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RESEACH ARTICLE

ONSET TIME AND DURATION OF ACTION OF PLAIN BUPIVACAINE AND BUPIVACAINE WITH DEXAMETHASONE CAUDAL BLOCK FOR POSTOPERATIVE ANALGESIA WITH IN UNDER FIVE CHILDREN FOR DAY CASE SURGERY

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4

Abstract

Background: Caudal block is done in children which can easily wear off and the need for adjuvant that can safely prolong its analgesic duration. The fear of the adverse effects of opioids especially respiratory depression, emesis and sedation have restricted their usage. This study was designed to evaluate the onset time and duration of action of plain bupivacaine and bupivacaine with dexamethasone caudal block in children. **Methods:** This was a clinical trial involving ninety (90) under 5 years children who had infra-umbilical surgeries . They were assigned to two groups. Group A had caudal block with 0.5 ml/kg plain bupivacaine with saline and Group B had caudal block with 0.5 ml/kg bupivacaine added with 0.1 ml/kg dexamethasone. Postoperative analgesia was assessed using FLACC, at 0-hour arrival at PACU and vital signs were recorded hourly for the first 3 hours, then 4 hourly for 24 hours. Paracetamol was given whenever FLACC score **Results:** The was no significant difference in the mean onset of analgesia. The mean time to first analgesic request was significantly longer after caudal block with dexamethasone additive (Group B)compared with bupivacaine only Group. **Conclusion**: The study has shown that addition of dexamethasone to plain bupivacaine for caudal block was more efficient and showed longer duration of analgesia compared to caudal block with plain bupivacaine alone.

Key words: onset time, duration of action, bupivacaine, dexamethasone, caudal block.

INTRODUCTION

Analgesia during surgery is one cardinal goal in the mind of an anaesthetist but the Goal standard has not yet been found as started by Treede (2015). Angie (2020) defines pain as an unpleasant sensory and emotional experience associated associated with actual or potential tissue damage. Postoperative pain is associated with negative effect on the recovery. Evidences suggest inadequate relief of postoperative pain result in harmful physiological and psychological consequences that increase morbidity and mortality. Almajali *et al.* (2017) stated that Pain following surgeries in children result in crying, restlessness,

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agitation, sleep deprivation, bleeding and delay in wound healing. Every invasive procedure causes unpleasant sensation therefore pain needs to be anticipated and properly treated during every surgical procedure.

Although good pain relief is achieved in caudal block with plain bupivacaine, moderate to severe pain develops as the block soon wears off. Dexamethasone a corticosteroid prevents the release of inflammatory agents and prolongs the pain relief actions of local analgesics in peripheral nerve blocks. Wiegele M, et al (2019). A single short dexamethasone is safe and not associated with the side effects seen in chronic users. Prabha *et al.* (2018). In contrast to other anti-inflammatory agents, dexamethasone has additional benefits for treatment of nausea and vomiting suitable for perioperative use. Prabha *et al.* (2018). These properties, when explored can make a suitable adjuvant for caudal block in postoperative analgesia.

