Original Article

A randomised study comparing the extent of block produced by spinal column height and body weight-based formulae for paediatric caudal analgesia

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ABSTRACT

Background and Aims: Height and weight-based formulae are used for calculation of dose of medications for caudal analgesia but these have not been compared. We compared spinal column height-based Spiegel and weight-based Takasaki and Armitage formulae for achieving maximum height of sensory neuraxial block after caudal epidural analgesia in paediatric patients. **Methods:** In this double-blind randomised study, children aged between 1 and 6 years and planned for infra-umbilical surgery were randomly allocated to receive caudal epidural block (targeting T_{10} level block) with 0.25% bupivacaine, using a volume calculated by modified Spiegel formula (group I), Takasaki formula (group II), and Armitage formula (group III). The Institute ethics committee reviewed and approved the study protocol. The primary endpoint of the study was the difference in the number of spinal segments blocked as assessed by pinprick method. The secondary endpoint was the difference in volume of 0.25% bupivacaine used among the groups. The groups were compared using one-way ANOVA. **Results:** Seventy-five patients (25 in each group) completed the study as per protocol. The mean number of spinal segments blocked was significantly different among groups ($P < 0.001$) with patients in group I (13.8 ± 0.83) showing significantly lower number of spinal segments blocked as compared to that in group II (15.8 ± 1.06; $P < 0.001$), and group III (16.8 ± 1.28; $P < 0.001$). The mean volume of 0.25% bupivacaine used in group I was significantly lower ($P < 0.001$) than that in group II and group III. **Conclusion:** Dose calculation in caudal epidural analgesia as per spinal column height-based modified Spiegel formula was more precise than bodyweight-based Takasaki and Armitage formulae.

Key words: Bupivacaine, caudal analgesia, epidural block, regional anaesthesia

INTRODUCTION

Caudal epidural analgesia is a frequently performed regional anaesthetic technique in paediatric patients undergoing surgical procedures because of its long-standing familiarity, high success rate and good safety profile.[1-6] It is prudent to use the minimal effective dose of local anaesthetic solution for caudal epidural analgesia, that yields a predictable level of neuraxial blockade whilst avoiding an undesirable high level of blockade and providing a greater margin of safety in the event of inadvertent intravascular injection. A number of studies have attempted to derive formulae in order to determine an optimal volume of local anaesthetic required to achieve a predictable dermatomal level of neuraxial block in caudal epidural block.[7-12] Various factors such as dose (volume x concentration), site of injection along the neuraxis, rate of injection, posture of the patient, height, body weight and age affect the spread of local

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anaesthetics in caudal epidural block.[13,14] It might not be practically feasible to consider all these factors while deriving these formulae.

Scientific literature does not reveal direct comparisons between different formulae and anaesthesiologists use formulae based on their personal judgment and experience. However, concerns about the actual level of blockade that would be achieved and inadvertent higher level of blockade always exist.[15] Therefore, we planned to compare the level of sensory neuraxial blockade achieved by a dose of 0.25% bupivacaine calculated using three commonly used formulae namely, spinal column height-based Spiegel formula (modified for T_{10} blockade), body weight-based Takasaki formula, and body weight-based Armitage formula in paediatric patients undergoing infra-umbilical surgeries.[7,8,12] The primary endpoint of the study was the difference in the number of spinal segments blocked amongst the three groups. The secondary endpoint was the difference in volume of 0.25% bupivacaine used amongst the three groups.

