ORIGINAL ARTICLE

Caudal analgesia for herniotomy: Comparative evaluation of two dose schemes of bupivacaine

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Abstract

Objective: There is currently a wide range of volume schemes for bupivacaine caudal anesthesia. This study evaluated the quality of caudal analgesia achieved with a dosing scheme of 0.75 ml/kg compared with 0.5 ml/kg of 0.25% plain bupivacaine for herniotomy.

Methods: After the institutional approval, American Society of Anesthesiologists I–II patients aged between 1 and 6 years scheduled for unilateral inguinal herniotomy with consenting parents/guardian were recruited. The subjects were randomized to receive 0.5 ml/kg (Group 1) or 0.75 ml/kg of 0.25% bupivacaine. Anesthesia was maintained solely with halothane 0.5–1% in 100% oxygen. Postoperatively, pain was assessed using the objective pain scale (OPS). A favorable pain score was defined as <4 (8 point scale) or <5 (10 point scale). The primary outcome was the proportion of subjects with favorable pain scores.

Results: Fifty-six patients were enrolled and there was no difference in sociodemographic parameters, preoperative hemodynamic variables, or duration of surgery. Proportions of subjects with favorable OPS scores showed marked differences from 45 min and peaking at 180 min (11 [39%] favorable scores in Group 1 compared to all [100%] favorable scores in Group 2, $P < 0.0001$). Mean time to first analgesic requirement was 126 ± 34.2 min in Group 1 compared to 249 ± 23.7 min in Group 2 ($P < 0.0001$). There was no difference in the incidence of adverse events between groups.

Conclusion: This study shows that 0.75 ml/kg of 0.25% plain bupivacaine is superior to the use of 0.5 ml/kg of the same concentration for postherniotomy caudal analgesia with low side effect profile.

Key words: Bupivacaine, caudal anesthesia, herniotomy, postoperative analgesia

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Introduction

Scientific drug use is based on the concepts of efficacy and safety. Although safety issues remain paramount, nonefficacy renders a drug useless for the recipient and defeats the main goal of anesthesiology: Safe relief from pain.[1]

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Herniotomy ranks among the most common procedures in pediatric surgical practice, offering surgical cures with a high success rate for childhood inguino-scrotal hernias.[2] The surgical incision and manipulation consistently involves an anatomical area innervated by the iliohypogastric, ilioinguinal, and genitofemoral nerves, corresponding to upper lumbar dermatomes and the lowest thoracic dermatome.

Caudal analgesia using bupivacaine is a widely employed technique for achieving both intraoperative and early

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postoperative pain relief. 0.5 ml/kg of 0.25% plain bupivacaine is favored by many practitioners who employ this fixed scheme for procedures involving sacral dermatomes (circumcision, hypospadias repair) as well as lower thoracic dermatomes (orchidopexy).[2] However, there are other dosing regimens for caudal blocks with variable analgesic success rates: These include 0.75 ml/kg, 1.0 ml/kg and 1.25 ml/kg.[3]

The different dosing regimens have been provoked by the need for prolonged pain-free period after caudal anesthesia. Indeed, the use of adjuncts has been tried with variable successes. Nafiu *et al*.[4] in a prospective randomized study compared the analgesic effects of caudal ketamine, caudal bupivacaine, and a caudal ketamine-bupivacaine mixture. Subjects receiving the ketamine-bupivacaine mixture exhibited a median time to first analgesic request of 14 h, which was significantly longer than the 8 h exhibited by the ketamine only group, and the 4 h of the bupivacaine only group. The use of a 0.125% solution of bupivacaine may have accounted for the much shorter duration of analgesia experienced by the bupivacaine only group. S-ketamine, the preservative-free stereoisomer suitable for the caudal space, as well as these other adjuncts are not commonly available in the West African subregion.

Furthermore, a major obstacle to elucidating success rates at different dermatomal levels has been the grouping of procedures involving widely separated dermatomes. Edomwonyi and Egwakhide[5] studied 62 children aged 1–12 years undergoing either unilateral inguinal herniotomy or orchidopexy. The study examined the efficacy of 0.25% bupivacaine, comparing local infiltration and nerve block to the caudal administration of 0.5 ml/kg. A success rate of 90% for the caudal group was reported. There is no information on the proportion of patients undergoing either orchidopexy or herniotomy, and so the success rate for herniotomies specifically remained undetermined. In addition, the dermatomal innervations for herniotomy and orchidopexy are different, and the level of block required may also vary.

