

Bilateral suprazygomatic maxillary nerve blocks vs. infraorbital and palatine nerve blocks in cleft lip and palate repair

A double-blind, randomised study

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BACKGROUND. Cleft defects are common craniofacial malformations which require early surgical repair. These patients are at high risk of postoperative airway obstruction and respiratory failure. Cleft surgery may require high doses of opioids which may contribute to these complications.

OBJECTIVES. To compare the effectiveness of proximal and distal approaches to blocking the maxillary nerve in patients undergoing cleft lip or cleft palate surgery.

DESIGN. Randomised, controlled and double-blind study.

SETTING. The current study was carried out in Guwahati (Assam, India) between April 2014 and June 2014.

PATIENTS. A total of 114 patients older than 6 months who underwent cleft lip or cleft palate surgery were included. Exclusion criteria included coagulation disorders, peripheral neuropathy or chronic pain syndrome, infection in the puncture site, allergy to local anaesthetics, lack of consent and language problems or other barriers that could impede the assessment of postoperative pain.

INTERVENTIONS. Patients were randomly assigned to one of two groups: proximal group (bilateral suprazygomatic maxillary nerve blocks) and distal group (bilateral infraorbital nerve blocks for cleft lip repair and bilateral greater and lesser palatine nerve blocks and nasopalatine nerve block for cleft palate surgery).

MAIN OUTCOME MEASURE. The primary endpoint was the percentage of patients requiring extra doses of opioids. Secondary endpoints included pain scores, respiratory and nerve block-related complications during the first 24 h .

RESULT. S In the intra-operative period, there was a significant reduction of nalbuphine consumption in the proximal group (9.1vs. 25.4%, $P = 0.02$). The percentage of patients requiring intra-operative fentanyl was lower in the proximal group (16.4vs. 30.5%, $P = 0.07$). There were no differences in either postoperative pain scores or in postoperative complications. No technical failure or block-related complications were reported.

CONCLUSION. Bilateral suprazygomatic maxillary nerve block is an effective and safe alternative to the traditional peripheral nerve blocks for cleft lip and cleft palate surgery, in a paediatric and adult population.

Introduction

Cleft lip and palate are some of the most common craniofacial malformations, with an incidence ranging between 0.1 and 1.1 per 1000 births.¹ Cleft defects require early surgical repair to minimise feeding difficulties and provide optimal speech function.² Cleft surgery is a painful procedure that may require high doses of opioids.^{3,4} Inadequate peri-operative analgesia may contribute to an increased risk of bleeding, suture

dehiscence and unacceptable surgical outcomes. Moreover, these patients are at high risk of postoperative airway obstruction and respiratory failure.²⁻⁵ Opioids may contribute to these complications. Appropriate use of regional anaesthesia may mitigate or eliminate many of these concerns.

The maxillary nerve is responsible for the sensory innervation of the midface, including the hard and soft palates, upper jaw, upper dental arch and upper lip.⁶⁻⁸ Recently, the successful use of maxillary nerve block by the suprazygomatic approach has been reported in children undergoing cleft palate surgery.⁹ However, the use of this block has not been described in large series of patients, and the effectiveness of the suprazygomatic approach has not been evaluated in patients undergoing cleft lip surgery. Moreover, the success of the technique described by Captier et al.¹⁰ in children has never been evaluated in adults. Finally, as far as we are aware, this technique has not yet been compared with traditional peripheral blocks techniques.

The primary aim of this study was to compare the percentage of patients requiring extra doses of opioids. Secondary aims were to evaluate pain scores, postoperative and nerve block-related complications during the first 24 h .

Methods

The current study was done in accordance with the principles of good clinical practice, and the ethical principles in the Declaration of Helsinki. Ethical approval for this study was provided by the Operation Smile India Institutional Ethics Committee, Mumbai, India (Chairperson: Dr Rajeev Kapur) on 19 March 2014 with permission of Operation Smile International. Written informed consent was obtained from all patients, a legal surrogate, or the parents or legal guardians for minors, before randomisation.

