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Ultrasound guided pediatric caudal dose: a two-center randomized controlled trial

Kartik Syal[1], Ankita Chandel[1*] and Manjit Singh Kanwar[2]

Abstract

Background The drug volume to be used in caudal in pediatric patients has remained an unmet issue since long. We determined the minimum drug volume required to reach T10 level in pediatric patients using ultrasonography and compared it with the already established volume by Armitage formula.

Aim To determine the minimum effective caudal local anesthetic dose using ultrasound guidance.

Methods Study was performed at two centres and at each centre, 50 pediatric patients (Total 100 patients), aged 1 to 3 years, undergoing below umbilical surgeries were included and randomised into two groups of 25 each (Total 50) to receive ultrasound guided drug volume vs. Armitage formula based volume. The volume required to reach T10 level was assessed with ultrasound in one group. Also, maximum height achieved, cutaneous level achieved after 15 min, FLACC scores 30 min post extubation and parental satisfaction scores were noted.

Results The mean drug volume required to reach T10 level in Group U was 0.755 ± 0.053 ml/kg with a P value < 0.001. (Compared to the drug volume of 1 ml/kg using one sample t test). The highest level achieved in both groups were calculated as the mode value of T8 and T7 in Group U and Group A respectively. The highest cutaneous level achieved after 15 min was also calculated as the mode value of T4 in both groups. FLACC scores at 30 min were also comparable. Satisfaction scores were comparable in both groups.

Conclusion A volume of 0.7 ml/kg of local anaesthetic in pediatric caudal block is sufficient to achieve a target of T10 level for infraumblical surgeries.

Keywords Caudal, Anesthesia, Hernia, Ultrasonography, Epidural, Anesthetics, Local, Pediatric anesthesia, Pain

Introduction

Single-shot caudal anaesthesia has remained the most important component of anaesthesiologist's armamentarium not only as a stand-alone procedure for surgical anaesthesia but also for post-operative pain relief in pediatric patients. It was first described in 1933, by Meredith Campbell, a urologist, for cystoscopies in children and today it is an established method of pain relief in pediatric post surgical patients [1].

Over decades, there has been lot of refinements in technique but the drug volume to be given, has remained a topic of debate. There are innumerable age, weight and height based formulae to calculate the volume of local anaesthetic to be given in caudal with no single consensus till date. Because, the spinal volumes show a linear correlation to height and weight whereas a curvilinear correlation has been found for age [2], the universally used weight based formula was given by, Armitage in 1949 [3]. He advocated a volume 0.5 ml/kg of 0.25%

*Correspondence:
Ankita Chandel
ankitachauhanchandel@gmail.com
[1]Department of Anaesthesia, Indira Gandhi Medical College and Hospital, Shimla, India
[2]Department of Anaesthesia, Dr Radhakrishnan Gandhi Medical College and Hospital, Hamirpur, India

bupivacaine for lumbosacral region (L1), 1 ml/kg for low thoracic (T10) region and 1.25 ml/kg for high thoracic (T6) region. But this solely was based on clinical experience and was only published as a letter to the editor, without any details on how he had arrived at the recommended volumes.

More modern attempts which objectively visualise the cranial spread of caudal blocks immediately after the caudal injection by radiography or ultrasonography, have given contrasting results and showed that the injectate rarely goes beyond the level T10 attributed to the lumbar spinal cord enlargement (tumenescence) in combination with CSF rebound phenomenon regardless of whether 0.5 ml/kg or as much as 1.5 ml/kg was injected [4, 5]. Thus, literary research further focussed mainly on evaluating the cutaneous level reached at different volumes and it has been seen that cutaneous levels attained after 15 to 20 min are much higher than the actual drug distribution seen [6].

On the other hand, it is considered 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.

Based on these, we hypothesized that the Armitage formula overestimates the drug volume required to reach T10 level and that the volume of local anaesthetic required to reach T10 level in infraumblical surgeries in pediatric patients can be visualised in real time using ultrasonography. The primary end point of the study was the volume required to reach T10 level and then compare it with the volume advocated by Armitage formula. The maximum height reached with this particular volume was further evaluated both by using real time ultrasonography and cutaneous testing performed after 15 min.