Regions below the umbilicus and other organs within the perineum are very sensitive with moderate to severe pain sensation. Ecoffey *et al.* (2010), Adudu *et al.* (2011) found that there is still lack of training and adequate skills in paediatric acute pain service (PAPS). They reported lagging trend in intraoperative pain relief for paediatric surgical cases with the old generation opioid medications and old modalities of pain treatment up to 87.7%, while caudal block was only 7.1% in paediatric patients. This has set a laudable call for the use of caudal block and possible improvement in pain relief modalities. The denial of the paediatric age group of pain treatment has been a long time issues which physicians need to overcome. Charlton *et al.* (2016) reported some unpleasant effects of pain on patients when improperly treated. Some may result to prolonged hospital stay or unplanned hospital admission. Others used as adjuvants: alpha-2 agonists (clonidine and dexmedetomidine), ketamine, midazolam, neostigmine and others used as adjuvants have side effect that discourages their usage Lillieborg (2004), Dexamethasone a corticosteroidith long-acting anti-inflammatory effects can provide postoperative analgesia and improvement in morbidity such as nausea, vomiting, fever, delayed emergence and improve oral intake in paediatric postoperative day case surgery Prabha *et al.* (2018). Postoperative pain is assomission and lack of patients satisfaction have been encountered. Evidences suggest inadequate relief of postoperative pain results in harmful physiological and psychological consequence, hence increases morbidity and mortality. Ideal adjuvant is still a matter of contention and the quest for a drug that provides maximal analgesia with minimal side effects for caudal block in children continues till date. Regional anaesthesia when well explored can provide efficient analgesia and reduce the use of general anaesthesia with related complications that are associated with intubation in children. Caudal block is a gold standard in children for many surgical procedures in children yet it is not a common practice in many centres. Infraumbilical surgeries such as herniotomy, circumcision, orchidopexy and other perineal procedures makes the bulk of everyday surgical procedures in must hospitals which can be done under caudal block with good postoperative analgesia. Caudal block gives good analgesia but only for a short duration, one way to increase the duration and efficacy of the block is to use a high concentrated local anaesthetic agent in large volume, this result in unwanted motor blockade; hence the need to balance efficacy becomes needful. To avoid these problems, many additives have been tried to improve the quality of caudal block without increasing the dose of local anaesthetic agents but results are not yet exhaustive.

Dexamethasone has strong anti- inflammatory properties prolong analgesia and treat nausea and vomiting. Dexamethasone is readily available, cheap and not a controlled drug in Nigeria, yet only few researches have been conducted on it in this country and northern Nigeria in particular. Charlton and Jonathan (2016). If dexamethasone is found to be effective as an adjuvant to bupivacaine it will go a long way in providing prolonged analgesic effect, reducing the dose of bupivacaine and minimize the side-effects encountered with other adjuvants used for caudal analgesia and prolong the postoperative analgesic duration in caudal block.

The aim of the study was to compare and evaluate the and the onset time of Caudal block block and the duration of analgesia after caudal block with plain bupivacaine alone and bupivacaine with dexamethasone in under five children for day case surgery.

MATERIALS AND METHODS

The study was a prospective interventional double blinded randomize control study (clinical trial) among under five age children with Nigeria of American Society of Anesthesiologists' (ASA) classification I and II, who had infraumbilical day case surgery at Federal Teaching Hospital Gombe. Gombe State, Nigeria. Institutional approval for this study was obtained from the Research and Ethics committee of Federal Teaching Hospital Gombe. A written consent was obtained from the parent or guardian of each patient during preoperative evaluation. Patients with Hypersensitivity to any of the local anaesthetic agents, Hypersensitivity to corticosteroids, Bleeding diathesis, Infection at the site of injection and Congenital abnormality of the spine or neurological disease and those with Cardiorespiratory problems were excluded from the study

All the patients had preoperative review at the Out Patient clinic. Patient's biodata such as age, sex, and weight for drug dosages were documented. History of fever, respiratory difficulty, cough, chest pain, drug allergy, seizure and apnoea were documented. General physical examination was done for pallor, jaundice, fever, nutritional status and any other abnormalities. Basic laboratory investigations; haemoglobin (Hb) electrolytes and urinalysis were reviewed and optimized accordingly. Those selected were based on the inclusion criteria. Parents/guardians were instructed to fast each base on the fasting guideline to abstain from oral intake: 6 hours for solid food, 4 hours for breast milk and 2 hours for Clear fluid. Those who participated in the study (anaesthetists, the PACU nurses and patient's relative) also were trained on how to use the FLACC for the assessment of postoperative pain one week to the commencement of the study. Pain score charts of FLACC were pasted in the post anaesthesia care units for this study and was also given to each patient's parent or care giver.

