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Research article

Bilateral suprazygomatic maxillary nerve block versus palatal block for cleft palate repair in children: A randomized controlled trial

Mohamed M. Abu Elyazed, Shaimaa F. Mostafa*

Department of Anesthesia and Surgical ICU, Faculty of Medicine, Tanta University, Egypt

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ABSTRACT

Background and objectives: Airway obstruction and respiratory compromise are frequently encountered complications of cleft palate (CP) repair. We compared the analgesic efficacy of bilateral suprazygomatic maxillary nerve block (SMB) versus palatal block (PB) in pediatric patients undergoing CP repair.

Methods: 90 patients aged 3–24 months were allocated into three groups: **Control group (C):** patients received general anesthesia only**. Maxillary block group (M):** patients received ultrasound-guided bilateral SMB using 0.15 ml/kg bupivacaine 0.25%. **Palatal block group (P):** 0.5 ml bupivacaine 0.25% was injected bilaterally at greater, lesser and nasopalatine foraminae. CHIPPS score, rescue analgesic consumption and time till tolerance of oral feed were assessed.

Results: On admission to PACU till 8 h postoperative, CHIPPS score was lower in M and P groups compared to C group. At 6 h and 8 h, CHIPPS score was lower in M group compared to P group. Postoperative rescue analgesic consumption was decreased in M and P groups (0.72 ± 2.22 mg) and (3.73 ± 5.92 mg) compared to C group (8.07 ± 5.47 mg) with significantly lower values in M group compared to P group. Time to first request of rescue analgesia was significantly prolonged in M and P groups (482.50 ± 38.62 min) and (260.00 ± 31.62 min) compared to C group (79.71 ± 30.34 min). Time to feed was lower in M and P groups compared to C group.

Conclusion: Ultrasound-guided bilateral SMB provided better postoperative analgesia and decreased rescue analgesic consumption and time to tolerate oral feeding compared to PB without increased side effects.

1. Introduction

Cleft lip and/or palate are considered to be the most frequently encountered craniofacial malformation [1,2]. Early surgical intervention for cleft palate (CP) repair is essential for proper feeding and phonation as well as reduction of complications such as frequent sinusitis and other respiratory tract infections [3,4].

The surgical procedure can be complicated by airway obstruction and respiratory complications [2,5]. Systemic analgesia using opioids has been associated with increased risk of airway obstruction and respiratory dysfunction [2,6].

Postoperative analgesia can be successfully achieved in infants and neonates using regional anesthesia without additional risk of respiratory depression [7].

When performed within the pterygopalatine fossa, maxillary nerve block can provide intra-operative and postoperative analgesia of both hard and soft palate [8].

Greater palatine (GP) nerve innervates the posterior part of the hard palate, lesser palatine (LP) nerve supplies the soft palate and nasopalatine (NP) nerve supplies the soft and hard tissues of the palate from canine to canine. Post palatoplasty analgesia can be successfully achieved by blocking these nerves [9].

The aim of this study was to compare the effects of ultrasound-guided bilateral suprazygomatic maxillary nerve block (SMB) versus palatal block (PB) on the perioperative systemic analgesic consumption as well as the duration of analgesia in pediatric patients undergoing CP repair.

2. Materials and methods

The study was approved by the Hospital Ethics Committee in Faculty of Medicine, Tanta University, Egypt (protocol number 31586/06/17 on 01/06/2017) and registered in the Pan African Clinical Trial Registry (PACTR201710002695410). After informed written parental consent, 90 pediatric patients aged 3 months to 2 years, of either gender, ASA I-II, scheduled for surgical CP repair in the department of

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* Corresponding author at Moheb Street, Almahalla Alkobra, Egypt.
E-mail address: shaimaafarouk7777@yahoo.com (S.F. Mostafa).

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pediatric surgery, Tanta University Hospital were enrolled in the study. The study was carried out between June and November 2017.

Exclusion criteria: Lack of parental consent, patients with a history of allergy to local anesthetic (LA) or cutaneous infection around the sites of the blocks were excluded from the study.

Any unexpected complication encountered during the course of the research were disclosed to the participants' parents as well as the ethical committee on time. Every patient's guardians received a thorough explanation for the purpose of the study during the preoperative visit.

Patients were randomly allocated into three groups of 30 patients each. Patients were randomized using computer-generated randomization numbers in sealed opaque envelopes. The envelope was chosen by each patient's parent which determined his group.