This is a parallel, randomised, double-blind study conducted in Guwahati Comprehensive Cleft Centre in Assam, India. All patients older than 6 months scheduled for cleft lip or cleft palate surgery under general anaesthesia between April 2014 and June 2014 were approached for consent. Exclusion criteria included the presence of coagulation disorders, peripheral neuropathy or chronic pain syndrome, local infection or lesion in the puncture site, allergy to local anaesthetics and lack of consent/assent from patients or their parents. Patients with language problems or other barriers that could impede the assessment of postoperative pain were also excluded.

The patients did not receive premedication. Noninvasive blood pressure (BP), ECG, pulse oximetry (SpO_2), capnography (ETCO_2) and axillary temperature monitoring were used for all patients. In paediatric patients, anaesthesia was induced with sevoflurane (6 to 8% inspired in 100% oxygen) and propofol (2 to 5mgkg^{-1}) to facilitate orotracheal intubation without skeletal muscle relaxants. In older patients anaesthesia was induced with propofol 2 to 5mgkg^{-1} . Both groups also received fentanyl 1 to $2\mu\text{g kg}^{-1}$ to help blunt the sympathetic response associated with intubation. Oral preformed (RAE) uncuffed tubes were used in patients younger than 1 year, and oral RAE cuffed tubes in those over that age. Anaesthesia was maintained with sevoflurane 1.5 to 2.0% in 100% oxygen. Spontaneous ventilation was maintained, and supported modes were utilised when necessary to maintain ETCO_2 between 4.0 and 4.7 kPa (30 and 35 mmHg). All patients received paracetamol either rectally (40mgkg^{-1}) after tracheal intubation or orally (15mgkg^{-1}) before anaesthesia induction according to the patient's age, and 0.2 to 0.3mgkg^{-1} of intravenous dexamethasone (maximum 8 mg) as part of multimodal analgesia.

After tracheal intubation, patients were randomly assigned in a 1: 1 ratio to one of two parallel arms to receive either bilateral suprazygomatic maxillary nerve blocks (proximal group) or bilateral infraorbital blocks for lip surgery or bilateral greater and lesser palatine nerve blocks and nasopalatine nerve block for cleft palate surgery (distal group). Patient randomisation was performed with a simple randomisation formula using a computerised randomised sequence generated by the department of biostatistics at the institution. The blocks were done by an independent anaesthesiologist not providing the anaesthesia. Needle entry points at the suprazygomatic fossa and the infraorbital area were covered with a small piece of tape for blinding. Patients, nurses and the clinical investigator were blinded to the type of block performed during the procedure.

The suprazygomatic maxillary nerve block approach was performed with a 27-gauge 38 – mm needle following aseptic preparation of the skin and using the anatomical landmarks defined previously by Captier et al.¹⁰ The puncture site was at the frontozygomatic angle formed by the zygomatic arch and posterior orbital rim as shown

in Fig. 1. After inserting the needle perpendicular to the skin and contacting the greater wing of the sphenoid (approximately 20 mm deep), the needle was partially withdrawn, reoriented approximately 20° anterior and 10° inferior, and advanced 35 to 38 mm to direct the needle into the pterygopalatine fossa. Following a negative aspiration test, 0.15mlkg⁻¹ of local anaesthetic consisting of bupivacaine 0.25% and adrenaline 1: 200000 was injected by hand (maximum of 5 ml per side).

Palatal and infraorbital peripheral nerve blocks were performed using a 25-gauge 16-mm needle. Local anaesthetic consisting of 0.25% bupivacaine with adrenaline 1: 200000 was administered up to 3 ml in total, depending on the size and weight of the patient. Infraorbital block was performed by an extra oral approach as defined by Bösenberg and Kimble¹¹ in children and by Song et al.¹² in adults, along with hard-tissue landmarks. The puncture site in children

