Anaesthesia, 2005, **60**, pages 348–353

Effects of a height and weight adjusted dose of local anaesthetic for spinal anaesthesia for elective Caesarean section*

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Summary

In this prospective, randomised, double-blind study, we compared the effects of two dosage regimens. Pregnant patients at term were randomly assigned to two groups to be given diamorphine 0.4 mg in hyperbaric bupivacaine 0.5% 2.4 ml or diamorphine 0.4 mg in a volume of hyperbaric bupivacaine 0.5% adjusted according to the patient's height and weight. Adequate anaesthesia was provided in all patients in both groups. The onset of the sensory block for cold and pinprick was faster with the fixed dose regimen ($p = 0.01$). There were more spinal blocks to above the first thoracic dermatome in the fixed dose group (17.1% vs. 2.2%, $p = 0.022$). Hypotension occurred in 71.7% vs. 50.0% of patients in the fixed dose and adjusted dose groups respectively ($p = 0.035$). In the fixed dose group, more patients required ephedrine to treat hypotension (79.5% vs. 56.8%, $p = 0.022$) and a larger median dose was administered (9 mg vs. 6 mg, $p = 0.042$). The decrease in mean (SD) arterial pressure was less in the adjusted group (35.0 (16.4) mmHg vs. 28.0 (13.5) mmHg, $p = 0.036$).

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**An abstract based on this study was presented at the Annual Meeting of the European Society of Anaesthesia, Lisbon 2004.*
Accepted: 4 November 2004

Spinal anaesthesia with bupivacaine is routinely used to provide anaesthesia for both elective and emergency Caesarean section. This local anaesthetic, particularly when in combination with an opioid, provides good anaesthesia and is therefore in common use. However, the technique is associated with a significant incidence of hypotension resulting from sympathetic blockade [1–3]. Maternal hypotension not only presents with distressing symptoms of dizziness, nausea and vomiting, but also impairs placental perfusion and may compromise fetal outcome [4, 5].

A recent survey of practice in the UK revealed that a large variety of dosage regimens are in use for spinal anaesthesia for Caesarean section [6]. Whereas some anaesthetists favour a fixed dosage regimen, others adjust the dose of bupivacaine according to the patient's characteristics. This approach is supported by pharmacodynamic data that suggest that the onset time for achieving an adequate sensory level for surgery increases linearly with height and decreases with increasing weight [7]. In addition, clinical observation confirms that weight [8] and height [9] are significant variables in predicting the final level of the block. Consequently, if the extent of the block depends on the height and weight of the patient, a dose of bupivacaine adjusted for these variables should provide an optimal dermatomal level of anaesthesia without excessive maternal hypotension. Such an adjusted dosage regimen has been in use for 15 years in our unit, and retrospective data suggest that successful spinal anaesthesia for Caesarean section has been associated with a low incidence of hypotension [10].

In this prospective, randomised study, we aimed to test whether adjusting the dose of intrathecal bupivacaine according to the patient's height and weight would provide

adequate surgical anaesthesia for elective Caesarean section while decreasing the incidence of maternal hypotension and the use of ephedrine to treat hypotension.

Methods

After Local Research Ethics Committee approval and written, informed consent, we recruited ASA physical status 1 or 2 women with term, singleton pregnancies scheduled for elective Caesarean section under spinal anaesthesia. We excluded patients with pre-existing or pregnancy-induced hypertension, cardiovascular or cerebrovascular disease, contraindications to spinal anaesthesia, those weighing < 50 kg or > 110 kg, and those taller then 180 cm or shorter than 140 cm. The study was conducted between January 1998 and November 2000. In view of a conflict between the study protocol and recommendations published in 2000 with respect to the level of insertion of spinal needles [11], we stopped the trial prematurely after recruiting 84 rather than the planned 100 patients.