Methodology

A total of 100 pediatric patients, aged 1 to 3 years, undergoing below umbilical surgeries under general anaesthesia were included over a period of 2 months from April 2023 till June 2023, at two centres with 50 patients at each centres, after obtaining written informed parental consent. It was a prospective, randomized, observer-blinded clinical trial and was registered with trial registry number CTRI/2023/04/051251 dated 3/4/2023. Children with known blood coagulation disorders, systemic inflammation, inflammation in the area of the site of injection, and anatomical abnormalities of the lumbosacral spine were excluded from the study.

At each centre, 50 pediatric patients aged 1 to 3 years, undergoing below umbilical surgeries under general anaesthesia were included. They were randomly allocated with the help of computer generated random charts into two groups of 25 each to receive ultrasound guided local anaesthetic (LA) volume vs. Armitage formula based LA volume.

Prilocaine cream and an adhesive sterile tape was placed at the predetermined venous and caudal puncture sites and premedication was done with oral midazolam 0.5 mg/kg, 30 min before the procedure. The child was then transferred to the operation theatre and standard monitoring was applied (ECG, SpO2, non-invasive blood pressure). Incremental induction with 6 L fresh gas flow (FGF) and the sevoflurane dial set at 2% in a 2:1 mixture of N_2O and O_2 was done. The dial setting was increased by 1% every 2–3 breaths until loss of eyelash reflex, with a mean induction time of 1–2 min. After induction a peripheral venous access was established. Thereafter, sedation was supplemented with Inj. Fentanyl 2 ug/kg and I gel of appropriate size was then put and checked for the bilateral chest rise and by capnography. Spontaneous ventilation with sevoflurane (2%) in O2:N2O in a ratio of 33:66 was continued.

Ultrasound investigation, identification of T12 level, and conus medullaris

The child was then placed in the left lateral decubitus position with flexed lower limbs. We identified the 12th rib using linear 7–13 MHz ultrasound transducer (SonoSite Inc., Bothell, WA, USA) covered with transparent sterile adhesive and tracked it medially, thereby identifying the12th vertebral body and subsequently, the levels of the spinous process from T6 down to the conus medullaris were marked on the skin with skin marker. Subsequently, the probe was kept in transverse plane in the interspinous area, starting from level T12 till T4 and at each level the distance from ligamentum flavum to duramater was noted down.

Caudal block under ultrasound observation

Group U

The ultrasound probe was then kept over the sacral cornuae and the sacrococcygeal membrane was identified for the exact identification of the injection site. The sacrococcygeal membrane was punctured with a 24G short bevelled tip cannula confirmed by longitudinal probe orientation.

After that the ultrasound probe was kept in the median plane transversely at the level of T10 interspinous space and doppler mode was selected on ultrasound, to mark the color flow seen with advancement of drug on ultrasound [7]. After negative aspiration, 0.25% bupivacaine was injected at a speed of 0.5 ml/second and the drug injection was stopped immediately once the color flow in doppler was seen at T10 level. (Fig. 1) The drug volume was noted and dose of bupivacaine was calculated from the used drug volume in mg/kg. Because, even after stopping the drug, it still traverses into higher spaces so

