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A prospective, double-blind, randomized trial of caudal block using ropivacaine 0.2% with or without fentanyl 1 μg kg^{-1} in children

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Background. It has been reported that ropivacaine produces vasoconstriction in contrast to vasodilation produced by bupivacaine. It is possible that additives to ropivacaine can provide further analgesic advantages compared with bupivacaine. We thus evaluated whether the addition of fentanyl to ropivacaine prolonged the duration of analgesia after a single shot caudal block.

Methods. A total of 36 children undergoing surgical procedures below the umbilicus were randomly allocated to one of two groups: Group F received ropivacaine 0.2%, 1 ml kg^{-1} with fentanyl 1 μg kg^{-1} and Group S received ropivacaine 0.2%, 1 ml kg^{-1} with saline. The analgesic effect of the caudal block was evaluated using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) and sedation was assessed using the Steward score at 30 min after extubation and at 1, 2, 4, 6, 12 and 24 h. The first analgesic requirement time and side-effects in a 24 h period were also recorded.

Results. There were no differences in characteristics between the groups. The end-tidal concentration of sevoflurane at extubation in Group F was significantly lower than in Group S. However, there was no significant difference in time from discontinuation of the volatile anaesthetics to tracheal extubation. No statistical differences were found in the CHEOPS and Steward score, and the time to first analgesia. The incidence of postoperative vomiting was not significantly different.

Conclusion. We found that the addition of fentanyl 1 μg kg^{-1} to ropivacaine 0.2% for caudal analgesia provides no further analgesic advantages over ropivacaine 0.2% alone.

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Introduction

Single shot caudal block is used commonly in paediatric patients. The duration of surgical analgesia provided by single shot of local anaesthetics is limited. Thus, addition of various drugs, such as clonidine,[1–3] ketamine[4] or opioids,[2 3 5–7] to local anaesthetics have been used to prolong the pain-free period. Fentanyl is one of the common adjuvants with local anaesthetics[8] and the effect of adding fentanyl to local anaesthetics has been reported. Caudal block with bupivacaine 0.25% and fentanyl 1 μg kg^{-1} provides no further analgesic advantages to bupivacaine alone.[6 7] On the other hand, addition of fentanyl 1 μg kg^{-1} to the mixture of local anaesthetics (bupivacaine 0.25% with epinephrine and lidocaine 1% in equal parts) prolonged the duration of postoperative analgesia.[2] Vasoconstrictive property of epinephrine might contribute to prolong the duration of analgesia. It has been reported that ropivacaine produces vasoconstriction in contrast to vasodilation produced by bupivacaine.[9–11] Thus, it is possible that addictives to ropivacaine can provide further analgesic advantages compared with bupivacaine. In this prospective, randomized, double-blind study, we evaluated whether the addition of fentanyl 1 μg kg^{-1} to ropivacaine prolonged the duration of analgesia after a single shot caudal block.

Methods

After obtaining Institutional Ethics Committee approval and written informed parental consent, ASA I–II, 36 boys aged 3–7 yr scheduled to undergo surgical procedures below the umbilicus were enrolled in the study. Patients were excluded if a history of allergic reactions to local anaesthetics, bleeding diathesis, contraindications to caudal anaesthesia, or pre-existing neurological or spinal disease was present. The study used a prospective, randomized, double-blind design.

Children were premedicated 30 min before surgery with midazolam 0.5 mg kg^{-1} orally. In the operating room, the patient was prepared for arterial pressure (non-invasive), peripheral oxygen saturation (Sp_{O_2}) and electrocardiographic monitoring. Anaesthesia was induced by facemask with sevoflurane and nitrous oxide 66% in oxygen. After placement of an i.v. cannula, the trachea was intubated without the use of a neuromuscular blocking agent and the lungs were ventilated mechanically. Anaesthesia was maintained with sevoflurane (0.6 MAC corrected for age) and nitrous oxide 66%. We measured end-tidal sevoflurane concentration using calibrated Capnomac Ultima (Datex, Finland). Caudal anaesthesia was performed in the lateral position with 25 gauge Axillary Block Needle (Becton Dickinson, USA) and one of the two different mixtures described below was administered.

