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Comparison of bilateral infraorbital nerve block versus intravenous ketorolac for cleft lip repair in children: a randomised controlled trial

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Abstract

Introduction: Cleft lip repair in children is associated with significant postoperative pain, which, if inadequately managed, may lead to complications such as wound dehiscence and delayed recovery. Bilateral infraorbital nerve block (BIONB) with 0.25% bupivacaine has emerged as a potential alternative to intravenous ketorolac for postoperative analgesia. This randomized trial compares the analgesic efficacy and safety of BIONB with intravenous ketorolac in paediatric cleft lip repair.

Methods: This randomized, prospective, double-blind study included 74 children aged 12–60 months undergoing elective cleft lip repair under general anaesthesia at a tertiary hospital in Nigeria. Participants were randomized into two groups: Group BO (BIONB with 1 mL of 0.25% bupivacaine per side) and Group KO (0.5 mg/kg intravenous ketorolac). The primary outcome was postoperative pain, assessed using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS). Secondary outcomes included analgesic duration, rescue analgesic consumption, and complications. Data were analysed using independent sample t-tests, with $p < 0.05$ considered statistically significant.

Results: A total of 74 children were randomized, with 34 patients in each group contributing data to the primary outcome. BIONB demonstrated significantly lower mean CHEOPS scores in the immediate postoperative period (0-hour: 4.12 ± 0.5 vs. 8.61 ± 0.6, p=0.03). Analgesic duration was significantly longer in Group BO (8 hours) compared to Group KO (6 hours, p=0.03). Total rescue analgesic consumption over 24 hours was significantly lower in Group BO (223.08 ± 214.12 mg vs. 657.83 ± 248.49 mg, p=0.02). No complications were reported in either group.

Discussion: Bilateral infraorbital nerve block with 0.25% bupivacaine is a safe and effective analgesic technique for cleft lip repair in children, providing superior pain control, prolonged analgesia, and reduced postoperative analgesic requirements compared to intravenous ketorolac. This technique should be considered as a valuable addition to postoperative pain management protocols in paediatric surgical patients.

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Introduction

A cleft lip is a congenital deformity characterised by a vertical cleft or pair of clefts in the upper lip, with or without involvement of the palate. Cleft lip, palate and alveolus are common craniofacial birth defects which result in distortion and disfigurement of the upper lip, palate and alveolus.[1] The congenital defects are repaired between the ages of 3 and 17 years depending on the affected part of the craniofacial area. [2]

Cleft lip surgery involving the lower eyelid, cheek, upper lip and alae nasi is associated with appreciable postoperative pain in children.[2] The surgery requires that the child should be pain free during the postoperative period so that handling does not affect the healing process. Alleviation of postoperative pain is important in these patients because inadequate postoperative pain relief associated with vigorous crying may lead to wound dehiscence, discomfort to the child and parents, accidental removal of surgical dressing, intravenous catheters and drains, requirement of extra nursing care and have adverse physiological effects.[3]

Hence, several modalities of postoperative analgesia have been used in the past; these include the use of intravenous opioids (fentanyl, tramadol, pentazocine), intramuscular/intravenous Nonsteroidal anti-inflammatory drugs (ketorolac, ketoprofen, diclofenac) and the use of regional blocks such as, infraorbital nerve blocks for postoperative pain relief. The use of opioids in neonates and infants raises justifiable concern regarding post-operative sedation, respiratory depression and consequent airway compromise.[3] Infraorbital nerve block is being increasingly used as alternative to opioids and non-opioids for pain relief. It is commonly used in conjunction with general anaesthesia as it also provides good pre-emptive analgesia.[4] Moreover; it is becoming increasingly popular with the accumulating evidence of advantages such as smooth intraoperative course, decreased requirement of general anaesthetic drugs and decreased stress response to surgery and anaesthesia.

Infraorbital nerve blocks are not associated with the risks of airway compromise, respiratory depression and apnoea that are commonly associated with opioid analgesia which is the most popular analgesic technique for cleft lip repair.[6] However, infraorbital nerve blocks may be associated with complications, which include swelling and ecchymosis of the lower eyelid, orbital injection of anaesthetic solution resulting in excessive pain, diplopia, exophthalmos and blindness.[2] This study compared the postoperative analgesic efficacy and safety of bilateral infraorbital nerve block with 0.25% plain bupivacaine and intravenous 0.5mg kg^{-1} of ketorolac for cleft lip repair in children.

