

# Caudal Ropivacaine Versus Bupivacaine For Paediatric Day-case Circumcision Procedures

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## Abstract

### Background

Ropivacaine is an aminoamide local anaesthetic allegedly characterised by less motor blockade, less neuro/cardiotoxicity but similar analgesic properties when compared with bupivacaine.

### Aim

This study was designed to compare the quality of caudal analgesia and incidence of motor blockade produced by ropivacaine versus bupivacaine in paediatric patients scheduled for elective circumcision in the ambulatory setting.

### Methods

A total of 112 patients, aged between 5 to 12 years were randomly allocated to receive 0.5 ml.kg<sup>-1</sup> of either caudal 0.2% ropivacaine or 0.2% bupivacaine through the caudal route following induction of general anaesthesia. Postoperative pain and motor blockade scores were assessed by a blinded investigator using the the visual analogue and modified Bromage scales respectively.

### Results

There were no significant differences in pain intensity and degree of motor blockade between the two groups upon awakening from anaesthesia, and 1- and 2 hours post-caudal injection. The times to unsupported ambulation and discharge were also similar for both groups.

## INTRODUCTION

Caudal anaesthesia is a useful adjunct to general anaesthesia for lower abdominal surgery in children as it provides for postoperative analgesia and reduces perioperative narcotic requirements. [1] Unfortunately, motor blockade resulting from caudal block may be a cause of distress to children in the postoperative period and could lead to delayed hospital discharge [2].

Bupivacaine has a well defined role in regional anaesthesia and analgesia for several years. However, ropivacaine allegedly offers a wider margin of safety, less motor blockade, less neuro/cardiotoxicity and similar duration of analgesia in comparison to bupivacaine. [1,3] These properties suggest advantages compared with bupivacaine

for regional anaesthesia and analgesia in the ambulatory setting and recent studies [4,5,6,7,8,9,10,11,12,13,14] have reported on its efficacy and safety in younger children.

The objective of this study was to compare the quality of caudal block and attendant side effects, especially motor block, using either ropivacaine or bupivacaine in equimolar dosages for paediatric patients scheduled for day-case elective circumcision procedures.

## METHODS

After obtaining institutional ethics committee approval and written parental consent, 112 unpremedicated, ASA class 1 and 2 patients, aged between 5 to 12 years, scheduled for elective circumcision were studied using a double blind

protocol. Randomisation was achieved using a computer generated random number sequence. Exclusion criteria include contraindications to caudal anaesthesia and inability to comprehend the visual analogue scale (VAS) scoring system.

The recruited patients were instructed on the proper use of the visual analogue sliding (VAS) scale [0 = no pain, 100 = worst pain imaginable] on arrival in the induction room. General anaesthesia was induced using either intravenous (IV) thiopentone 5mg/kg-1 or inhalation with 7% inspired sevoflurane. Anaesthesia was then maintained at an end-tidal (ET) sevoflurane concentration of 1 – 1.5% and 70% nitrous oxide in oxygen with the patients breathing spontaneously via a face mask. Continuous electrocardiograph, noninvasive blood pressure, heart rate, and pulse oximetry measurements were recorded at 3 minute intervals during the surgery. Haemoglobin oxygen saturation was kept above 95% and ET carbon dioxide levels between 30 – 45 mm Hg during the procedure.

All patients were randomised to receive caudal anaesthesia under general anaesthesia with 0.5 ml/kg-1 of either 0.2% bupivacaine or 0.2% ropivacaine by the attending anaesthetist. The time of caudal injection was noted and surgical incision was allowed after at least 5 minutes had elapsed subsequently. The caudal block would be deemed unsuccessful if there was a persistent increase of more than 30% in heart rate or mean arterial blood pressure values above baseline following surgical incision. These patients were given intravenous fentanyl 1 µg/kg-1 and were withdrawn from the study. At the end of surgery, all anaesthetics were stopped and 100% oxygen administered.

VAS pain scores and modified Bromage scores [0 = no motor block, 1 = inability to raise an extended leg, 2 = inability to flex knee nor raise an extended leg, 3 = inability to flex ankle, flex knee nor raise an extended leg] were elicited upon emergence from anaesthesia, and at 1- and 2 h post-caudal by a blinded investigator. Other adverse events such as nausea and vomiting were also noted.

Rescue medication (IV fentanyl 1 µg/kg-1) was administered if the VAS pain score exceeded 50 at any time. The times from caudal injection to first unsupported standing after anaesthesia and hospital discharge were also documented.

All patients were discharged home with syrup paracetamol with instructions that 10 mg.kg-1 be given at the first complain of pain. A telephone interview was made 24 hr

later to review the necessity for additional postoperative analgesics as well as to note the time when it was first served following hospital discharge.

### **STATISTICAL ANALYSIS**

Assuming that the incidence of bupivacaine induced motor blockade (modified Bromage score > 0) is 75% from previous studies [5,6], an a priori power analysis established that a sample size of 50 patients in each group would have 80% power of detecting a difference of 30% in motor block at a significance level of  $p < 0.05$  between the two groups.

Data analysis was performed using the Student's t-test for weight, age, unsupported walking time and hospital discharge time comparisons. The Mann-Whitney U test was used to compare VAS pain scores and the Chi-square test for analysing the incidence of rescue medication required. Results are presented as means SDs, numbers or percentages, and a p value of  $< 0.05$  was considered statistically significant.

### **RESULTS**

There were no statistically significant differences between the two groups with respect to demographic data and duration of surgery (table 1). Although a total of 115 patients were recruited for the study, 2 patients in the ropivacaine group and 1 patient from the bupivacaine group were withdrawn due to block failure.

