Comparison of 0.125% Levobupivacaine with Dexmedetomidine and 0.25% Levobupivacaine in Ultrasonography-guided Pediatric Caudal Block: A Prospective, Randomized, Double-blinded Study

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Abstract

Background: Caudal anesthesia is a safe and reliable technique for infraumbilical surgeries in pediatric patients. Addition of dexmedetomidine to local anesthetic (LA) in caudal block prolongs the duration of block, but the effect on reducing the concentration of LA drug has not been extensively evaluated. This study was, therefore, designed to evaluate the efficacy of addition of dexmedetomidine to lower concentration of levobupivacaine required for ultrasonography (USG)-guided caudal block. Methods: A total number of 60 children with American Society of Anesthesiologists Grade I and II, aged 2–8 years from both sexes, and undergoing infraumbilical surgeries were recruited in a prospective, double-blinded, randomized controlled study over a duration of 1 year. The study children were allocated into groups A and B (n = 30 each) via computer-generated randomization. Group A children received caudal 0.25% levobupivacaine 0.75 ml/kg with 1 ml of normal saline and Group B children received 0.125% levobupivacaine 0.75 ml/kg with 1 µg/kg dexmedetomidine in 1 ml of normal saline after induction and the insertion of I-gel. Heart rates, blood pressure, and SpO2 were monitored perioperatively. Postoperative hemodynamic monitoring; face, legs, activity, cry, and consolability (FLACC) pain score up to 24 h; time to first rescue analgesia; and emergence delirium using Watcha scale and Ramsay sedation score were recorded. Rescue analgesia was administered when FLACC pain score was >4. Any adverse events were noted and documented. Results: The study groups were comparable in terms of demographic characteristics and nature/duration of surgery. The mean FLACC pain scale in Group B was significantly lower compared to Group A. The mean duration of analgesia was statistically prolonged in Group B (P < 0.05) as compared to Group A (1299 ± 145 min in Group B vs. 348 ± 36 min in Group A). Emergence delirium as measured by Watcha scale was significantly lower in Group B (P < 0.05). Perioperative hemodynamic parameters were stable in the two groups, and no clinically significant adverse effects were noted. Conclusion: Addition of 1 µg/kg of dexmedetomidine decreases the effective concentration of levobupivacaine required for USG-guided caudal block, extends the duration of analgesia, and lowers the incidence of emergence delirium among pediatric patients undergoing infraumbilical surgery.

Keywords: Dexmedetomidine, levobupivacaine, ultrasound-guided caudal block

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INTRODUCTION

Caudal block combined with general anesthesia is one of the most popular anesthesia techniques for infraumbilical surgeries in children.[1] In addition to providing satisfactory postoperative analgesia, it also mitigates the intraoperative requirement for anesthetic agents and attenuates stress response to surgery.[2] Effect of single-shot caudal block is limited by short duration of postoperative analgesia. To overcome this problem, various additives have been used in addition to local anesthetic (LA) drugs for caudal block.[3]

Advent of ultrasonography (USG) and real-time imaging of the needle and surrounding structures has facilitated the use of reduced and safer volumes of LAs, thereby proving of advantage in younger children as this reduces the risk of LA toxicity.[4]

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Levobupivacaine, an S enantiomer of bupivacaine, is shown to have a safer pharmacologic profile with decreased cardiovascular and neurologic adverse effects attributed to its faster protein-binding rate.[2] Different concentrations of levobupivacaine have been used in pediatric caudal blocks. Lower concentration of levobupivacaine for caudal block favors early motor recovery, but at the expense of shorter duration of analgesia.[5]

Dexmedetomidine as an adjuvant to caudal block has been shown to improve the quality and duration of analgesia with minimal side effects.[6] However, there is a scarcity of literature on whether addition of dexmedetomidine to LA lowers the concentration of LA required for caudal block. This study was, therefore, designed to evaluate the efficacy of dexmedetomidine as an additive to lower concentration of 0.125% levobupivacaine required for USG-guided caudal block.

The primary objective of the study was to assess the efficacy of addition of 1 μg/kg of dexmedetomidine to lower concentration (0.125%) of levobupivacaine in terms of postoperative pain using FLACC scale.

