Asian Biomedicine Vol. 5 No. 1 February 2011; 93-99 DOI: 10.5372/1905-7415.0501.011

Original article

Caudal block with 3 mg/Kg Bupivacaine for intra-abdominal surgery in pediatric patients: a randomized study

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Background: Caudal block with the use of an adequate dose of bupivacaine, and combined with a general anesthesia (GA) provides intra-operative anesthesia and postoperative analgesia. No study has examined the use of 3 mg/Kg bupivacaine for intra-abdominal surgery in pediatric patients in clinical practice.

Objective: Compare the effectiveness of three mg/Kg bupivacaine administered as 1.2 mL/Kg 0.25% bupivacaine and 1.5 mL/Kg 0.2% bupivacaine for caudal block in pediatric patients undergoing intra-abdominal surgery.

Methods: In a randomized, double-blinded clinical trial, patients (age: 6 months -7 years) were randomly assigned into one of two groups (n= 40) to receive a caudal block with either 1.2 mL/Kg 0.25% bupivacaine (group A) or 1.5 mL/Kg 0.2% bupivacaine (group B), with morphine 50 μg/Kg. The effectiveness of intra-operative anesthesia, complications, and requirements for post-operative analgesia were evaluated.

Results: Data were available for 74 pediatric patients. There were no significant differences between the two groups in baseline characteristics. Intra-operatively, the numbers of patients who required a rescue analgesic were comparable between the groups (67% in group A and 63% in group B). The numbers of patients who required a muscle relaxant were also comparable between groups (49% in group A and 57% in group B). The time from discontinuation of the volatile anesthetic to extubation was significantly shorter in group B (9.5±1.1 minutes) than group A (14.3±0.9 minutes), $p < 0.01$. The time from initial caudal block to the first analgesic required in the recovery room was significantly longer in group B (202±45 minutes) than in group A (149±27 minutes). The time from the caudal block to the first analgesic required in the ward was significantly longer in group B (10.4±3.1 hours) than in group A (8.2±2.0 hours). Overall fentanyl requirements were comparable between groups, 52.5±2.0 μg in group A and 49.5±3.0 μg in group B.

Conclusion: Caudal block by either 1.2 mL/Kg 0.25% bupivacaine plus morphine 50 μg/Kg or 1.5 mL/Kg 0.2% bupivacaine plus morphine 50 μg/Kg provided effectively equivalent intra-operative analgesia and surgical relaxation. However, a caudal block with 1.5 mL/Kg 0.2% bupivacaine plus morphine 50 μg/Kg provided superior prolonged analgesic advantages compared with 1.2 mL/Kg 0.25% bupivacaine plus morphine 50 μg/Kg in pediatric patients undergoing intra-abdominal surgery.

Keywords: Bupivacaine, caudal block, effectiveness, intra-abdominal surgery, pediatric patients, postoperative analgesia

Caudal block has been shown to be safe in various pediatric lower body surgical procedures [1-8]. It is usually combined with a general anesthesia (GA) that provides intra-operative anesthesia (analgesia and muscle relaxation) and postoperative analgesia, when used with an adequate dose of local anesthetic. The three principal

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dosing factors to be considered in caudal solutions are the volume, concentration, and total drug mass of the local anesthetic in a clinically safe dose. The volume administered is determined by the dermatome to be anesthetized, and the concentration required is determined by the degree of surgical relaxation needed. The total drug mass (volume x concentration) is the most important in establishing successful caudal anesthesia. To provide adequate anesthesia for intra-abdominal surgery, a greater initial total drug mass with adjusted volume and concentration of caudal solution must be administered to ensure a successful initial block.

In Thai pediatric patients that underwent intra-abdominal surgery, a strong opioid and/or muscle relaxant are often supplemented intra-operatively under GA combined with 0.25% bupivacaine of caudal block. Previous studies have demonstrated that 0.25% bupivacaine administered at higher doses of 3-5 mg/Kg is generally safe [7, 9, 10], while Breschan et al. [11] found systemic toxicity at a dose of 3.1 mg/Kg. According to Eyres et al. [12], caudal administration of 0.25% bupivacaine in a dose of 3 mg/Kg in pediatric patients produces plasma levels less than 2 μg/mL, which is very safe. However, no study has explicitly examined the use of 3 mg/Kg bupivacaine for intra-abdominal surgery in pediatric patients in clinical practice.