Fig. 1



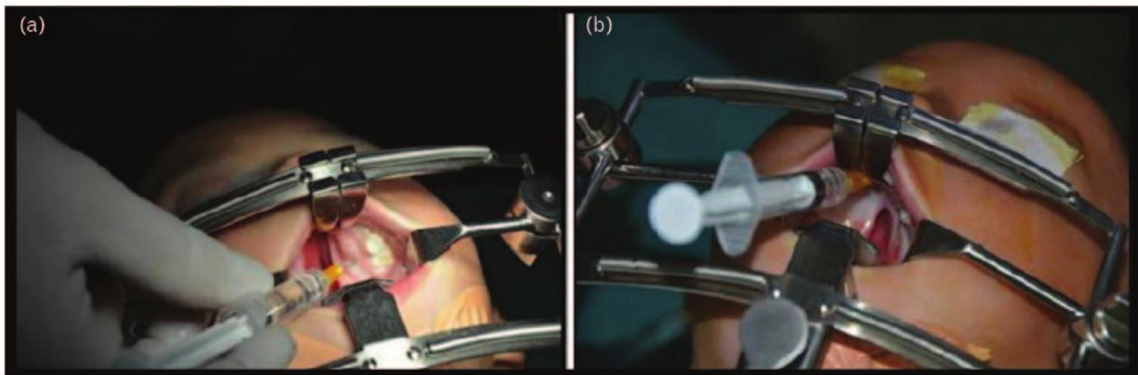
Description of the suprazygomatic maxillary nerve block technique by suprazygomatic approach (for details, refer to Methods section). was located at the midpoint of a line drawn between the palpebral fissure and ipsilateral lip commissure, about 7.5 mm lateral to the ala of the nose. In adult patients the puncture site was located at 7 mm lateral and 15 mm above the ala of the nose. In all patients, the needle was oriented at a 45° angle in an inferior and medial direction to avoid entering the infraorbital foramen and to allow the local anaesthetic to spread following the infraorbital nerve branches.⁷ Once the maxilla was contacted and after negative aspiration, the local anaesthetic was injected while manual pressure was applied in the infraorbital edge to favour the caudal distribution of the local anaesthetic. Digital pressure was maintained for 2 min at the puncture site to minimise hematoma formation.

Palatal nerve block was performed according to the technique previously described by Malamed and Trieger¹³ and subsequently evaluated by Jonnavithula et al.¹⁴ after patient positioning and once the Dingman retractor was in place. Palatal nerve block was performed on the hard palate in the region of the greater palatine foramen (about 1 cm medial to the 3rd upper molar) using a standard dental cross mouth injection technique. The injection was performed 0.5 cm anterior to the rear edge of the hard palate and 1 cm medial to the palatal aspect of the alveolar process. The needle was intentionally not inserted into the greater palatine canal to avoid vascular pedicle injury (Fig. 2a). The

lesser palatine nerve was blocked immediately posterior and lateral to the greater palatine foramen, generally at the midpoint between the rear edge of the hard palate and the pterygoid hamulus. The nasopalatine nerve was blocked by a single injection of anaesthetic in the incisive papilla at the level of the incisive foramen. In cases of complete cleft lip and cleft palate in which a nasopalatine foramen did not exist, anaesthetic solution was injected into the incisor on both sides of the slit pulp (Fig. 2b).

Block-related complications such as systemic toxicity (seizures, cardiac conduction abnormalities), bleeding at the puncture site, pupillary abnormalities or eye injury were recorded.

Fig. 2



Description of palatine nerve block (a) and nasopalatine nerve block (b) (for details, refer to Methods section).

The surgeon infiltrated the surgical area using 1% lignocaine with adrenaline 1: 200000 (maximum 5mgkg^{-1} of lignocaine) to provide surgical haemostasis. To differentiate increased BP and heart rate (HR) related to adrenaline or pain, surgeons were requested to wait 10 min after infiltration to start the surgery.

Patient characteristics, type and duration of the procedure and intra-operative and postoperative opioid consumption were recorded. Pain intensity was assessed using the FLACC pain scale (face, legs, activity, cry, consolability) for paediatric patients unable to report pain for themselves.¹⁵ In patients able to express pain by themselves, this was assessed using a scale from 0 to 10 or by visual analogue scale (VAS), depending on patient characteristics. All information was collected by an independent observer who was blinded to the study group to which each patient belonged.

Elevations in BP or HR ($>20\%$ above baseline) were documented and treated with $0.5\mu\text{g kg}^{-1}$ of intravenous fentanyl. This dose was repeated after 5 min if haemodynamics did not improve. In cases of persistent hypertension or tachycardia despite two doses of fentanyl, 50 to $100\mu\text{g kg}^{-1}$ of intravenous nalbuphine was administered. The trachea was extubated in the operating room after pharyngeal aspiration and recovery of airway-protective reflexes.