Patients were premedicated with oral ranitidine 150 mg the night before and the morning of surgery. Standard monitoring, comprising non-invasive blood pressure, ECG and pulse oximetry, was attached to the patient, and baseline blood pressure and heart rate were recorded. We inserted a 16G intravenous cannula under local anaesthesia. In accordance with routine practice in our unit, we preloaded with lactated Ringer's solution 1000 ml over 10 min before inducing spinal anaesthesia. After skin infiltration with lidocaine, a 25G Whitacre spinal needle was inserted at the $L_{2\text{-}3}$ vertebral interspace with the patient in the sitting position and, after aspiration of cerebrospinal fluid, the following anaesthetic solutions were injected over 5 s:

- patients in the Fixed Dose Group were given diamorphine 0.4 mg in normal saline 0.4 ml added to hyperbaric bupivacaine 0.5% 2.4 ml;
- patients in the Adjusted Dose Group were given diamorphine 0.4 mg in normal saline 0.4 ml added to a volume of hyperbaric bupivacaine 0.5% determined by reference to a dosage regimen detailed in Table 1.

Patients were then immediately turned into the supine position with a 15° left lateral tilt. We did not give oxygen unless S_pO_2 decreased to < 94%. We treated bradycardia, defined as a heart rate of < 60 beats.min^{-1}, with intravenous atropine 0.6 mg. We treated hypotension, defined as a > 30% decrease in baseline systolic blood pressure or a systolic blood pressure < 100 mmHg, with intravenous ephedrine 3 mg. Ephedrine 3 mg was also given if the patient suffered dizziness, nausea or vomiting. Surgical incision was allowed when loss of cold and pinprick sensation reached the T_4 dermatome bilaterally. If the sensory blockade was inadequate 8 min after the insertion of the spinal anaesthetic, the assessor positioned the patient in a 10° head-down tilt. If patients reported discomfort during the operation, nitrous oxide 50% in oxygen was given via a clear facemask. If the discomfort continued, we gave up to four intravenous boluses of alfentanil 250 μg. We offered conversion to general anaesthesia if these measures proved inadequate. After delivery, we gave intravenous oxytocin 10 IU and cefuroxime 1.5 g by slow intravenous injection. Rectal diclofenac 100 mg was given at the end of the operation. Postoperative analgesia comprised regular oral paracetamol 1 g and oral diclofenac 50 mg.

Table 1 Adjusted dose regimen for hyperbaric bupivacaine 0.5% when used for spinal anaesthesia for Caesarean section. Values are millilitres.

Patient weight; kg	Patient height; cm								
	140	145	150	155	160	165	170	175	180
50	1.5	1.7	1.8	1.9					
55	1.5	1.6	1.8	1.9	2.0				
60	1.4	1.6	1.7	1.8	2.0	2.1			
65	1.4	1.5	1.7	1.8	1.9	2.1	2.2		
70	1.3	1.5	1.6	1.8	1.9	2.0	2.2	2.3	
75		1.4	1.6	1.7	1.9	2.0	2.1	2.3	2.4
80		1.4	1.5	1.7	1.8	2.0	2.1	2.2	2.4
85			1.5	1.6	1.8	1.9	2.1	2.2	2.3
90			1.4	1.6	1.7	1.9	2.0	2.2	2.3
95				1.5	1.7	1.8	2.0	2.1	2.3
100				1.5	1.7	1.8	1.9	2.1	2.2
105					1.6	1.7	1.9	2.0	2.2
110						1.7	1.8	2.0	2.2

We randomly assigned the patients to two groups using computer-generated randomisation codes that were placed in sealed, sequentially numbered envelopes. The study was conducted in a double-blind fashion such that the patient and the assessor were unaware of the group allocation of the patient; only the practitioner administering the spinal anaesthetic knew the group allocation. We measured the upper sensory level of anaesthesia by assessing loss of pinprick and cold sensation at the midclavicular line at 2-min intervals. We also recorded time to surgical incision, the sensory block level at 25 min, the use of head down tilt, supplementary analgesia and conversion to general anaesthesia. Mean arterial blood pressure and heart rate were recorded at baseline and then measured at 2-min intervals, starting 2 min after the spinal injection and continuing until the start of surgery, after which recordings were made at 5-min intervals. The incidence of nausea and vomiting was recorded, as was the dose of ephedrine given. The attending midwife, who was blinded to the patient's group allocation, assessed Apgar scores at 1 min and 5 min.