Between 2002 and 2003, at the Department of Anesthesiology, Songklanagarind Hospital, Thailand, we had 109 pediatric patients that underwent intra-abdominal surgery under GA combined with 0.25% bupivacaine of caudal block. Approximately 65% of them required a supplement of a strong opioid and/or muscle relaxant intra-operatively. In this study, we evaluated the effectiveness of a constant drug mass of 3 mg/Kg bupivacaine, administered as a caudal block and varied concentration and volume in two groups, by comparing 1.2 mL/Kg 0.25% bupivacaine and 1.5 mL/Kg 0.2% bupivacaine in pediatric patients undergoing intra-abdominal surgery (exploratory laparotomy). The effectiveness of intra-operative analgesia, abdominal muscle relaxation, and complications were considered as primary outcomes, with requirements for post-operative analgesia considered as a secondary outcome.

Materials and methods

Patients

This study was approved by Ethics Committees of the Faculty of Medicine, Prince of Songkla University. Written informed consent from the parents or guardians was obtained.

We recruited 80 pediatric patients, aged from six months to seven years, who were classified into the American Society of Anesthesiologists (ASA) physical status I or II. They were scheduled to undergo elective intra-abdominal surgery between November 2004 and September 2009. All were scheduled to receive GA combined with caudal block. Patients were excluded if a history of allergic reaction to local anesthetics, bleeding diathesis, contraindications to caudal block, or preexisting neurological or spinal disease were present.

Anesthesia technique and caudal block

All patients were fasted six hours prior to anesthesia. After applying standard monitors, GA was induced either by facemask with sevoflurane and 66% nitrous oxide in oxygen or by intravenous (*iv*) 5-7 mg/Kg of thiopental. Succinylcholine 1 mg/Kg *iv* was given to facilitate tracheal intubation. Anesthesia was maintained with isoflurane and 40% oxygen in air. The caudal block was performed in the lateral decubitus position under aseptic conditions. A 22-G short-bevel needle was inserted through the sacro-coccygeal membrane until loss of resistance was detected, followed by gentle aspiration to detect absence of either cerebrospinal fluid or blood. One of two different mixtures was then administered on a patient's weight-related basis into the caudal space. The total volume was administered not less than one minute after negative test dosing. Two anesthesiologists were involved in the study. One anesthesiologist, blinded to group allocation, performed the GA, clinical care, and data collection. The second anesthesiologist, unconnected with clinical care and data collection, performed the caudal blocks.

Clinical trial

The patients were randomly allocated to receive either 1.2 mL/Kg of 0.25% bupivacaine (Marcain®, AstraZeneca, Sydney, Australia) with 50 μg/Kg preservative-free morphine (Group A, n = 40); or 1.5 mL/Kg of 0.2% bupivacaine with 50 μg/Kg preservative-free morphine (Group B, n = 40) in a double-blinded fashion. All caudal solutions were freshly prepared with 5 μg of epinephrine added per mL of caudal solution. A 0.9% normal saline solution was used as diluents if needed. The surgical incisions

were started not less than 10 minutes after caudal administration to ensure complete caudal blocks. Patients received no further analgesics or muscle relaxants unless, in the judgment of the attending anesthesiologist, the caudal block was ineffective.

During surgery, the children received 5% dextrose in 0.33% normal saline given at a rate of 2 mL/Kg/h, plus a balanced salt solution, given at a rate of 10 mL/Kg/h for replacement of the ongoing fluid loss. Heart rate (HR) and systolic blood pressure (SBP) were recorded before induction, before incision (baseline values), at five minutes intervals until the surgery ended, arrival at the recovery room (RR) and discharge ward, after the beginning of the caudal block. For each procedure, we recorded time-duration of anesthesia and surgery, and time-duration from discontinuation of the volatile anesthetic to extubation. At the end of the surgery, the neuromuscular blockade, if used, was antagonized with neostigmine 0.05 mg/Kg and atropine 0.02 mg/Kg. Then, conventional extubation was done and the patients were transferred to the RR.