VAS pain scores at all the study time intervals between the two groups were also not significantly different. (Table 2)

The incidence of patients requiring rescue fentanyl in the recovery room and the times (mean SD) to administration of rescue analgesia post-caudal were not statistically significant for the 2 study groups.

No significant motor block was evident (modified Bromage score = 0) in either study group during the study intervals. Neither were there any episodes of nausea or vomiting in either group. The patients did not experience haemodynamic instability (fall in MAP of 20 % from baseline) after caudal administration of the 2 study drugs.

There were also no significant differences between the unsupported walk time and hospital discharge times between the two groups (table 2).

Within the first 24 hr postoperative period, no patient required more than two doses of paracetamol. All the children slept well during the night after the operation and

were at their normal level of activity by the next day.

**Figure 1**

Table 1. Patient characteristics and duration of surgery

	Ropivacaine (n = 55)	Bupivacaine (n = 57)
Weight (age)	23 ± 6	24 ± 5
Age (mths)	85 ± 29	91 ± 24
Duration of surgery (mins)	10 ± 2	10 ± 2

**Figure 2**

Table 2. Visual analogue scale (VAS) scores for pain, proportion of patients requiring rescue analgesics, and times to requirement for rescue analgesics, unsupported walking and hospital discharge

	Ropivacaine (n = 55)	Bupivacaine (n = 57)
VAS pain scores		
At emergence	64 ± 21	65 ± 18
1 hr post-caudal	82 ± 18	66 ± 13
2 hr post-caudal	83 ± 15	76 ± 13
Requiring analgesics (%)	5	3
Time to:		
require analgesics (min)	47 ± 14	48 ± 11
unsupported walking (min)	120 ± 40	110 ± 30
hospital discharge (min)	180 ± 60	172 ± 50

**DISCUSSION**

When comparing postoperative analgesia conferred by caudal administration of either ropivacaine or bupivacaine, previous investigations produced equivocal results. Some showed superior postoperative analgesia [7] and a significantly lower incidence of motor block [5] with ropivacaine whereas the others [6, 11, 12] revealed no difference between ropivacaine and bupivacaine in terms of duration and quality of analgesia and motor block.

Our data suggest that 0.2% ropivacaine was similar to 0.2% bupivacaine in providing analgesia by the caudal route for circumcision in children with comparable motor sparing. Several early studies on epidurally-administered ropivacaine suggest that it produces less motor impairment than bupivacaine; [1]

however, recent work indicate that this is probably a potency-related rather than a drug-specific effect [15, 16]. Ropivacaine administered by the caudal route is reported to

be ~ 40% less potent than bupivacaine at equal doses [15], implying that when higher concentrations of ropivacaine are used for centroneuraxial blockade (at equipotent doses as bupivacaine), significant motor block and delayed hospital discharge may ensue. [2,14]

Most reports comparing perioperative pain relief and motor block with caudal ropivacaine versus bupivacaine in children studied concentrations of ( 0.25%. Da Conceicao and Coelho showed in two separate studies [5, 6] that there were no significant differences in pain scores three hours after surgery and no difference in time to first postoperative analgesia, but demonstrated a significant difference in the degree of motor block at 2, 3 and 4 hours after completion of surgery between ropivacaine and bupivacaine at 0.25% and 0.375% concentrations. In our study, we chose to compare ropivacaine and bupivacaine at a lower concentration of 0.2% to elicit if ropivacaine could produce effective sensory blockade with even less motor blockade, since significant motor block may be concentration-dependent. Ropivacaine is available in a 0.2% preparation in our hospital and 0.2% bupivacaine was obtained from diluting a 0.5% solution.

The difference in potency ratios of the two local anaesthetics may pose as a deficiency in our study which compared equimolar and not their equipotent dosages. Our data revealed that 0.2% ropivacaine appears to produce analgesic and motor sparing effects similar to 0.2% bupivacaine. However, we acknowledge that the more subjective modified Bromage scoring system rather than the more sensitive isometric motor testing with mechano-transducers was utilised. [17] Also, we found from our telephone interviews on the first postoperative day that there were no consistent caregivers for the patients following hospital discharge and paracetamol was served on an ad hoc basis rather than in response to pain. The time to first analgesia following discharge was thus not accurately indicative of the duration of caudal analgesia.

Given the established safety profile of ropivacaine in children and the salutary results obtained in our study, ropivacaine would seem a reasonable alternative to bupivacaine for regional anaesthesia in the paediatric patient. However, ropivacaine costs significantly more than bupivacaine (table 3) and its exclusive use may increase healthcare costs.

**Figure 3**

Table 3. Cost (in approximate US dollars) of the study drugs in our institution

0.2% ropivacaine 10 ml	\$ 6.20
0.5% bupivacaine 4 ml	\$ 1.50
0.5% bupivacaine 10 ml	\$ 2.30

In a recent literature synthesis comparing motor blockade from similar concentrations of ropivacaine and bupivacaine, only 23% of studies demonstrated a statistical reduction in motor block with ropivacaine. [18] Moreover, ropivacaine has also been reported to induce seizures and cardiac dysrhythmias [19] with inadvertant intravenous injection [20] so its so-called “safety” aspects may also be questionable.

In conclusion, the lower cost-effectiveness of ropivacaine demonstrated in our study, coupled with the lack of evidence suggesting that it produces less motor block than bupivacaine, suggest that it should not routinely supplant bupivacaine for paediatric circumcision procedures. Nevertheless, future studies should recruit more sensitive testing to elucidate the purported theoretical advantages of ropivacaine so that cost-outcome issues pertaining to these two drugs can be determined.

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