Secondary objectives included time to first rescue analgesia, effect on emergence delirium using Watcha score, hemodynamic parameters, block characteristics, sedation score, and any adverse events.

Methods

Following approval by the institutional ethics committee, written informed consent was obtained from the parents of all children. The study was conducted in 60 children (males and females) with American Society of Anesthesiologists Grade I and II, aged 2–8 years, and undergoing elective infraumbilical surgeries. Patients undergoing emergency procedures; parental refusal to participate; and patients having a history or evidence of back infection, known drug allergy, bleeding/coagulation disorder, developmental delay, sepsis, and preexisting neurological or spinal diseases were excluded. Patients were randomly allocated to groups A and B using a computer-generated random number table (Random allocation software version 1.0 by Mahmood Saghaei. MD., Department of Anesthesia, Isfahan University of Medical Sciences, Isfahan, Iran. May, 2004). Allocation was concealed with numbered sealed envelopes.

All the patients were visited 1 day before the surgery, and the parents were explained about the procedure and the anesthetic technique. An anesthesiologist not participating in the study prepared the drugs as per patient’s body weight in sterile syringes. Group A patients received 0.25% levobupivacaine 0.75 ml/kg with 1 ml of normal saline and Group B patients received 0.125% levobupivacaine 0.75 ml/kg with 1 μg/kg dexmedetomidine in 1 ml of normal saline.

Patients were kept nil orally as per the standard NPO guidelines. Premedication was done with oral midazolam 0.5 mg/kg 45 min before surgery and kept under monitoring and thereafter shifted to operation theater. Baseline electrocardiogram (ECG) and noninvasive blood pressure (NIBP) were recorded and a pulse oximeter (SpO₂) was attached. Induction was done with 6%–8% sevoflurane in oxygen with spontaneous ventilation. After achieving adequate depth of anesthesia, appropriate size of I-gel was inserted and patients were placed into lateral position. Under aseptic conditions, ultrasound-guided caudal block was performed.

The sacral hiatus was visualized via an out-of-plane technique at the level of sacral cornus via the linear transducer of an ultrasound machine at 13 MHz (M-Turbo C® ultrasound machine; SonoSite Inc., Bothel, Washington, USA), with the depth and gain adjusted to optimal visual quality. The ultrasound transducer was first placed transversely at the midline to obtain a transverse view [Figure 1] and then was rotated 90° to view the sacral hiatus and the caudal epidural space [Figure 2]. Using an in-plane technique, a 5-cm short beveled 25-gauge needle was advanced at an angle of 45° passing through the sacrococcygeal ligament into the sacral canal in real time to a distance of 1 cm. The study drug was then injected following confirmation of absence of blood/cerebrospinal fluid upon aspiration.

Intraoperative monitoring and postoperative observation were carried by an anesthesiologist who was unaware of the content of the syringes. The time of caudal block was recorded, and surgery was allowed to start 10 min after caudal injection. In case the block was inadequate as suggested by nonrelaxed anal sphincter and movement on surgical incision or tachycardia, patients were administered fentanyl 2 μg/kg and excluded from the study. Failure of the caudal block was not reported in any patient.

Anesthesia was maintained with sevoflurane 1%–2% in 50% oxygen and 50% N₂O with spontaneous ventilation. No other analgesic, sedatives, or narcotics were used intraoperatively. All patients were monitored by a standard protocol during anesthesia and surgery. Continuous monitoring of vital parameters, such as heart rate (HR), ECG, respiratory rate, NIBP, and SpO₂, was done, and the values were recorded before and after premedication and induction, immediately...
after caudal block, then every 5 min for first 30 min, and then every 15 min up to 90 min. Total duration of surgery was recorded. The occurrence of intraoperative hypotension (fall in systolic blood pressure >20% from baseline) requiring fluid bolus and bradycardia (fall in HR <60/min) requiring atropine was recorded.

After surgery, patients were shifted to pediatric HDU for monitoring and management. Adverse events such as nausea, vomiting, hypotension, bradycardia, respiratory depression, and urinary retention were monitored for 24 h and treated accordingly. Nausea and vomiting was treated with intravenous (IV) ondansetron.