Methods

Ethics and Consent

This randomized, prospective, double-blind study was conducted at the Federal Teaching Hospital Gombe, Nigeria, following ethical approval by the institution's ethical review committee (Approval Reference: NHREC/25/10/2013). Written informed consent was obtained from the parents or guardians of each participant before enrolment. Data collected were kept confidential and used solely for the purposes of this research. Parents or guardians were informed of their right to withdraw their child from the study at any time without negative consequences for the medical care provided to their child.

Participants

Children aged 12 to 60 months, classified as American Society of Anaesthesiologists (ASA) physical status I or II, scheduled for elective cleft lip repair under general anaesthesia, were included in the study. Exclusion criteria were local infection at the block injection site, a history of drug allergy, systemic diseases compromising cardiovascular, respiratory, or neurological function, other congenital anomalies, a history of upper or lower airway disease, coagulation disorders, thrombocytopenia, and sleep apnoea requiring postoperative ventilation.

Randomisation

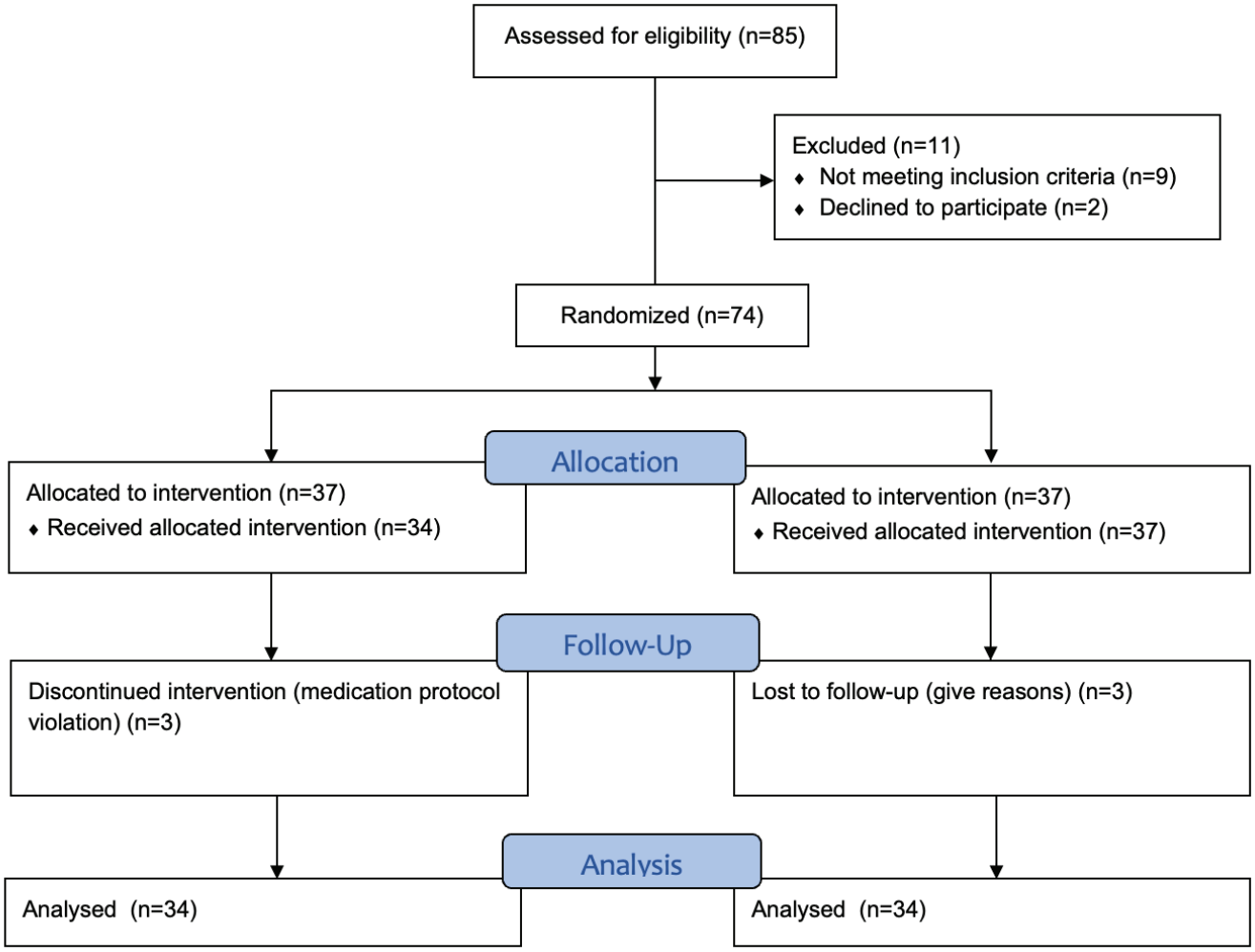
Patients were randomised into two groups on the morning before surgery using a coin toss. A result of "heads" assigned the patient to the bilateral infraorbital nerve block group (BO), while "tails" assigned the patient to the intravenous ketorolac group (KO). Since the study was not blinded, not attempt to conceal these allocations were made between randomisation and intervention delivery.