All children were premedicated with oral midazolam (0.5 mg/kg) 30 min prior to surgery. Monitoring, included pulse oximetry, non-invasive blood pressure and body temperature measurement, electrocardiography, and end-tidal CO_2 ($PECO_2$). General anesthesia was induced in all children using 4–6% sevoflurane and intravenous fentanyl (1 μg/kg). After endotracheal intubation, mechanical ventilation was initiated and ventilator parameters were adjusted according to patient's age so that $PECO_2$ was maintained at 4.6 ± 0.25 kPa (35 ± 2 mmHg). Anesthesia was maintained with 50% oxygen in air and 1 minimum alveolar concentration of sevoflurane.

Group I: Control group (C): Patients received general anesthesia only.

Group II: Maxillary block group (M): Patients received bilateral ultrasound-guided SMB using 0.25% bupivacaine 0.15 ml/kg over 20 s after induction of general anesthesia.

2.1. Technique of ultrasound-guided SMB [10]: (Fig. 1)

SMB was performed after induction of general anesthesia before starting the surgical procedure using a 25 gauge 50-mm Sprote needle (Nanoline; Pajunk, Geisingen, Germany), following previously established anatomic landmarks which include zygomatic arch, posterior orbital rim, greater wing of sphenoid and most importantly the temporal muscle [5,11].

A high frequency 8–13 MHz linear transducer (SonoScape SSI 6600-China) was applied over the maxilla in the infrazygomatic area. The needle was inserted perpendicularly at the angle between the posterior orbital rim and the superior border of the zygomatic arch then advanced using the out-of-plane approach about 20 mm towards the greater wing of the sphenoid. Reorientation and advancement of the needle for 35–45 mm deep to the pterygopalatine fossa were then performed. The needle direction and depth of insertion were independent of patient age [11]. After negative aspiration, 0.15 ml/kg bupivacaine 0.25% was injected bilaterally.

Group III: Palatal block group (P): After induction of general anesthesia, greater palatine, lesser palatine and naso palatine nerves were blocked bilaterally at their corresponding foraminae using 0.5 ml bupivacaine 0.25% at each point with a total volume of 2.5 ml bupivacaine 0.25%.

2.2. Technique of PB [9]: (Fig. 2)

A cotton swab was pressed opposite the first molar tooth then moved posteriorly until it fell into a depression, the GP foramen, situated at the junction of alveolar and palatine bone. A 23G needle was used to block GPN bilaterally just anterior to the GP foramen by injecting 0.5 ml local anesthetic solution 1 cm medial to 1st / 2nd maxillary molar at a depth < 1 cm without entering the canal. 0.5 ml local anesthetic solution was injected bilaterally to block LPN at the LP foramen, identified just lower and lateral to GP foramen, at a depth of less than 1 cm. NPN was blocked lateral to the incisive papilla using 0.5 ml of the solution at a depth of < 1 cm. A single injection was sufficient to achieve bilateral block. In case of a complete cleft, the block was performed at the incisive papilla as the vessels will be emerging from the incisive foramen (IF).

No submucosal or peri-incisional local anesthetic infiltration was administered.

Intraoperatively, fentanyl (0.5 μg/kg) was injected intravenously when more than 15% increase in the preoperative mean arterial pressure or heart rate was noted. Fentanyl boluses were recorded. At the end of surgery, patients were extubated following prompt reversal with neostigmine (0.05 mg/kg) and atropine (0.02 mg/kg) then admitted to the PACU.

Any encountered side effects e.g. nausea, vomiting, failed block, LA toxicity, hematoma, sedation, pupil alteration or ocular injury were recorded.

Children and Infants Postoperative Pain Scale (CHIPPS) score [12] was recorded on admission to PACU, at 1 h, 2 h, 4 h, 6 h, 8 h, 12 h, 18 h and 24 h to assess the quality of analgesia. The score consists of 5 points; crying, facial expression, posture of the trunk, leg posture and motor restlessness each scored from 0 to 2 with a total score of 0–10.

Routine postoperative analgesia in the form of IV paracetamol (perfalgan) 15 mg/kg/ 6 h was administered to all patients. IV pethidine (0.5 mg/kg) was given as rescue analgesia for patients if CHIPPS was > 3/10. Time to first request of rescue analgesia as well as total pethidine consumption were recorded. Patients' parents satisfaction was also recorded on a 3-point scale where 1 = satisfied, 2 = fair and 3 = unsatisfied.