In the RR, the patients were evaluated at 15 minutes intervals for their hemodynamic state after their surgery. Pain was assessed with the Face, Legs, Activity, Crying, and Consolability (FLACC) observational pain score instrument [13] every 15 minutes for the first two hours by one of the nurse anesthetists who were unaware of the study randomization. Patients with a pain score greater than 3 were treated with *iv* fentanyl 0.5 μg/Kg, repeated at 15-minute intervals if the pain score remained unchanged. The overall fentanyl requirements were recorded. Sedation was assessed using a three-point sedation score (0 = awake, 1 = drowsy, 2 = asleep) at 30, 60, 90 and 120 minutes after extubation. Motor block of the lower extremities was assessed using a three-point motor power score (0=unable to move, 1= possible to move, horizontal movement, 2= raise legs) at 30, 60, 90, and 120 minutes after extubation. The degree of recovery from GA was assessed using the Aldrete's recovery score [14], and the patient was discharged from the RR and transferred into the ward when they achieved a score of ≥ 9. Patients had their pain and sedation assessed every four hours for 24 hours postoperatively.

Outcome measurements

For the primary outcomes, an inadequate analgesia was defined by an increased HR or SBP of more than 30% of baseline values, at the start of the procedure with the 1.5 minimal alveolar isoflurane concentrations. The patient was given supplementary *iv* fentanyl during the operation. If the abdominal muscle relaxation was considered inadequate by the evaluation of the surgeon on the peritoneal and abdominal muscle traction, the patient was given a supplementary *iv* muscle relaxant (atracurium or cis-atracurium) during the operation. For the secondary outcome, the effectiveness of post-operative analgesia was assessed by the 24 hours of postoperative pain scores and the time of the first requirement of fentanyl in the RR and at the ward.

Safety outcomes were evaluated by the occurrence of hypotension, bradycardia, oxygen de-saturation, or cardiac arrest. Hypotension was defined as SBP less than 70% of baseline SBP and was treated by increasing the rate of *iv* fluid infused, lower inhalation concentration or *iv* ephedrine 0.1 mg/Kg every one minute as required to keep the SBP above 70% of baseline values. Bradycardia was defined as HR less than 60 beats/min and was treated by *iv* atropine 0.02 mg/Kg. Oxygen de-saturation was defined as peripheral oxygen saturation <95% and was treated according to the cause.

Statistical analysis

The sample size for this study was 80 children, based on a review of caudal 1 mL/Kg 0.25% bupivacaine with an incidence of failed effectiveness during surgery. Considering a 50% reduction of patients that needed a rescue dose of *iv* analgesic and assuming a two-sided type 1 error of 0.05 and power of 0.8, 40 children were required in each group to demonstrate a significant difference in the block's effectiveness during surgery.

Patients scheduled for intra-abdominal surgery were enrolled consecutively. Randomization was performed by computer generation.

Data were presented as mean ± standard deviation (SD) or median (inter-quartile ranges IQR) and qualitative data as frequency (number) and percentage (%). Data were compared by unpaired t-test and the Mann-Whitney U test for independent continuous variables. A value of $p < 0.05$ was considered statistically significant. Data were analyzed with SPSS version16 for Windows.

Results

Three patients in group B were excluded because

of protocol violations (patients received fentanyl or atracurium before caudal administration, which would have affected the data analysis. Another three patients did not complete the study because of failure of the caudal block (one in group A and two in group B), leaving data from 74 children in the final analysis, 39 in group A and 35 in group B. There were no significant differences among the groups in sex, age, weight, ASA classification, duration of surgery, duration of anesthesia, time-duration from caudal block to incision, baseline HR and SBP and surgical incision between the groups ($p > 0.05$) **(Table 1)**.

There were no differences between the groups in HR and SBP during the procedures. Compared with baseline values, a small insignificant reduction in HR and SBP was observed in both groups after the caudal block, which was followed by a significant increase greater than 30% above baseline values during the time of incision or/and peritoneal traction. The average HR and SBP were maintained thereafter with a slight increase during emergence from GA and recovery period.

