Spinal anaesthesia for paediatric day-case surgery: a double-blind, randomized, parallel group, prospective comparison of isobaric and hyperbaric bupivacaine

H. KOIKI, K. TUOVINEN AND H. HENDOLIN

Summary
We have compared bupivacaine 5 mg ml⁻¹, either isobaric in saline 0.9% or hyperbaric in 8% glucose, for spinal anaesthesia in 100 children, aged 2–115 months, in a double-blind, randomized, parallel group, prospective study. Children were premedicated with diazepam 0.5 mg kg⁻¹ orally. Seventy-two children were sedated before, and 25 children after, lumbar puncture, with either propofol or thiopental (thiopentone). After lumbar puncture in the lateral decubitus position with a 24–27-gauge paediatric spinal needle, isobaric or hyperbaric bupivacaine 5 mg ml⁻¹ was injected in a dose of 0.3–0.5 mg kg⁻¹ using a blinded procedure. Maximum cephalad extent of the block was tested by transcutaneous electrical stimulation. The success rate of the block was greater with hyperbaric bupivacaine (96%) compared with isobaric bupivacaine (82%) (P=0.025, 95% confidence intervals (CI) 0–28%). Intense motor block was associated with adequate sensory block. Spread and duration of sensory block showed a similar wide scatter in both groups. The highest median level of sensory block was T4 (range T1–12) in the isobaric group and T4 (T1–7) in the hyperbaric group. Times to two segment regression of block were similar: 80 (55–190) min in the isobaric and 80 (30–190) min in the hyperbaric group. Cardiovascular stability was good. Etilefrin was administered to one child to treat hypotension and atropine to one child to treat bradycardia. The study gave an impression of a delayed onset time of spinal block, as most of the nine children who required either fentanyl or a sedative for a mild reaction to skin incision had complete block when transferred to the recovery room after operation. Five children developed a mild, position-dependent headache. (Br. J. Anaesth. 1998; 81: 502–506).

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Spinal anaesthesia produces rapid onset, profound and uniformly distributed analgesia with good neuromuscular block. Spinal anaesthesia permits the use of a small dose of local anaesthetic with a low risk of toxicity. The amide local anaesthetics are used regularly for spinal anaesthesia in children, and of these bupivacaine and lidocaine (lignocaine) are used almost exclusively. However, the duration of action of intrathecally injected lidocaine may be too short in some children undergoing paediatric day-case surgery. Bupivacaine is an amide local anaesthetic with a moderately rapid onset and a long duration of action. It is highly protein bound and metabolized mostly in the liver. For spinal anaesthesia, bupivacaine is most commonly used as an isobaric or hyperbaric solution. Isobaric bupivacaine is formulated using normal saline as a diluent, with a specific gravity of 1.000 at 37°C. Hyperbaric bupivacaine in 8% glucose has a specific gravity of 1.021 at 37°C. Both isobaric and hyperbaric bupivacaine have been used for spinal anaesthesia in children with good results. The hyperbaric solution has been administered more frequently: the isobaric solution has received less attention. These two bupivacaine solutions have not been compared previously in children.

The aim of our study was to compare the use of isobaric and hyperbaric bupivacaine for spinal anaesthesia in paediatric day-case surgery. We assessed quality and spread of analgesia and anaesthesia, time to regression of sensory block by two dermatomes, total time to recovery from block and time required to reach the criteria for discharge from hospital.

Patients and methods
The study was approved by the Ethics Committee of Kuopio University Hospital and conducted in accordance with the Declaration of Helsinki. Parents of the patients and children old enough to understand the study gave informed consent. We studied 100 children, ASA I–II, aged 2–115 months, undergoing day-case surgery. Patients with known contraindications to spinal puncture, such as increased intracranial pressure, haemorrhagic diathesis or infection at the puncture site were excluded. Children with a neurological disorder or allergy to bupivacaine or other local anaesthetics were also excluded.