The primary outcome was the total 24 h postoperative rescue

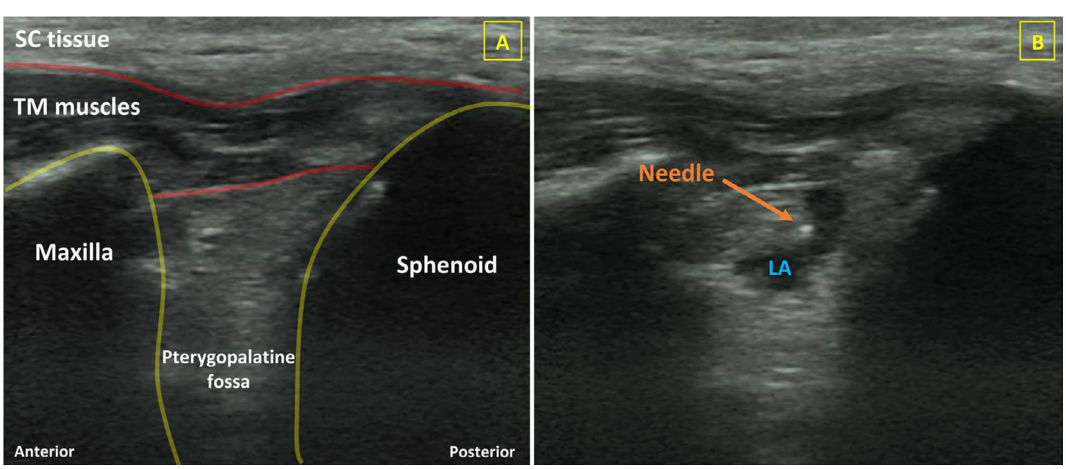

Fig. 1. Ultrasound guided demonstration of suprazygomatic maxillary nerve block: (A) sonographic anatomy of pterygopalatine fossa. TM: tempromaxillary muscle. (B) needle location indicated by an arrow with local anesthetic (LA) deposited within the pterygopalatine fossa.

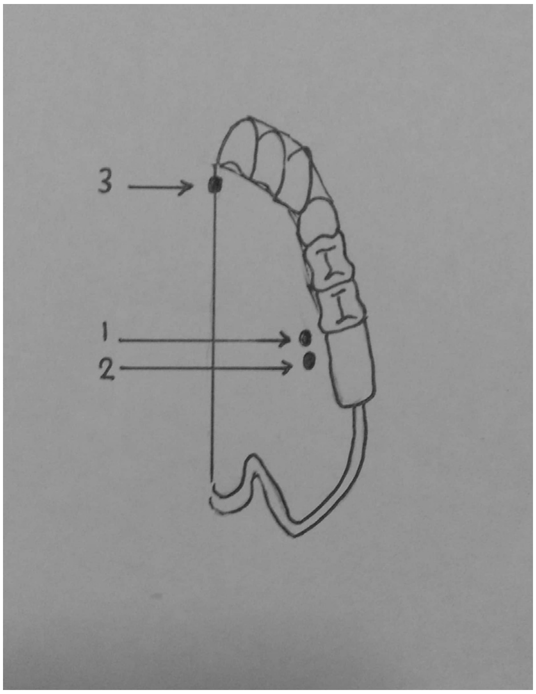

Fig. 2. Diagram showing injection sites for palatal block: 1: Greater palatine nerve block. 2: Lesser palatine nerve block. 3: Nasopalatine nerve block.

analgesic consumption. Secondary outcomes were postoperative pain score and time to feed after tracheal extubation (defined as the time taken for the child to tolerate milk feeds following an initial trial of water).

2.3. Statistical analysis

The sample size was calculated based on the consumption of postoperative analgesia. Based on the results of the previous study [5], 28 patients were needed to detect 25% difference of the consumption of postoperative analgesia between groups at α error 0.05 and power of the study of 80%.

SPSS 16 software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Kolmogorov–Smirnov test was performed for verification of the assumption of normality. Quantitative data were described as mean ± SD and one-way ANOVA with post hoc Tukey's HSD test was used for comparison between groups. Kruskal-Wallis test was used to analyze and compare postoperative CHIPPS score between groups. Categorical data were described as number or frequencies (%) and Chi-square test was used for comparison between groups. P-value < 0.05 was considered significant.

3. Results

90 patients were enrolled in this study (Fig. 3).

Demographic data and duration of surgery were comparable in the studied groups (Table 1). Twenty patients received intraoperative doses of fentanyl in C group compared to 5 patients in M group and 9 patients in P group (P value < 0.001) (Table 2). Intraoperative fentanyl consumption was significantly higher in C group (0.61 ± 0.52 μg) compared to M and P groups (0.08 ± 0.19 μg & 0.16 ± 0.29 μg) respectively (P value < 0.001). The difference between M and P groups was statistically insignificant (P value = 0.203) (Table 2).