METHODS

This study was conducted at a large tertiary care referral hospital. All children aged between 1 and 6 years and planned for an infra-umbilical surgery were eligible for enrolment. Patients with physical status >II as per the American Society of Anesthesiologists (ASA) physical status classification system, history of allergy or adverse effects with local or regional anaesthetic use, local infection, bleeding diathesis, spinal deformities, or neuropathies, those taking aspirin or any other anticoagulants, total dose of local anaesthetic exceeding 2.5 $mg.kg^{-1}$ and children of unwilling parents were excluded from this study. The Institute ethics committee reviewed and approved the study protocol (HP/pp 1634/2010). After informed consent from parents or legal guardians, subjects were randomly allocated into three groups using computer-generated random allocation number. Allocation concealment was ensured by having the random group assignment enclosed in serially numbered, sealed opaque envelopes. The sealed envelope was opened by an anaesthesiologist not involved in the study. The patient and the investigator who assessed the level of segmental blockade were blinded to group allocation. Spinal height and weight were measured in all subjects. The subjects received caudal epidural block with 0.25% bupivacaine after the completion of surgery with dose calculated as per designated formula. In group I, spinal column height-based Spiegel formula was used (effective for twenty segments i.e., T_3 level block)[8] i.e.,

$$Volume\ for\ T3\ block(ml) = \left\{4+\left(\frac{D-15}{2}\right)\right\},$$

(Where D is the distance from C_7 to sacral hiatus in cm). It was modified for T_{10} level block i.e., for 13 spinal segments as follows:

$$Volume\ for\ T10\ block(ml) = \left\{4+\left(\frac{D-15}{2}\right)\right\} X 13/20$$

(Where 20 represents number of segments from S_5–T_3, and 13 represent the number of segments from S_5–T_{10}). Group II patients received 0.25% bupivacaine calculated according to the body weight-based Takasaki formula (for T_{10} level block)[7] i.e.,

*Volume for T*10 *block* (*ml*) = {(*Body wt in kg* x 0.078)-(0.17)*X* 13}

(Where 0.078 and 0.17 are constants and 13 is number of spinal segments up to T_{10}). Group III patients received 0.25% bupivacaine according to body weight (in kg) based Armitage formula for lower thoracic level[12] i.e.,

Volume for T10 block (ml) =1 ml per kg body weight

All subjects were pre-medicated with 0.5 $mg.kg^{-1}$oral midazolam, 30 min before induction of anaesthesia. Continuous monitoring of oxygen saturation (SpO_2), lead-II electrocardiogram (ECG), heart rate (HR) and intermittent non-invasive monitoring every five min of mean arterial pressure (MAP) were done during the operative procedure and post-operatively in the post-anaesthesia care unit (PACU). General anaesthesia was induced with either halothane in oxygen or thiopentone 5 $mg.kg^{-1}$ with fentanyl 2 $\mu g.kg^{-1}$ (depending upon the presence of intravenous cannula). Tracheal intubation was done under the effect of atracurium 0.5 $mg.kg^{-1}$, and anaesthesia was maintained with 60% nitrous oxide in oxygen and 0.5% halothane.

After the completion of surgery before extubation, caudal block was performed in left lateral position using a 25-gauge caudal needle (MEDEREN, 30 mm)

under aseptic precautions and the calculated volume of 0.25% bupivacaine was administered. Neuromuscular blockade was reversed with neostigmine 0.05 mg.kg^{-1} and glycopyrrolate 0.01 mg.kg^{-1} after administration of caudal block. In the PACU, the level of sensory blockade and sedation score were assessed using pin-prick method and Ramsay sedation score, respectively, at 5, 10, 15, 20, 30, 60 and 120 min. In subjects ≤4 years, a positive response to pin prick was recorded when reflex movement along with wincing or cry and increase in heart rate to more than 10% of the baseline values were observed. In subjects >4 years, verbal response to pin prick were recorded. HR, SpO_2 and MAP were monitored at 5, 10, 15, 20, 25, 30, 45, 60, 75, 90, 105 and 120 min post-operatively. The children were transferred to the ward from PACU either after four segment regressions of sensory level or after two hours whichever was earlier, provided all other criteria for discharging from recovery room were also fulfilled. FLACC (face, legs, activity, cry and consolability) pain score was assessed prior to sensory blockade assessment. Caudal block was labelled as a failure whenever the FLACC pain score was >4 at 30 min post-operatively.[16] Post-operatively, intravenous paracetamol (15 mg.kg^{1}) was planned as rescue analgesic whenever FLACC pain score was >4. The duration of analgesia was defined as the time from administration of caudal block till the need of first rescue analgesic dose in the post-operative period. Haemodynamic compromise (fall in mean arterial pressure by more than 20% of baseline), motor weakness (modified Bromage score ≤4) or need of urinary catheterisation (assessed every 2 h based on clinical evidence of distension of urinary bladder or no passage of urine for 4 h after the procedure) were recorded as adverse events.

