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ORIGINAL ARTICLE

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A randomised controlled trial of the effect of a head-elevation pillow on intrathecal local anaesthetic spread in caesarean section

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ABSTRACT
Background: A head-elevation pillow places a patient in a ramped posture, which maximises the view of the larynx during laryngoscopy, particularly in obese parturients. In our institution an elevation pillow is used pre-emptively for neuraxial anaesthesia. We hypothesised that head-elevation may impair cephalad spread of local anaesthetic before caesarean section resulting in a lower block or longer time to achieve a T6 level. We aimed to investigate the effect of head-elevation on spread of intrathecal local anaesthetics during anaesthesia for caesarean section.
Methods: One-hundred parturients presenting for caesarean section under combined spinal-epidural anaesthesia were randomised to either the standard supine position with lateral displacement or in the supine position with lateral displacement on an head-elevation pillow. Each patient received intrathecal hyperbaric bupivacaine 11 mg, morphine 100 μg and fentanyl 15 μg. Patients were assessed for adequacy of sensory block (T6 or higher) at 10 min.
Results: Sensory block to T6 was achieved within 10 min in 65.9% of parturients in the Elevation Pillow Group compared to 95.7% in the Control Group ($P<0.05$). Compared to the Control Group, patients in the Elevation Pillow Group had greater requirements for epidural supplementation (43.5% vs 2.1%, $P<0.001$) or conversion to general anaesthesia (9.3% vs 0%, $P<0.04$).
Conclusions: Use of a ramped position with an head-elevation pillow following injection of the intrathecal component of a combined spinal-epidural anaesthetic for scheduled caesarean section was associated with a significantly lower block height at 10 min.

Keywords: Combined spinal-epidural anaesthesia; Caesarean section; Head elevation pillow

Introduction

Head elevation beyond the sniffing position by raising the back and shoulders is known as the ramped position, and facilitates alignment of the pharyngeal, laryngeal, and oral axis of the airway during difficult laryngoscopy.[1–4] Use of a solid foam pillow that achieves an angle of 20° with the horizontal, places the head and neck of the patient with a high body mass index (BMI) in the recommended position for airway management.[5] At our institution, this device has become a routine measure of safety for patients with high BMI; however, its impact on the height and speed of intrathecal local anaesthetic spread is an ongoing topic of research.[6]

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Methods

Ethical approval for this trial was obtained from the Research Ethics Committee of the National Maternity Hospital, Dublin, Ireland. The trial was registered on the International Standard Randomised Controlled Trial (ISRCTN) registry (ISRCTN50624101). Written informed consent was obtained from all eligible parturients presenting for elective and semi-elective caesarean section. Inclusion criteria were age $\geqslant$18 years and singleton pregnancy of over 32 weeks of gestation presenting for elective and semi-elective caesarean section (category 3 or 4).[7] Exclusion criteria were body mass index (BMI) $\geqslant$40 kg/m^2, contraindications to neuraxial anaesthesia and parturient preference for general anaesthesia. Participants were randomised to either control or intervention group by use of sealed, sequentially numbered envelopes between May and October 2013. Blinding group allocation was not possible in practice;

however, study personnel were blinded to the allocation sequence, and data analysis was blind to group labels.

A standardised protocol for combined spinal-epidural (CSE) anaesthesia was followed. With the parturient in a seated position an 18-gauge Tuohy needle was inserted into the epidural space at the L3–4 interspace, using loss of resistance to air. With a needle-through-needle technique, a 27-gauge Whitacre needle was inserted intrathecally and a mixture of 0.5% hyperbaric bupivacaine 2.2 mL (11 mg), fentanyl 15 μg and preservative-free morphine 100 μg was injected. An epidural catheter was threaded 4 cm into the epidural space to facilitate augmentation of spinal anaesthesia, if required. Parturients were positioned either supine with their head on a common pillow (Control Group, Fig. 1a) or supine on an elevation pillow with their head on a common pillow (Elevation Pillow Group, Fig. 1b). Left uterine displacement was applied to all patients, by use of a standard wedge under the right hip. Sensory block level was checked 10 min after spinal injection by loss of touch sensation to ethyl chloride sprayed in the mid-clavicular line.[8] An epidural top-up was administered if the block failed to reach T6 within 10 min, or when the parturient reported pain. Epidural top-ups comprised boluses of 2% lidocaine with 1:200 000 adrenaline 5 mL every 5 min until the block became satisfactory (T6 or higher). Conversion to general anaesthesia was performed for a neuraxial block that was unsatisfactory after epidural supplementation.

