Motor blockade is reduced with ropivacaine 0.125% for parturient-controlled epidural analgesia during labour

Alex Tiong-Heng Sia MMED,
Poopalalingam Ruban MMED,
Jin Long Chong MMED,
Kahoe Wong MMED

Purpose: To compare the effect on the incidence of motor block by reducing the concentration of ropivacaine from 0.2% to 0.125% in parturient-controlled epidural analgesia (PCEA) for labour.

Methods: Randomized, controlled and double- blind trial involving parturients in early labour who received demand-only PCEA regimen (bolus 5 ml, lockout 10 min, maximum volume per hour of 20 ml) with either 0.2% (R0.2 group, $n=25$) or 0.125% (R0.125 group, $n=25$) ropivacaine. Pain scores, the degree of motor block, the rate of drug consumption, the proportion of good to total PCEA demands and the overall satisfaction scores were documented.

Results: Fewer parturients in the R0.125 group had lower limb motor block (4 *vs* 11, $P < 0.05$) although the degree of block was mild in all the affected parturients. The ratio of good to total PCEA demands was more favourable in the R0.2% group (median 0.72 *vs* 0.52, $P < 0.01$) although the hourly rate of ropivacaine consumption, the degree of pain relief, the maternal-fetal outcome and the overall satisfaction scores were similar.

Conclusion: Both ropivacaine 0.2% and 0.125% provided comparably effective analgesia but motor block occurred more commonly in the 0.2% group.

Objectif : Comparer l'effet, sur l'incidence du blocage moteur, de la réduction de la concentration de ropivacaïne de 0,2 % à 0,125 % pendant l'analgésie épidurale contrôlée par la patiente (AECP) en travail obstétrical.

Méthode : On a procédé à un essai randomisé, contrôlé et à double inconnu auprès de parturientes, au début de leur travail, qui ont reçu un régime d'AECP sur demande seulement (un bolus de 5 ml, une période réfractaire de 10 min, un volume maximal de 20 ml à l'heure) avec, soit de la ropivacaïne à 0,2 % (groupe R0.2, $n = 25$), soit à 0,125 % (groupe R0.125, $n = 25$). On a documenté : les scores de douleur, l'intensité du blocage moteur, la fréquence de la prise de médicament, la proportion de demandes efficaces sur les demandes totales d'AECP et l'indice de satisfaction globale.

Résultats : Peu de patientes du groupe R0.125 ont eu un blocage moteur des membres inférieurs (4 *vs* 11, $P < 0,05$) bien que le blocage n'ait pas été important chez les parturientes touchées. La proportion de demandes efficaces sur les demandes totales d'AECP a été meilleure dans le groupe R0.2 % (médiane de 0,72 *vs* 0,52, $P < 0,01$), mais la fréquence horaire de consommation de ropivacaïne, le degré de soulagement de la douleur, l'évolution fœto-maternelle et la satisfaction globale ont été similaires.

Conclusion : La ropivacaïne 0,2 % et 0,125 % produisent des effets analgésiques comparables, mais le blocage moteur survient plus souvent avec une concentration de 0,2 %.

From the Department of Anaesthesia, KK Women's and Children's Hospital, 100 Bukit Timah Road, Singapore 229 899, Singapore.
Address correspondence to: Dr. Alex TH Sia. Fax: 65-2912661; E-mail: athsia@kkh.com.sg
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ROPIVACAINE, because of its reduced cardiotoxicity and its motor sparing effect in comparison with bupivacaine, holds promise for obstetric analgesia. However, the expected advantage of reduced lower limb weakness was not evident in earlier studies which had compared ropivacaine 0.25% with bupivacaine 0.25% for epidural analgesia administered by intermittent top-ups or continuous infusion.[1,2]

A recent study found that, for ropivacaine 0.2%, demand-only parturient controlled epidural analgesia (PCEA) was associated with a lower incidence of lower limb motor block (30% *vs* 70%) compared with a continuous infusion of 8 ml·hr^{-1}.[3] There are so far no published reports with regard to the effect of different concentrations of ropivacaine on lower limb motor block with respect to PCEA for labour and delivery.

In the current study, we investigated the impact of a lower concentration of ropivacaine, 0.125%, on the incidence lower limb motor block compared with ropivacaine 0.2% using a parturient-controlled epidural technique.

Methods

With the approval of the Hospital Clinical Research Ethics Committee, this randomized, controlled study was conducted on 50 parturients upon written, informed consent for participation in the study. All the parturients were nulliparous, of ASA physical status I and in established labour of at least one painful contraction every five minutes. Parturients who had any of the following criteria were excluded: cervical dilatation > 5 cm, bodyweight >100kg, age >40 yr and the presence of obstetric complications (e.g. non-vertex presentation, previous Cesarean delivery, prematurity and non-singleton pregnancy).