All patients received alternating dose of oral paracetamol (15mgkg^{-1} every 8 h) and ibuprofen (10mgkg^{-1} every 8 h). When the pain score was greater than 3/10 despite the scheduled medication $50\mu\text{g kg}^{-1}$ of nalbuphine was administered every 15 min until the pain score was 3/10 or less.

All assessments were performed every 15 min during the first hour and every 30 min until the patient was shifted from the postanaesthesia care unit (PACU), and finally, every 4 h during the first 24 postoperative hours. Late block-related complications such as numbness, drooling or infection were recorded at a 30-day follow-up.

Statistical analysis

The primary endpoint was the percentage of patients requiring extra doses of opioids postoperatively. Based on Chiono's study,¹⁶ we estimated a 25% difference in the percentage of patients requiring additional doses of opioid during the postoperative period between proximal and distal groups. Assuming a two-sided type I error protection of 0.05 and a power of 90%, a sample size of 49 subjects per treatment group was needed for this study. Assuming a drop-out rate of 10%, a total sample size of 110 subjects (55 per treatment group) was planned. Secondary endpoints included pain scores, and respiratory and nerve block-related complications during the first 24 h. Continuous data were expressed as mean (95% CI), or median and interquartile range [IQR] as appropriate, and frequencies and percentages (%) for categorical data. To study the possible relationship between qualitative variables, Pearson χ^2 test or Fisher's exact test was used. To study the relationship between a quantitative variable and a dichotomous qualitative test, Student's *t*-test or Mann-Whitney *U* test were used as appropriate.

Analysis was performed by intention to treat and per protocol analysis. Significant values of *P* less than 0.05 were considered significant. Statistical analysis was performed using SPSS 14.0 statistical package (IBM Corp., Armonk, New York, USA).

Results

The current article adheres to the applicable CONSORT guidelines. Of the 120 patients enrolled, six were excluded; two of them for postoperative bleeding requiring re-operation and four due to incomplete information in the records. Out of 114 patients analysed, 55 were in the proximal group (35 with cleft lip and 20 with cleft palate) and 59 in the distal group (45 with cleft lip and 14 with cleft palate) (Fig. 3). The median age was 4 [1 to 15.2] years and 18(15.8%) patients were older than 18 years of age. There were no statistically significant differences in patient characteristics or type of cleft between patient group (Supplemental Digital Content, SDC 1, <http://links.lww.com/EJA/A177>).

Fig. 3

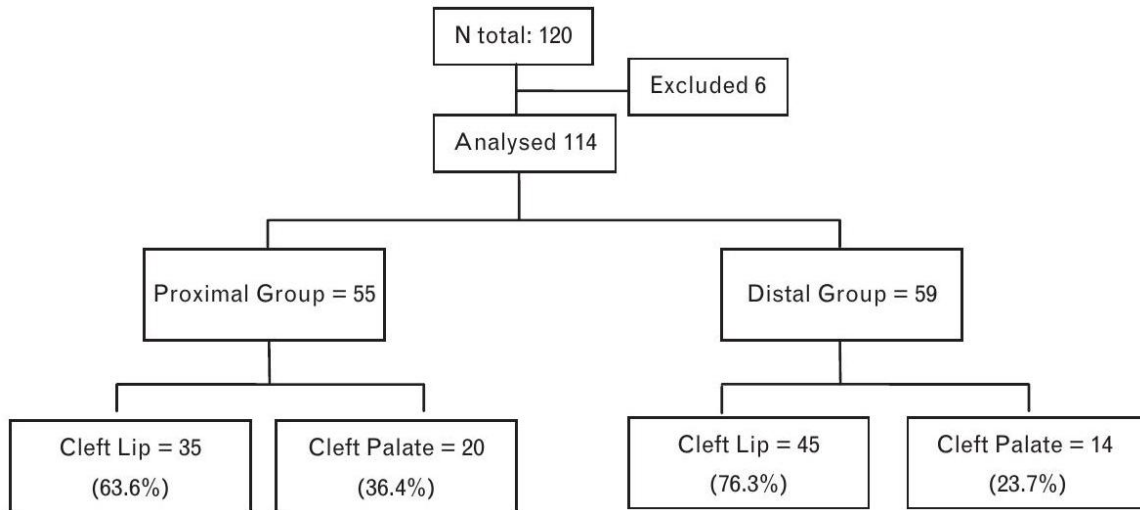


Table 1 Patients characteristics, peri-operative opioid consumption and postoperative complications