Table 2 shows intra-operative and post-operative clinical outcomes and complications. Intra-operatively, the number of patients who required a rescue analgesic was comparable between groups. The number of patients requiring a muscle relaxant was also comparable between groups. Excluding three children who were kept intubated postoperatively and one patient who was re-intubated in PACU, the time from discontinuation of the volatile anesthetic to extubation was shorter in group B than in group A. Post-operatively, the number of patients who had a FLACC score > 3 in the RR was comparable between groups. The average time-duration from the caudal block to the first analgesic required in the recovery room was significantly longer in group B than in group A. The average time-duration from the caudal block to the first analgesic required in the ward was significantly longer in group B than in group A.

Table 3 shows post-operative pain scores. Overall fentanyl requirements were comparable between groups. The postoperative pain scores were significantly lower in group B at 8 and 12 hours, compared with group A. We note no significant differences between the groups in post-operative sedation scores.

The number of patients with vomiting was 8/36 (22%) in group A and 6/34 (17.6%) in group B, which was not statistically significantly different ($p > 0.05$). After excluding the patients who required retained urinary catheterization postoperatively, the number of patients with urinary retention was 7/22 (32%) in group A, and 8/20 (40%) in group B, which was not statistically significantly different ($p > 0.05$). No other side effects were seen.

Table 1. Patient characteristics.

	Group A (n=39)	Group B (n=35)
Sex (male: female)	27:12	25:10
Age (months)*	35.5±4.2	38.2±3.7
Weight (Kg) *	12.6±1.1	11.3±0.7
ASA classification (I:II) (number)	18:21	14:11
Duration of surgery (minute)*	86±11	98±15
Duration of anesthesia (minute)*	115±13.6	125±17.4
Time from caudal block to incision (minute)*	13.3±2.1	15.7±1.7
Baseline HR (beat/min)*	125.0±22.1	133.4±25.1
Baseline SBP (mmHg)*	100.4±9.9	96.9±3.7
Surgical incision (number)		
Midline-below umbilicus	21	17
Right sub-costal	5	7
Transverse-below umbilicus	2	1
Lumbotomy (flank)	1	0

*Data are mean ± SD. There were no significant differences between groups. Group A: 1.2 mL/Kg 0.25% bupivacaine, Group B: 1.5 mL/Kg 0.2% bupivacaine.

Table 2. Intra-operative and postoperative clinical outcomes and complications.

	Group A (n=39)	Group B (n=35)
Patients requiring rescue analgesic (number,%)	26 (67)	22 (63)
Patients requiring muscle relaxant (number,%)	19 (49)	20 (57)
Time from discontinuing inhalation anesthetic to extubation (minute)**+	14.3±0.9 ⊥	9.5±1.1 ⊥
FLACC > 3 in RR (number)	14	11
First fentanyl required in RR (minute)*	149±27 ⊥	202±45 ⊥
Sedation score #	1 (0-2)	1 (0-2)
Motor power score #	1 (0-2)	1 (0-2)
First fentanyl required on ward (hour)*	8.2±2.0 ⊥	10.4±3.1 ⊥
Overall fentanyl dosages (μg)*	52.5±2.0	49.5±3.0
Complications (number)		
Hypotension	0	0
Bradycardia	0	0
Oxygen de-saturation	2	4
Cardiac arrest	0	0

*Data are mean ± SD, # Data are median (IQR). Group A: 1.2 mL/Kg 0.25% bupivacaine, Group B: 1.5 mL/Kg 0.2% bupivacaine. First analgesic required in RR and on ward represents the interval between caudal block and first fentanyl administration in RR and on ward, respectively. ⊥p <0.05, +Group A (n=36) and group B (n=34).

Table 3. Post-operative pain scores.

Pain score	Group A (n=39)	Group B (n=35)
On arrival at ward	2 (0-4)	2 (0-5)
At 4 hour	2 (0-4)	2 (0-4)
At 8 hour	3 (0-6)	2 (0-4) ⊥
At 12 hour	3 (0-6)	2 (0-5) ⊥
At 16 hour	3 (0-4)	3 (0-4)
At 20 hour	4 (0-6)	3 (0-5)
At 24 hour	3 (0-4)	2 (0-4)

Pain scores are expressed as median (IQR), ⊥p <0.05. Group A: 1.2 mL/Kg 0.25% bupivacaine, Group B: 1.5 mL/Kg 0.2% bupivacaine.