It may be worthwhile to investigate surgical procedures with similar dermatomal innervations and determine the duration of analgesia in the postoperative period. Hence, this study compared two dosing regimens in a population of children for the same procedure: Herniotomy. We hypothesized that the administration of 0.75 ml/kg of plain bupivacaine 0.25%, would achieve improved quality of postoperative analgesia compared to a dose of 0.5 ml/kg.

Methods

This prospective randomized comparative study was conducted at the University of Benin Teaching Hospital. American Society of Anesthesiologists (ASA) I or II children aged between 1 year and 6 years scheduled for unilateral herniotomy were recruited for the study. Parent's or guardian's refusal, known allergy to bupivacaine, need for over 20 ml of the study medication, co-existing neurological disease, sacral bone deformities precluding needle insertion, and coagulopathy in any patient were excluded from the study.

Approval was sought and received from Institutional Research and Ethics Committee. Eligible patients were identified, and the study procedure explained to the parents or responsible guardian. After that, consent was obtained during the preoperative evaluation. There was no premedication. At any time, the patient/guardian may wish to withdraw from further participation in the study and such decision did not affect the quality of care received.

A computerized randomization schedule was generated assigning subjects to one of two groups using sealed envelopes: Group 1 received 0.5 ml/kg, and Group 2 received 0.75 ml/kg of 0.25% plain bupivacaine. The assessor, and not the operator, was blinded to the medications received by patients in each group.

Baseline vital signs were obtained and recorded before induction of anesthesia using a multiparameter monitor and included: Respiratory rate, heart rate, blood pressure, and oxygen saturation. Anesthesia was induced with incremental doses of halothane (0.5–2%) in 100% oxygen via a face mask. The principal investigator (Dafe Daniel Akpoduado) performed the caudal blocks and the assistant, the registrar anesthetist did the intraoperative monitoring and recording of patients' physiological parameters. Following induction, the patients were placed in the left lateral decubitus position with hip and knee flexion, the skin over the sacral region to the natal cleft was disinfected using povidone solution, and the sacral hiatus was identified employing palpation of both sacral cornua; a 22-gauge short bevel needle was used for caudal puncture perpendicularly to the skin surface and advanced 1 cm parallel to the skin after penetration of the sacrococcygeal membrane. Aspiration was done to exclude subarachnoid or intravascular placement of the needle. Bupivacaine at the appropriate concentration and volume dose was then injected into the caudal space. The patients were then returned to the supine position for surgery. Vital signs were measured every 5 min till the end of surgery. Anesthesia was maintained solely with halothane at concentrations of between 0.5% and 1.0% in 100% oxygen with the patient breathing spontaneously using a face mask. In the recovery room, after consciousness was regained, the recovery room nurse, who was educated on the use of the objective pain scale (OPS), performed pain assessment. After transfer to the ward, the ward nurses, also educated on the use of the OPS, performed pain assessment using the OPS [Table 1].[6]

Pain scores were assessed every 15 min for the 1st h and then hourly for the next 6 h. Scores exceeding 5 points for patients who could self-report and exceeding 4 points for those who could not were treated using oral paracetamol at a dose of 15 mg/kg. The aim was for a transition to simple oral analgesics following offset of caudal analgesia.

The proportion of subjects scoring either <5 points if self-reporting, and <4 points if not self-reporting on the OPS formed the primary outcome. Other outcomes of interest included: Time to first analgesic requirement; mean analgesic consumption; incidence of side effects, hypotension, respiratory depression, vomiting, and urinary retention.

Sample size determination was based on the incidence of 60% of successful analgesia in a population of children receiving 0.5 ml/kg of 0.25% bupivacaine for herniotomy.[5] We wished to achieve a 30% improvement in the proportion of children with good analgesia the following herniotomy. Using a formula for sample size calculation based on proportions with two-sided tests, accepting a Type I error rate of 0.05 and a Type II error rate of 0.2, 26 patients were required in each group with a planned recruitment of 56 patients for the study.

