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Original Contribution

# A prospective study comparing the onset and analgesic efficacy of different concentrations of levobupivacaine with/without dexmedetomidine in young children undergoing caudal blockade☆,☆☆

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**Abstract**

**Study objective:** To investigate the onset and analgesic effect of adding dexmedetomidine to levobupivacaine for caudal block in young children.

**Design:** Randomized, prospective, double-blind study.

**Setting:** Women and Children Medical Center and university hospital.

**Patients:** Two hundred twelve children, American Society of Anesthesiologists physical status I or II, aged between 1 and 3 years and weighing between 8 and 18 kg, who were scheduled for elective inguinal hernia repair or hydrocele.

**Interventions:** Children were randomly allocated, using a computer-generated sequence of numbers, into 1 of 3 groups: caudal 0.25% levobupivacaine (Group $L_{0.25}$), caudal 0.20% levobupivacaine (Group $L_{0.20}$), or caudal 0.20% levobupivacaine plus 2 μg/kg dexmedetomidine (Group LD).

**Measurements and main results:** The primary end point of the study was the onset time of caudal levobupivacaine in children. The secondary end points of the study were the duration of analgesia and the degree of motor block in children. The 50% and 95% effective onset time (95% confidence interval) values of levobupivacaine were 8.19 minutes (7.30-9.08) and 11.17 minutes (9.44-12.91) in Group $L_{0.25}$, 10.16 minutes (8.90-11.41) and 15.85 minutes (13.14-18.57) in Group $L_{0.20}$, and 9.91 minutes (8.55-11.28) and 16.39 minutes (13.32-19.46) in Group LD, respectively. The mean durations of analgesia in these children were 7.23, 5.84, and 19.6 hours in Groups $L_{0.25}$, $L_{0.20}$, and LD, respectively. There were no significant differences in postoperative residual motor block among the 3 groups.

**Conclusions:** Dexmedetomidine added to levobupivacaine does not have a significant effect on the onset time; however, it prolongs the duration of analgesia during caudal block in children.



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## 1. Introduction

Caudal block is one of the most commonly used analgesic techniques for abdominal and lower limb surgery in children [1–3]. Bupivacaine, levobupivacaine, and ropivacaine, which are the long-acting agents, are most commonly encountered for caudal block. Also, various additives such as midazolam [1–3], neostigmine [1,3], opioids [4], ketamine [1–3], clonidine [4,5], and dexmedetomidine [5–7] have been used as adjuvant of local anesthetics to improve the analgesic efficacy of a single-shot caudal block.

Dexmedetomidine, a highly selective alpha-2 adrenoreceptor agonist, is approved as an analgesic and sedative drug. Caudal dexmedetomidine prolonged the duration of analgesia and reduced the minimum local anesthetic concentration of levobupivacaine during caudal blockade in children [8]. Dexmedetomidine added to levobupivacaine for axillary brachial plexus block shortened the onset time and prolonged the duration of postoperative analgesia [9]. However, no reported studies have evaluated the effect of caudal dexmedetomidine on the onset time of levobupivacaine for caudal block.

The aim of this prospective, randomized, double-blind study was to investigate the onset time, degree of motor blockade, and postoperative analgesic effects as well as adverse effects as a result of caudal block produced by 0.25% levobupivacaine, 0.20% levobupivacaine, or 0.20% levobupivacaine with 2 μg/kg dexmedetomidine.

## 2. Materials and methods

This clinical trial was conducted with the ethics committee approval of Guangzhou Women and Children Medical Center. For each pediatric patient, a written informed consent was obtained from his or her parents or legal guardians. The study enrolled 212 American Society of Anesthesiologists physical status I or II children, aged between 1 and 3 years and weighing between 8 and 18 kg, who were scheduled for elective inguinal hernia repair or hydrocele. Children were excluded if they had neurologic, neuromuscular, psychiatric, or blood-clotting disorders; known history of active and severe renal, hepatic, respiratory, or cardiac disease; or known allergy to systemic or local anesthetics. The enrolled patients were randomly allocated, using a computer-generated sequence of numbers, into 1 of 3 groups: caudal 0.25% levobupivacaine (Group $L_{0.25}$), caudal 0.20% levobupivacaine (Group $L_{0.20}$), or caudal 0.20% levobupivacaine plus 2 μg/kg dexmedetomidine (Group LD).

All the children were fasted for 6 hours before surgery but not premedicated. Upon arrival in the operating room, each of the subjects was monitored for electrocardiography, pulse oximetry, heart rate, and noninvasive arterial blood pressure. Anesthesia was induced with sevoflurane and oxygen via face mask if the patient did not have intravenous catheter before being taken to the operation room; then a 22-gauge intravenous cannula was placed in the upper limbs after loss of the eyelash reflex, and all inhalational agents were discontinued. Propofol was given to maintain a suitable depth of anesthesia in a single dose of 2 mg/kg or repeated doses. The patient was turned into the left lateral decubitus position, and a 22-gauge intravenous catheter was introduced in the caudal space using sterile technique. The local anesthetic solution was injected via the catheter over 60 seconds (total volume, 1 mL/kg) after negative aspiration of blood or cerebral spinal fluid. The patient was then repositioned supine for surgery. Midazolam (0.1 mg/kg intravenous bolus) and propofol (4 mg/[kg h] continuous intravenous infusion) were administered to maintain sedation.

The primary end point of the study was the onset time of caudal levobupivacaine, which was studied using the response to skin incision in each pediatric patient. The response of each child was observed for 60 seconds after skin incision and evaluated as "successful" or "unsuccessful." "Unsuccessful" was recorded when skin incision caused motor responses or change in hemodynamic parameters (heart rate and mean blood pressure) more than 20% of the preincision values. Each group has 7 target time points (5, 7, 9, 11, 13, 15, and 17 minutes), which were defined as the time in minutes between local anesthetic injection and skin incision, to observe the response to skin incision in each child after caudal block. Children were randomized to receive 1 of 7 different time points by means of a computer-generated random list in each group, and each target time point had 10 subjects to observe the response to skin incision in each group.

The secondary end points of the study were the duration of postoperative analgesia and the degree of residual motor block in children. Postoperative pain was evaluated using the Children and Infants Postoperative Pain Scale (Table 1). A Children and Infants Postoperative Pain Scale of 4 or more points was regarded as inadequate analgesia and was

**Table 1** Children and Infants Postoperative Pain Scale

| Item | Structure | Points |
|---|---|---|
| Crying | None | 0 |
| | Moaning | 1 |
| | Screaming | 2 |
| Facial expression | Relaxed/smiling | 0 |
| | Wry mouth | 1 |
| | Grimace(mouth and eyes) | 2 |
| Posture of trunk | Neutral | 0 |
| | Variable | 1 |
| | Rear up | 2 |
| Posture of legs | Neutral, released | 0 |
| | Kicking about | 1 |
| | Tightened legs | 2 |
| Motor restlessness | None | 0 |
| | Moderate | 1 |
| | Restless | 2 |