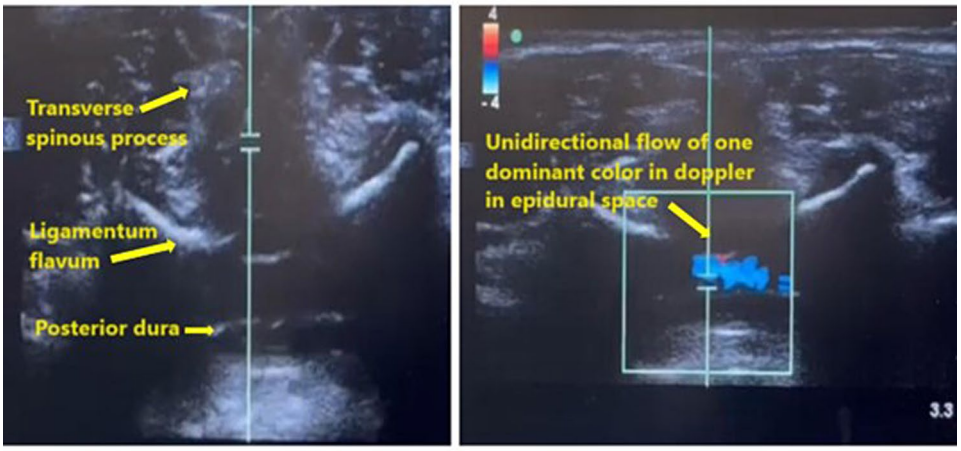

Fig. 1 Pre and post injection images of T10 epidural space visualizing the dominant color seen on doppler after the drug reaches T10 level

the same was noted by once again measuring the distance from ligamentum flavum to duramater from T12 to T4 interspaces, keeping probe in transverse plane and thus the maximum level reached was calculated by comparing the pre and post dilatation difference at each level. The highest level, where this difference was more than 20% was labelled as the maximally dilated highest space.

Group A

The drug volume was given as per Armitage formula that is 1 ml/kg of 0.25% bupivacaine for thoracolumbar region (T10) again at a 0.5 ml/second speed. The maximum level reached was also noted similarly as mentioned above.

One anesthetist was dedicated to perform the caudal block, including drawing-up and injecting the correct amount of local anesthetic, whereas a separate person was assigned to perform and evaluate the ultrasound scan. A second anaesthetist blinded to the drug volume injected performed the cutaneous testing at 15 min post-injection, to assess the highest dermatomal level of the block by observing flinching and facial expression in response to ice cube placed inside glove at different dermatomes.

Skin incision was performed 20 min after injection of the local anaesthetic. A successful block was defined as no motor (movements of extremities) or haemodynamic response (change in heart rate by more than 15%) to skin incision or during the surgical procedure, with no need for the administration of supplemental analgesics. In the case of a pain response (defined as: movements of the lower extremities, heart rate increase 15% from the baseline), children received analgesic supplementation as per institutional protocol in which case the block was considered a failure and the case was excluded from the study.

At the end of surgery I gel was removed after discontinuing inhaled anaesthetic agent and suctioning through I gel. Patients were observed in post anaesthesia care unit and then were sent to the ward after recording FLACC scores at 30 min post extubation as per institutional protocol [8]. The motor function of the lower extremities and the caudal puncture site was assessed in all children on the first postoperative day.

After 24 h, parental satisfaction scoring was assessed based on the NRS scale, that is score of 1,2,3,4,5 for totally satisfied, satisfied, moderately satisfied, somewhat satisfied and not at all satisfied respectively.

Statistical analysis

The data collected was recorded in MS Excel and analyzed viz. epinfo VT software. Qualitative variables were demonstrated as frequency and percentage. Quantitative variables were expressed as mean and standard deviation. Differences between both groups were studied by applying the Chi-square test and T-test according to study variables with P value <0.05 was taken as statically significant. The sample size was calculated taking Confidence Interval of 95%, power of study 80% considering post operative pain at 30 min after shifting to PACU in Armitage group is 2.40 with SD of 0.58 and post operative pain at 30 min after shifting to PACU in ultrasound group is 1.08 with SD of 0.53 in previous study [9]. The final sample size came out to be as 60 (30 in each group) but to account for attrition and failures we took 50 in each group.