Data were analyzed using SPSS version 11 (SPSS Inc., Chicago, Illinois, USA). The demographic characteristics (age, sex, height, and weight), duration of anesthesia, time to completions of herniotomy, baseline heart rate, and respiratory rate were summarized as means (standard deviation). Continuous data were analyzed using Student's *t*-test with Welch correction. The proportion of subjects with favorable pain scores at each observational period was determined. The categorical data were presented as counts and frequencies. The association between dose of bupivacaine and quality of analgesia was determined using contingency tables and Fisher's exact test. The value of $P < 0.05$ was considered statistically significant. All statistical tests were two-sided.

Results

A total of 56 subjects ASA Class I or II were enrolled for this study; 28 children to each group. The caudal block was successfully placed in all subjects. The demographic characteristics were similar in both groups [Table 2].

Intraoperative parameters were similar in both groups. There were apparent increases from baseline values in the hemodynamic variables in both groups: Mean heart rate (0.56, *t*-test) and systolic blood pressure (0.81), but the differences did not achieve statistical significance. Median oxygen saturation values were also comparable. The duration of surgery was similar in both groups [Table 3].

Table 1 shows the parameters on the OPS. OPS scores below 4 on the 8 point scale and below 5 on the 10 point

Table 1: Objective pain scale

Parameter	Finding	Points
Systolic blood pressure	<20% of preoperative	0
	Between 20% and 30% of preoperative	1
	>30% of preoperative	2
Crying	Not crying	0
	Responds to age appropriate nurturing	1
	Does not respond to nurturing	2
Movements	Relaxed	0
	Moving about constantly	1
	Thrashing	2
	Rigid	2
Agitation	Asleep or calm	0
	Mild agitation	1
	Hysterical	2
Complaints of pain	Asleep	0
	States no pain	0
	Cannot localize	1
	Localizes	2

Table 2: Demographic characteristics of patients

Parameter	Group 1 (*n*=28)	Group 2 (*n*=28)	*P*
Age (year)	3.26±1.907	2.96±1.805	0.5480
Height (cm)	90.9±20.12	88.1±17.36	0.5795
Weight (kg)	15.08±4.799	14.89±4.653	0.8810
Male/female	22/6	26/2	0.2516

Table 3: Intraoperative vital signs and duration of surgery

Parameter	Group 1	Group 2	*P*
Heart rate (/min)	119.75±11.212	122.04±17.213	0.5582
Systolic blood pressure (mmHg)	100.54±13.50	99.7±12.95	0.8131
SpO_2 (%)*	99	99	
Duration of surgery	32.7±4.54	34.5±3.95	0.13

*Data presented as median

Table 4: Proportion of subjects with favorable objective pain scale scores at each measurement interval

Interval (min)	Group 1	Group 2	*P*
0	28/0	28/0	1.0000
15	28/0	28/0	1.0000
30	26/2	28/0	0.4909
45	19/9	28/0	0.0018
60	15/13	28/0	<0.0001
120	12/16	28/0	<0.0001
180	11/17	28/0	<0.0001
240	13/15	27/1	<0.0001
300	13/15	23/5	0.0111
360	18/10	22/6	0.3753

Table 5: Time to first analgesic requirement and Paracetamol consumption

Feature	Group 1	Group 2	*P*
Time to first analgesic requirement (min)	126±34.2	249±23.7	<0.0001
Paracetamol consumption (mg)	165.0±68.55	139.2±76.68	0.1901

Table 6: Incidence of adverse events

Event	Group 1	Group 2	*P*
Urinary retention	0/28	0/28	1.000
Bradycardia	0/28	0/28	1.000
Hypotension	2/28	1/28	0.987
Vomiting	1/28	0/28	0.999

scale were regarded as indicative of the absence of pain. Proportions of subjects with favorable scores were identical for both groups at the 0 and 15 min interval [Table 1]. Statistically significant differences first emerge at 45 min with 9 unfavorable scores in Group 1 compared to none in Group 2 ($P = 0.0018$, Fisher's exact test). The difference becomes more significant at 60, 120, 180, and 240 min. At 360 min more subjects in Group 1 still have unfavorable scores (10–6), but the difference did not achieve statistical significance [Table 4].

Time to first analgesic requirement was significantly longer ($P < 0.0001$) in Group 2 compared to Group 1 (249 min vs. 126 min). Mean paracetamol consumption was more in Group 1, this did not achieve statistical significance [Table 5].