Interventions

- Group BO: Patients received a bilateral infraorbital nerve block with 1 mL of 0.25% bupivacaine on each side. The infraorbital foramen was identified by palpation using anatomical landmarks. A 25G needle was inserted perpendicular to the skin until bony resistance was felt. After negative aspiration for blood, the study drug was injected.
- Group KO: Patients received intravenous ketorolac at a dose of 0.5 mg/kg at the end of the surgery.

In both groups, general anaesthesia was maintained using 5% sevoflurane in oxygen, delivered via Ayre's T-piece breathing circuit. Analgesics included 1 µg/kg fentanyl and 15 mg/kg paracetamol. All patients were allowed to breathe spontaneously throughout the surgery. Postoperatively, patients were transferred to

Figure 1: Participant flow diagram



the Post-Anaesthetic Care Unit (PACU) for pain and hemodynamic monitoring.

Study Procedure

On the day of surgery, a preoperative check was conducted to ensure the availability and functionality of all necessary equipment, including the anaesthetic machine, suction machine, and monitoring devices. Emergency drugs, such as atropine and adrenaline, were prepared and made available. Patients were induced with 5% sevoflurane in 100% oxygen. Intubation was performed using an appropriate-sized cuffed endotracheal tube after the administration of 1 µg/kg fentanyl and 15 mg/kg paracetamol. Hemodynamic parameters, including non-invasive blood pressure, oxygen saturation, end-tidal CO2, and electrocardiography, were continuously monitored throughout the procedure.

Outcome Measures

The primary outcome was the immediate postoperative pain score, assessed using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)[5]. The scale, designed for children aged 1–7 years, includes six categories of pain behaviour: cry, facial expression, verbal response, torso movement, touch response, and leg movement, with scores ranging from 4 (no pain) to 13 (worst pain). Postoperative pain was assessed immediately on arrival at the PACU by the PACU nurse, then hourly for the first 4 hours. After transfer to the paediatric surgical ward, pain assessments were conducted every 4 hours for the next 24 hours. Secondary outcomes included:

- Duration of analgesia (time to the first request for rescue analgesia).
- Total dose of rescue analgesia consumed within the first 24 hours.
- Complications such as hemodynamic instability, respiratory depression, or hematoma formation.

Outcome assessment

Outcome assessors completed pain scores after talking to patients and collected data on analgesic use and complication from notes. Patients, medical teams, and

outcome assessors were not blinded to study allocation.

Sample Size Calculation

The sample size was calculated using a formula for comparing means, assuming a 95% confidence level (Zα/2=1.96Zα/2=1.96), 80% power (Zβ=0.84Zβ=0.84), a standard deviation of 2, and a clinically significant difference of 0.98 at the 8 hours pain measurement on the CHEOPS scale. The calculated sample size was 65 patients, requiring 33 patients in each arm. To account for medication protocol violations and losses to follow-up, 9 additional participants were recruited, resulting in a total sample size of 74 patients, with 37 planned to be randomised in each group.