Postoperative respiratory depression was defined as respiratory rate <10/min or fall in SpO₂ <95% requiring supplement oxygen.

Postoperative pain status was evaluated with the pediatric observational face, legs, activity, cry, and consolability (FLACC) pain scale, having a range of 0–10. Each patient’s pain intensity was assessed every hour till 6 h, every 3 h till 12 h, and every 6 h till 24 h or until the first dose of rescue analgesia was administered and there after monitored till 24 h postoperatively. Rescue analgesic in the form of paracetamol 15 mg/kg IV was given wherever FLACC scale ≥4 was observed.

Duration of analgesia or time to first administration of rescue analgesic was noted.

The level of sedation was recorded using Ramsay sedation score at 15 min, 30 min, and 60 min after extubation and thereafter hourly until the Ramsay sedation score became 2 or less in all patients. The effect on emergence delirium was assessed using Watcha scale, which comprises four points: 1 = calm child, 2 = crying child that can be consoled, 3 = crying child that cannot be consoled, and 4 = child is agitated and thrashing around. Furthermore, on awakening, postoperative motor block was assessed with modified Bromage scale that consisted of four points: 1 = full motor strength (free movement of legs and feet), 2 = just able to flex knees with free movement of feet, 3 = unable to flex knees, but with free movement of the feet, and 4 = unable to move the legs or feet.

**Statistical analysis**

The primary outcome measure was postoperative pain score using FLACC scale. Based on the previous data and with power of 80% (α = 0.05), a sample size of sixty patients (30 in each group) was considered adequate. The data were analyzed using IBM SPSS Statistics for Windows, Version 20.0, IBM Corp., Armonk, NY, USA. Numerical variables were presented as mean and standard deviation, and categorical variables were presented as percentages. Post hoc analysis was performed using Tukey’s test for between-group comparisons of categorical variables. A repeated measures ANOVA was used for comparison of hemodynamic data within each group, whereas unpaired t-test was used for comparisons between the two groups.

Student’s t-test and the Mann–Whitney U-test were used for analysis of difference of means for quantitative data. For all statistical analyses, P < 0.05 was considered statistically significant.

**Results**

A total of 65 patients were enrolled and screened for eligibility to participate in this trial [Figure 3]. Three patients did not meet the inclusion criteria and parents of two patients did not give consent. The remaining 60 patients were allocated to one of the two study groups using a computer-generated random number table [Figure 3]. There was no statistically significant difference between the two groups with regard to demographic data (age, weight, and sex) and duration and type of surgery [Table 1].

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**Figure 2:** Longitudinal view of the caudal canal. Probe positioned longitudinally over the midline of the sacrum. SP: Spinous process, N: Needle tip, CSF: Cerebrospinal fluid

**Figure 3:** CONSORT diagram
Figure 4 shows changes in HR recorded throughout the surgery and up to 1 h postoperatively. As compared to the baseline, there was a decrease in HR in the two groups at different time intervals following caudal block. There was a statistically significant decrease in HR starting 15 min after caudal block in Group B compared to Group A and continued throughout intraoperative period extending up till 1 h postoperatively ($P < 0.05$) [Table 2]. Bradycardia was not noted in any of the patients, and none of the patients required any intervention for the same.

Figure 5 shows changes in MABP (Mean Arterial Blood Pressure) in the two groups. On intergroup comparison, there was a statistically significant difference in MABP 20 min postcaudal block and continued till postoperative period ($P < 0.05$) [Table 3]. There was no incidence of hypotension requiring intervention in any of the patients.

Comparison of the FLACC scale between the two groups at different time intervals showed a statistically significant decrease in FLACC scale in Group B compared to Group A ($P < 0.05$) [Table 4]. The mean FLACC scale was >4 in patients of Group A after 5 h, whereas the FLACC scale was <4 in patients of Group B up to 21 h postoperatively. The comparison of FLACC scale between the two groups showed a statistically significant difference at all times in the postoperative period with lower FLACC scale in Group B ($P < 0.05$) [Table 4].