Children were allocated randomly in one of two groups by opening a sealed envelope. Group F received 1 ml kg^{-1} of ropivacaine 0.2% and fentanyl 1 μg kg^{-1} and Group S received 1 ml kg^{-1} of ropivacaine 0.2% and saline 0.02 ml kg^{-1}. The maximum volume of ropivacaine 0.2% was 30 ml; patients >30 kg were excluded so that all subjects received an equivalent dose by weight. Caudal solution was prepared by another anaesthesiologist who was not involved in the study.

Heart rate (HR), mean arterial pressure (MAP) and Sp_{O_2} were recorded before induction, after induction and then 5 min after caudal anaesthesia. During surgery, adequate analgesia was defined by haemodynamic stability, as indicated by the absence of an increase in MAP or HR of more than 15% compared with baseline values obtained just before the surgical incision. If HR or MAP increased by more than 15%, analgesia was considered inadequate and subsequent data obtained from those children were no longer considered. During surgery, children received acetate Ringer's solution 5 ml kg^{-1} h^{-1}. Time from discontinuing the volatile anaesthetic to tracheal extubation and end-tidal sevoflurane concentration at extubation were recorded.

MAP, HR and Sp_{O_2} values were recorded 30 min after extubation and at 1, 2, 4, 6, 12 and 24 h. The analgesic effect of caudal block was evaluated using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS[12]) 30 min after extubation and at 1, 2, 4, 6, 12 and 24 h. When the CHEOPS score was greater than 6, analgesic was given in previous studies.[2 3] In the present study, if the patient's CHEOPS was greater than 6, or if the patient complained of pain at the surgical site, i.v. pentazocine (0.3 mg kg^{-1}) was administered. If no pentazocine was necessary within 24 h, the duration of analgesia was counted as 24 h. No analgesics other than i.v. pentazocine were given in the study period. In addition, sedation was assessed using Steward score[13] 30 min after extubation and at hours 1, 2, 4 and 6. Recovery criteria were met when a Steward score of 6 was achieved. All measurements were recorded by the same anaesthesiologist who did not know which medication was administered. The incidence of side-effects (vomiting and pruritus) was recorded. Finally, global assessment of the duration of effective analgesia was performed by comparing the time from caudal block to administration of the first analgesic.

Statistical analysis

Power analysis for duration of analgesia was calculated by referring the previous study.[14] Fourteen patients in each group allows a >95% chance of rejecting the null hypothesis (Group S patients would require a rescue analgesic medication within 8 h and Group F patients would require a rescue analgesic within 16 h, SD=5 h) at the usual level of significance (α=0.05). Patients' characteristics, duration of surgery and anaesthesia, time to extubation, the end-tidal concentration of sevoflurane at extubation and time to first analgesics were analysed for independent samples using the *t*-test. The Mann–Whitney *U*-test was used to compare means of sedation and pain score at each time point.

Results

One subject in Group F was excluded from analysis because he was very agitated at emergence and midazolam was administered i.v. in the operating room. No patient demonstrated signs of a failed block. Data from 35 children were analysed. There were no differences between the groups in terms of age, height, weight, duration of surgery or duration of anaesthesia (Table 1). There were no differences between the groups in haemodynamic and respiratory parameters (data not shown). The end-tidal concentration of sevoflurane at extubation in Group F [mean (SD), 0.33 (0.079)%] was significantly lower than in Group S [0.38

Table 1 Patient demographics and clinical data. Data are presented as mean (range) or (SD). There were no differences between the groups

	Group F (*n*=17)	Group S (*n*=18)
Age (months)	48.1 (36–83)	51.6 (36–85)
Height (cm)	100 (8.6)	101 (8.7)
Weight (kg)	15.4 (2.3)	16.5 (2.9)
Duration of surgery (min)	124 (44)	133 (56)
Duration of anaesthesia (min)	172 (48)	184 (58)
Type of surgery		
Hypospadias repair	12	14
Orchiopexy	3	2
Correction of vesicoureteral reflux	2	2