Results

Patient Characteristics

A total of 85 patients were screened for eligibility and 74 patients were randomised (37 patients in each group, Figure 1). The male-to-female ratio across the groups was 1:1, with 40 males (54.1%) and 34 females (45.9%). The groups were similar in terms of age, gender, weight, ASA classification, and whether the anomaly was unilateral or bilateral ($p > 0.05$), as shown in Table 1.

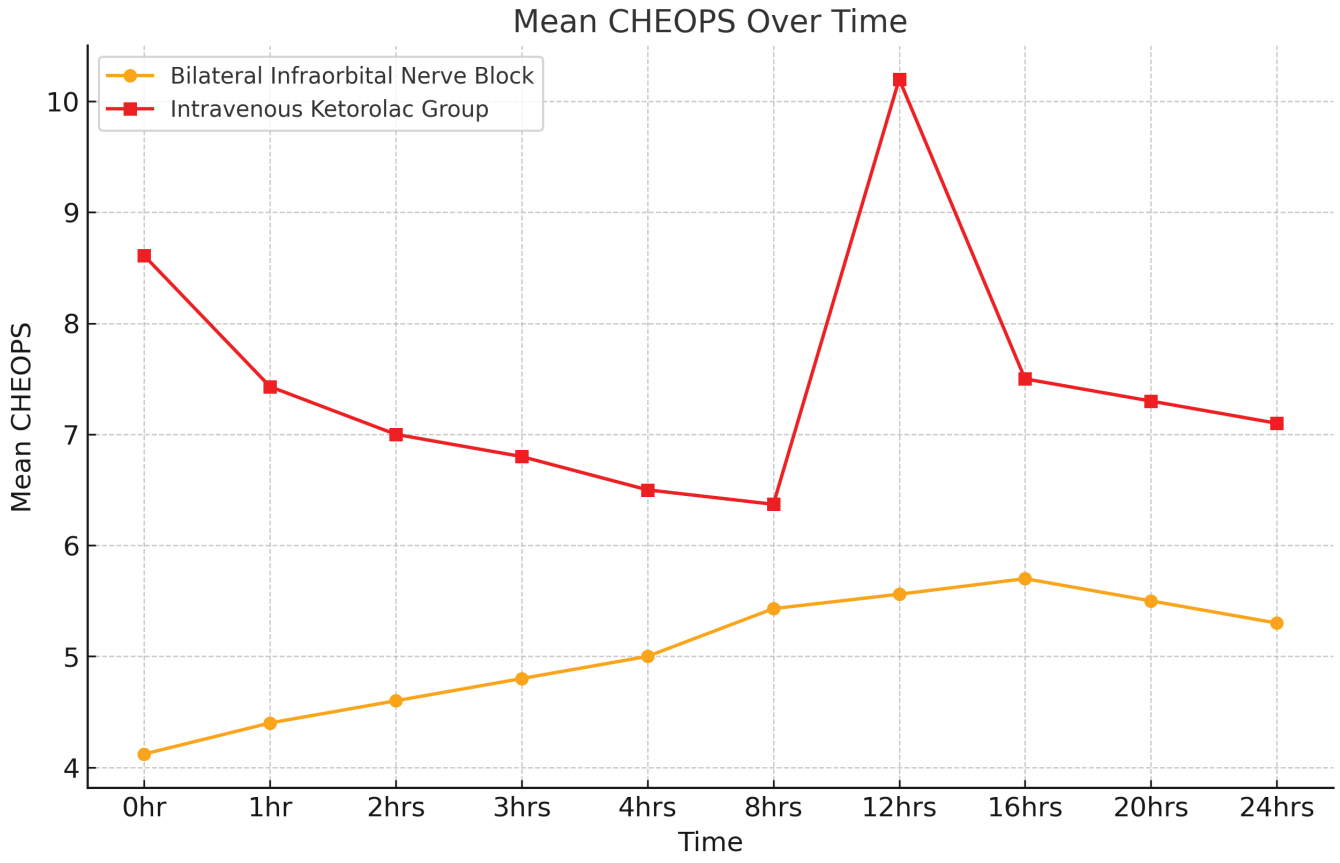
Primary Outcome: Postoperative Pain Scores