There are no studies comparing these formulae with each other. Assuming a type 1 error of 5%, power of 80%, effect size of 0.6 for number of spinal segments blocked between any two groups (out of three) and a standard deviation of 0.74, a sample size of 25 for each group was deemed sufficient to detect any significant difference between any two groups out of three. A further consideration for 20% drop outs gave the final sample size of 30 for each group. This meant a total sample size of 90 for the study. Data were analysed using statistical package for the social sciences (SPSS) software for windows, version 20.0 (IBM Corp., ARMONK, NY, USA). Continuous data were presented as mean with SD or median (with range) and categorical data were presented as frequencies. The three groups were compared using one- way ANOVA. Post-hoc multiple comparisons between groups were done with Tukey test. All *P* values were two tailed and considered significant when <0.05.

RESULTS

Over a period of 36 months (from July 2010 to June 2013), 100 patients were screened for enrolment in this study [Figure 1]. However, eight patients were ASA physical status >II, one patient had bleeding diathesis and parents of one patient refused consent. Ninety patients were enrolled as per the study protocol. Finally, 25 patients in each group completed the study protocol and were considered for statistical analysis. Rescue analgesic in the form of intravenous paracetamol was not required for any patient in any group during the study period. Patient characteristics are shown in Table 1. The three groups were comparable to each other with respect to age, sex, weight, spinal height, type of surgery and duration of surgery.

The sensory neuraxial blockade corresponding to T_{10} was achieved in all patients except one in group I who had blockade till T_{11}. In group I, the mean number of spinal segments blocked (13.8 ± 0.8) was significantly lower than that in group II (15.8 ± 1.1; $P < 0.001$) and group III (16.8 ± 1.3; $P < 0.001$). In group I, the mean

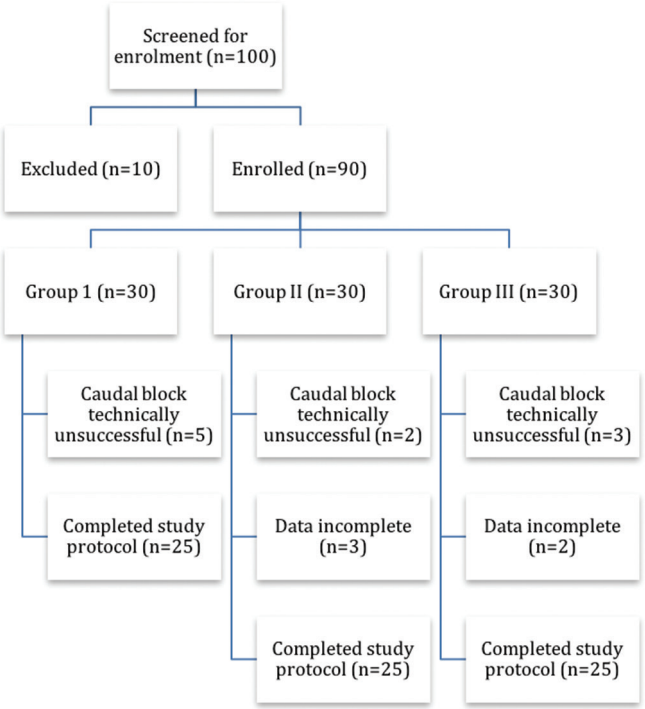

Figure 1: Patient enrolment in this study. *Excluded patients: Refused consent (*n* = 1), American Society of Anesthesiologists physical status >II (*n* = 8), Bleeding diathesis (*n* = 1)

volume used (8.7 ml ± 0.9) was significantly lower than that used in group II (11.1 ml ± 3.0; $P = 0.001$) and group III (13.1 ml ± 2.4; $P < 0.001$) [Table 2]. The post-operative sedation score, duration of analgesia, modified Bromage score, MAP, HR and SpO_2 did not differ significantly amongst the three groups [Table 3]. No events of hypotension or bradycardia requiring intervention were observed in any patient.

