WD Ngan Kee 顏 傑
BB Lee 李美明
FF Ng 吳 鳳
TK Lau 劉子建
ELY Wong 黃麗儀
KS Khaw 許金山

Randomised double-blind comparison of obstetric outcome after epidural labour analgesia using ropivacaine or bupivacaine

Key Messages

1. Instrumental and operative delivery rates remain high for women in Hong Kong who choose to have epidural analgesia in labour.
2. Use of low concentration ropivacaine is associated with a shorter first stage of labour compared with the equivalent solution of bupivacaine; however, this was not accompanied by a difference in the eventual mode of delivery.
3. Further research in Hong Kong should be directed towards identifying other factors associated with the high interventional delivery rate in women who have epidural analgesia in labour in Hong Kong.

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The Chinese University of Hong Kong: Department of Anaesthesia and Intensive Care
WD Ngan Kee
BB Lee
FF Ng
ELY Wong
KS Khaw
Department of Obstetrics and Gynaecology
TK Lau

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Principal applicant and corresponding author:
WD Ngan Kee
Department of Anaesthesia and Intensive Care
The Chinese University of Hong Kong
Shatin, NT
Hong Kong SAR, China
Tel: (852) 2632 2735
Fax: (852) 2637 2422
E-mail: warwick@cuhk.edu.hk

Introduction

The provision of analgesia to labouring women is a fundamental aspect of obstetric care and an essential function of a modern hospital obstetric unit. However, it is important to minimise any detrimental effects that the methods used may have on obstetric outcome. Of the methods currently available to treat labour pain, epidural analgesia remains by far the most effective. However, audit data in Hong Kong have revealed a high incidence of instrumental delivery and Caesarean section in patients who have epidural labour analgesia. The reasons for this are undetermined. Methods of optimising obstetric outcome after epidural analgesia are controversial. Recently, there has been a move toward the use of very low concentrations of local anaesthetics combined with a lipophilic opioid such as fentanyl. However, motor block can still occur, even with low concentrations. We hypothesised that it might be possible to improve outcome by using a local anaesthetic drug with a high sensory:motor differential block ratio, such as ropivacaine,[1] which was introduced into Hong Kong at the time of the design of this study.

Aims and objectives

The aim of this study was to test the hypothesis that the rate of spontaneous vaginal delivery would be increased in women having epidural analgesia using low concentration ropivacaine compared with the current standard, low concentration bupivacaine. Secondary objectives were comparison of analgesia, motor block, hypotension, patient satisfaction, and neonatal outcome.

Methods

This study was conducted from April 2000 to May 2003. We recruited 350 healthy labouring women with term cephalic singleton pregnancies who requested epidural analgesia into this prospective, randomised, double-blind trial. Parturients were randomly allocated to receive either epidural ropivacaine (n=175) or bupivacaine (n=175). Using a standard technique, analgesia was initiated using 5 mL increments of 0.25% solution and maintained using a continuous infusion of 0.1% solution plus fentanyl 0.0002% at 4 to 12 mL/h. Further boluses of 0.25% solution were given for breakthrough pain.

Parturients were nursed in a semi-lateral position, with continuous cardiotocograph monitoring. Hypotension was managed with intravenous fluids and ephedrine as required. Epidural infusions were maintained throughout labour and were continued through the second stage. However, if maternal effort was judged to be inadequate, the infusion was reduced or stopped as considered appropriate. The attending obstetricians and midwives, who were blinded to the study, managed the second stage of labour according to a standardised written labour ward protocol, which remained unchanged for the study.

Patient assessments were made before inserting the epidural catheter, at 5-

Table 1. Outcome of labour*

	Ropivacaine group (n=173)	Bupivacaine group (n=173)	P value	Between-group difference (95% CI)
Mode of delivery				
Spontaneous vaginal	66 (38.2%)	72 (41.6%)	0.72	3.4 (-6.8 to 13.6)%
Instrumental vaginal	46 (26.6%)	41 (23.7%)		2.9 (-6.2 to 12.0)%
Caesarean delivery	61 (35.2%)	60 (34.7%)		0.5 (-9.4 to 10.5)%
Duration of labour (min)	(n=113)	(n=114)		
1st stage	520 (377-745)	645 (460-820)	0.009	125 (35 to 205)
2nd stage	77 (25-106)	78 (33-116)	0.50	