In the morning of the days for the surgery with patients at the waiting room of the theatre, they were randomly assigned to one of the two groups: group A plain bupivacaine only and group B bupivacaine with dexamethasone by balloting using sealed numbers in an envelope. Cock pit drill was done each morning day of the surgery checking for the availability of stable light source, functionality of anaesthetic machine, suction machine, multi-parameter monitors and different airway adjuncts. Drugs for caudal block bupivacaine and dexamethasone were drawn in a labelled syringe by the primary assessor, agents for general anaesthesia and resuscitation drugs (atropine, adrenaline, hydrocortisone, promethazine, aminophylline) were made available in each suit before patients were moved into the operating room. Each time patients were brought into the operating room and placed on the operating table, base line vital signs were taken and recorded using a multi-parameter monitor (NOVA 3M by Andromeda USA) with pulse-oximeter for monitoring pulse rate (PR) and oxygen saturation (SPO_2), non-invasive blood pressure (NIBP), axillary temperature (T), electrocardiography (ECG). All patients in both groups were pre-oxygenated with 100% oxygen 3-5 minutes (by the research assistant who is a registrar in the department of anaesthesia was blinded to the group allocation) induced each patient with incremental doses of halothane or sevoflurane from 1-3% in 100% oxygen before intravenous (IV) access was secured with 20-24G cannula while patients were asleep and maintained on isoflurane. All patients were premedicated with atropine 0.01 mg/kg. Intravenous crystalloid 4.3% dextrose in 0.18 saline was commenced with estimated maintenance requirement following the 4,2,1 guide: 4 mls/kg/hour for the first 10 kg, 2 mls/kg/hour for the second 10 kg and 1 ml/kg/hr for every 10 kg above 20 kg. General anaesthesia was maintained with isoflurane MAC of 1-2% in 50% oxygen and air. Airway patency was maintained using laryngeal mask airway (LMA) or oropharyngeal airway size 0, 1 or 2.

Patients were placed in lateral decubitus position under aseptic condition; sacral hiatus at S5 above the anal cleft was identified by palpation. The thumb and the middle finger were placed on both left and right posterior superior iliac spines (visible skin dimples) the index finger palpated the sacral hiatus about 2 centimetres above the anal cleft. A 22 or 23 G gauge needle was introduced through the skin at 45 then 15after piercing the sacro-coccygeal ligament advancing about 2 centimetres in the cephalic direction. The end point was indicated by loss of resistance to air in syringe. Caudal block instituted after negative aspirate to exclude subarachnoid or intravascular injection with 0.5 ml/kg of 0.25% plain bupivacaine mixed with normal saline 0.9% for those in group A and bupivacaine 0.25% mixed with dexamethasone 0.1

mg/kg (friedship pharmaceutical) for those in group B. All patients in both groups received a total caudal sacral volume of 0.5 ml/kg not exceeding 2 mg/kg dose of bupivacaine. The total volume was divided 3:1, (¾ for bupivacaine and ¼ for dexamethasone or saline). Patients were returned to supine position for surgery with time for block noted. Drugs allowed to fix not longer than 20 minutes. Loss of pain was tested using heart rate (HR) increase in response to pin prick at the perineum. Increase in HR more than 15% of base line was considered failed caudal block. Anaesthetized patient not responding to ordinary pinprick may respond to pinch with forceps or skin incision if block is not adequate. Adequacy of block in each group was assessed by stability of heart rate within 15% from the baseline. Systemic analgesic iv fentanyl 1-2 mcg/kg was given to anyone with signs of inadequate block (tachycardia, tachypnoea, hypertension and lacrimation) during the course of surgery. Precordial stethoscope was attached to patient and continuous monitoring of patient's vital signs was done in both groups every five minutes using multipara-meter monitor (NOVA 3M Andromedia USA); Pulse rate (PR) and oxygen saturation (SPO_2), electrocardiography (ECG), peripheral (axillary) temperature (T) and non-invasive blood pressure (NIBP were recorded every 5 minutes up to the end of each surgical procedure.