A total of 0.5 L Ringer's lactate solution *iv* was given to every parturient. A baseline pain score was obtained prior to epidural analgesia on a 0-100 visual analog scale (VAS), with 0=no pain and 100=worst pain imaginable. A preblock systolic blood pressure (measured non-invasively on the left arm) was also obtained.

An epidural catheter was then inserted in the left lateral position at the L_{2-3} or L_{3-4} level. The epidural space was accessed with a 17G Weiss needle by employing the "loss of resistance to air" technique (PERISAFE, BECTON DICKINSON set). A total of 3 cm of the catheter was left in the epidural space. Five minutes after a negative aspiration test for blood and a "test dose" of 3.5 ml lidocaine 1.5%, 8 ml ropivacaine 0.2% (NAROPIN, ASTRA) in 4 ml aliquots were administered. The parturients were then placed in the left lateral tilt position.

For the first 30 min after this, the following assessments were made: systolic blood pressure (every five minutes), pain scores (every 15 min) and the highest sensory block to cold (using ice, every 15 min). Only parturients who had an adequate block (defined as VAS ≤ 30 and a bilateral block to cold at T_{10} level or higher but not more cephalad than T_4) at 30 min were included in the study.

The parturients were then randomly assigned by sealed envelopes to receive PCEA either with ropivacaine 0.125% (R0.125 group) or 0.2% (R0.2 group). For both groups, the following PCEA regimen was used: demand bolus 5 ml, no background infusion, lockout interval 10 min and maximum hourly dose of 20 ml (delivered by GRASEBY 9300 PCA PUMP). All parturients were instructed to activate the pump by pressing the button once when mild contraction pain was felt. They were also reassured about the safety of activating the pump as often as necessary, but they were told that only one dose would be given in 13 min (the pump would take about three minutes to administer each bolus before the 10 min lock-out period) and further attempts at activating the pump during this lock-out period would be ineffective.

All fetal cardiotocograms were confirmed to be reactive prior to analgesia and continuous fetal heart monitoring was instituted on every parturient.

The parturients in both groups were monitored two-hourly by an investigator (not involved with the preparation of the ropivacaine solution, hence "blinded") on the following:

1. pain score at rest,
2. systolic blood pressure and if it decreased > 20% of preblock value, 6 mg ephedrine boluses *iv* would be given,
3. level of sensory block. If the block was higher than T_4, the parturient would be excluded to investigate for the possibility of subarachnoid /subdural catheter placement,
4. degree of motor block (using modified Bromage scale, i.e.: 0=no motor impairment of both lower limbs, 1=unable to raise either extended leg, able to move knee and feet, 2=unable to raise extended leg or flex knee but able to move feet, 3= not able to move feet or knee),
5. the total volume and mass of the local anesthetic used,
6. the proportion of successful attempts at activating the PCEA pump during the first stage of labour.

Epidural analgesia was continued through the second stage of labour. Physician top-ups of up to 10 ml ropivacaine 0.2% per hour would be available at any

time if VAS was > 30. An additional 5 ml ropivacaine 0.2% plus 50 μg fentanyl would be given during the second stage if necessary. Data on side effects (hypotension, nausea, vomiting and shivering), obstetric outcome (mode of delivery and duration of second stage) and neonatal characteristics (Apgar scores and birth weight) were also collected. The overall satisfaction score with regard to analgesia was obtained based on the 0-100 visual analog scale (0=very satisfied, 100=extremely dissatisfied) one hour after delivery.

The unpaired student's t test was used in the intergroup comparison of parametric data such as age, weight, height and blood pressure. The Mann U Whitney test was used for comparison of pain scores, amount of local anesthetic used, the highest sensory block achieved and satisfaction scores. Fisher's exact test was used for comparison of proportions. The sample size was determined to detect a 30% reduction in the occurrence of motor block in the R 0.125 group compared with R 0.2 group, with the power of 0.8 and α value of <0.05.

Results

The demographic profile, cervical dilatation and the use of oxytocin before epidural analgesia were similar in both groups of parturients. (Table I)

Both groups also had similar baseline preblock VAS as well as during the first stage of labour at two, four and six hours after the initiation of epidural analgesia. There was no difference in the mass of ropivacaine used per hour between the two groups and, as a corollary, the total volume of the local anesthetic used per hour was lower in the R0.2 group ($P < 0.01$). However, the proportion of successful demands (as a percentage of the total number of demands) for analgesia during the first stage of labour was higher in the R0.2 group ($P < 0.01$). Despite that, the overall satisfaction score was the same in the R0.125 group as in the R0.2 group. (Table II) Three parturients in each group had required at least one extra physician administered bolus during the first stage of labour. Five parturients in R0.125 group and three in the R0.2 group had pain during the second stage of labour ($P > 0.05$).