* Values are expressed as No. (%) or median (interquartile range)

Table 2. Characteristics of epidural analgesia*

	Ropivacaine group	Bupivacaine group	P value
Upper sensory level (dermatome)			
Right	T9 (T11-T8)	T9 (T11-T8)	0.09
Left	T10 (T11-T8)	T9 (T10-T8)	0.20
Motor block (Bromage scale)			
Right	0 (0-1)	0 (0-1)	0.44
Left	0 (0-1)	0 (0-1)	0.08
Motor block Bromage score >1 (n)	10 (5.8%)	21 (12.1%)	0.06
Epidural infusion rate (mL/h)	8 (8-8.4)	8 (8-8.5)	0.41
Supplementary top-ups (mg)	12.5 (0-25)	12.5 (0-25)	0.21
Total dose of local anaesthetic consumed (mg)	85 (62-123)	95 (65-129)	0.25
Hypotension (n)	26 (15.0%)	30 (17.3%)	0.89
Patient satisfaction (n)			
Good/excellent	164 (95%)	158 (91%)	0.60
Fair/poor	9 (5%)	15 (9%)	

* Values are expressed as median (interquartile range) or No. (%)

min intervals while initial analgesia was established, and then at 2-h intervals throughout the first stage of labour, starting 1 h after insertion of the epidural catheter. Visual analogue scale (VAS) pain scores were recorded at the peak of a uterine contraction. The level of sensory block was determined using ice and motor block was assessed using a modified Bromage score (0-3). We recorded maternal blood pressure, heart rate, mode of delivery and indication, duration of each stage of labour, duration and rates of epidural infusion, epidural top-ups, total drug dose, birthweight, Apgar scores and umbilical cord blood gases, postpartum satisfaction and complications.

Power analysis was based on a reduction of interventional delivery rate from 72% (rate from audit data) to 59% (the magnitude of difference reported when higher concentrations of local anaesthetic were compared[2]). This showed that a sample size of 164 patients per group was required to have 80% power at an alpha level of 0.05. To allow for a maximum potential dropout rate of 5%, we increased the sample size to 175 patients per group. Power analysis was based on one-tailed calculations but all subsequent analyses were two-tailed. Data were analysed using Student's *t* test, the Mann-Whitney *U* test, and the Chi squared test. Multinomial logistic regression was used to identify factors associated with operative delivery. Relative risks were calculated for patients who delivered by instrumental vaginal and Caesarean delivery, with reference to patients with normal vaginal delivery. Values of $P<0.05$ were considered statistically significant.

Results

Three hundred and forty-six patients completed the study. There were no differences in demographic data. The majority of patients were nulliparas.

Of the patients who delivered vaginally, the duration of the first stage of labour was shorter in the ropivacaine group compared with the bupivacaine group (median [interquartile range], 520 [377-745] min vs 645 [460-820] min; P=0.009). However, there was no difference between groups in the interventional delivery rate (Table 1).

Characteristics of epidural analgesia, pain scores, sensory and motor block, incidence of hypotension and vasopressor requirement, supplementary epidural top-ups, duration of epidural infusions, total dose of local anaesthetic used, birthweight, umbilical cord blood gases, Apgar scores, and patient satisfaction were similar between groups (Table 2, Fig). The only independent predictors of mode of delivery were parity and birthweight. Overall, parity and birthweight were both associated with Caesarean delivery, but only nulliparity was associated with instrumental vaginal delivery.

Discussion

This study showed that, despite similar pain relief, the median duration of the first stage of labour was shorter by approximately 2 hours when epidural analgesia was administered using ropivacaine compared with bupivacaine. This indicates that the choice of local anaesthetic drug does have a significant effect on the progress over labour. However, there was no difference in the mode of delivery. This suggests that other factors may be more important in determining the eventual obstetric outcome.