After the surgery, patients were taken to post anaesthesia care unit (PACU) where assessment and continuous monitoring of oxygen saturation (SpO_2), heart rate (HR) and NIBP with multi- parameter monitor was done. Pain was assessed at interval of 0-hour base line on arrival to PACU using FLACC (face leg activity cry consolability) scale by trained personnel and patient relative then hourly for minimum of 3 hours. Parenteral intravenous paracetamol (PCM) 15mg/kg was made available for every patient with pain score of 4 or more as rescue analgesia. No patient was allowed to walk until motor functions were recovered with Bromage score of ≥ 4. Each patient with post anaesthesia discharge scoring value (Aldrete score) of 9 or more, motor function fully resumed and able to micturate were discharged home and followed up through phone call.

Phone calls were made every four hours for patients' assessment at home. The time rescue analgesia was given and the total amount consumed over 24 hours were recorded. The study ended 24 hours post-operatively. All data collected were analysed using IBM® SPSS Chicago, USA version 23. The demographic characteristics of the patient such as age, sex, weight, were presented in frequency tables. Data analysis was done using statistical package for social sciences (IBM® SPSS Chicago, USA) Version 23. Mean time to first analgesic request and total amount consumed by patients in each group, the haemodynamic changes and the complication were all recorded. The results were presented in tables, figures and graphs. Pain scores, complications and other variables were compared using ANOVA. All the tests were doubled tailed and a $P<0.05$ was considered as statistically significant.

Primary Outcome Measures were

- To assess the duration of postoperative analgesia between the two groups

Secondary Outcome Measures:

- To assess the haemodynamic changes of the two study drugs

- To assess the effects/complications associated with each drug

RESULTS

A total of ninety (90) under 5 years ASA I and II patients booked for infraumbilical day case surgery at Federal Teaching Hospital, Gombe were recruited for this study. One (2.22%) patient had failed block and was converted to GA in group B and two (4.44%) patients from the same group B could not complete the twenty-four (24) hours pains assessment because the parents/guardian were not certain of the time they served the last rescue analgesia and hence, all the 3 (6.66%) of the patients had failed block. Socio-demographic characteristics and physical status of the patients for the two study groups have no significant statistical difference ($p<0.05$). Thirty-nine (86.7%) patients and thirty-five (83.3%) patients were ASA I for groups A and B respectively; 6 (13.3%) patients and 7 (16.7%) patients were ASA II for group A and B respectively; $p = 0.66$. There were 44 (97.8%) and 40 (95.2%) patients male in groups A and B respectively. More male than female in both groups; 40:1 and 40:2

(male to female ratio) in groups A and B respectively with no significant difference between the two groups, p = 0.52 (Table 1).

The surgical procedures done in this study included circumcision, cystostomy, rectal biopsy, herniotomy, orchidopexy, hypospaedia repair, planta wart excision, meatal dilatation, urethral dilation and anal dilatation. The mean ages of patients were 25.44 ± 18.60 and 20.69 ± 16.03 months in groups A and B respectively with no statistically significant difference p=0.21. The mean weights of the patients were 10.70 ± 3.89 and 9.69 ± 2.96 kg in groups A and B respectively; p=0.18 (Table 2).

The mean duration of surgery was compared among the two study groups; with 18.38 ± 5.92 minutes and 19.21 ± 5.46 minutes in groups A and B respectively. There was no statistically significant difference; p=0.5. The mean postoperative duration of analgesia were 352.16 ± 99.88 minutes and 915.69 ± 159.39 minutes in groups A and B respectively, p < 0.01. In Group A, the minimum duration of analgesia was 250 minutes (4 hours) and the maximum duration of analgesia observed was 450 minutes (7 hours), while in Group B, the minimum duration of analgesia was 450 minutes (8 hours) and maximum was 24 h, beyond which monitoring was not done. There was marked statistical difference between the two study groups (P< 0.01). The mean onset of analgesia was comparable in both study groups with 11.23 ±57.01and 11.14 ± 27.10 minutes in groups A and B respectively with no significant difference (p=0.63). as shown in Table 3.