There was no difference between the two groups in terms of duration of labour after epidural analgesia, the duration of second stage of labour, the mode of delivery or the neonatal outcome. (Table III)

The R0.2 group had a higher proportion of parturients with lower limb motor block, albeit mild (i.e., Bromage score =1), $P < 0.05$. There was no correlation between motor block and duration of labour in both groups. There was no difference in the other side effects. (Table IV)

Discussion

Our results showed that a reduction of concentration of ropivacaine from 0.2% to 0.125% decreased the

TABLE I Parturient demographic profile in mean ± sd), cervical dilatation in median (range) and proportion with oxytocin used before epidural analgesia

	R0.125 group (n=25)	*R0.2 group (n=25)*
Age (years)	27.1 ±5.6	26.9 ±4.9
Weight (kg)	66.0 ±7.9	66.6 ±8.8
Height (cm)	157.2 ±4.8	156.8 ±5.3
Cervical dilatation (cm)	3 (2-5)	3 (2-5)
Use of oxytocin	6/25	8/25

No differences were detected between the two groups

TABLE II Characteristics of epidural analgesia

	R0.125 group	*R0.2 group*
Pain 0-100 VAS, hours (hr) after epidural analgesia		
0 hr (preblock VAS, *n*=25 in both groups)	74 (46 – 100)	80 (35-100)
2h hr (*n*=20 in R0.125 group, *n*=21 in R0.2 group)	0 (0-20)	5 (0-60)
4 hr (*n*=17 in R0.125 group, *n*=16 in R0.2 group)	13.5 (0-62)	8 (0-32)
6 hr (*n*=8 in R0.125 group, *n*= 10 in R0.2 group)	14 (0-42)	14 (0-40)
8 hr (*n*=3 in R0.125 group, *n*=4 in R0.2 group)	5 (0-38)	8.5 (0-20)
Total mass of ropivacaine used ($mg \cdot hr^{-1}$)	8.9 (4.5-17.25)	9.0 (5-19.7)
Total volume of ropivacaine used ($ml \cdot hr^{-1}$)	7.1(3.6-13.8)	4.8 (2.5-9.8)*
Highest thoracic dermatomal block	T_8 (T_{6-8})	T_7 (T_{5-9})
Proportion of successful/total demands (%)	51 (34-76)	72 (40-100)*
0-100 Satisfaction Score	90 (71 – 100)	100 (52 – 100)

All values are expressed as median (range)

The progressively smaller *n* over time (for pain VAS) was due delivery. None of the parturients were excluded because of complications.

*Significant difference between the two groups ($P < 0.01$)

TABLE III Obstetric and neonatal outcome

	R0.125 group	*R0.2 group*
Duration of labor after epidural analgesia (hr)	5.9 ±2.7	6.4 ±2.6
Duration of second stage of labor (min)	83.7 ±47	99.5 ±55
Mode of delivery		
Normal	13	10
Instrumental (forceps/vacuum)	5	13
Abdominal (Cesarean section)	4	2
Neonatal birth weight (kg)	3.40 (0.33)	3.17 (0.34)
Apgar score > 7		
1 min	23/25	22/25
5 min	25/25	25/25

All values (except *n* for mode of delivery and Apgar scores>7) are expressed as mean ± sd.

No significant differences were found between the two groups.

TABLE IV Incidence of side effects

	R0.125 group	*R0.2 group*
Motor block		
Bromage score 1	4/25	11/25*
(None of the parturients had Bromage score>1)		
Hypotension	2/25	3/25
Shivering	5/25	7/25
Nausea	0/25	1/25

The numbers indicate the proportion of parturients with side effects.

* Significant difference between the two groups ($P < 0.05$).

incidence of lower limb motor block despite a similar total mass of ropivacaine consumption per hour in both groups. The importance of concentration as a determinant of motor block rendered by local anesthetic agents administered epidurally is supported by an earlier animal study. In that study, based on the analyses of somatosensory evoked potentials and the withdrawal reflex, there was a greater likelihood of higher concentrations of a constant mass of bupivacaine in causing paresis due primarily to the effect of greater penetrability on the spinal cord. Hence, with a higher concentration of bupivacaine, there was more pronounced attenuation of neural transmission at the interneurons in the dorsal horn gray area as well as the corticospinal tract.[4]

In our current study, we used the modified Bromage score for the assessment of motor impairment after epidural block. This inherently takes into account the integrated effect of intensity as well as the extent of spread of the volume of the local anesthetic on the major groups of muscles in the lower limbs, which are innnervated by lumbo- sacral nerve roots. Our results suggested that the group which utilized a higher concentration, but lower volume, had a higher incidence of lower limb motor block. Therefore, we could infer that with the same total dose of ropivacaine used at low concentrations, the concentration and not the volume of the local anaesthetic is the determinant with regard to motor block with the current PCEA regimen.