We used a double-blind, randomized, parallel group, prospective study design. Patients were allocated randomly to receive spinal anaesthesia with either isobaric (in normal saline) or hyperbaric (in 8% glucose) bupivacaine 5 mg ml⁻¹ (Astra, Sweden). A block randomization method of four children at a time was used to keep the number of subjects...
balanced in the two groups. A dose of 0.5 mg kg$^{-1}$ was used for children less than 10 kg, 0.4 mg kg$^{-1}$ for children weighing 11–19 kg and 0.3 mg kg$^{-1}$ for those more than 20 kg. The doses selected were based on previous studies with spinal anaesthesia where children weighing less than 10 kg needed more bupivacaine than those weighing more than 20 kg to achieve the same height and duration of block.\textsuperscript{24} Commercial ampoules with erased drug names were prepared and coded in the hospital pharmacy. Their identical appearance allowed blinding of the study. One study ampoule (No. 48) was accidentally broken. The next ampoule and study number were used for that child. The pharmacy prepared a new No. 48 ampoule which was used for the next child who entered the study and was coded as study No. 48.

Children were not allowed solid food or milk products for 4–6 h before anaesthesia. Clear fluids were allowed up to 2 h before induction of anaesthesia. Each child was premedicated with diazepam 0.5 mg kg$^{-1}$ orally, up to a maximum dose of 10 mg. EMLA cream was used at the lumbar and venepuncture sites. An infusion consisting of 0.9% saline was given at 10 ml kg$^{-1}$ h$^{-1}$. Children breathed room air spontaneously for as long as $\text{SpO}_2$ remained >90%. I.v. ketoprofen 2 mg kg$^{-1}$ or rectal paracetamol 40 mg kg$^{-1}$, or both, was given for pre-emptive pain treatment.

Intraoperative monitoring consisted of non-invasive arterial pressure measurements every 5 min, continuous ECG, ventilatory frequency, peripheral arterial oxygen saturation ($\text{SpO}_2$) and end-tidal carbon dioxide concentration, using a nasal adapter. Appropriate treatment was given if systolic arterial pressure decreased to less than 75% of preoperative levels, if heart rate decreased to less than 75% of baseline, if the $\text{SpO}_2$ decreased to less than 90% breathing room air or if end-tidal carbon dioxide partial pressure increased to more than 7 kPa. All adverse effects were recorded.

Children who were anxious or felt uncomfortable after premedication or during operation were sedated with an i.v. bolus of thiopental (thiopentone) 2–3 mg kg$^{-1}$ followed by 1 mg kg$^{-1}$ as needed, or propofol 0.5–1 mg kg$^{-1}$ followed by infusion of 2–4 mg kg$^{-1}$ h$^{-1}$. Sedation was used in 97 children (74 children received propofol and 23 thiopental). Sedated children had a similar distribution in both groups. Seventy-two children were sedated before, and 25 after, lumbar puncture, with a similar frequency in each group. The most common reason for sedation was the young age of the child (79 cases). Seven children were sedated because they were anxious and 11 children expressed the wish to be sedated during operation. All sedated children were monitored closely by the anaesthetist or by an anaesthetic nurse using intraoperative monitoring.

All spinal blocks were performed by the same anaesthetist (H. K.). Lumbar puncture was performed in the lateral decubitus position using a midline approach at the L3–4 or L4–5 interspace. Paediatric spinal needles (50-mm long, 25-gauge Quincke; 25-mm long, 26-gauge Atracanacl; 37-mm long, 27-gauge Whitacre; or 35-mm long, 24-gauge Sprotte) without an introducer were used for spinal puncture. The bevel of the needle was facing laterally, parallel to the longitudinal dural fibres. Correct placement of the spinal needle was verified by free flow of cerebrospinal fluid (CSF). After injection of local anaesthetic, free back flow of CSF was again verified and the child was placed in the supine, horizontal position.

If there were signs of inadequate anaesthesia (reaction to skin incision, increase in heart rate, arterial pressure or ventilatory frequency) i.v. fentanyl or general anaesthesia was given for supplementary analgesia. This was recorded and the case designated as failed spinal block.