34 patients in each arm contributed data to primary outcome assessment. On arrival at the PACU (0-hour assessment), patients in the BO group (bilateral infraorbital nerve block) had significantly lower mean CHEOPS scores (4.12 ± 0.5) compared to the KO group (intravenous ketorolac) (8.61 ± 0.6; p=0.03, Figure 2). At the 1-hour mark, the mean CHEOPS scores remained significantly lower in the BO group (4.40 ± 0.43) compared to the KO group (7.43 ± 0.45). By the 8th hour, the CHEOPS scores were 5.43 ± 0.98 for BO and 6.37 ± 0.34 for KO, with no statistically significant difference (p=0.35). However, by the 12th hour, the BO group again demonstrated significantly lower pain scores (5.56 ± 0.21 vs. 10.2 ± 0.6, p=0.02). These results demonstrate superior pain control in the BO group compared to the KO group, particularly in the immediate postoperative period.

Secondary Outcome: Duration of Analgesia

The mean duration of analgesia, defined as the time to the first analgesic request, was significantly longer in the BO group (8 hours) compared to the KO group (6 hours; p=0.03). This reflects the prolonged analgesic effect of the bilateral infraorbital nerve block compared to

Figure 2: Mean trend of post-operative CHEOPS within the first 24 hours between bilateral infraorbital nerve block versus intravenous ketorolac group:



intravenous ketorolac.

Secondary Outcome: Total Rescue Analgesia Consumption

The total dose of rescue analgesia (paracetamol) consumed over 24 hours was significantly lower in the BO group (223.08 ± 214.12 mg) compared to the KO group (657.83 ± 248.49 mg; p=0.02). The higher consumption of paracetamol in the KO group is attributed to the shorter duration of analgesia in this group, necessitating earlier and more frequent administration of rescue analgesics.

Secondary Outcome: Complications and Haemodynamic Stability

The use of the CHEOPS scale in this study provided a validated and reliable method for assessing postoperative pain in children. The findings align with those of Gurpreeti et al., who reported lower postoperative pain scores in the infraorbital nerve block group compared to the pentazocine group ($p < 0.05$). Their study recorded pain scores of 2 for the nerve block group and 5 for the pentazocine group at 30 minutes postoperatively, with continued superiority of the nerve block at subsequent time points. While their study and the present study demonstrate the immediate efficacy of infraorbital nerve block, the use of the Faces Pain Rating Scale in their research may introduce variability in assessing pain, particularly in preverbal children, compared to the

Table 1: Demographic characteristics of the patients between study groups.

Group	Bilateral infraorbital nerve block (n=37)	Intravenous ketorolac (n=37)	P value
Age (Mean ±SD) years	775	2.55 ± 1.23	0.150
Male (%)	19 (51.4)	21 (56.8)	0.640
Female (%)	18 (48.6)	16 (43.3)	0.580
ASA I (%)	21 (56.8)	25 (67.6)	0.340
ASA II (%)	16 (43.3)	12 (32.4)	0.320
ASA I:II	1:1	1:1	
Weight (Mean ±SD) kg	11.91 ± 4.27	13.72 ± 3.57	0.940
Unilateral cleft (%)	30 (81)	25 (67.6)	0.290
Bilateral cleft lip (%)	7 (18.9)	12 (32.4)	0.310

No complications were observed in either group during the study. All patients remained haemodynamically stable, with no cases of haemodynamic instability, respiratory depression, or haematoma formation recorded.

Discussion

This study demonstrated that bilateral infraorbital nerve block with 0.25% bupivacaine provides superior postoperative analgesia compared to intravenous ketorolac following cleft lip repair in children. The primary advantages of this technique included lower pain scores in the immediate postoperative period, longer duration of analgesia, and reduced need for rescue analgesics.

CHEOPS scale used in this study. The CHEOPS scale offers a validated behavioural observation method, making it more appropriate for this context. Gurpreeti et al. also used a behavioural assessment tool designed for patients with cognitive impairments, which may not be ideal for assessing pain in otherwise healthy children[7].

Rajamani et al. similarly demonstrated the superiority of bilateral infraorbital nerve block over intravenous fentanyl, with significantly lower postoperative pain scores in the nerve block group (mean pain score 2.81 ± 1.38 vs. 4.71 ± 1.89; $p < 0.01$). This finding aligns with the present study, where the nerve block group consistently exhibited lower

Table 2: Mean duration before first analgesic request and total analgesic consumed in 24 hours between the two study groups.