Whether and how epidural analgesia affects the progress

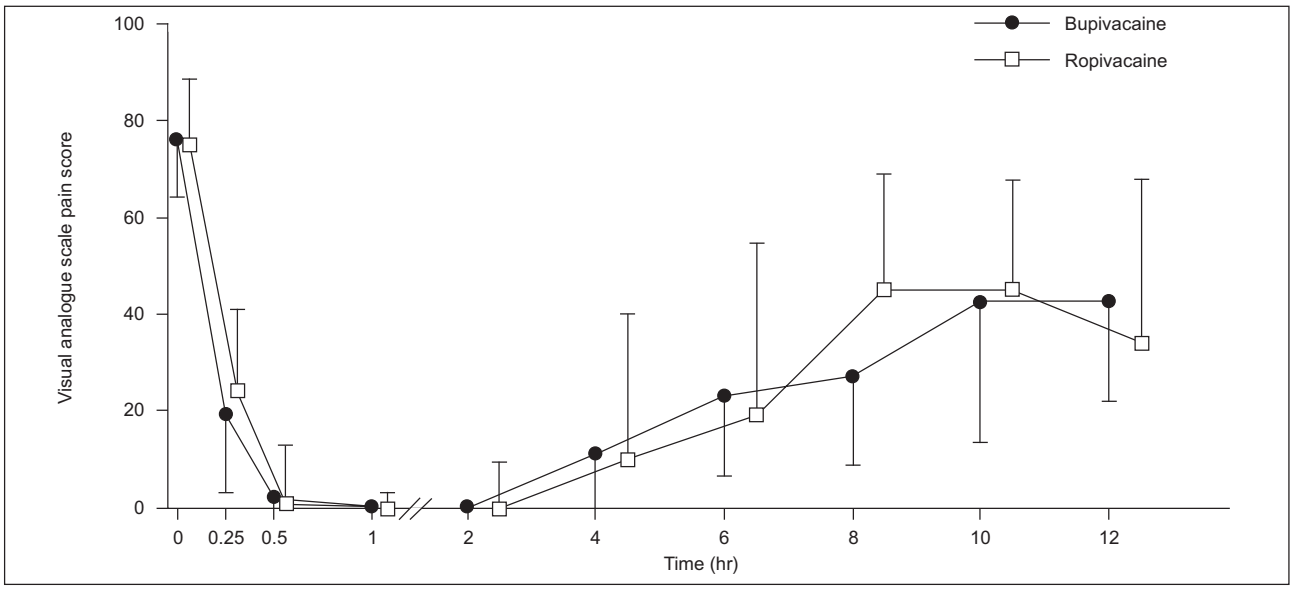

Fig. Visual analogue scale pain scores during the first stage of labour
Pain scores were similar between groups. Values are median and 25th centile (bupivacaine) and 75th centile (ropivacaine)

and outcome of labour has been the topic of much debate.[3] One of the factors implicated is motor block from the epidural local anaesthetic. This may decrease maternal mobility, and relaxation of pelvic floor muscles may predispose to inadequate rotation of the foetal head.[4] Motor block from local anaesthetic can be minimised by reducing the concentration of local anaesthetic.[5] However, the advantage of using a local anaesthetic with a high differential sensory:motor block ratio, such as ropivacaine, is more controversial.

Previously, a prospective meta-analysis of ropivacaine 0.25% versus bupivacaine 0.25% showed that the instrumental vaginal delivery rate was lower for ropivacaine compared with those who received bupivacaine (27% vs 40%, P<0.01).[2] In contrast, in our study using 0.1% solutions, although the median duration of the first stage of labour was shorter in the ropivacaine group, there was no difference in the mode of delivery. This may be more relevant to current clinical practice since most obstetric anaesthesiologists now use low concentration local anaesthetic.

In contrast to other studies,[2] we found the incidence of motor block was low and equal between groups. This suggests that at low concentrations, the difference in motor block between ropivacaine and bupivacaine is small; the concentration or dose of local anaesthetic may be more important than the choice of agent.

As this is a negative study, the chance of a type II error needs to be considered. Retrospective power analysis based on the observed interventional delivery rate in the bupivacaine group showed that, with the number of patients successfully recruited, our study had 78.3% power to detect a 13% reduction in the interventional delivery rate (the primary outcome) in the ropivacaine group with type I error probability of 0.05 (one-tailed). Therefore, our study had a 21.7% chance of type II error. However, no trend was observed in the primary endpoint data to suggest the likelihood of a type II error.

This study found that a high rate of interventional delivery persisted when epidural analgesia was administered using a dilute solution of a local anaesthetic with a low propensity to cause motor block. This indicates that further research should be directed towards identifying other factors associated with the high interventional delivery rate in women who have epidural analgesia in Hong Kong.

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