The mean baseline (Table 4) and trend of patients who received rescue analgesia (Table 5) at (FLACC score ≥4) hourly and 4 hourly assessments first 24 hours between the two study groups showed significant statistical difference, p < 0.05.No patient in the two groups had FLACC ≥ 4 while at PACU. The mean post-operative FLACC Score within the first 4 hours showed no statistical significance between the two study groups; 0.8±0.991 and 0.619±0.764 in groups A and B respectively (p=0.25). At eight (8) hours postoperatively, sixteen (35.56 %) and two (4,76 %) patients in groups A and B respectively had FLACCS ≥ 4. This showed significant statistical difference between the two study groups, p =0.01. Every four hourly assessment of the two study groups; at 8th, 12th, 16th, 20th and 24th hours postoperative were 35.56% and 4.76%, 17% and 9.52%, 8.89% and 4.78%, 55.56 % and 38.18%, 11.11% and 4.76% in groups A and B respectively, which showed significant statistical difference, p < 0.05 (Table 5).

Table 1: Socio-demographic characteristics and physical status of the patients in the two study groups.

Variable	Group A (Mean ± S. D.)	Group B (Mean ± S. D.)	P-value
Age (month)	25.44 ± 18.67	20.69 ± 16.03	0.21
Sex (male/female) n (%)	44/1(2.27)	40/2(5)	0.52
Weight ((kg)	10.70 ± 3.89	9.69 ± 2.96	0.18
ASA I (%)	39 (86.7)	35(83.3)	0.66
ASA II (%)	6 (13.3)	7 (16.7)	

n= number, ns = (P>0.05)

TABLE 2: Types of surgeries among the two study groups

Surgical procedures	Group A n (%)	Group B n (%)	p-value
Circumcision	30(66.67)	21(46.67)	
Cystostomy	0(0)	1(2.22)	
Rectal biopsy	0(0)	1(2.22)	
Herniotomy	11(24.44)	13(28.89)	
Orchidopexy	1(2.22)	1(2.22)	
Hypospadias repair	0(0)	2(4.44)	
Planta wart excision	0(0)	1(2.22)	
Meatal dilatation	0(0)	1(2.22)	
Urethral dilatation	1(2.22)	0(0)	
Anal dilatation	2(4.44)	1(2.22)	
Total	**45(100)**	**42(93.3)**	**0.44**

ns - P-value=0.44

Table 3: Mean duration of surgery, onset and postoperative analgesia between the two study groups.

Variable	Group A (Mean ± S. D.)	Group B (Mean ± S. D.)	P-value
Duration of surgery (min)	18.38 ± 5.92	19.21 ± 5.46	0.50
Onset of analgesia	11.23 ± 57.01	11.14± 27.10	0.06
Duration of analgesia (min)	352.16 ± 99.88	915.69 ± 159.39	<0.01

S= (p<0.05)
ns = P>0.05)

Table 4: Baseline mean pre-operative haemodynamic parameters and SPO_2 of the patients in the two study groups.

Variable	Group A (Mean ± S. D.)	Group B (Mean ± S. D.)	P-value
PR (bpm)	126.51±15.16	128.79 ± 11.98	0.44
RR (cpm)	24±3.10	24.81±2.8	0.34
MAP (mmHg)	62.112 ± 7.28	60.775 ± 5.95	0.35
SPO_2 (%)	98.755 ±0.91	98.619±1.10	0.53

ns = P>0.05)

Table 5: Patients that received postoperative analgesic at (FLACCS >4), hourly and 4 hourly for 24 hour