Results

A total of 100 patients were enrolled, with 50 patients at each centre with 25 in each group at each centre (Fig. 2). The patients were comparable in demographic variables (Table 1). The mean drug volume required to reach T10 level in Group U was 0.755 ± 0.053 ml/kg with a P value <0.001. (Compared to the drug volume of 1 ml/kg using one sample t test) (Fig. 3). The highest level achieved in both groups were calculated as the mode

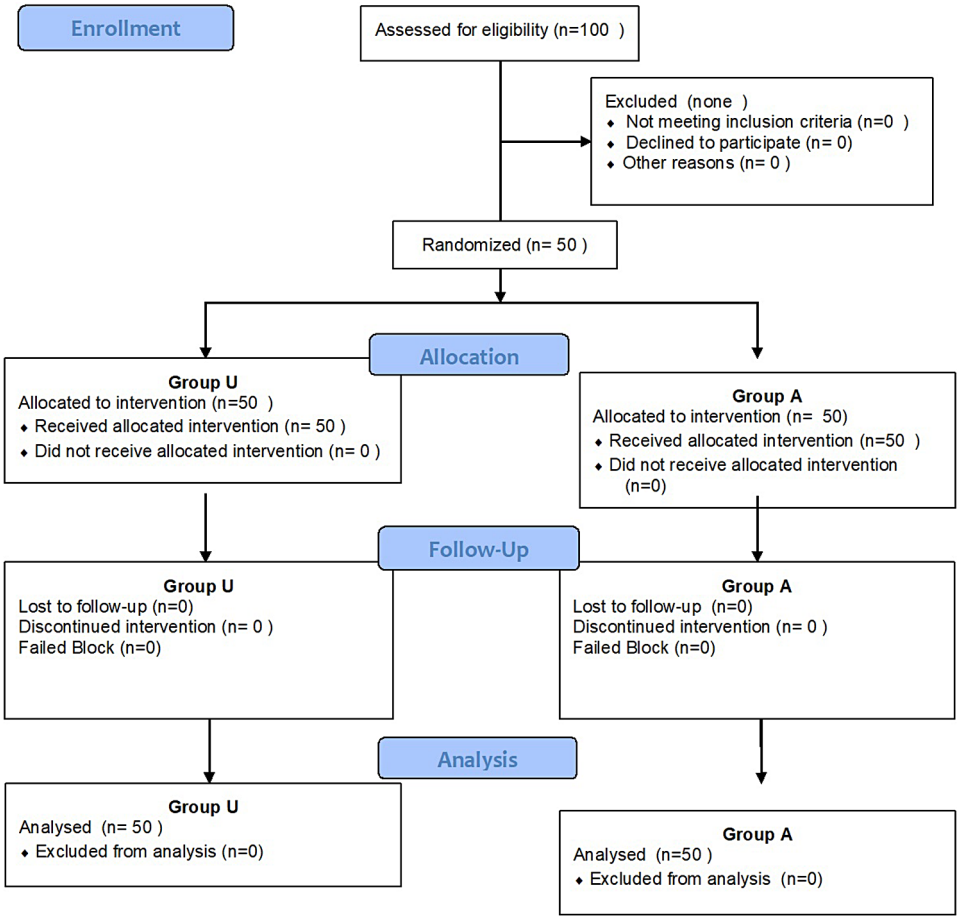

Fig. 2 Consolidated Standards of Reporting Trials (CONSORT) flow diagram of patient selection

Table 1 Demographic variables of the patients

Parameter	Group U (Mean ± SD)	Group A (Mean ± SD)	*P* value
Age (years)	3.5 ± 1.8	3.3 ± 1.9	0.590
Weight	13.7 ± 3.1	13.8 ± 3.9	0.887
Duration of surgery	75 ± 5.8	73 ± 4.7	0.07
Male/Female	42/8	43/7	