Table 5 shows the comparison of duration of analgesia or time to first rescue analgesia between the two groups. The mean duration of analgesia was prolonged in Group B as compared to Group A, and the same was statistically significant (1299 ± 145 min in Group B versus 348 ± 36 min in Group A) ($P < 0.05$).

The mean Watcha scale of Group B was <2 up to 1 h postoperatively, whereas Group A had Watcha scale >2 at 30, 45, and 60 min in the postoperative period. The difference at all times in between the two groups was statistically significant ($P < 0.05$) [Table 6].

There was also a statistically significant prolongation of the duration of sedation recorded using Ramsay sedation score.
The results of the present study revealed that the addition of dexmedetomidine 1 μg/kg to 0.125% levobupivacaine provided longer duration of analgesia and lowered the incidence of emergence delirium compared to 0.25% levobupivacaine for USG-guided caudal block in pediatric patients undergoing infraumbilical surgeries.

Levobupivacaine is as efficacious as bupivacaine and has a superior pharmacokinetic profile. It is reported to cause more vasoconstriction in lower concentrations,[11,12] thereby slowing the systemic absorption, prolonging the sensory blockage, and reducing the risk of toxicity. Levobupivacaine is known to provide equal analgesia with less motor block than bupivacaine.[13] In the present study, a significantly prolonged duration of postoperative analgesia was noted with 0.125% levobupivacaine group as compared to 0.25% levobupivacaine.

Ivani et al.[5] compared caudal block characteristics using three different concentrations of levobupivacaine 0.125%, 0.2%, and 0.25% in children undergoing infraumbilical surgery. They reported that 0.125% levobupivacaine provides a short duration of analgesia but allows more rapid return of motor functions and 0.2% levobupivacaine provides both significant analgesia and quick motor recovery. We noted a prolonged duration of analgesia with 0.125% levobupivacaine with dexmedetomidine 1 μg/kg. This increase in the duration of postoperative analgesia can be temporally attributed to the addition of dexmedetomidine.

Dexmedetomidine is a highly selective alpha 2 adrenoceptor agonist. It possesses a selective affinity for alpha 2 adrenoceptor subtype A, which causes it to be much more effective sedative and analgesic without undesirable side effects from alpha 1

**Table 4: Face, legs, activity, cry, and consolability score in the postoperative period**

| Time interval (postoperative) | Group A (n=30) | Group B (n=30) | P  |
|------------------------------|----------------|----------------|----|
| 1 h                          | 1.16±1.05      | 0.2±0.48       | <0.0001 |
| 2 h                          | 1.4±1.10       | 0.23±0.50      | <0.0001 |
| 3 h                          | 1.6±1.10       | 0.26±0.52      | <0.0001 |
| 4 h                          | 1.86±1.10      | 0.33±0.60      | <0.0001 |
| 5 h                          | 4.21±1.24      | 0.43±0.72      | <0.0001 |
| 6 h                          | 4.63±1.54      | 0.56±0.81      | <0.0001 |
| 9 h                          | 3.8±1.49       | 0.6±0.85       | <0.0001 |
| 12 h                         | 5.53±1.85      | 0.96±1.03      | <0.0001 |
| 18 h                         | 5.76±1.56      | 2.16±1.17      | <0.0001 |
| 24 h                         | 6.23±1.61      | 4.57±1.49      | <0.0001 |

**Table 5: Time to first rescue analgesia**

| Time to analgesia (min) | Group A (n=30) | Group B (n=30) | P  |
|-------------------------|----------------|----------------|----|
|                         | 348.03±36.48   | 1299.1±145.98  | <0.0001 |

**Table 6: Watcha scale of the two groups**

| Time interval postoperative | Group A (n=30) | Group B (n=30) | P  |
|-----------------------------|----------------|----------------|----|
| Immediate                   | 1.83±0.53      | 1.06±0.25      | <0.0001 |
| 15 min                      | 1.96±0.55      | 1.1±0.30       | <0.0001 |
| 30 min                      | 2.03±0.55      | 1.13±0.34      | <0.0001 |
| 45 min                      | 2.1±0.54       | 1.16±0.37      | <0.0001 |
| 60 min                      | 2.33±0.50      | 1.2±0.40       | <0.0001 |