On admission to PACU, at 1 h, 2 h and 4 h postoperative, CHIPPS score was significantly lower in M and P groups compared to C group. The difference between M and P groups was statistically insignificant. At 6 h, 8 h and 12 h postoperative, CHIPPS score was significantly lower in M and P groups compared to C group with significantly lower values in M group compared to P group at 6 h and 8 h and comparable values at 12 h postoperative. At 18 h and 24 h postoperative, no significant difference in CHIPPS score was detected between the studied groups (Table 3).

As regards postoperative rescue pethidine consumption, 23 patients received pethidine in C group compared to 3 patients in M group and 11 patients in P group (P value < 0.001). Pethidine consumption was significantly lower in M (0.72 ± 2.22 mg) and P (3.73 ± 5.92 mg) groups compared to C group (8.07 ± 5.47 mg) (P value < 0.001) with significantly lower values in M group compared to P group (P value = 0.006) (Table 2).

Time to first analgesic request was significantly prolonged in M (482.50 ± 38.62 min) compared to C (79.71 ± 30.34 min) and P groups (260.00 ± 31.62 min) with a more significant prolongation in M group compared to P group (P value < 0.001) (Table 2).

Time to feed was significantly lower in M (5.53 ± 1.74 h) compared to C (10.27 ± 1.72 h) and P groups (7.17 ± 1.91 h) (P value < 0.001), with a significant difference between M and P groups (P value = 0.002) (Table 2).

No significant complications were detected in any of the studied groups. Parent satisfaction was significantly higher in M and P groups compared to C group. However, satisfaction was comparable between M and P groups (Table 4).

4. Discussion

The results of our study showed that both ultrasound-guided bilateral SMB and PB decreased postoperative pain score compared to control group. However, SMB provided better postoperative analgesia and decreased rescue analgesic consumption as well as time to tolerate oral feeding compared to PB without increased side effects.

Systemic opiates have been used for post palatoplasty analgesia in infants, however, the occurrence of respiratory depression was unpredictable [13]. In addition, hypoxemic episodes have been frequently reported after CP repair and have been attributed to the possible reduction of airflow in the infant airway.

Takemura et al. [3] reported that continuous infusion of systemic opiates has been associated with an increased incidence of airway obstruction following CP repair. Doyle and Hudson [6] investigated 143 cases of CP repair and reported three cases of severe respiratory depression. They attributed one case to opiate consumption and the other two to Pierre–Robin syndrome. Many regional anesthetic techniques have been shown to decrease the occurrence of morphine-related respiratory complications.

With the exception of the middle meningeal nerve, maxillary nerve branches are located within the pterygopalatine fossa [11]. Blocking the maxillary nerve can achieve sensory blockade of both soft and hard palate [8]. Ultrasound-guided technique for maxillary nerve block allows direct visualization of the internal maxillary artery, proper needle positioning, and LA spread thus less risk of iatrogenic vessel or nerve damage [11]. In the suprazygomatic approach used in our study, the maxillary artery is situated inferior and ventral to the nerve and thus it is much safer than the infrazygomatic approach [11]. Moreover, the suprazygomatic approach avoids the risk of ocular injury previously reported with infrazygomatic and infraorbital blocks [14].

Consistent with our results, Mensil et al. [5] reported that bilateral MB was an efficient and applicable technique for intra and postoperative analgesia with decreased consumption of opioids.

Chiono et al. [4] in their randomized, double-blind study demonstrated that bilateral SMB significantly reduced morphine consumption for 48 h postoperative following surgical repair of CP compared to placebo.

In addition, Sola et al. [10] reported lower postoperative CHIPPS scores following ultrasound-guided SMB in CP repair in children.