Statistical analysis

The primary outcome was defined as loss of touch sensation to ethyl chloride spray at the T6 dermatome (defined as the level of the xiphisternum) or higher at 10 min.[8] Secondary outcomes included the rate of conversion to general anaesthesia, and the proportion of patients requiring epidural supplementation to achieve a satisfactory block to T6 or higher. The required sample size was estimated based on a chi-square test to compare proportions of parturients with a T6 block at 10 min. Effect size was estimated from clinical experience as data on this measure are sparse in the literature. Assuming 95% of control patients would achieve satisfactory sensory block to T6 at 10 min, a sample of 49 patients per group would permit the detection of a 20 percentage point difference (75%) in the Elevation Pillow Group with 80% power while controlling the type I error rate at 5%. Low or no attrition or withdrawal was anticipated, so a total of 100 patients were set as the recruitment target. Success of the trial on the primary outcome difference was tested with a Pearson chi-square statistic (without continuity adjustment) with no adjustment required for multiple comparisons. Logistic regression was applied to examine the effect of the group while controlling for patient BMI, as a further exploratory analysis.

Results

One hundred patients were recruited and randomised to two groups in a 1:1 ratio. Due to difficulties in storage of the randomisation envelopes in a working theatre environment, five randomisation envelopes were lost before allocation. This was addressed by proceeding with the next envelope in sequence, and recreating the missing envelope from the concealed allocation list which was reinserted into the sequence at the earliest possible opportunity; the result of the primary analysis was insensitive to exclusion of these individuals. All patients recruited maintained participation and were analysed on an intention-to-treat basis.

Fig. 2 shows the patient flowchart. Complete data were not collected for nine parturients due to inability to assess the primary outcome. Four were from the Control Group: failure to site CSE (n=1), vasovagal attack (n=1), unspecified (n=2); and five were from the Elevation Pillow Group: failure to site CSE (n=2), dural puncture leading to the procedure being abandoned (n=1), incorrectly completed data collection sheets (n=2). The latter two were marked as "Yes" for the primary endpoint of loss of touch, rather than a record of the vertebral level of bilateral loss-of-touch; the result of the primary analysis was insensitive to these two records. Descriptive statistics for the two groups (Table 1) showed that randomisation generated comparable groups in terms of demographic characteristics with no significant differences between groups (all P>0.05). The time between intrathecal injection and positioning the patient supine was not statistically significant between groups (Control Group 151 ± 64 s vs. Elevation Pillow Group 123 ± 70 s; P=0.053).

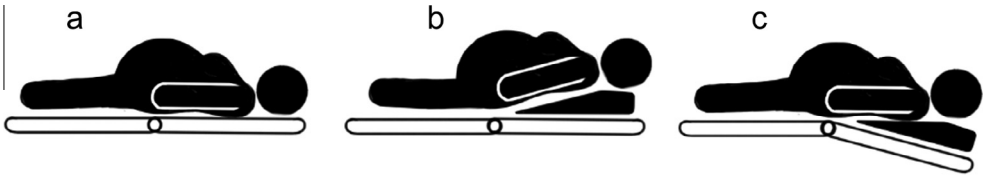

Fig. 1 Depiction of (a) standard supine position, (b) supine with the head-elevation pillow, and (c) supine with the elevation pillow and table manipulation to restore horizontal position of the patient, with extension at the neck to open the airway