Prospective power analysis was based on the primary outcome, which we defined as the dose of ephedrine given. Using data from a retrospective pilot study, we calculated a required sample size of 50 patients per group. This was based on a clinically relevant difference (SD) of ephedrine of 6 (9) mg, a power 0.9 and an α significance level of 0.05. Data were analysed using an unpaired Student's *t*-test, the Mann–Whitney test and Fisher's exact test, as appropriate. Data were not adjusted for multiple testing. We considered a probability value of 0.05 to be significant. Analyses were performed using SPSS 10.1.4 for WINDOWS (SPSS, Chicago, IL) and STATXACT-5 for WINDOWS (Cytel Software Corporation, Cambridge, MA).

Results

All 84 patients completed the study and were included in the analysis. Forty-five patients in the Adjusted Dose Group received a median[IQR] dose of heavy bupivacaine 0.5% of 1.9 [1.8–2.0] ml. Thirty-nine patients in the fixed dose group received heavy bupivacaine 0.5% 2.4 ml (significantly different to the dose given to the Adjusted Dose Group, $p < 0.001$). Patient characteristics are given in Table 2.

Table 3 shows the dermatomal levels of sensory blockade seen during the study. We were unable to assess loss of pinprick sensation at the T_6 level in two patients before the start of surgery, and we could not assess the loss of cold and pinprick sensation in five patients at 25 min after insertion of the spinal anaesthetic. The onset of the sensory block for cold and pinprick, on both the right and left sides, was faster with the fixed dose than with the adjusted dose ($p = 0.02$). Pinprick sensation was abolished after a median time of 6 min in both groups, with smaller interquartile ranges in the Fixed Dose Group than in the Adjusted Dose Group. In the Fixed Dose Group, six patients had loss of cold sensation to above the T_1 dermatome at 25 min after insertion of the spinal anaesthetic (one patient to C_8 and five patients to C_7). In the Adjusted Dose Group, two patients had a block to cold to C_8. In the Fixed Dose Group, six patients had loss of pinprick sensation to above the T_1 dermatome at 25 min after insertion of the spinal anaesthetic (three patients to C_8 and three patients to C_7). In the Adjusted Dose Group, one patient had a block to pinprick above T_1.

Table 2 Patient characteristics. Values are mean (SD), median [range] or number (percentage).

	Fixed Dose Group (*n* = 39)	Adjusted Dose Group (*n* = 45)
Age; years	33.0 (3.4)	31.9 (4.7)
Height; cm	161.0 (6.6)	162.3 (6.2)
Weight; kg	81.3 (11.9)	76.2 (9.1)
Gestation; weeks	39 [38–39]	38 [38–39]
Parity; *n*	1 [0–4]	1 [0–4]
Previous Caesarean section; *n*	25 (64%)	25 (56%)
Baseline systolic arterial pressure; mmHg	132.6 (15.3)	131.3 (12.7)

Supplementary analgesia with nitrous oxide and alfentanil (to a maximum of 500 μg) was given to two patients in the Adjusted Dose Group. Five patients in the Adjusted Dose Group and no patients in the Fixed Dose Group required head-down tilt. No patient in either group required conversion to general anaesthesia. There were no differences between the groups in fetal Apgar scores at 1 min and 5 min.

Table 4 presents cardiovascular data. Minimum blood pressures were not recorded in three patients. The incidence of hypotension after spinal anaesthesia was 71.7% in the Fixed Dose Group and 50.0% in the Adjusted Dose Group ($p = 0.035$). More patients in the Fixed Dose Group were given ephedrine (79.5% vs. 56.8%, $p = 0.02$), and a larger median dose was administered (9 mg vs. 6 mg, $p = 0.042$). The decrease in mean arterial pressure was less in the Adjusted Dose Group than in the Fixed Dose Group ($p = 0.036$). The percentage of patients in the Fixed Dose Group who vomited was 17.9%, compared to 4.5% in the Adjusted Dose Group ($p = 0.052$). There was no difference in the number of patients reporting nausea.

Discussion

To our knowledge, this is the first published evidence that a dose of hyperbaric bupivacaine calculated according to patients' height and weight can, if combined with diamorphine 0.4 mg, provide adequate anaesthesia for elective Caesarean section. In this prospective, double-blind, randomised study, this dosage regimen was associated with a decreased incidence and severity of maternal hypotension and decreased ephedrine requirement. The onset time for adequate sensory blockade, and consequently the time interval between spinal insertion and surgical incision, was longer in the Adjusted Dose Group than in the Fixed Dose Group. The incidence of high sensory blockade, defined as being higher than the T_1 dermatomal level, was lower in the Adjusted Dose Group.