Few adverse events were observed in both groups. No subject had urinary retention or bradycardia. Two patients in Group 1 and one in Group 2 developed hypotension with spontaneous resolution. One patient in Group 1 had an episode of vomiting. These events did not achieve statistical significance between groups [Table 6].

Discussion

The results indicate that plain bupivacaine 0.25% at a dose of 0.75 ml/kg compared to a dose of 0.5 ml/kg when administered for herniotomies provides improved quality of caudal analgesia with a low side effects profile. There were consistently more patients with favorable OPS scores at all timelines, increased the time to the analgesic request with similar postoperative consumption of paracetamol in the group of patients who received 0.75 ml/kg of 0.25% bupivacaine.

The proportion of subjects with favorable scores at each measurement interval formed the primary outcome of this study. Considering the absence of statistically significant differences between both groups in demographic, preoperative and intraoperative vital signs parameters, the differences observed in the proportion of favorable and unfavorable scores between groups may thus be adduced to the administration of either 0.5 ml/kg or 0.75 ml/kg of 0.25% plain bupivacaine. The reliable measurement of pain intensity has assumed an important dimension in the face of recent knowledge demonstrating the detrimental effects of untreated pain.[7] The OPS developed by Hannallah *et al*.[6,8] was adopted as the means of pain assessment during the 6 h postoperative observation period of this study. The OPS is a well-validated tool for pain assessment in children, especially when evaluating nonhomogenous groups of preverbal and verbal groups. Kundra *et al*.,[9] using the OPS for measurement of pain intensity, demonstrated the preemptive analgesic effects of caudal bupivacaine and morphine. This further confirms the reliability of the OPS in the assessment of pain in children.

The time to first analgesic requirement may also be indicative of the quality of analgesia. Mean time to the analgesic requirement as observed in this study was 249 min in Group 2 compared to 126 min in Group 1 ($P < 0.0001$), a highly significant finding similar to reports from other investigators. Nafiu *et al*.[4] also reported a mean time to first analgesic request of 4 h (240 min) in subjects receiving plain bupivacaine. However, limitations to the interpretation of this similarity include differences in dosing patterns: 0.125% bupivacaine, 1 ml/kg in their study compared to 0.25%, 0.75 ml/kg in this study. Several authors have reported variable time to first analgesic request[6,10,11] However, it is evident that employing 0.75 ml/kg for surgical procedures involving the lowest thoracic dermatome, such as in herniotomy, provides a better quality of analgesia compared to 0.5 ml/kg of 0.25% plain bupivacaine as shown in this study.

Mean analgesic consumption also constitutes a parameter by which the efficacy of an analgesic technique may be measured. However, limitations exist in the use of this parameter and include difficulties in standardizing the dosage, especially when oral formulations are employed. The subjective nature of pain assessment in children also implies nonuniformity in the administration of supplementary analgesics: Caregivers may withhold the drug if in their opinion the child is not in pain, and may administer the drug if they consider the child to be in pain. Their opinion however, may be at variance with reality. In this study, subjects with unfavorable scores were treated with oral paracetamol syrup. Although, the intention of this study was to administer the oral formulation at a dose of 15 mg/kg, available formulations made this impractical as a teaspoon dose of 5 ml contains 120 mg; only integral increments of 120 mg could be measured with accuracy. Thus, age was used as the factor for dosing. This may have accounted for the lack of difference observed in the mean paracetamol consumption among the groups (165 mg in Group 1, 139 mg in Group 2).

Another study assessing mean analgesic consumption following caudal blocks with bupivacaine have reported similar results when the analgesic has been provided in the form of oral formulations. Anatol *et al*.[12] did not detect statistical differences in the need for supplementary analgesia between three groups receiving 0.5% bupivacaine either by skin infiltration, caudal block or a combination of both. Supplementary analgesia was also provided by oral formulations. The similarity of results reflects the difficulty of interpreting mean analgesic consumption data when the analgesic is provided in oral formulations.