	BO (n=37)	KO (n=37)	P-value
The time to first analgesic request (Mean ±SD), hr	775	4.30 ± 80.52	0.030
Total analgesic consumed in 24hrs (Mean ±SD), mg	223.08 ± 214.12	657.83 ± 248.49	0.020

pain scores. Both studies administered the nerve block and intravenous drugs at the end of surgery, contributing to the observed similarities. However, Rajamani et al. included a broader age range (3 months to 13 years) and used ketamine as the induction agent, which possesses inherent analgesic properties. These differences may account for slight variations in outcomes[8].

The findings of Gaonkar et al. also support the immediate analgesic efficacy of bilateral infraorbital nerve block, with lower pain scores (<3) in the nerve block group compared to the peri-incisional group (pain score 4) in the immediate postoperative period. However, their use of the Hanallah's Objective Pain Discomfort Scale, which includes variables such as blood pressure, crying, and movement, may not be ideal for preverbal children, as non-pain-related factors such as hunger or respiratory distress can affect these parameters[9].

The duration of analgesia in this study was significantly longer in the bilateral infraorbital nerve block group (8.43 ± 73.12 hours) compared to the intravenous ketorolac group (6.30 ± 80.52 hours; p = 0.03). This finding is consistent with Ayman et al., who reported a duration of approximately 8 hours (7 hours 21 minutes) using the same dose of 0.25% bupivacaine in primary cleft lip repair. The similarity between these findings likely reflects the standardized dose and similar surgical context[10]. However, variations in reported analgesic durations in the literature may be attributed to differences in local anaesthetic volumes, adjuncts, and patient characteristics.

For instance, Naveen et al. reported a longer duration of analgesia (16.5 ± 5.15 hours) using bilateral infraorbital nerve block. This extended duration was attributed to the use of a larger volume (10 mL) of local anaesthetic and the addition of 2% lidocaine with adrenaline to 0.5% bupivacaine. The vasoconstrictive properties of adrenaline likely contributed to the prolonged analgesia. Additionally, their smaller sample size (20 patients) may have influenced their results[11]. Similar findings of extended analgesic durations (18–20 hours) have been reported in other studies where additives such as adrenaline or clonidine were used in conjunction with local anesthetics[12,13].

Jonnavithula et al. reported an even longer duration of analgesia (24 hours) when pethidine was added to 0.25% bupivacaine for infraorbital nerve block. Pethidine enhances analgesia by acting on peripheral opioid receptors and potentiates the effects of bupivacaine through its structural similarity to local anaesthetics. These mechanisms explain the significantly longer analgesic duration in their study compared to the present one[14]. The addition of clonidine to bupivacaine, as reported by Parul et al., also resulted in a longer analgesic duration (12 hours) compared to the present study (8 hours). Clonidine prolongs local anaesthetic effects through vasoconstriction and direct binding to alpha-2 adrenergic receptors, modifying neuronal excitability. It has also been suggested that clonidine exerts a peripheral analgesic effect by releasing enkephalin-like substances, further contributing to its efficacy[17,18,19,20].

The variations in analgesic duration between the present study and others highlight the impact of different techniques, local anaesthetic formulations, and patient factors. Despite these differences, the present study demonstrates the clinical utility of bilateral infraorbital nerve block as a safe and effective method for managing postoperative pain in children undergoing cleft lip repair. Compared to intravenous ketorolac, it provides superior pain relief, longer analgesia, and reduces the need for rescue analgesics, making it a valuable option for postoperative pain management in paediatric surgical patients.

Bilateral infraorbital nerve block with 0.25% bupivacaine provided superior postoperative analgesia compared to 0.5 mg/kg intravenous ketorolac following cleft lip repair in children. It resulted in longer analgesic duration and reduced postoperative analgesic consumption. This technique is a reliable and effective method for pain management in paediatric cleft lip surgery.

References

1. Al-Thunyan AM, Aldekhayel SA, Al- Meshal O, Al-Qattan MM. Ambulatory cleft lip repair. Plast Reconstr Surg. 2009; 124:48-53.