This study shows that satisfactory anaesthesia for elective Caesarean section can be provided with doses of bupivacaine that are lower than those usually used in UK obstetric anaesthetic practice. Patients in the Adjusted Dose Group received a median dose of bupivacaine of

Table 3 Bupivacaine dose, block data and supplementary analgesia in the two groups studied. Values are expressed as median (IQR [range]) or number (percentage). Confidence intervals refer to the difference between the groups.

	Fixed Dose Group		Adjusted Dose Group		95% confidence intervals	p-value
	n		*n*			
Dose of bupivacaine 0.5%; ml	39	2.4 (2.4–2.4)	45	1.9 (1.8–2 [1.6–2.2])	0.4–0.6	<0.001
Time from insertion of spinal anaesthetic to incision; min	39	6 (4–8 [2–14])	45	8 (6–10 [4–20])	0–2	0.022
Time to loss of cold sensation to T_4 on right; min	39	6 (4–8 [2–14])	45	8 (6–10 [4–20])	0–2	0.011
Time to loss of cold sensation to T_4 on left; min	39	6 (4–7 [2–14])	45	8 (6–10 [4–20])	0–2	0.004
Time to loss of pinprick sensation to T_6 on right; min	38	6 (4–8 [2–14])	45	6 (6–10 [4–20])	0–2	0.018
Time to loss of pinprick sensation to T_6 on left; min	37	6 (4–6 [2–14])	45	6 (6–10 [4–20])	0–2	0.001
Time to loss of cold sensation to > T_1; min	35	6 (17.1%)	44	2 (4.5%)	−1.4–29.3%	0.072
Time to loss of pinprick sensation to > T_1; min	35	6 (17.1%)	44	1 (2.2%)	2–31.3%	0.022
Head-down tilt used; *n*	39	0 (0%)	45	5 (11.1%)	−24.4–1.2%	0.034
Supplementary analgesia given; *n*	39	0 (0%)	45	2 (4.4%)	−15.6–4.8%	0.220
Conversion to general anaesthesia; *n*	39	0 (0%)	45	0 (0%)	−8.6–10.3%	1.0

Table 4 Cardiovascular and other data. Values are mean (SD), median (IQR [range] or number (percentage).

	Fixed Dose Group		Adjusted Dose Group		95% confidence intervals	p-value
	n		*n*			
Difference between baseline and minimum mean arterial pressure; mmHg	36	35.0 (16.4)	45	28.0 (13.5)	0.5–13.5	0.036
Hypotension; *n*	39	28 (71.7%)	45	22 (50.0%)	1.4–42.7%	0.035
Ephedrine given; *n*	39	31 (79.5%)	45	25 (56.8%)	3.3–42.8%	0.022
Ephedrine dose given; mg	38	9 (3–18 [0–57])	45	6 (0–13.5 [0–60])	0–9	0.042
Nausea; *n*	39	24 (61.5%)	45	24 (54.5%)	−13.4–29.0%	0.460
Vomiting; *n*	39	7 (17.9%)	45	2 (4.5%)	−0.1–29.4%	0.052
Apgar score at 1 min	39	9 (9–9 [5–10])	45	9 (9–9 [6–10])	0.0001–0.0001	0.143
Apgar score at 5 min	39	10 (9–10 [9–10])	43	10 (9–10 [8–10])	0.000–0.000	0.809

