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Prospective Randomized Trials

The analgesic effects of rectal diclofenac versus rectal paracetamol following caudal-bupivacaine for pediatric day-case inguinal herniotomies: a randomized controlled prospective trial

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ABSTRACT

Background: Postoperative pain is a common complaint in day-case inguinal herniotomy, thus there is a need to provide effective analgesia. This study compared the postoperative analgesic effects of the combinations of caudal-bupivacaine and rectal diclofenac with caudal-bupivacaine and rectal-paracetamol in children scheduled for daycase inguinal-herniotomy.

Methods: Ninety children of ASA I scheduled for elective day-case inguinal-herniotomy were randomly assigned into Group A (1 ml/kg of 0.25% caudal-bupivacaine and 1 mg/kg rectal-diclofenac), Group B (1 ml/kg of 0.25% caudal-bupivacaine and 30 mg/kg rectal paracetamol) and Group C (1 ml/kg of 0.25% caudal-bupivacaine). The duration of analgesia, pain scores, postoperative analgesic consumption and side effects were assessed and recorded. Data collected was analyzed with the statistical package for social sciences 17 for windows.

Results: Eighty-seven children completed the study, and it was found that the duration of analgesia was prolonged in Group A compared to Groups B and C ($p < 0.01$).

Conclusion: Caudal-bupivacaine and rectal-diclofenac combination provides a more prolonged postoperative analgesia, and lower pain score compared to caudal-bupivacaine and rectal-paracetamol combination or caudal-bupivacaine alone.

Level of evidence: Level 1 evidence treatment study. Randomized controlled trials with adequate statistical power to detect differences (narrow confidence intervals) and follow up >80%.

Pain experienced at home following day-case inguinal herniotomy is a major cause of suffering and discomfort in children with incidence as high as 72% in Nigeria [1]. Good immediate postoperative analgesia can be achieved with caudal anesthesia, but may not be adequate to relieve the pain felt at home [1,2]. The inadequate provision of analgesia for children are influenced by the beliefs that children either do not feel pain or feel less pain, fears of drug toxicity, as well as difficulty in assessing pain in the young children [3–5].

Rectal-diclofenac and rectal-paracetamol as adjuncts of caudal-bupivacaine have been evaluated separately, and found to be adequate and effective in postoperative pain management in day case inguinal herniotomy (DCIH) [5]. However, the comparable quality of analgesia for postoperative DCIH using a combination of caudal-bupivacaine and rectal-diclofenac or rectal-paracetamol is yet to be exclusively evaluated. We hypothesized that postoperative analgesia may be prolonged by a combination of caudal anesthesia with a rectal analgesic. The purpose of our study was to compare the postoperative analgesic effects of the combinations of caudal-bupivacaine and rectal-diclofenac with caudal-bupivacaine and rectal-paracetamol in children scheduled for DCIH.

1. Methods

Ninety children aged 1–6 years were included in this prospective, randomized comparative study. They were ASA physical status I and underwent elective, day case unilateral inguinal herniotomy. The study was carried out at the University of Port Harcourt Teaching Hospital and was approved by the institution's ethics and research committee. The parents of the children gave written informed consent. Patients were excluded if they had huge unilateral inguinal hernia as indicated by the surgeon because this was not a routine herniotomy, was judged difficult to repair, and likely to be associated with increased surgical trauma and pain. Other exclusion criteria were patients scheduled for emergency inguinal herniotomy, ASA II-V patients, known allergy to the study medicines, and bleeding disorder. Those who did not meet the fasting criteria were rescheduled.

All children were evaluated in the morning of the surgery. They were randomized by a computer-generated number assignment to 3 groups

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Table 1
Demographic characteristics.

Variable	Group A (n = 29) mean ± SD	Group B (n = 28) mean ± SD	Group C (n = 30) mean ± SD	p value
Age (y)	2.38 ± 1.36	2.68 ± 1.49	2.73 ± 1.57	0.61
Weight (kg)	12.88 ± 4.01	14.01 ± 4.65	13.57 ± 4.85	0.64
Height (m)	0.94 ± 0.16	1.03 ± 0.19	0.93 ± 0.18	0.06

of 30 children each. A sample size of 30 patients for each group (A, B and C), including the attrition rate of 10% was derived, by applying the formula for comparison of means [5–7]. All the children were premedicated with rectal midazolam 0.5 mg/kg and intravenous 4.3% dextrose in 0.18% saline was commenced [8]. The Dash 4000 monitor (GE Medical system information technologies Inc. USA) was used for monitoring systolic, diastolic and mean arterial blood pressures (SBP, DBP, MAP), heart rate (HR) and rhythm, respiratory rate (RR), arterial oxygen saturation (SaO_2) and peripheral temperature.

General anesthesia was induced with halothane in 100% oxygen via a facemask, with a gradual increase of halothane up to 3%. An appropriate sized laryngeal mask airway (LMA) was inserted into the pharynx, connected to a capnosat and breathing circuit. Anesthesia was maintained with 0.75–1.5% halothane in oxygen and the patient allowed to breathe spontaneously via Mapleson F circuit for patients weighing <25 kg or Bain's circuit for patients weighing >25 kg, using a fresh gas flow rate of 2.5 x minute ventilation.

All patients had caudal-block with 1 ml/kg of 0.25% isobaric-bupivacaine. In the diclofenac group (A), the children received rectal diclofenac 1 mg/kg. In the paracetamol group (B), the children received rectal paracetamol 30 mg/kg. Group C received no other analgesic. Surgical site preparation and surgery was commenced about 10–15 min after caudal injection. Investigators were blinded regarding the patients' study medication.