DISCUSSION

In our study, sensory level blockade corresponding to T_{10} was uniformly achieved in all the three study groups. The volume calculated using weight-based Takasaki and Armitage formulae turned out to be higher and hence, consistently led to a higher level of neuraxial blockade (median blockade up to T_6 in Armitage and T_7 in Takasaki as compared to T_9 in Spiegel).

Various studies have shown that the injectate volume is a key determinant of the height of block and that the spread is higher when weight-based dosage administration is used in younger individuals.[17-19] In a study that investigated the spread of 1.5 ml/kg of 0.2% single shot ropivacaine using real-time ultrasound, the cranial spread was found to be inversely related to age, weight and height of the patient.[20] However, in a study by Thomas *et al*. where they compared different volumes (0.5, 0.75, and 1 $ml.kg^{(-1)}$) of local anaesthetic solutions containing radio-opaque contrast, a modest increase in spread of injectate with increasing volume was observed. The authors also noted that a volume of <1 ml/kg was unlikely to ascend to vertebral level higher than L_2.[21] The use of the minimal yet adequate volume for achieving the sensory blockade of target dermatome is imperative to avoid complications associated with higher volumes such as local anaesthetic systemic toxicity (LAST), decreased cerebral flow and haemodynamic instability. Recently, Lundbald *et al*. observed a decline in mean cerebral blood flow (CBF) velocity and oxygenation after using higher volume (1.5 $ml.kg^{-1}$) in caudal block in infants with unaffected systemic haemodynamic parameters

Table 1: Patient characteristics

Parameter	Group I (*n*=25) [Mean±SD or frequency]	Group II (*n*=25) [Mean±SD or frequency]	Group III (*n*=25) [Mean±SD or frequency]
Age (year)	3.5±1.7	3.3±1.8	3.2±1.5
Weight (kg)	13.6±2.4	13.4±3.0	13.1±2.4
Spinal height (C7 to sacral hiatus in cm)	33.9±2.7	33.7±4.2	33.1±2.5
Duration of surgery (minutes)	74±4.8	69±5.3	71±4.5
Male	19	21	20
Female	6	4	5
Herniotomy	15	13	16
Orchidopexy	5	4	4
Circumcision	2	3	3
Club foot surgery	2	2	1
Others	1	3	1

Table 2: Comparison of level of sensory neuraxial blockade and volume used in different groups

Parameter	Group I Mean±SD	Group II Mean±SD	Group III Mean±SD	*P**	*P* (I vs II)	*P* (I vs III)	*P* (II vs III)
Volume used (ml)	8.7±0.9	11.1±3.0	13.1±2.4	<0.001	0.001	<0.001	0.007
Volume used (ml/kg)	0.65±0.07	0.82±0.46	1±0	<0.001	<0.001	<0.001	<0.001
Number of spinal segments blocked	13.8±0.8 14 (1) [12-15]#	15.8±1.1 16 (1.5) [14-18]#	16.8±1.3 17 (4) [15-19]#	<0.001	<0.001	<0.001	0.005
Volume per segment (ml)	0.64±0.07	0.70±0.37	0.79±0.17	0.003	0.083	0.002	0.06

*Comparison amongst groups based on one-way ANOVA. *Post-hoc* tests were done for comparison between two groups. #Expressed as median (IQR) [minimum - maximum]

Table 3: Comparison of Ramsay sedation score, Modified Bromage score and Duration of analgesia in different groups

Parameter	Group I Mean±SD	Group II Mean±SD	Group III Mean±SD	*P**
Ramsay Sedation Score#	2.9±1.0	2.8±0.8	2.9±1.0	0.82
Modified Bromage Score#	5.4±0.5	5.6±0.5	5.5±0.5	0.54
Duration of Analgesia (h)	4.1±0.3	4.2±0.3	4.2±0.3	0.69

