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Research Article

A Comparative Study of Bilateral Infraorbital Nerve Block with Intravenous Pentazocine on The Immediate Postoperative Pain Management Following Cleft Lip Repair in Infants

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Abstract

Purpose: Comparative evidence of the effectiveness of bilateral infraorbital nerve block for immediate postoperative pain management in infants after cleilorrhaphy especially in Africans is lacking. This study aimed to compare the efficacy of bilateral infraorbital nerve block using Bupivacaine with intravenous Pentazocine for the control of immediate postoperative pain in an infant age group following cleft lip repair.

Methods: This was a prospective randomized controlled clinical study. The sampled population was patient aged 3 to 12 months undergoing cleft lip repair at a tertiary health facility in Lagos, Nigeria. Study patients were randomly allocated to either group 1 (Bupivacaine infraorbital nerve block) or group 2 (intravenous Pentazocine). Primary outcome was the duration of analgesia following the administration of both drugs. Assessment of immediate postoperative pain was done using the FLACC (Face, Leg, Activity, Cry, Consolablity) pain scale. Scoring was done at hourly intervals postoperatively, observing the child for 1 minute at each hour and rescue analgesia (intravenous paracetamol) given when FLACC score exceeds 3. The duration of analgesia was the time of from administration of the intervention to the time rescue analgesia was administered. Calculated sample size was 20 participants per group. Descriptive and comparative statistics were computed using SPSS and the p-value was set at <0.05.

Results: Analysis of result included 44 participants. Mean age was 5.2 months and 52.5% were females. The mean duration of analgesia in the Bupivacaine group was 291.80 ± 95.4 minutes i.e 4 hours 52 minutes and that of Pentazocine group was 151.50 ± 24.9 minutes i.e 2 hours 32 minutes. This difference was statistically significant (p=0.001). At the 3rd hour, 75% of participants in the Pentazocine group received rescue analgesia, in contrast to only 10% in the Bupivacaine group. Only participants in the Bupivacaine attained the 8th hour.

Conclusion: A bilateral infraorbital nerve block with 0.5% plain Bupivacaine at 2mg/kg provided a longer duration of analgesia in the postoperative period in comparison with intravenous Pentazocine 0.5mg/kg in an infant age group following cleft lip repair.

Keywords: *Bilateral infraorbital nerve block; pentazocine; pain management, cleft lip repair.*

Introduction

Oro-facial clefts are the most visible and most common congenital defect of the head and neck.[1] Cleft lip with or without cleft palate affects 1 in 700 live birth worldwide with reported incidence ranging from (3.6:1000) in Native Americans to 0.5:1,000 in Africans.[1,2] It is also the second most common congenital deformity, after club foot.[3] Surgical repair of cleft lip is most commonly done at age 3 to 6 months of life,[4,5] with the condition that the child is at least 10 pounds of weight, white blood count <10,000 mm^3, and 10g/dl of haemoglobin,[6] so as to minimize the anaesthetic risk.[7,8]

Surgical repair of cleft lip and/or palate is usually accompanied by moderate to severe postoperative pain.[9] Children do not only experience pain but they also feel it more acutely than adults.[10,11] This immediate postoperative pain makes the quality of paediatric care and proper management challenging. Acute pain often makes the child agitated, cry vigorously, and tend to touch the operated site. This may lead to wound dehiscence, disrupting the healing process and inadvertently compromise the aesthetic result.[9,12] Good pain management minimizes the oxygen requirement, reduces cardio-respiratory demands, and promotes early recovery.[13,14] The society of Paediatric Anaesthesia, at its 15th annual meeting, clearly defined the alleviation of pain as a "basic human right", irrespective of age.[15,16] Available modalities of postoperative analgesia in cleft lip surgery include opioids therapy, non-opioids therapy, local anaesthesia infiltration, regional nerve block.[17–19] Opioids have been the mainstay in the management of moderate to severe postoperative pain.[20–22] In our environment, pentazocine, a synthetic opioid is commonly used following cleft surgeries because it is easily available, cheap, has multiple parenteral routes of administration and its property to increase plasma catecholamine accounts for the increase in heart rate, which is desirable in infants.[13] The use of opioids in neonates and infants has however, raised concerns regarding postoperative over sedation, nausea, vomiting, respiratory depression and airway compromise. Due to the fear of these side effects, children are therefore likely to be undermedicated leading to inadequate immediate postoperative analgesia and its complications.[18,19,23] This emphasis the need for a safer and equally potent analgesic technique.