Safety report

Specific adverse events from the procedural caudal block, such as detection of cerebrospinal fluid or vascular cannulation, were not observed. The occurrence of complications was comparable in both groups, as shown in **Table 2**. One patient had oxygen de-saturation to 88% during the period of anesthesia induction, caused by laryngeal spasm, with return to baseline values after positive pressure ventilation was applied. Four patients had oxygen de-saturation but not below 90% after tracheal extubation, with return to baseline values upon receiving oxygen supplementation. Three patients were kept intubated and admitted to the pediatric intensive care unit post-operatively because of a distended abdomen. One patient had respiratory depression and was re-intubated in the RR, because of a suspicion of opioid-induced respiratory depression, and was admitted to the PICU thereafter for mechanical ventilation. No patients experienced cardiac arrest.

Discussion

The present results showed that the patients with caudal 1.5 mL/Kg 0.2% bupivacaine had longer-lasting analgesia than those with 1.2 mL/Kg 0.25% bupivacaine. However, the clinical difference between

the therapies of the two groups was small, while patients with caudal 1.5 mL/Kg 0.2% bupivacaine had seemingly one hour of longer analgesia in the RR and two hours of longer analgesia afterwards.

This study is the first study to compare these modalities in pediatric patients undergoing intra-abdominal surgery. Previous studies evaluated the effectiveness of caudal blocks on peritoneal traction with comparable findings. Hong et al. [15] demonstrated that caudal administration of a high volume, low concentration (HVLC) local anesthetic provided longer postoperative analgesia than a low volume, high concentration (LVHC) regime in children undergoing orchiopexy. Verghese et al. [2] demonstrated that a HVLC caudal block is more effective than a LVHC administration in blocking the peritoneal response during spermatic cord traction during orchiopexy. These results are consistent with our results, suggesting that if a greater volume of bupivacaine is used for a caudal block, the post-operative outcome may be better, but not necessarily intra-operatively.

Volume per kilogram dosage produces a tight linear correlation with the number of dermatomes anesthetized [16]. Although 1 mL/Kg of LA administered caudally can spread to T10 [4], this level is not adequate for intra-abdominal surgery. However, McGown RG [3] reported that caudal block at a volume of 1.7 mL/Kg might provide an excessively high block, leading to cardiac arrest. Schrock et al. [17] and Gunter et al. [18] reported that at least 0.175% bupivacaine could provide adequate surgical relaxation for lower abdominal surgery. Therefore, our study had a rationale based on these previous studies in the two volumes of 1.2 mL/Kg and 1.5 mL/Kg, and two concentrations of 0.25% and 0.2% bupivacaine.

In all our patients, HR and SBP in both groups decreased (not significantly) during the first 60 minutes after the block. This was different from a study by Larousse et al. [19] where a caudal block with 1 mL/Kg 0.25% bupivacaine resulted in no changes in either HR or mean blood pressure. This difference might be because our use of 1.2 mL/Kg of 0.25% bupivacaine produces a wider dermatome spread, resulting in a drop in SBP and increase in HR. This should be noted in children with borderline hemodynamics. We noted a 3.75% failure of caudal block in our children, which is higher than 1% failure in the report of by Dalens et al. [20].

In conclusion, a caudal block by either 1.2 mL/Kg 0.25% bupivacaine or 1.5 mL/Kg 0.2% bupivacaine provides comparable intra-operative analgesia and surgical relaxation when administered immediately after induction of GA in children undergoing intra-abdominal surgery. However, the stronger caudal block of 1.5 mL/Kg 0.2% bupivacaine plus morphine 50 □g/Kg provided more prolonged post-operative analgesic advantages than the 1.2 mL/Kg 0.25% bupivacaine plus morphine 50 □g/Kg regimes. It is suggested that for intra-abdominal surgery, GA combined with a caudal block of 1.5 mL/Kg 0.2% bupivacaine plus morphine 50 □g/Kg is the anesthesia of choice.

Acknowledgements

This study was financially supported by the Faculty of Medicine, Prince of Songkla University. The authors wish to thank Dr. S. Nimmaanrat (Department of Anesthesiology, the Faculty of Medicine, Prince of Songkla University) for her comments on the manuscript, and Mr. Dave Patterson for his assistance with the English language.

The authors have no conflict of interest to report.

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