Time (hr)	Group A (%)	Group B (%)	P-value
0.00	NA	NA	NA
1.00	NA	NA	NA
2.00	NA	NA	NA
3.00	NA	NA	NA
4.00	NA	NA	NA
8.00	16 (35.56)	2 (4.76)	0.01
12.00	8 (17.78)	4 (9.52)	0.03
16.00	4 (8.89)	4 (4.76)	0..04
20.00	25 (55.56)	16 (38.18)	0.04
24.00	5 (11.11)	2 (4.76)	0.03

S= (p<0.05)

DISCUSSION

In this study the mean onset of analgesia following caudal in the two study groups were comparable in groups A and B and with no significant statistical difference (P=0.63). The reason may not be far-fetched that the addition of dexamethasone to bupivacaine in the caudal block was not associated with changes of the onset of action of caudal block. This was similar to the findings by Meehan (1987) where, he found the onset time of caudal analgesia in different age groups was < 15 minutes despite being a long-acting local anaesthetic agent. This was similar to the findings by Hong *et al.* (2010), who conducted a study on the effect of dexamethasone added to bupivacaine in caudal analgesia for postoperative pain in day-case paediatric orchidopexy in which they found no difference in the onset time was observed between the study groups. Higher dose of dexamethasone additive (0.5 mg/kg) was used in that study but showed no change in onset time of analgesia. These similarities in onset of actions from various studies may be due to the fact that caudal bupivacaine onset of action is not affected by dexamethasone.

The main aim of postoperative pain management is to relieve or where possible eliminate pain and discomfort with a minimum adverse effect from the agent or technique used. This showed that addition of dexamethasone to bupivacaine in caudal block prolongs the duration of analgesia. This was similar to the finding by Parameswari *et al.* (2017) where they reported a significant increase in the duration of analgesia following addition of dexamethasone to bupivacaine in caudal block among children. The minimum duration of analgesia was 240 min and the

maximum duration of analgesia observed was 960 min, while in the dexamethasone group, the minimum duration of analgesia was 300 min and maximum was > 24 hrs. p=0.005. This supported the study that was done by Bani-hashem et al. (2011). The similarities seen in these studies could be due to the anti-inflammatory properties of dexamethasone. Dexamethasone can block serotonin and bradykinin which are proinflammatory agents, pharmacological properties which are associated with pain treatment. Different finding was reported in other studies that dexamethasone can reduces pain by blocking transmission of nociceptive C-fibres inhibiting ectopic neural Prabha P *et al.* (2018). Dexamethasone blocks nuclear factor kappa light chain enhancer of activated B cell (NF-kB) a pro-inflammatory protein which activates the gene for inflammatory cytokine and leukotrienes Gashaw *et al.* (2020). This was Similar to another study that was reported by Gashaw *et al.* (2020). They reported a prolonged duration of postoperative analgesia greater than 24 hours in caudal block with dexamethasone additive. Even though they conducted their own studies among older aged group (1–14 years). The group with dexamethasone added to bupivacaine had significantly prolonged postoperative analgesia compared with the group that used bupivacaine-alone, p <0.001. This showed a prolong analgesic property of caudal bupivacaine with dexamethasone in older age group higher than the under-five children used in our own study. Single shot dexamethasone additive in caudal or intravenous have been found to prolong analgesic duration without side effects. Abd-Elshafy *et al.* (2016) These similarities may be due to anti-inflammatory properties of dexamethasone and probably not affected by age.

Conclusion

The study has shown that addition of 0.1mg/kg dexamethasone to 0.5 ml/kg of 0.25% plain bupivacaine for caudal block was efficient and showed longer duration of analgesia, with lesser analgesic consumption when compared to caudal block with 0.25% plain bupivacaine alone in under five years children for infra-umbilical day case surgeries.

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Conflict of Interest

There was no conflict of interest

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Authors' Contributions

PSU; Wrote the article from the results of the research and was the corresponding Author. He was involved from the conception of the research to the publication. BFY: Was the that started the concept of the research IN, Was also involved in the concept development and literature review, ASA was the one who suggested the topic and was involved from the concept to the data collection. JPD, Was also involved in the concept development and literature review.

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