual analogue (VAS) pain scores in the 15-min and the 5-min lockout groups. Data are medians and interquartile ranges. (a) Pain expressed as a function of time (h) after epidural catheter insertion. (b) The same data expressed as a function of time (h) before delivery. With the exception of one time point (\* $P < 0.05$ ), no difference exists between groups at individual time points (Mann Whitney U test). N in A = Number of patients in the 15-min group left in the analysis at that time point. N in B = Number of patients in the 5-min group left in the analysis at that time point.

None was associated with fetal heart rate abnormalities and no maternal bradycardia occurred.

Motor power scores ranged from 1-4 with a median of 4 in both groups at all stages of labor.

**DISCUSSION**

The findings demonstrate that a 5-min lockout interval offers similar labor analgesia to a 15-min lockout interval. No differences in pain scores, physician interventions, side effects, drug use, or patient satisfaction were demonstrated in this pilot study.

When trying to detect differences in analgesic quality of PCEA as opposed to the loading dose, it seems justified to exclude patients from the analysis who did not use the PCEA button at all and likewise exclude the 30-min data of all patients. We used a large loading dose (15 mL), which resulted in three patients becoming comfortable for the duration of their short labor and thus not using the PCEA button and being excluded from the analysis. This is similar to previous results.<sup>13,14</sup>

The purpose of expressing the data as a function of time before delivery was to synchronize the dataset to an event of interest (delivery) so that at any given time point a greater proportion of the study population would be at the same stage of labor. Since labor pain is a

**Table 2. PCEA use patterns as a function of time before delivery**

Group	N		Users		Attempts		Bolus		Drug volume	
	A	B	A	B	A	B	A	B	A	B
7 hours	8	5	5 (63)	1 (20)	13	2	7	1	13	11
6 hours	17	9	9 (53)	5 (56)	25	15	15	9	14	15
5 hours	22	14	13 (59)	5 (36)	27	12	16	12	12	18
4 hours	28	23	18 (64)	10 (44)	58	20	28	19	14	16
3 hours	31	26	22 (71)	17 (65)	62	38	33	32	11	15
2 hours	31	29	20 (65)	21 (72)	58	43	27	37	13	15
1 hour	31	29	10 (32)	12 (41)	27	40	15	26	14	17

A = 15-min lockout group; B = 5-min lockout group; N = Total number of women in the study during that hour; Users = number (%) of women per group using PCEA demand button; Attempts = total number of attempts by all patients using the PCEA demand button during that hour; Boluses = total number of boluses delivered to all patients using the PCEA demand button during that hour; Drug volume = average hourly volume of 0.125% bupivacaine plus fentanyl 2 µg/mL administered epidurally per patient using the PCEA button. Physician-activated boluses are not included.