In our approach of continual fixed volume demand-only PCEA over time, the total volumes used in both groups, despite the difference in their concentrations, would have been dictated by the predominant need of fulfilling analgesia. For this reason, the "spread" of the local anesthetic agent was, to a large extent, controlled by the necessity of clinically achieving at least a $T_{10\text{-}12}$ thoracic dermatomal block for the first stage of labour. As all the epidural catheters were placed in the midlumbar region, a critical volume as well as mass of a local anesthetic agent would be necessary to achieve this objective. Indeed, our study showed that the degree of dermatomal block was indistinguishable between the two groups. Hence, for our current demand-only PCEA regimen, one could infer that the higher volume used in the 0.125% group had not caused the solution to spread extensively in the cephalad direction and away from the crucial lumbosacral region (which determined lower limb motor block) as much as providing the optimal mass of ropivacaine required for analgesia. Our finding is supported by a recent study on PCEA for postoperative patients which also arrived at the conclusion that lesser concentrations of ropivacaine (in this instance, in combination with fentanyl) produced a lower incidence of lower limb motor block despite the equivalent eventual mass consumed.[5]

However, this conclusion appears to be in sharp contrast with the findings of another study which demonstrated that for the same dose of bupivacaine administered epidurally, a lower concentration but higher volume resulted in a higher degree of motor block.[6] The authors in that study showed with a single bolus of 20 mg bupivacaine, a higher incidence of motor block was achieved by a 10 ml 0.2% (or 20 ml 0.1%) solution than with 4 ml 0.5% solution. The latter solution was also found to be ineffective for analgesia. This could have been due to inadequate spread of the 4 ml solution to effect a lower thoracic sensory block ($T_{10\text{-}12}$) necessary for analgesia during the first stage of labour. Although no other concentration-volume permutations were included, one could not rule out the existence of a "critical" volume within the range of 4 ml to 10 ml (e.g. 5 ml of 0.4% or 8 ml of 0.25%) that could have resulted in motor block at least

as severe as that rendered by the 10 ml 0.2% (or 20 ml 0.1% solution), while providing a comparable degree of analgesia. Thus, for a finite epidural dose of local anesthetic, the suggestion of a positive relationship of an increased volume on the incidence of motor block must be carefully re-examined.

In our current study, we used a demand-only PCEA regimen to allow the maximum freedom for self administration and "titration" of analgesia. The incidence of 16% of lower limb motor block produced by ropivacaine 0.125% in our study compared favourably against the 75% obtained from a previous study by Owen *et al.* which had employed a baseline infusion of 6 $ml \cdot hr^{-1}$ of the same concentration of ropivacaine in addition to PCEA.[7] To date, the use of a background infusion in PCEA for labour is controversial even though the report by Ferrante *et al.* suggested a trend towards an increased need for additional physician top-ups in the absence of a continuous infusion.[8,9] More research is warranted in this regard.

Our results also showed that the proportion of successful PCEA demands was higher in the group that received the solution of a higher concentration. We believe this to be due to the slower onset and sometimes ineffective first demand bolus received by the 0.125% group that had required a repeat attempt during the PCEA lockout period. In view of this, with our current PCEA regimen, we do not recommend any concentration lower than 0.125% if ropivacaine is used as the sole agent for labour analgesia. However, there was no difference in the satisfaction scores between the two groups in spite of the less favorable "successful-to-total demands ratio" in the R0.125 group. Moreover, our study was probably of insufficient power to detect any difference between the two groups, if at all, as both had very high satisfaction scores.

Previous studies have shown the dose sparing effect of PCEA in comparison with continuous infusions.[10,11] Additionally, an earlier study revealed that PCEA with ropivacaine 0.2% reduced the incidence of motor block and rendered a higher satisfaction score in comparison with a continuous infusion.[3] In the current study, only the incidence of motor block was reduced by decreasing the concentration of ropivacaine to 0.125%, which was accomplished by a less than ideal PCEA successful/total demands ratio. The use of an intermediate concentration (i.e. within the 0.125% and 0.2% range) may theoretically optimize the balance of motor block and PCEA demands ratio although from the results of the current study, this is unlikely to reduce the total dose required for analgesia. Alternatively, the addition of an adjuvant (such as a lipid soluble opioid) to a 0.125% or even more dilute ropivacaine solution may be considered.

In conclusion, both 0.2% and 0.125% ropivacaine provided effective analgesia. The 0.2% solution, by virtue of its higher concentration, produced a greater degree of motor block, albeit of questionable clinical importance in terms of obstetric outcome. The lower concentration, i.e. 0.125%, suffered from a poorer profile with regard to the successful: total demands ratio. Further studies on other concentrations of ropivacaine (with or without adjuvants) as well as other variants of dose regimen are required to establish the most suitable method for PCEA in labour.

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