Bilateral infraorbital nerve block is a regional anaesthetic technique that provides excellent postoperative analgesia for cleft lip repair.[10] Moreover, it is simple, easy and safe to perform, with high success rate and minimal complications. [10,23] Although regional anaesthetic technique has gained popularity in the past decade, their efficacy and safety in an infant age group has not entirely been established.

The aim of this study was to compare the duration of analgesia following the administration of Bupivacaine infraorbital nerve block with the duration of analgesia following the administration of intravenous Pentazocine after cleft lip repair in an infant age group.

This study hypothesis that there is no statistically significant difference in the analgesic efficacy of bilateral infraorbital nerve block with 0.5% plain Bupivacaine compared to intravenous Pentazocine for immediate postoperative pain in children undergoing cleft lip repair.

Methods

Study Design and Population

This is a prospective single-blinded randomized clinical study of patients presenting for management of non-syndromic primary unilateral or bilateral cleft lip with or without cleft palate, between September 2019 and December 2020 at a tertiary health facility in Lagos, Nigeria.

Selection of Participants

Inclusion Criteria

1. Participants with non-syndromic unilateral or bilateral, complete or incomplete cleft lip with or without cleft of the alveolus and palate.

2. Participants with American Society of Anaesthesiologist (ASA) status I and II with cleft lip with or without cleft of the alveolus and palate

Participants who met the above conditions and aged between 3 months and 12 months, certified fit for surgery by the Anaesthesiologist and Paediatric Cardiologist.

Exclusion Criteria

1. Participants with a medical history suggestive of allergy to bupivacaine or pentazocine.

2. Participants with systemic disease that compromises the cardiovascular, respiratory, or neurological function in whom postoperative ventilation may be required.

3. Participants with orofacial cleft based on Tessier's classification.

4. Participants presenting for lip revision.

5. Participants whose parent(s)/guardian(s) do not consent to participate in the study.

Study Variables

The predictor variable in this study was the type of intervention given for immediate postoperative pain following cleft lip repair (bilateral Infra-orbital nerve block with 0.5% plain Bupivacaine at 2mg/kg body weight through an extraoral approach or intravenous Pentazocine at 0.5mg/kg body weight through an intravenous assess). The primary outcome variable was the duration of immediate postoperative analgesia using the FLACC pain scale - Face, Leg, Activity, Cry, and Consolability (see Appendix 1). The duration of postoperative analgesia was noted as the time from administration of the postoperative intervention (bilateral bupivacaine infraorbital nerve block or intravenous pentazocine) to the time rescue analgesia (intravenous paracetamol at 20mg/kg body weight) was administered. Other variables measured included age, gender and weight of the participants, type of cleft defect, technique of cleft repair and duration of surgery.

Sample Size Calculation

The sample size was determined by using the sample size formula for comparison study for randomized control clinical equivalent trials with continuous outcome,[24] assuming alpha = 0.05 and power = 0.80 (beta = 0.20) using data from a previous study, [13] Standard Deviation (SD) was taken as 42.12 and 40 minutes as the minimum differences the investigators wished to detect. The sample size was calculated as 20 for each group.