An electric stimulator (Microstim Plus, Neuro Technology, Houston, TX, USA) was used to evaluate the width of the analgesic area, 15 and 30 min after injection of the anaesthetic. The metal electrodes of the device were moved in a rostral direction along the surface of the trunk using continuous high-frequency stimulation (50 Hz, pulse width 0.2 ms, amplitude 30–60 mA) until the patient responded, indicating the upper border of the anaesthetic area. Amplitude was adjusted to the lowest level so that the response could just be elicited. The procedure was repeated until the level of the first unanaesthetized segment was confirmed. Motor block was assessed using a modified Bromage scale recording the child’s ability to flex the ankle, knee and hip (0 = no motor block, 3 = complete motor block of the legs and feet).

After operation, children were transferred to the post-anaesthesia care unit (PACU) for continuous monitoring of vital signs and regression of block. Time to regression of block by two segments was tested every 5 min and the time recorded. All adverse effects were recorded. If the child was in pain, fentanyl 1 $\mu$g kg$^{-1}$ i.v. was given and the time recorded.

Patients were discharged from hospital when they were awake, able to walk unaided, had stable vital signs for at least 1 h, no pain or only mild pain, no nausea or vomiting and were able to tolerate clear fluids. Time to reach these criteria was recorded.

Power analysis suggested that 48 children would be needed in each group for a 90% chance at the 0.05 level of significance of detecting a 10% difference in success rate between groups. Statistical tests used for categorical data were chi-square test and Fisher’s exact test. For continuous data, analysis of variance (ANOVA) and Student’s $t$ test were applied to test the significance between means. Linear association between independent variables was tested by Pearson’s correlation. Results are presented as mean (SD), median, number (%) of cases and range or 95% confidence intervals for differences (95% CI), as appropriate. The level of significance was set at $P<0.05$.

Results

The groups were comparable in patient characteristics (table 1), procedures performed (table 2) and in the characteristics of spinal puncture (table 3).

The success rate of spinal block was higher in the hyperbaric compared with the isobaric group ($P=0.025$, 95% CI for difference 0–28%) (table 4). One child in the isobaric group did not develop sensory block and was excluded from analysis.

There was wide variation in cephalad spread of sensory block in both groups (table 5). Cephalad
spread of anaesthesia did not correlate with the age of the child or dose of bupivacaine used.

In the isobaric group, time to regression of sensory block by two dermatomes correlated with the interspace used for spinal puncture ($r_{p} = 0.35, P = 0.025$). In the hyperbaric group, there was no such correlation ($r_{p} = 0.07, P = 0.65$). There was no correlation between regression of block by two dermatomes and height of the initial block in either the hyperbaric ($r_{p} = 0.35, P = 0.053$) or isobaric ($r_{p} = 0.28, P = 0.13$) group.

Duration of sensory block did not correlate with either dose of bupivacaine or age of the child.

Fentanyl was administered to 52 children in the PACU for analgesia: 27 (55%) in the isobaric group and 25 (50%) in the hyperbaric group (table 5). Time to the first dose of analgesic was similar in both groups.

Oxygen was administered to two children in the isobaric group and to eight in the hyperbaric group because $SpO_2$ decreased to less than 90%. One child in the hyperbaric group was given one dose of etilefrin (Effortil, Boehringer Ingelheim, Ingelheim am Rhein, Germany) during operation for hypotension. One child in the isobaric group was administered atropine in the PACU to treat bradycardia. One child in the isobaric group and three children in the hyperbaric group experienced shivering in the PACU. There were no differences between groups in the incidence of adverse effects.