	Cleft lip, N = 80		P	Cleft palate, N = 34		P
	Proximal group, N = 35	Distal group, N = 45		Proximal group, N = 20	Distal group, N = 14	
Sex (male)	17 (48.6%)	16 (35.6%)	0.241	10 (50%)	10 (71.4%)	0.211
Age						
Median [IQR], years	5 (18)	3 (16)	0.524	3 (8)	5 (5)	0.252
≤ 5 years	N = 18(51.4%)	N = 26(57.8%)	0.571	N = 14(70%)	8 (57.1%)	0.440
Median [IQR], months	8.5 (41)	12.5 (22)	0.754	24 (23)	42 (38)	0.193
Median [IQR] surgical duration, min	78 (45)	75 (48)	0.616	80 (45)	72.5 (33)	0.443
Fentanyl extra OR ^a	5 (14.3%)	14 (31.1%)	0.079	4 (20%)	4 (28.6%)	0.562
Nalbuphine extra OR ^b	2 (5.7%)	11 (24.4%)	0.024	3 (15%)	4 (28.6%)	0.335

Nalbuphine PACU ^c	6 (17.1%)	7 (15.6%)	0.849	7 (35%)	3 (21.4%)	0.393
PONV ^d	0	4 (8.9%)	0.127	1 (5%)	0	0.403
SpO ₂ < 95%	4 (11.4%)	3 (6.7%)	0.693	0	1 (7.1%)	0.412

Values represent median [IQR] or number (%). ^a Number of patients requiring additional dose of intra-operative fentanyl. ^b Number of patients requiring nalbuphine intraoperatively. ^c Number of patients requiring one or more doses of nalbuphine in the postanaesthesia care unit (PACU). ^d PONV, postoperative nausea and vomiting. Bold *P* values indicate statistical significance.

During the postoperative period, 23.6% of the patients in the proximal group required extra nalbuphine vs. 16.9% in the distal group; difference of incidences: 6.7% (95% CI: -8.1 to 21.4), all of them during their early recovery in PACU. In the intra-operative period, there was a statistically significant difference for nalbuphine consumption (25.4% in the distal group vs. 9.1% in the proximal group; difference of incidences: 16.3%, 95% CI: 3 to 29.4). There was evidence for a weak difference in intra-operative fentanyl consumption (30.5% in the distal group vs. 16.4% in the proximal group; difference of incidences: 14.1%, 95%CI: 1.1 to 29.4). Five patients had postoperative nausea or vomiting, four of them in the distal group (6.8%). Four patients in each group had SpO₂ below 95%, but none of them required manoeuvres other than supplemental oxygen by facial mask (Supplemental Digital Content, SDC 1, <http://links.lww.com/EJA/A177>). FLACC and VAS scales were used in 83 and 31 patients, respectively. Most of the patients had pain scores less than or equal to 3 during the first 24 h in both groups and there were no statistically significant differences between them. After 20 h postsurgery, more than 25% of the patients experienced pain more than 3 in both groups (29.1% in the proximal group vs. 27.1% in the distal group; difference of incidences: 2%; 95% CI: -14.4 to 18.5) (Supplemental Digital Content, SDC 2, [http:// links.lww.com/EJA/A177](http://links.lww.com/EJA/A177)). There were no statistically significant differences between groups when analysing pain scores according to the scale used (Supplemental Digital Content, SDC 3 and SDC 4, [http://links.lww.com/ EJA/A177](http://links.lww.com/EJA/A177)).

Subgroup analysis regarding the type of block showed a statistically significant difference on the intra-operative nalbuphine consumption in patients who underwent cleft lip surgery (24.4% in distal group vs. 5.7% in proximal group; difference of incidences: 18.7%; 95% CI: 4 to 33.5). In cleft palate patients, the intra-operative nalbuphine consumption was 28.6% in the distal group vs. 15% in the proximal group; difference of incidences: 13.6%; 95% CI: -14.8 to 41.9 . No other statistically significant differences between groups for peri-operative opioid consumption or in postoperative complications have been found (Table 1). The percentages of patients not needing analgesic during the intra-operative and postoperative periods are shown in Fig. 4. No technical failure or block-related complications were reported.