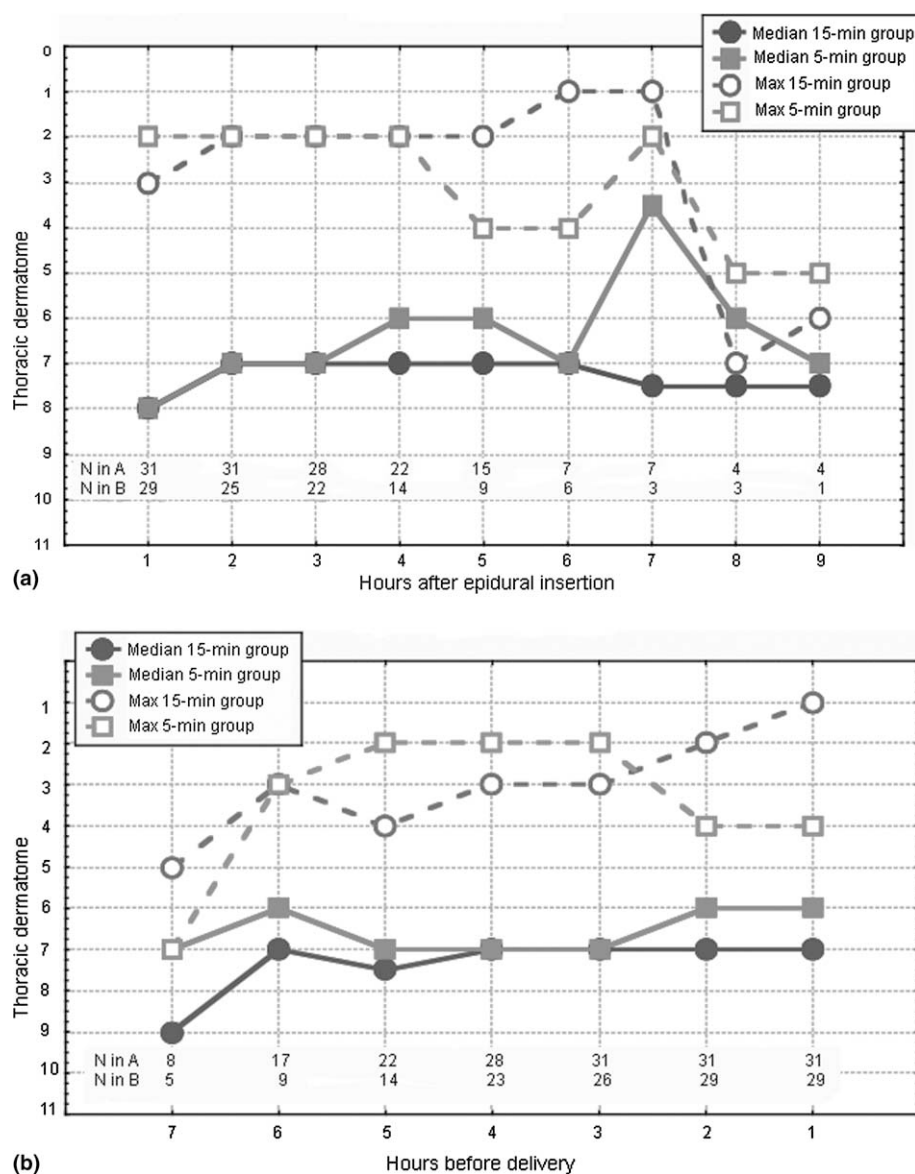
function of the stage of labor,<sup>15</sup> and since PCEA use should be a function of labor pain, the analysis of data in this manner seems justified, although no previous study had used this approach. The VAS pain curves obtained this way (Fig. 1b) show increasing pain scores as patients approach delivery in both groups. This is in accordance with the clinical experience of many obstetric anesthesiologists as well as with previous studies.<sup>16</sup> When a conventional analysis (hours after epidural insertion) is used, the VAS curves are consistent with those of previous investigations<sup>8,17,18</sup> but could not show the same increase of pain as patients approach delivery, since women are at different stages of labor relative to insertion of the epidural catheter. The effectiveness of the loading dose can be assessed this way but not the effectiveness of the PCEA. As with the pain data, analysis of sensory levels in this manner seems to offer the distinct advantage of synchronization of the dataset to the event of interest. This way thoracic dermatome levels parallel pain scores and the PCEA use pattern. We therefore suggest that future studies assessing effectiveness of PCEA analyze VAS pain scores and sensory levels as a function of time before delivery.

The 75<sup>th</sup> percentile of the VAS pain scores was consistently higher in the 15-min group than the 5-min group when analyzed as a function of time before delivery. The clinical significance of this is probably low for two reasons: First, the difference of pain scores observed here is probably negligible, given that either score (for example 7 vs. 3) represents a vast improvement from the baseline scores of approximately 75. Second, the median VAS scores remain close to zero in both groups, which may not be desirable and may even be counterproductive. Plummer and coworkers<sup>19</sup> studied almost 7000 patients prospectively over a 5-year period and found that after repeated intermittent epidural boluses the median pain score resulting in satisfactory analgesia was 10 (on a 100 mm scale) and that the most common cause for dislike of epidural analgesia was not severe pain at delivery but numbness. That is not to say that

all women with a pain score of zero in our study had numbness or were dissatisfied. The fact that the VAS pain scores in this study seem to be unrelated to satisfaction ratings may be due to factors unrelated to the pain scores entering the patient's satisfaction ratings.