Randomization of Participants

Study participants were randomly allocated into either group 1 (bilateral bupivacaine Infra-orbital nerve block) or group 2 (intravenous pentazocine) with the aid of a computer-generated random sequence (Quick-Cals, GraphPad Software, San Diego, CA). The randomization sequence was generated before the commencement of patient recruitment (numbers 1 to 50 were randomized into groups of 25 numbers each), concealed in an envelope that was handed to a staff nurse who was responsible for participant allocation into the study groups before the start of the surgical procedure.

Procedure

Surgical repair was performed under general anaesthesia. Unilateral cleft lips were repaired using either Millard rotational advancement or Tennison- Randall triangular surgical technique, while bilateral cleft lip was repaired by Modified Millard fork flap technique. Consultant Oral and Maxillofacial surgeons performed the surgical repairs, while the researcher assisted the cases. The researcher was the assessor of the immediate postoperative pain control and was blinded to the type of immediate postoperative analgesia given. Two research assistants (senior resident Doctors of the Department of Oral and Maxillofacial Surgery) were trained and calibrated, by doing a pilot study, for the administration of the Bupivacaine infraorbital nerve block and the intravenous Pentazocine.

Just before the last suture was placed, the researcher unscrubbed and left the operating suite before the postoperative analgesia was administered by the trained assistant.

For participants in Group 1, the infraorbital nerve was blocked by an extraoral approach with 0.5% plain Bupivacaine solution (2 mg/kg body weight). Participants were placed in the supine position, with the head in a median position and well supported. The infraorbital rim was palpated by running a finger from the outer canthus and moving it medially towards the medial canthus.

The infraorbital foramen was located at the intersection of a vertical line drawn from a point halfway between the mid-point of the palpebral fissure of the eye and a horizontal line through the angle of the mouth (approximately 7.5mm from the ala base) as shown in Figure 1. From this point, a short hypodermal syringe (insulin syringe and needle) with 29-gauge x 18 mm was introduced perpendicular to the skin and advanced until bony resistance was felt. The needle was then withdrawn slightly and after a negative aspiration test for blood, the local anaesthesia was deposited at the exit of the foramen. This procedure was repeated on the opposite side and haemostasis was achieved.

For participants in Group 2, intravenous Pentazocine at a dose of 0.5 mg/kg was given through intravenous access, which was already established by the Anaesthesiologist. The dosage of the drugs administered was weight dependent in the children. The time of administration of the Bupivacaine and the Pentazocine, which was immediately after the last suture was place, was noted and recorded.

At the end of the administration of the drugs, general anaesthesia was reversed, and participants were extubated by the Anaesthesiologist when deemed fit. Thereafter, they were transferred to the recovery room.

Data Collection Methods

Assessment of immediate postoperative pain was based on the observation of 5 categories of the FLACC pain scale - Face, Leg, Activity, Cry, and Consolability. Each of the five categories was scored 0 to 2, the total score obtainable for each child ranged from 0 to 10. These scores were designated as follows: 0 = No pain, 1-3 = Mild pain, 4-7 = Moderate, 8-10 = Severe pain. Scoring was done at hourly intervals postoperatively, observing the child for 1 minute at each hour. If participant cry inconsolably between the set assessment interval, a reassessment was done. Zero hour was the time the participant was extubated. If the FLACC pain score exceeded 3, rescue analgesia using intravenous Paracetamol at 20 mg/kg was administered, and the study was concluded for that participant. FLACC pain score exceeding 3 is considered a breakthrough pain requiring rescue analgesia. The duration of postoperative analgesia was noted as the time from administration of the postoperative intervention to the time rescue analgesia was administered.

Statistical Analysis

Data collection was performed using a proforma and analysis performed using statistical package for social sciences (SPSS) for Windows (version 21.0, IBM Corp., Chicago, IL, USA). Data are presented in form of tables and charts. Other descriptive and inferential statistics were used as appropriate. A comparison between the two study groups was done using Chi-square or Fisher's exact test (for cells whose expected counts are less than 5) and independent samples t-test as appropriate. The Mann-Whitney Wilcoxon sum rank test was used to test for significance in the duration of analgesia between the two study groups and as overall mean. For all comparisons $p<0.05$ was adopted as the criterion for establishing a statistical significance.