Discussion

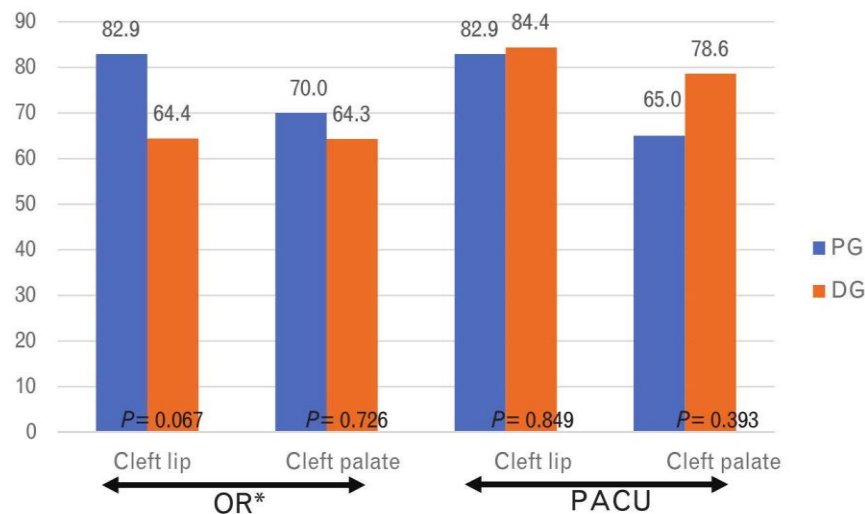
As far as we are aware, this is the first prospective, randomised, double-blind study comparing the bilateral suprazygomatic maxillary nerve blocks with the traditional

infraorbital and palatine nerve blocks during cleft surgery in a mixed paediatric and adult population. Our results showed that there are no statistically significant differences in the percentage of patients requiring postoperative opioids between the proximal group and the distal group.

Moreover, the proximal group was associated with a significant reduction in the percentage of patients requiring intra-operative nalbuphine compared with the distal group (9.1 vs. 25.4%). Furthermore, the percentage of patients requiring intra-operative fentanyl was lower in the proximal group.

There are three studies reporting the effectiveness of suprazygomatic blockade in children undergoing cleft palate surgery. Mesnil et al.⁹ retrospectively compared its use with a retrospective control group. Among those patients receiving the block, 45% required extra fentanyl intra-operatively, 80% required a bolus dose of nalbuphine during the early postoperative period and 18% of patients also received nalbuphine by continuous infusion. Opioid requirements were higher in the control group (90,100 and 80% for fentanyl, nalbuphine bolus and nalbuphine infusion, respectively). Sola et al. Described the effectiveness and sonographic features of this block in children. In their series, 64% of patients received a bolus of nalbuphine in the first 48 h and 20% required a nalbuphine infusion.¹⁷ Chiono et al. compared the use of a suprazygomatic block (ropivacaine 0.2%) vs. placebo. They found no differences in haemodynamic variables or intra-operative opioid consumption. However, they showed a 50% reduction of morphine consumption and a significant reduction in the number of patients requiring morphine infusion (3.6 vs. 31%).¹⁶ In all three studies, the average pain score was less than 3/10 in patients receiving the block.

Fig. 4



Percentages of patients not needing opioid analgesics during the intra-operative and postoperative periods. Subgroup analysis by type of surgery and intervention group. *Intraoperative opioid consumption includes both fentanyl and nalbuphine. DG, Distal Group; OR, Operation room; PACU, Postanaesthesia care unit; PG, Proximal Group.

In our series, the number of patients requiring additional doses of intra-operative fentanyl was lower than in other studies. This difference could be attributed to the use of lignocaine for local infiltration. In addition, fewer patients required nalbuphine throughout the peri-operative period, mainly in the proximal group, a fact that may reflect the effectiveness of the central block and the beneficial effect of multimodal analgesia in our protocol. The average value of the postoperative pain scale was less than or equal to 3 in both groups. No rebound was observed in opioid consumption during the 24 h of follow-up, in contrast to the findings reported by Chiono et al.¹⁶ However, more than 25% of our patients had pain scores greater than 3/10 after 20 h, probably related to the ending of the analgesic block.