#Assessed post-operatively at 15 min in PACU. *Comparison between groups based on one way ANOVA. *Post hoc* test showed similar Ramsay Sedation Score in Group I as compared to Group II (*P*=0.89) and Group III (*P*=0.98); similar Modified Bromage Score in Group I as compared to Group II (*P*=0.51) and Group III (*P*=0.84); and similar duration of analgesia in Group I as compared to Group II (*P*=0.68) and Group III (*P*=0.87)

and advised caution while using higher volumes in patients with intracranial pathology.[22] Various radioisotope visualisation studies have demonstrated limited spread of local anaesthetics to the thoracolumbar junction. However, Lundbald *et al*. recognised the secondary cranial spread of local anaesthetic that, resulted in higher cutaneous median levels on testing at 15 min (T_4) compared to ultrasonographic assessment at 0 min (T_{10}) and after 15 min (T_8).[23] In our study, we used the pin-prick method for checking the cutaneous sensations at 5, 10, 15 and 30 min, therefore it is unlikely that this delayed cranial spread would be missed out in our observations.

In comparison to Spiegel and Takasaki formulae, calculation of local anaesthetic dose as per Armitage formula is simple, but it does not take into account height of the patient. Despite the widespread use of this formula, the studies grossly express the level of neuraxial blockade as high thoracic, mid thoracic and sacral without any objective account of specific spinal segments or their number. Similarly, in a large number of studies, caudal epidural block was administered pre-operatively and its efficacy and level of neuraxial blockade was assessed intra-operatively under the effect of either sedation or general anaesthesia, by observing indirect parameters such as heart rate and blood pressure that lack objectivity.[7-9,11,12] In the light of newer observations of reduced CBF and LAST with larger volumes of local anaesthetic, use of the precise and smaller volumes of local anaesthetic appears more prudent.[22] Our study shows that the height of spinal segments (column) might be more significant than the body weight, which often varies grossly even among children with same height.

If we generalise the mean volume used, the segments above T_9 appear to accommodate a larger volume per segment from T_9 to T_7 (1.2ml per segment) and 2.0 ml per segment from T_7 to T_6. We did not use any objective method such as imaging or ultrasound to view the spread of local anaesthetic solution. Though it is difficult to explain this higher volume required to block the T_9–T_6 segments, the studies involving imaging and epiduroscopy suggest that mid-thoracic segments tend to accommodate larger volumes compared to upper or lower thoracic spinal segments.[14,24] These observations perhaps may explain this relatively higher volume requirement per segment.

Use of a smaller volume is often considered a compromise of longer duration of analgesia. Silvani *et al*. compared the post-operative duration of analgesia and motor blockade using low volume high concentration (ropivacaine 0.375% at 0.5 ml.kg^{-1}) with high volume low concentration (ropivacaine 0.1% at 1.8 ml.kg^{-1}) in caudal blockade and observed that the ''high volume, low concentration'' regimen produced prolonged analgesia and lesser motor block compared to the ''low volume, high concentration'' regimen.[25] The difference of volume (0.5 ml vs 1.8ml.kg^{-1}) is greater compared to our study (0.65 ml to 1.0 ml.kg^{-1}). Since our patients underwent different surgical procedures involving dermatomal levels from lower thoracic (cystolithotomy) to sacral (club foot surgery), comparison of the duration of analgesia would not have been rational.

None of the patients in any group experienced haemodynamic compromise, motor weakness or needed urinary catheterisation in the post-operative period. Modified Spiegel and Takasaki formulae consistently yielded lower local anaesthetic volume for T_{10} block as compared to Armitage formula. The relatively small number of patients and homogeneous population are important limitations of this study.

CONCLUSION

Our results show that dose calculation as per spinal column height-based modified Spiegel formula was more precise than body weight-based Takasaki and Armitage formulae for calculation of the volume of 0.25% bupivacaine for achieving T_{10} blockade in caudal epidural analgesia for post-operative pain relief in paediatric population undergoing infra-umbilical surgeries.

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Conflicts of interest
There are no conflicts of interest.

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