The availability of four 5-mL doses in 15 min on a 5-min lockout raises concern about increased side effects and complications such as high sensory block and hemodynamic instability. In case of an unexpected intrathecal catheter location, such a dose regimen (roughly 27 mg of bupivacaine over 15 min) could result in total spinal anesthesia. However, we showed that the 5-min group had a similar side effect profile to the 15-min group. Sensory levels of T2, as seen in both groups during the present study, can be associated with hemodynamic instability. However, the lowest recorded systolic pressure was 95 mmHg. A possible explanation may lie in the way that sensory levels were determined. The endpoint was cold sensation when an ice cube was moved across the skin starting from blocked segments proceeding cephalad to unblocked segments. Cold perception is highly sensitive to the rate of change of temperature.<sup>20</sup> A rapid change results in lag time of the perception of change in temperature. Thus, there is a possibility of overestimating the level of sensory blockade when moving the ice cube across the skin too quickly. Since this speed was not standardized across the five authors performing the assessment of sensory levels, it is possible that some of the high sensory levels observed are due to this phenomenon. Conversely, the study design may have allowed for underestimation of sensory levels because at the time of assessment, sensory levels may already have receded from a higher level in between observations. Either way, the highest sensory level was found in the 15-min lockout group and not in the 5-min group.

The incidence of hemodynamic instability (7%) in the present study accords with the available literature (2-15%).<sup>10,21-24</sup> Three of the four episodes of hypotension occurred after the initial epidural loading dose or



**Fig. 2** Median and maximal sensory levels in the 15-min and 5-min lockout groups. (a) Sensory levels expressed as a function of time (h) after epidural catheter insertion. (b) The same data expressed as a function of time (h) before delivery. Sensory levels are similar in the two groups (Mann Whitney U test). N in A = Number of patients in the 15-min group left in the analysis at that time point. N in B = Number of patients in the 5-min group left in the analysis at that time point.

**Table 3.** Side effects

	N		Nausea		Pruritus		Hypotension		Ephedrine	
	A	B	A	B	A	B	A	B	A	B
Group A: 15 min:										
Group B: 5 min										
Pre epidural	31	29	7	20	3	3	0	0	0	0
Post epidural 30 min	31	29	1	3	22	21	6	7	3	3
Post epidural 1 hour	31	29	1	2	23	25	0	0	0	0
Post epidural 2 hours	31	25	2	13	19	20	0	0	0	0
Post epidural 3 hours	28	22	1	7	19	16	0	0	0	0
Post epidural 4 hours	22	14	6	7	14	11	0	0	0	0
Post epidural 5 hours	15	9	5	5	6	5	0	0	0	0
Post epidural 6 hours	7	6	9	20	5	6	0	0	0	0

after subsequent 10-mL bolus doses by the anesthesiologist, suggesting that clinician boluses may have a greater potential to cause side effects than patient-delivered boluses. This is supported by findings of other authors.<sup>10</sup> In a study by Owen and coworkers,<sup>9</sup> in which the incidence of treatment of hypotension was 28%, the PCEA settings were identical to ours except for their use of a 10-min lockout. Unfortunately, their report did not state when the hypotensive episodes occurred, or what the treatment threshold was, so comparison of data is difficult. In the present study no parturient required pharmacologic treatment of hypotension as defined by either patient symptoms or fetal compromise.

Also the concern about increased motor block was not borne out in this study. Motor function remained good in both groups and the proportion of operative vaginal deliveries in the present study is similar to that reported in previous investigations.<sup>8-11,17,18,24</sup> In this study nausea scores paralleled pain scores, with highest scores occurring before epidural insertion and increasing towards delivery. Nausea scores were lowest 30-60 min after epidural insertion in both groups, just when epidural opioids have their maximum effect. This supports the findings of a previous study,<sup>25</sup> which suggested a stronger association between nausea and pain than between nausea and epidural opioid use. In contrast, pruritus scores peaked 30 min after epidural insertion and declined towards baseline thereafter. This agrees with previous findings of pruritus in patients receiving epidural opioids.<sup>10</sup>