Results

A total of forty participants' data were analyzed (Figure 1). There were 20 participants in each group. The mean age at repair of cleft lip in this study was 5.2 ± 1.45 months (range 3 to 12 months) and the average body weight of the study population was 6.38 ± 1.56 kg (range 4.5kg to 10.5kg). Females made up 52.5% (n = 21) of the participants. The mean duration of surgery was 43.13 ± 11.06 (range 20.0 to 61.0) minutes. The Millard's Rotation Advancement was the most used lip repair technique (n = 22, 55%), while the other were repaired using the Tennison-Randal triangular flap technique (n = 9, 22.5%) and the Modified Millard Fork Flap (n = 9, 22.5%). On comparison of the characteristics of the participants in both groups, no significance difference was found for all variables measured (Table 1).

The mean duration of analgesia in the participants in the of Bupivacaine group (291.80 ± 95.4 minutes i.e 4 hours 52 minutes) was longer than those in the Pentazocine group (151.50 ± 24.9 minutes i.e 2 hours 32 minutes). This difference was statistically significant ($p<0.001$) (Table 2).

Rescue analgesia was given at an earlier time (2nd hour) in the participants in the Pentazocine group than those in the Bupivacaine group which was given at the 3rd hour. At the 3rd hour, 75% of participants in the Pentazocine group received rescue analgesia, in contrast to only 10% in the Bupivacaine group. It was at the 5th hour that a significant number (n=7, 35%) of participants in the Bupivacaine group received rescue analgesia. Furthermore, only participants in the Bupivacaine group got to the 8th hour (Figure 2)

The difference of the average highest FLACC pain score between the two study groups was not statistically significant (p=0.689) (Table 3).

Overall, the mean highest component scores were comparable between the two groups (p>0.05). The Cry and Consolability components of the FLACC pain scale had the highest score in both groups (Table 4).