**Table 7: Postoperative Ramsay sedation score**

| Sedation score | Group A (n=30) | Group B (n=30) | P  |
|----------------|----------------|----------------|----|
| 15 min         | 1.33±0.47      | 2.6±0.49       | <0.0001 |
| 30 min         | 1.3±0.46       | 2.56±0.50      | <0.0001 |
| 45 min         | 1.4±0.49       | 2.5±0.52       | <0.0001 |
| 60 min         | 1.8±0.40       | 2.43±0.50      | <0.0001 |

**Table 8: Modified Bromage scale**

| Bromage grade | Group A (n=30) | Group B (n=30) | P  |
|---------------|----------------|----------------|----|
| Grade I       | 23             | 30             | 0.4928 |
| Grade II      | 5              | 0              | NA  |
| Grade III     | 2              | 0              | NA  |
| Grade IV      | 0              | 0              | NA  |

NA: Not available

**Table 9: Postoperative complications**

| Variables                  | Group A (n=30) | Group B (n=30) |
|----------------------------|----------------|----------------|
| Nausea and vomiting        | 3              | 1              |
| Hypotension                | 0              | 0              |
| Bradycardia                | 0              | 0              |
| Respiratory depression (SpO₂ <95%) | 0              | 0              |

**Discussion**

The results of the present study revealed that the addition of dexmedetomidine 1 μg/kg to 0.125% levobupivacaine provided longer duration of analgesia and lowered the incidence of emergence delirium compared to 0.25% levobupivacaine for...
Addition of dexmed to levobupivacaine in USG guided paediatric caudal block

receptor activation. Dexmedetomidine enhances the effects of local anesthesia without increasing the incidence of side effects.

Saadawy et al. evaluated the analgesic effect of addition of 1 μg/kg of dexmedetomidine to 0.25% bupivacaine in infraumbilical surgeries in pediatric patients and demonstrated that time to first rescue analgesia was 18 h in dexmedetomidine group compared to 6 h in the bupivacaine group. Our study also observed an efficacious 20 h postoperative analgesia with addition of dexmedetomidine. However, we used lower concentration, i.e., 0.125% of levobupivacaine, but comparable analgesic duration can be attributed to the harness of ultrasound in our study, leading to precise deposition of drug.

Tandale et al. studied the safety and efficacy of dexmedetomidine 1 μg/kg as an adjuvant to 0.25% levobupivacaine. They observed a significant reduction in the FLACC scale among patients receiving dexmedetomidine vis-a-vis levobupivacaine.

Fares et al. reported that addition of 1 μg/kg of dexmedetomidine to caudal bupivacaine 0.25% in pediatric major abdominal cancer surgeries resulted in significant postoperative pain relief for up to 19 h with lesser requirement of postoperative analgesia. Similarly, other studies also demonstrated significant prolongation of analgesia in patients receiving dexmedetomidine 1 μg/kg with 0.25% bupivacaine for caudal block in pediatric patients.

She et al. evaluated the effect of dexmedetomidine on the potency of levobupivacaine for caudal block. They concluded that addition of 1 and 2 μg/kg reduced the required concentration of levobupivacaine for caudal block in pediatric patients.

Use of ultrasound for caudal block allows real-time visualization of needle placement in the caudal space and drug deposition. A recent Cochrane review confirmed that the use of USG improves success rate of blocks and increases the duration of analgesia, especially in younger children. Caudal block is usually performed using large doses of local anesthesia fraught with dangers of systemic toxicity including cardiac arrest and seizures. The risk increases with the use of more concentrated long-acting LAs. Hence, reducing the concentration of LA for caudal block by addition of adjuvants such as dexmedetomidine, decreased antecedent toxicity without compromising efficacy, which is an important concern in pediatric patients.

Observations by She et al. and Ivani et al. in their respective studies also advocated the use of ultrasound for caudal block and addition of dexmedetomidine.