It has been established that sensory block regression follows a dermatomal pattern.[3] Grouping surgical procedures involving different dermatomal levels creates difficulties in the interpretation of findings when comparing groups for quality of analgesia. The design of this study has attempted to circumvent this difficulty by the restriction of patient recruitment to a single surgical procedure consistent in its dermatomal involvement. In herniotomy, the skin surgical incision is restricted to the inguinal region which has the twelfth thoracic nerve as the highest dermatomal sensory innervation. The equating quality of analgesia to time to first analgesic requirement, this study demonstrates that a better quality of analgesia is achieved with the use of 0.75 ml/kg compared to 0.5 ml/kg of plain bupivacaine 0.25% when the lowest thoracic dermatome is the upper limit of involvement in the surgical procedure.

The use of adjuvants seems to be the standard in Europe and North America[7,8,13,14] but this is yet to become routine in our institution.[5,15] Hence, the need for other dosing schemes to achieve better results. Hager *et al*.[16] dispensed totally with local anesthetics in evaluating the caudal analgesic effect of either S(+)-ketamine alone or in combination with clonidine in a prospective randomized trial. Although adequate analgesia seems to have been achieved over the 24 h observation period, especially in subjects receiving clonidine, time to sedation scores of 3 (reflecting a drowsy state) was only achieved after a median of 179 min, reflecting prolonged sedation. A difficulty yet to be overcome in resource-poor settings like ours is the availability of preservative-free formulations. Bupivacaine, one of the most available local anesthetics found in the West African sub-region. This study shows that bupivacaine improves the quality of analgesia after herniotomy. The dual role of augmenting perioperative surgical anesthesia and providing early postoperative analgesia, particularly in resource-poor settings like ours, underscores the use of 0.75% dosing pattern for herniotomy. Indeed, a recent meta-analysis demonstrated the usefulness of caudal block over other noncaudal techniques for inguinal surgeries in children.[17]

The rational use of a drug aims to maximize efficacy while minimizing toxicity and the incidence of adverse events. It is necessary to consider unwelcome effects from local anesthetics in two categories: Those effects arising from the blockade itself, for example, urinary retention, motor blockade, unintentional subarachnoid, or intravascular administration; and those arising from cardiovascular and central nervous system (CNS) toxicity, e.g., convulsions and cardiovascular collapse. Fears of toxicity may be responsible for the use of 0.5 ml/kg of 0.25% plain bupivacaine. However, the results of this study argue against the long-held position on the dose of 0.5 ml/kg. Urinary retention and bradycardia were not observed in any of the groups during the 6 h observation period. Other studies have used the time to voiding urine as an indicator of urinary retention, but since other factors may influence urine production (e.g., fluid balance), time to voiding may not reflect the true picture in all cases. Hypotension defined as a systolic blood pressure reduction of more than 20% of baseline values was minimal. Furthermore, CNS and cardiovascular toxicity were not observed in this study probably due to the meticulous attention to detail observed during the placement of the blocks. It should be noted, however, that considering the generally low incidence of adverse events from toxicity, this study may not be statistically powered to clearly demonstrate a difference between groups. Nevertheless, a retrospective analysis of 2088 cases of caudal block demonstrated a low incidence of side effects too.[18]

Several limitations were identified in this study. First, the age range studied (1–6 years) necessitated the evaluation of both preverbal and verbal children, introducing some degree of nonuniformity in the study sample. However, this age range represents the highest incidence of presentation for herniotomy, hence the compelling need to study this population. Secondly, paracetamol consumption could not be standardized on a weight basis due to the oral formulation employed. In addition, the scoring system does not account for other causes of crying in children: Presence of intravenous cannulae, the absence of parents/guardian, hunger, etc., These limitations notwithstanding, the strength of the observation of the quality of perioperative analgesia adds value to the available evidence for the use of caudal blocks for herniotomy. In addition, the low side effects profile seen in this study emphasizes the safety of caudal techniques even at a dose of 0.75 ml/kg.

Conclusion

This prospective, randomized, comparative study evaluated 2 doses of 0.25% plain bupivacaine (0.5 ml/kg vs. 0.75 ml/kg) so as to determine the quality of analgesia for herniotomy. The results showed that 0.75 ml/kg provided a better quality of analgesia as determined by improved scores on OPS and time to first analgesic requirement. In addition, minimal side effects were observed. The use of caudal analgesia with plain bupivacaine 0.25% at a dose of 0.75 ml/kg for herniotomy is effective and safe.

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Conflicts of interest
There are no conflicts of interest.

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