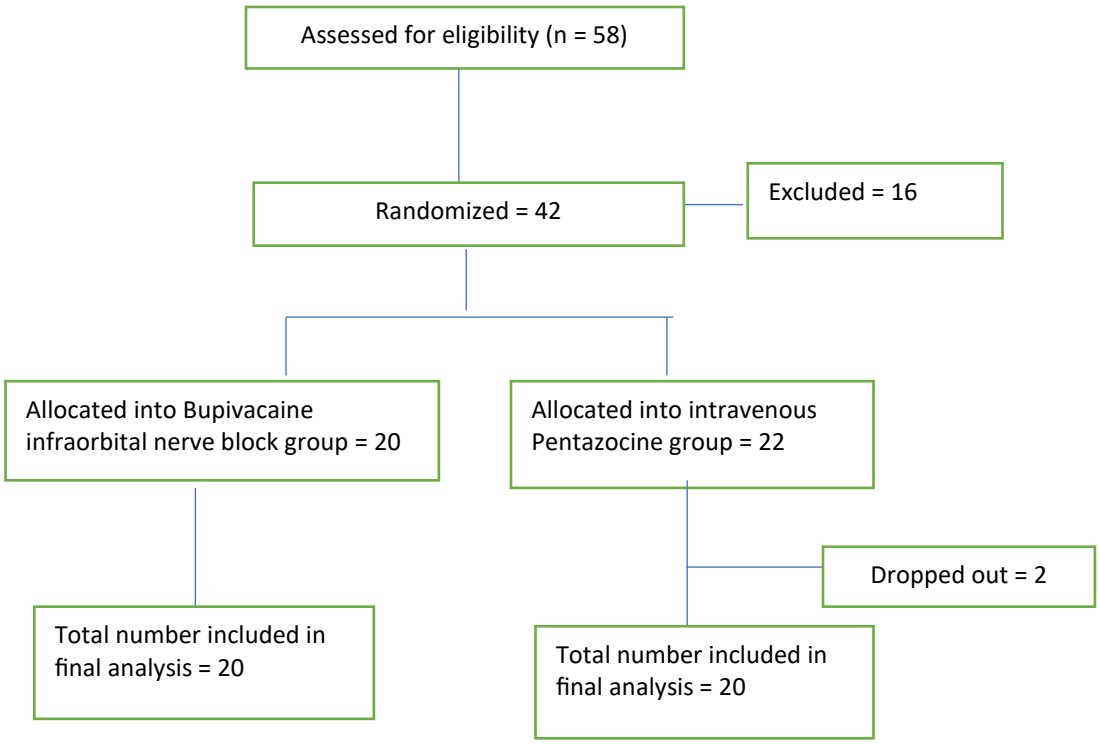


Figure 1: *Flow chart of participants recruited.*

Table 1: Summary of Comparison of Study Variables between the 2 Study Groups.

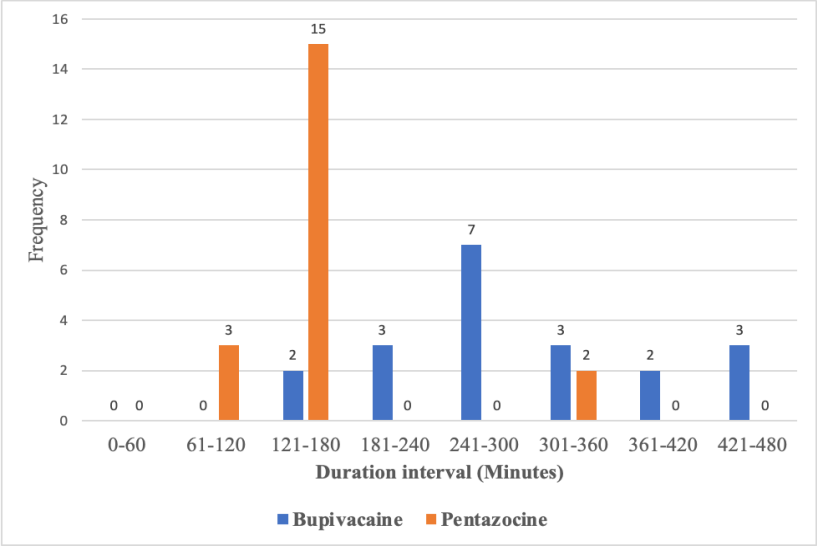
Variables		**Bupivacaine (N)**	**Pentazocine (N)**	**Total (N)**	**Test of sig *P* value**
Gender	Male	9	10	19	0.736
	Female	11	10	21	
	Total	20	20		
Type of cleft	BCLP	4	5	9	0.836
	LUCLA	5	4	9	
	RUCLA	5	4	9	
	LUCLP	5	4	9	
	RUCLP	1	3	4	
	Total	20	20		
Technique of repair	Millard's	11	11	22	0.705
	Tennison Randall	5	4	9	
	Modified Millard's	4	5	9	
	Total	20	20		
		Mean (SD)	Mean (SD)		
Age (months)		5.05 (1.5)	5.35 (1.4)		0.736
Weight (kg)		6.05 (1.75)	6.71 (1.3)		0.186
Duration of surgery (minutes)		43.2 (10.88)	43.05 (11.5)		0.966

Abbreviations: BCLP, bilateral cleft lip and palate; LUCLA, left unilateral cleft lip and alveolus; LUCLP, left unilateral cleft lip and palate; RUCLA, right unilateral cleft lip and alveolus; RUCLP, right unilateral cleft lip and palate.

Table 2: Comparison of duration of analgesia between the study groups.

Variable	**Group**		
	Bupivacaine	Pentazocine	*p* value
	Mean rank	Mean rank	
Duration of analgesia	28.50	12.50	<0.001*

* Mann-Whitney U = 40.0, significant at $p < 0.05$ level.