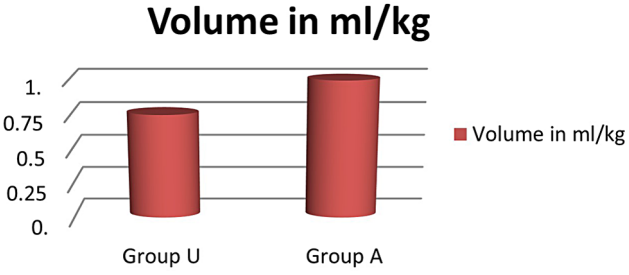

Fig. 3 Mean volume of drug required to reach T10 level in both groups

value of T9 and T8 in Group U and Group A respectively (Fig. 4). The highest cutaneous level achieved after 15 min in both groups was also calculated as the mode value of T4 in both groups (Fig. 5). The FLACC scores at 30 min post extubation were also comparable in two groups that is 2.2±1.0 in Group U vs. 2.1±0.9 in Group A with P value of 0.6004. In terms of satisfaction scores, they were comparable in both groups that is 1.39±0.573 in Group U vs. 1.47±0.618 in Group A with insignificant P value.

Discussion

The main finding in our study is that real time drug spread can be visualized using ultrasonography and a clinical successful block level can be achieved with a volume of 0.7 ml/kg for infraumblical surgeries in pediatric patients compared to the traditionally used volume of 1 ml/kg. Our results are in conjunction with a previously published study by Brenner et al. [5], who under dynamic ultrasound guidance measured the distance from conus medullaris to the level achieved by a fixed drug volume and found that one can reliably expect that inguinal hernia surgery can be successfully performed even using a volume as low as 0.7 ml/kg.

The modern-day concept of anaesthesia revolves around making it tailormade as per the requirement of the patient so as to ensure best results with minimal side

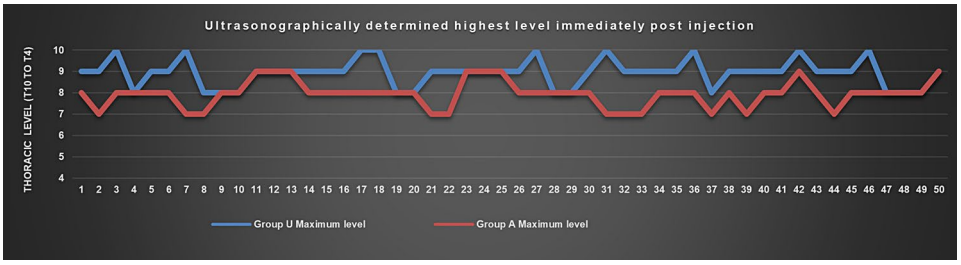

Fig. 4 Highest thoracic level immediately post injection in two groups, as seen with ultrasound. (Represented in y axis along with the case number in x axis)

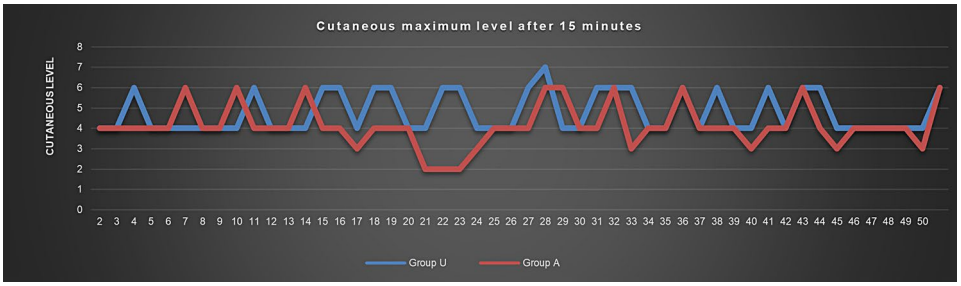

Fig. 5 Highest cutaneous level 15 minutes after caudal block

effects. Moreso, caudal anaesthesia is amongst the common blocks given in children for intraoperative and post operative pain relief. It accounts for 30–40% of regional techniques being used in pediatric patients [9]. Thereby, ensuring an adequate level of analgesia with minimal side-effects is of utmost importance, which further requires, calculation of an adequate amount to cater the same.

Thus, the findings in our study contradicts the established dose of 1 ml/kg which is based on Armitage formula. Armitage formula was submitted as a letter to the editor in 1979, based on the literary findings that the epidural space volume increases continuously from caudal to cranial, thus a volume of 0.5 ml kg^{-1} may be expected to reach sacral, 1.0 ml kg^{-1} lumbar, and 1.25 ml kg^{-1} mid-thoracic dermatomes [3].