PCEA use in general is considered quite safe. Paech did not report any serious adverse events in over 11 000 women whose management included PCEA.<sup>26</sup> In our practice a 5-min lockout has been used for the last five years and we have now managed more than 15 000 patients this way. No serious adverse effects have occurred and a 5-min lockout has become our routine. In the present study the 5-min lockout was not associated with more side effects. Comments about safety, however, cannot be made because of the small number of patients per group, which rapidly declined as patients started to deliver as early as one to two hours after epidural insertion. Immediately after epidural insertion, when the number of patients remaining in the study would have been sufficient to make a meaningful comparison of side effect profiles, the effect of the loading dose predominated, so that commenting on the safety of the PCEA regimen was not possible. Therefore, the theoretical safety concern remains until data from larger trials substantiate the safety of this regimen.

In this present study, the only difference between the two groups was a secondary endpoint of efficiency, the b/a ratio. The b/a ratios in the present study of 0.70 in the 15-min group and 0.88 in the 5-min group are greater than in previous studies where b/a ratios of 0.40-0.68

were observed.<sup>2,9,10</sup> A possible explanation for the high index of efficiency in both groups may be the effectiveness of the instruction not to "double-hit" the pump button. As physician workload increases in labor and delivery units, efficiency of drug delivery becomes increasingly important.<sup>27</sup> More efficient PCEA settings may make the difference between a parturient being able to make herself comfortable or being unsuccessful in catching up with painful episodes and ultimately dissatisfied with the labor analgesia provided. Although lacking statistical significance, there was a trend towards fewer demands per patient for an unscheduled visit by the anesthesiologist in the 5-min group (17% vs. 29% in the 15-min group). This intervention rate compares favorably with 35-54%, found by others.<sup>9,10</sup> The number of patients required in each group to achieve statistical significance with a one-tailed design for the number of requests for physician intervention per patient at 80% power and a 5%  $\alpha$  error would be 151 if the trend prevailed. Prior studies evaluating physician intervention rates as a function of the lockout<sup>2-10</sup> have had a similar sample size as the current investigation. It is therefore not surprising that no effect of lockout on efficiency has been demonstrated.

After pressing the PCA button it takes 2.5 to 3.5 min to deliver a bolus, depending on the pump used. In the present study, a Baxter pump was used, which delivers a 5-mL bolus over 3.5 min. The time of onset of epidural analgesia with this technique is not known. McMorland and coworkers<sup>16</sup> showed that the time to onset of epidural analgesia of 8 mL of 0.25% bupivacaine, as defined by the first painless contraction, is  $6.0 \pm 0.53$  min using a solution that was not pH-adjusted and  $3.2 \pm 0.24$  min in a pH-adjusted solution. The times to peak effect in that study were  $16.5 \pm 1.15$  and  $14.2 \pm 1.1$  min respectively. In a study by Cohen and coworkers,<sup>28</sup> a bupivacaine/fentanyl mixture had an onset time of 5 min. Patients participating in the present study were told to expect some relief within 10 min, which seems reasonable considering the above data and the fact that "some relief" is a different expectation from "painless contraction." Although in our experience some analgesia is usually observed within five minutes, we felt that instructing the patients to expect this could have introduced a bias towards more frequent use and thus greater efficacy, but also more side effects, of a 5-min lockout. Different instructions to patients may have the potential to change the characteristics of the analgesic regimen substantially.

The limitations of this study include: (a) its small sample size, which did not allow us either to assess safety or to confirm our clinical impression of greater efficiency and possibly better pain control, (b) the unequal parity between groups, which could have been avoided by stratified randomization, (c) the non-standardized assessment

of sensory levels and (d) progressive loss of statistical power as patients drop out of the analysis due to delivery. The latter shortcoming was, however, overcome by analyzing certain data in relation to time before delivery.

In conclusion, no differences in pain scores, physician interventions, side effects, bupivacaine and fentanyl consumption, or patient satisfaction were demonstrated in this small study comparing a lockout of 5 min with a lockout of 15 min. Although we believe either interval can be used in obstetrics, the 5-min lockout might be more efficient and has been used routinely in our practice for the past five years. A larger study would be required to confirm the efficacy, efficiency and safety of this regimen.

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