Emergence delirium is a common adverse event in pediatric patients that frequently accompanies newer short-acting volatile anesthetic agents such as sevoflurane and desflurane. The current data suggest that the incidence of emergence delirium varies from 20% to 80% of all pediatric anesthetics, with majority of allied literature suggesting it to be close to 20%.

Clonidine and dexmedetomidine can have a significant impact on reducing the incidence of emergence delirium, but at the expense of prolonged recovery time when given by IV route. In the present study, we used the Watcha scale to assess emergence delirium. Watcha scale is a practical tool to use and assess emergence delirium in the PACU as reported by Bajwa et al. In the present study, it was observed that Watcha scale remained <2, suggesting a calmer child in Group B up to 60 min postoperatively.

Saadawy et al. evaluated the effect of 1 μg/kg dexmedetomidine on the characteristics of bupivacaine in caudal block and concluded that the use of dexmedetomidine had an advantage of decreasing the incidence of agitation associated with emergence from sevoflurane anesthesia compared with bupivacaine group (7% vs. 27%). In another study, comparison was done to evaluate the analgesic effect of caudal dexmedetomidine and fentanyl when added to ropivacaine in pediatric patients. The findings of their study suggested that dexmedetomidine addition to caudal ropivacaine led to prolongation in arousable sedation and less emergence agitation.

In the present study, higher sedation scores were noted in immediate postoperative period and at 1, 2, and 3 h postoperatively in dexmedetomidine group compared to Group A, which were found to be statistically significant. Although sedation was prolonged in the dexmedetomidine group, the patients were easily arousable by verbal contact and none of them experienced fall in SpO2 or respiratory depression. Our findings were in agreement with the study of Tandale et al., who noted higher Ramsay sedation scores in patients receiving dexmedetomidine with levobupivacaine compared to the levobupivacaine group. Similarly, Fares et al. demonstrated higher sedation scores in dexmedetomidine group in the postoperative period.

Postoperative motor block was assessed using modified Bromage scale in the two groups. We did not observe motor blockade in any patients in Group B. However, in Group A, five patients had Grade II motor block and two had Grade III block in 1st h postoperatively. At the end of 3 h, no patients had residual motor blockade in Group A.
Our findings were in accordance with the findings of Ivani et al.,[31] who compared three different concentrations of levobupivacaine for caudal anesthesia. They concluded that 0.125% was free of postoperative motor blockade, whereas the number of patients with residual motor blockade increased with increasing concentration of levobupivacaine.

Da Conceicao et al.[31] also concluded that using ropivacaine in excess of 0.2% for caudal block in children was associated with an increased incidence of early motor block. In our study, combination of dexmedetomidine to lower concentrations of levobupivacaine, i.e., 0.125%, produced a synergistic effect. It facilitated the use of lower concentration of levobupivacaine, thereby reducing the risk of motor blockade in postoperative period as evident in our study. Decreasing the dose of LA also reduced the risk of significant local anesthesia toxicity as stated above. Second, the shorter duration of analgesia reported with 0.125% plain levobupivacaine as in a previous study[32] was significantly prolonged with the use of dexmedetomidine as an adjuvant to 0.125% levobupivacaine as in our study.

With regard to hemodynamic parameters, there was a decreasing trend in the HRs compared to baseline starting 15 min after caudal block and continued up to 1 h postoperative period in the two groups. Upon intergroup comparison, there was a statistically significant decrease in HRs in Group B continuing in the postoperative period. However, this decrease in HR was of no clinical significance. Similar changes were noted in the MABP recordings. There was a statistically significant difference in MABP readings in the two groups 15 min postcaudal and continued in the postoperative period. However, the fall in MABP was never 30% from the baseline value and none of the patients required intervention. Stable hemodynamic profile of dexmedetomidine has been published in other studies also.[15,23]

**Conclusion**

The findings of this study suggest that addition of 1 µg/kg of dexmedetomidine to 0.125% of levobupivacaine decreases the effective concentration of levobupivacaine required for caudal block, extends the duration of analgesia, and lowers the incidence of emergence delirium compared to 0.25% levobupivacaine among pediatric patients undergoing infraumbilical surgery.

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**Conflicts of interest**

There are no conflicts of interest.

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