Intraoperative SBP, DBP, and MAP were monitored every 5 min, while HR, heart rhythm, SaO_2, peripheral temperature, end tidal carbon dioxide and surgical blood loss were monitored continuously. Bradycardia and hypotension were managed with intravenous atropine 0.02 mg/kg and ephedrine 0.2 mg/kg respectively. Hypothermia was prevented in this study by giving warm intravenous fluids. The theater temperature was maintained at the range of 21–24 °C.

At the end of surgery, halothane was discontinued, the oropharynx suctioned, the LMA removed and the child was given 100% oxygen via a facemask for a minimum of 5 min before transferring to the post anesthesia care unit (PACU). Each child was monitored in the PACU for 4 h, and data were collected by a blinded PACU staff. Systolic blood pressure, DBP, MAP, SaO_2, HR and RR, temperature, motor-block, pain and sedation were monitored and recorded on arrival in the PACU (0 min), thereafter at 15 min, 30 min, 1 h, 2 h, 3 h and 4 h later. Pain was assessed with observational pain scale [5] as such: laughing – 1; happy, contended – 2; calm, asleep – 3; grimace, restless – 4; and crying, screaming – 5. The patients were classified as having no pain (1–3), mild/moderate pain (4), and severe pain (5). Pain score ≤3 was termed adequate analgesia. Time to micturition and ambulation were documented.

The duration of analgesia was taken as the interval between the caudal-bupivacaine injections to the time of first request for analgesia (observational pain score ≥4). The patients were discharge home from PACU after 4 h of monitoring and the parents were given a phone number to call in case of an emergency. Instructions given included ensuring the child had enough rest, keeping the operation site clean and dry, and returning to the hospital if there were concerns or they observed vomiting, fever, restlessness, swelling and bleeding at the operation site. Parents/guardian were asked to record (in a postoperative questionnaire) the pain scores at home every 4 h for 24 h. At pain score ≥4, first oral paracetamol 15 mg/kg was administered by the carer and documented, and supplemental doses given every 6 h. Patients were followed up by phone call up till the first post-operative visit 5 days later.

The data were analyzed with the statistical package for social sciences (SPSS) 17 for windows. A p-value of <0.05 was considered significant. chi-Square test was used to analyze the nominal data. Age, weight, height, pain score, duration of surgery, baseline blood pressures, lowest and highest blood pressures were analyzed with student's t-test. Parametric data was analyzed using two-tailed analysis of variance (ANOVA) for independent groups.

2. Results

Out of the 90 patients recruited for this study, one patient in Group A and two patients in Group B were excluded following surgical re-exploration to manage hematoma formation. Eighty-seven patients completed the study. The patients' demographic characteristics are summarized in Table 1. Patients in the three groups were comparable with respect to age (p = 0.61), weight (p = 0.64) and height (p = 0.06).

The perioperative characteristics are presented in Table 2. There were no differences between the three groups in terms of the duration of surgery (p = 0.11), caudal injection to incision time (p = 0.54), duration of recovery from halothane (p = 0.91), time to ambulate (p = 0.25), and time to micturate (p = 0.98). The duration of analgesia was prolonged in Group A (12.93 ± 4.46 h) compared to Group B (7.75 ± 3.12 h) and Group C (6.43 ± 2.94 h), and the difference was statistically significant (<0.01).

Table 3 details the intraoperative haemodynamic changes. The increase in the mean highest HR was more in Group A (153.00 ± 7.48 bpm), but the change was similar in the three groups (p = 0.10). The reduction in the mean lowest HR was more in Group B (79.67 ± 2.58 bpm), it was 79.83 ± 3.19 bpm in Group C, and 93.67 ± 1.86 bpm in Group A and the difference among the three groups was statistically significant (p < 0.01). The rise in the mean highest SBP was more in Group B (105.67 ± 7.29 mmHg) but the change was similar for the three groups (p = 0.12). The reduction in the mean lowest SBP was more in Group C (65.33 ± 2.73 mmHg) compared to that in Group B (67.83 ± 3.97) and Group A (68.17 ± 3.19), and the difference was not statistically significant (p = 0.3).

The mean highest DBP was observed to increase more in Group B (56.17 ± 1.47 mmHg) but the change was similar among the three

Table 2
Perioperative characteristics.

Variable	Group A (n = 29) mean ± SD	Group B (n = 28) mean ± SD	Group C (n = 30) mean ± SD	p value
Surgical condition (LIH/RIH)	17/12	18/10	18/12	
Duration of surgery (min)	25.79 ± 14.00	20.04 ± 8.79	21.93 ± 7.58	0.11
Caudal injection to incision Time (min)	14.00 ± 3.00	13.61 ± 3.56	13.03 ± 3.09	0.54
Duration of Recovery from halothane (min)	52.67 ± 16.25	53.07 ± 16.36	54.47 ± 18.90	0.91
Time to ambulate (min)	137.17 ± 38.32	155.29 ± 47.46	141.33 ± 41.90	0.25
Time to micturate (min)	118.90 ± 29.27	118.14 ± 27.95	117.6 ± 29.13	0.98
Duration of analgesia (h)	12.93 ± 4.46	7.75 ± 3.12	6.43 ± 2.94	<0.01*

* Significant.