Subgroup analyses regarding the type of surgery showed greater intra-operative nalbuphine consumption in cleft lip than in cleft palate patients. One possible explanation might be that temporomandibular joint pain caused by the Digman retractor during palate surgery could increase the intra-operative opioid consumption in both groups, thus masking the difference in analgesic effect in the blocked area. Moreover, sensory innervation of the soft palate and oropharynx involves other nerves besides the trigeminal nerve (glossopharyngeal and vagus). These nerves could be blocked with a long-acting local anaesthetic during palatal block but not during a proximal block, underestimating the benefit of the proximal approach.

A high risk of postoperative airway obstruction and hypoxaemia after cleft surgery has been reported, due to the decrease diameter of the airway. This risk may be increased in syndromic patients and patients receiving opioids.^{2,5,18} Doyle and Hudson¹⁹ reported three cases of severe respiratory depression in a series of 143 patients after cleft palate surgery, one directly related to opioid use and two others attributed to the presence of Pierre Robin Sequence. In our series, 8/114 patients had a documented SpO₂ less than 95% (four in each group) that was resolved with oxygen therapy through a face mask. Seven were cleft lip patients and one underwent cleft palate surgery. Four were children (three under 1 year and the other 9 years) and five had received additional opioids.

Different techniques have been used with the aim of reducing opioid consumption and consequently the risk of respiratory complications. The infraorbital nerve block is a good alternative for both intra-operative and postoperative pain management during cleft lip surgery, and it has been shown to be superior to intravenous fentanyl, placebo and local surgical infiltration.^{20–22} Palatal nerve block has also been proven effective for pain management after cleft palate surgery.^{14,23} However, several aspects have to be considered when performing these blocks. There is a wide anatomical variability in both the infraorbital foramen and the nerve, as well as in the palatine nerves themselves.^{7,8,12,24} The infraorbital nerve forms a plexus with facial nerve branches in the infraorbital space. Injury to these nerves has been associated with excessive salivation.^{8,25} Furthermore, the terminal branches of the infraorbital nerve do not provide sensory innervation of the premaxilla and the nasal floor. Therefore, infraorbital nerve block may provide incomplete analgesia for patients having a complete cleft lip defect repair. In the case of palatal block, injury of the vascular pedicle could compromise the overall success of the surgical procedure. Performing bilateral maxillary nerve blocks

could provide well tolerated and consistent anaesthesia and analgesia for both cleft lip and palate avoiding the potential complications previously mentioned.

Some limitations of our study should be considered. Including children and adults may be one of them because they are different populations, and mandate the use of different postoperative pain scales which are not interchangeable. However, each pain scale has been previously validated and we found no differences between groups when analysing pain scores according to the scale used. Moreover, FLACC scale can be used across populations of patients and settings, and the scores are comparable with those of the commonly used 0-to-10 number rating scale.²⁶ Furthermore, local infiltration with lignocaine and adrenaline may be considered a confounding factor. However, this technique was performed in all patients, and the analgesic effect of lignocaine does not exceed 2 to 3 h. In addition, we performed the maxillary nerve block in both children and adults, using the landmarks described by Captier et al.¹⁰ in infants and also we used a shorter needle than previously described in adult patients. This could have led to potential block failures in adults. It is difficult to recognise these failures in patients while under general anaesthesia particularly as a bilateral block is needed. Moreover, some patients did not receive nalbuphine despite having pain score more than 3/10. This is consistent with previous studies in which insufficient analgesia, especially in children, has been reported due to fear of potential complications related to opioids, particularly in the developing world where paediatric ICU or high dependency units are seldom available. On the other hand, due to the difficulties in differentiating pain from delirium in paediatric patients, nalbuphine (which has sedative properties) could have been given in pain-free children with emergence delirium.

In conclusion, this study shows that bilateral suprazygomatic block may be an alternative to the traditional peripheral nerve blocks for cleft lip and cleft palate surgery in a mixed paediatric and adult population.

Dosing titration studies, use of adjuvant to local anaesthetics, block performance, time evaluation and assessments of block reproducibility by inexperienced providers are important next steps in the evaluation of the suprazygomatic maxillary nerve block in the cleft lip and palate surgical population.

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Conflicts of interest: none.

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