Time (Minutes)

Figure 2: *Comparison of the Time of Administration of Rescue Analgesia in Both Groups.*

Table 3: Comparison of postoperative highest FLACC pain score between the two groups at the point of receiving rescue analgesia.

Variable	**Group**		**t-value**	***p* value (95% CI)**
	Bupivacaine	Pentazocine		
	Mean ±SD	Mean ±SD		
FLACC score	6.75±1.29	6.60±1.04	0.403	0.689 (-0.60 – 0.90)

Table 4: The score of the Component parts of the FLACC pain scale at the time rescue analgesia was administered.

	Bupivacaine	**Pentazocine**	**t-value**	***p*-value**
Face	1.05±0.4	1.10±0.6	-0.330	0.744
Legs	0.85±0.3	0.70±0.2	0.761	0.451
Activity	1.15±0.3	0.95±0.3	1.150	0.257
Cry	1.85±0.4	1.90±0.3	-0.467	0.643
Consolability	1.85±0.4	1.95±0.2	-1.042	0.304

Appendix 1: Postoperative pain assessment using FLACC pain scale.

Parameters	Findings	Scores
Face	No particular expression/smile	0
	Occasional grimace/frown, withdrawn, disinterested	1
	Frequent to constant quivering chin, clenched jaw	2
Legs	Normal position or relaxed	0
	Uneasy, restless, tense	1
	Kicking/leg drawn up	2
Activity	Lying quietly, normal position, moves easily	0
	Squirming, shifting back and forth, tense	1
	Arched, rigid, jerking	2
Cry	No cry (awake or asleep)	0
	Moans or whimpers, occasional complaints	1
	Crying steadily, screams or sobs, frequent complaint	2
Consolability	Content, relaxed	0
	Reassured by occasional touching, hugging/being talked to, distractible	1
	Difficult to console, comfort	2

Discussion

The main findings of this study showed that bilateral infraorbital nerve block with 0.5% plain Bupivacaine at 2mg/kg body weight (Group 1) provided a significantly prolonged duration of analgesia compared to intravenous Pentazocine at 0.5mg/kg body weight (Group 2) in an infant age group. This was 4 hours 52 minutes for Bupivacaine as against 2 hours 32 minutes for Pentazocine. Pain is perhaps the most distressing symptom of any disease. Children not only experience pain but they also feel it more acutely than adults.[23] Pain assessment is the most essential part of pain management.[25,26] Although self-report is considered the "gold standard" for pain assessment, immaturity in communication in young children could be a barrier to understanding their feelings or how they can express their pain. [27] The age group of participants in this study ranged from 3 months to 12 months. This category of participants is classified as infants, and cannot effectively communicate the pain they experience.[28] Therefore, validated behavioural-observation methods are recommended in infants.[26] The FLACC pain scale, a behavioural-observation scale was used for this study because of its ease of use (score generated by using 0 to 10 number rating scales), its excellent reliability and validity in assessing pain.[29] Kahsay[18] and other previous studies,[29,30] showed that FLACC pain scale has 98% sensitivity and 88% specificity in assessing pain levels. The use of regional nerve block for immediate postoperative pain relief has gained popularity, as it provides a good pain-free period and avoids the complications of opioid analgesics.

While the main finds of our study corroborates the findings in a similar study by Grewal *et al.,*[13] the reported duration of analgesia in the two groups were longer than in the present study. They observed a mean time for 1st request of rescue analgesia to be 3 hours 51 minutes for the intravenous Pentazocine group (0.5mk/kg) compared to 5 hours 58 minutes for the 0.25% Bupivacaine bilateral infraorbital nerve block group (2mg/kg). The longer duration of analgesia could be attributable to the difference in methodology. Grewal's group[13] recruited older participants age range 3 months to 13 years, while in our study only infants, age range 3 months to 1 year (12 months) were recruited. This differences in the methodology probably accounted for the slightly longer duration of mean time to the first analgesic requirement in their study, because older patients can adequately self-report and give a more accurate description of the pain discomfort they experienced. Also, younger children are likely to feel pain more acutely than older patients[10,11] because the developing sensory system in an infant is more sensitive to noxious inputs.[26,31]