However, it just gives an estimate of the volume required to reach these levels. Further research then followed and there were attempts to determine the volume dosing of caudal blocks using fluoroscopy guidance which largely failed to verify the results of these earlier publications [10, 11]. Rather, these studies mostly established that the maximum height under fluoroscopic visualisation rarely goes beyond T11 level. Though the clinical correlation, suggested that a midthoracic level is achieved clinically secondary to the phenomenon of cerebrospinal fluid rebound [4]. Also, the use of fluoroscopy is not dynamic and is limited by radiation exposure, cost, and special space requirement.

Regarding the maximum height achieved, there was no significant difference between ultrasound guided vs. formula-based group and clinically adequate anaesthesia (T10 level) was achieved in all patients which is consistent with the established literature that dermatomal level achieved is higher than actually visualized level [4].

Also, we through long term research in every other field of anaesthesia have learned that great individual variations exist in dosing and effect of anaesthetic drugs. The basic rule of anaesthesia that we should use minimum effective drugs in all patients, is more applicable to paediatric patients who have low range of safety to over dosing profile. Further it has been seen that high caudal doses can even lead to increase intracranial pressures, hence it is imperative to use just required doses rather than as much as possible [12]. Furthermore to stress this point it is also seen that paediatric patients suffer from LA toxicity even in doses which are well within the recommended LA dosing and that too in upto 41% of these cases [13]. This further reiterates our hypothesis of using minimum effective dosing in caudal anaethsia. Thus, individual patient based techniques are being universally applied in different domains of anaesthesia, from the use of BIS monitoring, to even concentration based drug infusion. But somehow caudal anaesthesia dosing is still relying on traditional nonobjective methods. As needle insertion in caudal space is now being done through ultrasonography in many centres and also epidual space is being visualized by same method, we through this study recommend the amalgamation of both to visualise spread of drug to epidural spaces for the purpose of estimate minimum effective dosing.

Though, there were some limitations in our study like the dermatomal levels were assessed only clinically with no objective testing and also marginally anaesthetized dermatomes might have been classified as properly blocked dermatomes owing to the additional effect of the sevoflurane anaesthetic being used. Also, we didn't used fluoroscopy which could have aided in further confirmation of drug spread and delineating phenomenon like CSF rebound.

We therefore advocate that real time ultrasonography should be used to place as well as to ascertain drug dosing via epidural space dilation/doppler color flow in caudal paediatric anaesthesia. We also advocate that a volume of 0.7 ml/kg of local anaesthetic in caudal block for infraumblical surgeries in pediatric patients compared to conventionally used volume of 1 ml/kg which is adequate to achieve surgical anaesthesia.

Real time ultrasonography can give objective individual based minimum effective dosing for caudal anaesthesia in paediatric patients and we found that a volume of 0.7 ml/kg of local anaesthetic in pediatric caudal block is sufficient to achieve a target of T10 level for infraumblical surgeries.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12871-024-02752-x.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Author contributions

KS concept and data collection and manuscript writing. AC manuscript text, final draft, data collection. MSK Data collection, final draft. All authors reviewed the manuscript.

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None.

Data availability

All data is included in the manuscript and any other queries can be sorted by communicating with the corresponding author.

Declarations

Ethics approval and consent to participate

This study was approved by the ethical review committee of Dr RKGMC Hamirpur, HP, India with reference no IEC/4/2023 (Ethics committee no ECR/1461/Inst/HP/2020ECR/1461/Inst/HP/2020) and registered with clinical trial registry of India, CTRI no - CTRI/2023/04/051251 dated 3/4/2023 All methods in this study were carried out in accordance with relevant guidelines and regulations. The patient's guardians provided written informed consent prior to participate in the study and were able to withdraw from the study.

Consent for publication

Taken from guardians.

Competing interests

The authors declare no competing interests.

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