9.5 mg (1.9 ml), and the lowest dose administered was 8 mg (1.6 ml). A survey of UK practice showed that the mean (SD) volume of bupivacaine 0.5% usually given is 2.57 (0.24) ml with a fixed dosage scheme, whereas a median [range] dose of 2.34 [1.2–3.0] ml is given with a variable dose scheme [6]. These doses are comparable to the fixed dose used in this trial. Interestingly, spinal anaesthesia was still adequate in the Adjusted Dose Group in almost all patients despite the low doses used; only two patients (4.4%) in this group experienced visceral discomfort, which responded well to supplementary analgesia with nitrous oxide and alfentanil. No conversion to general anaesthesia was necessary in either group. This figure is in agreement with a recent meta-analysis that showed that if opioids are added to the intrathecally administered local anaesthetic, 4% of patients require supplementary analgesia during their Caesarean section [12]. Although there was no difference in the incidence of administration of supplementary analgesia between the groups, the present study was not adequately powered to detect such a difference. However, it is of interest that the adjusted dosage regimen has been in routine use at our institution for approximately 15 years. We recently conducted a 3-year retrospective case record review of all patients undergoing spinal anaesthesia for elective Caesarean section. Amongst approximately 500 patients, we noted that supplementary analgesia was given to only 26 patients (5%), and inadequate sensory blockade requiring repeat spinal anaesthesia or conversion to general anaesthesia occurred in three (0.6%) and one (0.2%) patient, respectively [10]. These data appear to support the adequacy of sensory blockade with this dosage regimen. We accept that a further prospective study in a larger patient cohort is indicated to confirm our results. The median time to surgical incision was 2 min longer (8 min vs. 6 min) with the adjusted dose than with the fixed dose regimen; in patients undergoing elective Caesarean section, this difference is probably of little clinical significance. In contrast, this delay may be critical when providing regional anaesthesia for emergency Caesarean section, and we therefore suggest not using the adjusted dosage regimen in this setting.

The lower doses of bupivacaine used in the Adjusted Dose Group were associated with a lower incidence and less severe maternal hypotension. We hypothesise that the sympathetic blockade, although not formally tested, was less in this group. It is well established that less local anaesthetic, and hence sympathetic blockade, is required to provide anaesthesia for Caesarean section if an opioid is added to the local anaesthetic [12].

High spinal blockade is a common occurrence after spinal anaesthesia with unadjusted doses of local anaesthetic. Russell and Holmqvist [13], using a fixed dose of hyperbaric bupivacaine 0.5% 2.5 ml, showed that 25% of patients undergoing Caesarean section developed sensory blocks to the cervical dermatomal region, of which 10% were to C_1 or C_2. This is in agreement with our results in the Fixed Dose Group, in which 17% of the patients presented with cervical dermatomal block levels. In contrast, only 4.5% of the patients in the Adjusted Dose Group reported cervical dermatomal block levels. We therefore suggest that adjusting the dose to height and weight increases the safety margin of spinal anaesthesia. Although the incidence and severity of maternal hypotension were decreased in the Adjusted Dose Group, we cannot prove that this was associated with improved fetal outcome. Apgar scores, admittedly an insensitive tool to assess fetal outcome, were similar in the two groups at 1 min and 5 min. We cannot comment further on uteroplacental perfusion, as our study did not include the measurement of umbilical cord blood gas values or uteroplacental blood flow.

During the course of the study, it became apparent that inserting spinal anaesthesia above the level of the third lumbar vertebra may be associated with a higher incidence of neurological injury. This practice has subsequently been discouraged [11]. The technique used in this study was based on inserting the spinal anaesthetic at the $L_{2/3}$ interspace. We were concerned that changing the site of insertion to the $L_{3/4}$ interspace might affect the level of sensory blockade. Interestingly, changing the level of spinal injection in non-pregnant patients from $L_{2/3}$ to $L_{3/4}$ does not appear to affect the highest level of analgesia [14, 15]. The situation is less clear in pregnant patients; we could not identify any published work on this patient group. We therefore decided to stop the study prematurely after recruiting 84 patients, as we did not want to put patients at risk of an adverse outcome or to introduce a potential confounding variable by modifying the protocol.

In conclusion, we have shown that adjusting the dose of hyperbaric bupivacaine to patients' height and weight, if used in combination with diamorphine 0.4 mg, provided adequate anaesthesia for elective Caesarean section. This technique was associated with a decreased incidence and severity of maternal hypotension, decreased ephedrine administration and a lower incidence of high spinal block.

Acknowledgements

We thank Dr A. Davies for designing the dosage regimen that we used for this study. We thank the Robertson Institute for Biostatistics for statistical advice. This study was funded from departmental research funds. The authors do not have any conflicts of interest to declare.

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