On the other hand, the result of our study is at variance with the study of Jonnavithula *et al.,*[10] and Mane and co-worker[23] who compared the efficacy of bilateral infraorbital nerve block with Bupivacaine alone with a combination of Bupivacaine and an opioid. Jonnavithula *et al.,*[10] compared Bupivacaine alone with Bupivacaine-Pethidine combination. Mane *et al.,*[23] on the other hand had four groups of participants, that had either a combination of Bupivacaine with Pethidine or with Fentanyl. The two studies reported a markedly longer duration of analgesia in the Bupivacaine combination with the opioid group. In the study of Jonnavithula *et al.,*[10] the duration of analgesia in the Bupivacaine alone group was 18 hours compared to the 29 hours in the Bupivacaine-Pethidine combination group. Also, in the report of Mane *et al*.,[23] the duration of the analgesia in the Bupivacaine only group was 17.8 hours while the Bupivacaine-Pethidine combination and Bupivacaine-Fentanyl combination were 23.53 hours and 35.13 hours, respectively. The addition of opioid to local anaesthetics as an adjunct has been shown to prolong the duration of action.[10,23] This is because opioids have direct local anaesthetic effect due to their structural similarities to local anaesthetics and similar pH, pKa and molecular weight. Opioids act both on peripheral opiate receptors and potentiates a local anaesthetic effect by central opiate receptor action.[10] Also, the pharmacological interaction between fentanyl and bupivacaine is synergistic.[32] Even though Jonnavithula *et al.,*[10] used the same pain scale (FLACC) as we did, the difference in the results is not surprising. In their study the infraorbital nerve blocks were administered preoperatively, before the onset of surgical incision which probably gave an advantage of pre-emptive analgesia.

Gaonkar and Daftary[33] in their study observed the mean time to first analgesic requirement using 0.25% Bupivacaine in 1:200,000 adrenaline (1 ml on each side) administered preoperatively for the bilateral infraorbital nerve block to be 29 hours. The addition of adrenaline to the Bupivacaine in infraorbital nerve block in their study and the administration of the drug preoperatively probably prolonged the analgesic duration despite using a lower concentration of Bupivacaine.

In the present study, none of the participants in the two groups required rescue analgesia in the first hour, however, at the 2nd hour, (N=3) 15% of participants in the Pentazocine group had FLACC pain score greater than 3, and hence received rescue analgesics while none of the participants in Bupivacaine group required rescue analgesics. Only 2 (10%) in the Pentazocine group exceeded the 3rd hour. By the 6th hour, all participants in Pentazocine had had pain score exceeding 3, necessitating the need for rescue analgesia, compared to (N=15) 75% in the Bupivacaine group who had received supplementary analgesia. 5 participants in the Bupivacaine group exceeded the 6th hour. Of these, 2 received rescue analgesia by the 7th hour and the remaining 3 at the 8th hour. This showed a more prolonged action of Bupivacaine in providing immediate postoperative analgesia.

The FLACC pain score remained low throughout the period during which the drugs were effective in both groups. During the study, it was noted that the majority of the participants in the Pentazocine group slept as soon as the drug was administered while most of those in the Bupivacaine stayed awake. From our study, it appears that the sedative effect of Pentazocine was an additional advantage for participants in the Pentazocine study group as it appeared to increase the depth of analgesia during the period drug was effective.

Also, it appeared that the **C**ry and **C**onsolability components of the FLACC pain scale are the most important components of this scoring system as they had the highest values in both groups, and the values were comparable in the two study groups. Further studies can be done to investigate these two components.