2. Davis PJ, Cladis FP, Motoyama EK. Anesthesia for plastic surgery. In: Smiths Anaesthesia for Infants and Children. 8th ed. Philadelphia, PA: Elsevier Mosby; 2011; 831-833.

3. Bosenberg AT, Kimble FW. Infraorbital nerve block in neonates for cleft lip repair: Anatomical study and clinical application. Br J Anaesth. 1995: 74: 506-508.

4. Adenekan AT, Faponle AF, Oginni FO. Anaesthetic challenges in oro-facial cleft repair in Ile-Ife, Nigeria. Mid-East J Anaesthsiol 2011; 21:335-9.

5. McGrath PJ, Johnson G, Goodman JT, et al: CHEOPS: A behavioral scale for rating postoperative pain in children. *In:* Advances in Pain Research and Therapy. Vol. 9. Fields HL. Dubner R, Cervero F (Eds). New York, Raven Press, 1985, pp 395-402

6. Kwari DY, Chinda JY, Olasoji HO, Adeosun OO. Cleft lip and palate surgery in children. Anaesthetic considerations Afr J Paediatr Surg. 2010; 7: 174-177.

7. Morton NS. Local and regional anaesthesia in infants. Continuing Education in Anaesthesia; Crit Care Pain.2004; 4:148-51.

8. Zuppa AF, Mondick JT, Davis L, Cohen D. Population pharmacokinetics of ketorolac in neonates and young infants. AM J Ther. 2009; 16: 143-146.

9. Rajamani A, Kamat V, Rajavel VP, Murthy J, Hussain SA. A comparison of bilateral infraorbital nerve block with intravenous fentanyl for analgesia following cleft lip repair in

children. Paeditr Anaesth 2007;17(2):133-139.

10. Naveen E, Ashish C, Dildeep P, Rajiv C. Regional anesthesia for cleft lip repair: A preliminary study. Indian J Plast Surg 2005; 37: 138-140.

11. Rajesh SM, Sanikop CS, Dhulkhed K, Gupta T. Comparison of Bupivacaine Alone and in Combination with Fentanyl or Pethidine for Bilateral Infraorbital Nerve Block for Postoperative Analgesia in Paediatric patients for Cleft Lip Repair. J Anaesthesiol 2011; 27: 23-26.

12. Yaster M. Analgesia and anaesthesia in neonates. Pediatr J 1987; 111:394-396.

13. Rajamani A, Kamat V, Rajavel VP, Murthy J, Hussain SA. A comparison of bilateral infraorbital nerve block with intravenous fentanyl for analgesia following cleft lip repair in children. Paeditr Anaesth 2007;17(2):133-139.

14. Prabhu KP, Grewal S. Bilateral infraorbital nerve block is superior to peri-incisional infiltration with analgesia after repair of cleft lip. Scand J Plat Reconstr Surg Hand Surg 1999;33(1)83-87.

15. Arvind R, Vijaylakshmi K, Vardarja P, Jyotsona M. A comparison of bilateral infraorbital nerve block with intravenous fentanyl for analgesia following cleft lip repair in children. Paediatr Anaesth. 2007; 17: 133-139.

16. Counsins MJ, Mather LE. Intrathecal and epidural administration of opioids. Anesthesiology 1984; 61: 276-310.

17. Oldroyd GJ, Tham EJ. An investigation of local anaesthetic effects of pethidine in volunteers. Anaesthesia 1994; 49: 503-506.

18. Parul J, Gurieet K, Sariju D, Sharma JP. Intra and postoperative outcome of adding clonidine to bupivacaine in infraorbital nerve block for young children undergoing cleft lip surgery. Saudi J Anaesth. 2011; 5: 289-294.

19. Reuben SS, Steinberg RB, Klatt JL, Klatt ML. Intravenous regional anaesthesia using lidocaine and clonidine. Anaesthesiology 1999; 91:654-658.

20. Edomwonyi NP, Isah IJ, Obuekwe ON. Cleft lip and palate repair: Intraoperative and recovery room complications: Experiences at the University of Benin Teaching Hospital. Pan African Anaesthesia symposium, Nairobi Kenya;2008.