All children met the criteria for discharge from hospital within 7 h after spinal puncture. Median time was 220 min in the isobaric group and 205 min in the hyperbaric group. Three children in the isobaric group and two in the hyperbaric group developed a position-dependent headache with a duration of 1–3 days. One child also had stiffness in the neck, nausea, vomiting and fever. All headaches were mild and no epidural blood patches were performed.
Discussion

In this study, the success rate of spinal anaesthesia was high with both isobaric and hyperbaric bupivacaine. One spinal anaesthetic failed and general anaesthesia was required. In another, spinal anaesthesia was converted to general anaesthesia because surgery outlasted the duration of sensory block. As neither thiopental nor propofol have analgesic properties at subanaesthetic doses, the use of light sedation did not mask possible failed blocks. Sedatives are required frequently during regional anaesthesia, and this is especially true in small children, to produce a calm, compliant patient. However, deep sedation is contraindicated as the presence of paralgesia during needle placement may not be identified, increasing the risk of persistent neurological injury.

Several techniques have been used in children to assess the width of sensory block, such as reaction to skin incision, cold stimulus with ice, presence of pinprick or touch sensation, and somatosensory evoked potentials. In this study, transcutaneous electrical stimulation (TES) was used to measure the anaesthetic area achieved with spinal block. TES has been found to be equivalent to surgical incision. TES is a reproducible stimulus and may be better than pinprick for assessment of height and duration of surgical anaesthesia in sedated children. However, it is most important to reduce the amplitude to the lowest possible to avoid unnecessary distress.

Onset of spinal block with bupivacaine in infants has been reported to be fast (<2 min). In this study, onset time was not measured. However, the impression was that in the age group 1–7 yr, onset time was prolonged as most of the nine children in whom fentanyl or a sedative was administered because of mild reactions to skin incision, had complete block by the end of surgery. In adults, Sanderson and colleagues observed that onset of spinal block with bupivacaine in 8% glucose was faster than that with plain bupivacaine. This may also be true in children, as more supplementation was needed in the isobaric group. The possible slow onset time of spinal block must be taken into account when test doses are used in epidural anaesthesia in children. Delayed spinal anaesthesia may develop but still not be complete after 30 min. Onset time of sensory block with intrathecal bupivacaine in children needs further study.

Spread and duration of anaesthesia were similar but variable and unpredictable with both isobaric and hyperbaric bupivacaine. In other studies using bupivacaine for spinal anaesthesia in children, a similar variability has been shown. With bupivacaine 0.3 mg kg\(^{-1}\), the mean upper level of sensory block was one segment lower than in our study. In children aged 1–5 yr given bupivacaine 0.4 mg kg\(^{-1}\), spread of anaesthesia was similar but duration of block was shorter compared with our study. In a study using isobaric bupivacaine 0.5 mg kg\(^{-1}\), mean segmental spread of sensory block was T3 after 15 min and had reached T2 after 45 min. However, duration of block was similar to our study. Mitchell and co-workers compared hyperbaric and isobaric bupivacaine in adults at a dose of 0.42 mg kg\(^{-1}\). They found no differences between the groups in mean spread or duration of spinal block but the upper level of block varied widely from C8 to T11 with both solutions.

The degree of motor block in this study was similar to that in previous studies in children and adults, confirming that spinal anaesthesia with bupivacaine produces adequate relaxation for surgery below the umbilicus. However, as the shortest duration of sensory block may be less than 60 min, the anaesthetist must always be prepared to deal with inadequate block and be able to convert to general anaesthesia if the surgery is prolonged and outlasts the block.

Cardiovascular alterations, hypotension and bradycardia, are normal physiological responses during spinal anaesthesia because of sympathetic fibre blockade. In children, cardiovascular stability during spinal anaesthesia is good. It has been recommended that \(\text{SpO}_2\) should remain >94%. However, in 10% of children, \(\text{SpO}_2\) decreased to less than 90% on room air. This emphasizes the necessity for appropriate respiratory monitoring and administration of supplementary oxygen in all patients undergoing surgical procedures under regional anaesthesia with sedation. In addition, it is our practice to monitor ventilation by measuring end-tidal carbon dioxide partial pressure using a nasal adaptor.

In summary, we have demonstrated that the use of spinal anaesthesia in paediatric day cases was associated with a 10% failure rate and a relatively low incidence of adverse effects. However, further work is required to determine if the use of spinal anaesthesia alone in children undergoing day-case surgery is associated with fewer adverse effects compared with general anaesthesia.

References