Jonnavithula *et al.,*[10] in their study concluded that pain scores remained low throughout the period during which the infraorbital nerve block was effective with a maximum pain score lower than 2 ,on the FLACC pain scale, in most patients. Also, a comparison between the two groups (Bupivacaine infraorbital nerve block versus Bupivacaine-Pethidine combination infraorbital nerve block) of the highest pain score did not show any significant statistical difference.

Jindal *et al.,*[12] also compared the pain score using Bupivacaine alone for bilateral infraorbital nerve block versus a combination of Bupivacaine with Clonidine (an antihypertensive agent) for bilateral infraorbital nerve block in patients less than 24 months. Pain score in their study was comparable with this study. The FLACC pain score remained low throughout the period during which the infraorbital nerve block was effective.

Simion *et al.,*[34] compared bilateral infraorbital nerve blocks using Bupivacaine with intravenous fentanyl for postoperative analgesia following cleft lip surgery in infants and concluded that there were no significant differences in the pain scores between the two groups over time, but additional analgesia was required earlier in the fentanyl-only group.

On the other hand, the study by Takmaz *et al.,*[35] comparing bilateral infraorbital nerve block using Bupivacaine with saline (placebo) infraorbital nerve block in children under 2 years of age scheduled for cleft lip surgery showed that the FLACC pain score in the first 4 hours was less in the group that received Bupivacaine compared to the saline group, finding which was statistically significant (p=0.001). Abdellatif *et al.,*[36] also showed in their study a significantly higher pain score in the group that received saline infraorbital nerve block than the group that was administered bupivacaine nerve block. They concluded that the infants receiving infraorbital nerve blocks required fewer analgesics in the postoperative period.

Grewal and co-workers[13] observed that the Bupivacaine group had a lower pain score compared with the Intravenous Pentazocine group onto the 4 hours after surgery. Also, by the 4th hour, only 16.6% of the participants in the group receiving Bupivacaine infraorbital nerve block were in pain, in contrast, 76.6% in the Pentazocine group were in moderate to severe pain and required rescue analgesics. In a larger study with eighty-two children aged 3 months to 10 years, Rajamani *et al.,*[37] found that bilateral infraorbital nerve block was superior to fentanyl in terms of analgesia, and early feeding.

A pilot study was carried out for our research and it was discovered that the extraoral technique was an easier technique in administering the bilateral infraorbital nerve block following cleft lip repair. This is because it eliminated the need to touch the surgical site when everting the upper lip to insert the needle into the mucobuccal fold in the intraoral technique which could lead to wound dehiscence and disruption of the healing process. For these reasons, the extraoral approach for infraorbital nerve block was adopted for this study. The technique of analgesia using bilateral infraorbital nerve block with 0.5% plain Bupivacaine at 2mg/kg body weight through an extraoral approach was found in this present study to be relatively safer.

Conclusion

The result of this study showed that bilateral infraorbital nerve block with 0.5% plain Bupivacaine provided a longer duration of analgesia in the immediate postoperative period in comparison with intravenous Pentazocine 0.5mg/kg in an infant age group.

Study Limitations

Pain is subjective and difficult to properly assess. Assessing pain in children is even more challenging, mainly because infants are unable to self-report their pain experience due to age or developmental status. FLACC pain score is a subjective pain assessment tool and may be hampered by observation bias. Better assessment can be done with objective tools but are very expensive and not available in our environment.

Recommendations

Based on the results of this study, bilateral infraorbital nerve block with Bupivacaine may be considered an alternative to Opioids which are presently the mainstay in the management of moderate to severe immediate postoperative pain in infants undergoing cleft lip repair. Bupivacaine is safe to use and the technique of application is easy to perform.

Ethical Consideration

This study approval from the Health Research and Ethics Committee (HREC) of the Lagos University Teaching Hospital ADM/DCST/HREC/APP/2502 and written parental informed consent was obtained before enrollment into the study.

Conflict of Interest

The authors declare no conflict of interest.

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