In contrast to our results, Botros et al. [15] demonstrated that

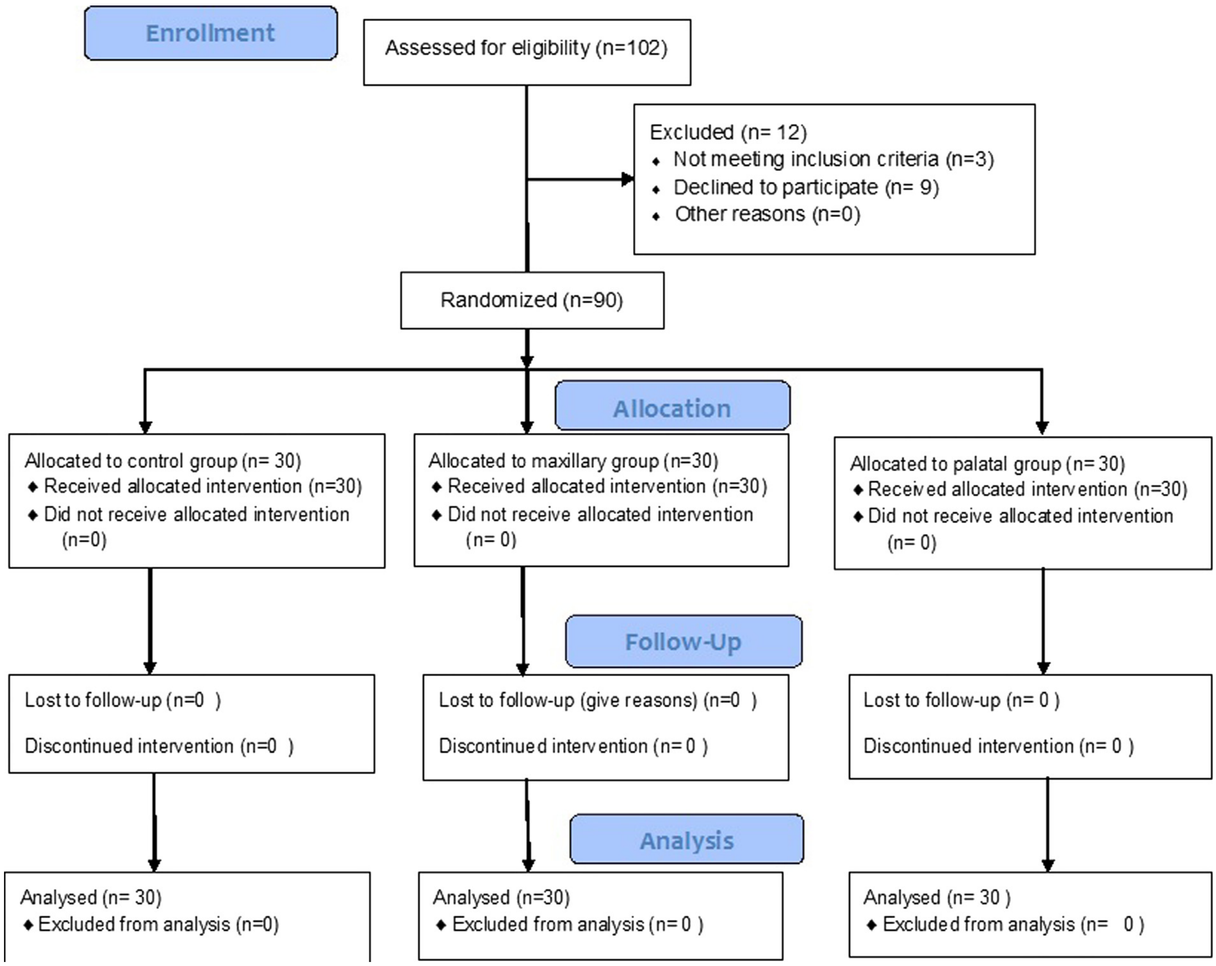

Fig. 3. CONSORT flow diagram of participants through each stage of the randomized trial.

Table 1
Demographic data in studied groups.

	Control group (C)	Maxillary group(M)	Palatal group (P)	P value
Age (months)	8.93 ± 4.59	7.90 ± 4.41	8.50 ± 3.72	0.642
Sex (M/F)	25/5	26/4	24/6	0.786
Weight (kg)	8.57 ± 1.94	7.93 ± 1.78	8.43 ± 1.79	0.377
Duration of surgery (min)	92.67 ± 22.69	95.33 ± 17.37	97.67 ± 16.75	0.600

Data presented as mean ± SD or patient number.
*P < 0.05 denotes statistical significance.

Table 2
Perioperative analgesic consumption and time to feed.

		Control group (C)	Maxillary group (M)	Palatal group (P)	P value	P1	P2	P3
Intraoperative fentanyl (μg)	Number (%)	20 (66.66%)	5 (16.66%)	9 (30%)	< 0.001*	< 0.001*	0.005*	0.360
	Consumption	0.61 ± 0.52	0.08 ± 0.19	0.16 ± 0.29	< 0.001*	< 0.001*	< 0.001*	0.203
Postoperative pethidine (mg)	Number (%)	23 (76.67%)	3 (10%)	11 (36.67%)	< 0.001*	< 0.001*	0.002*	0.015
	consumption	8.07 ± 5.47	0.72 ± 2.22	3.73 ± 5.92	< 0.001*	< 0.001*	0.003*	0.006*
Time 1st analgesic request (min)		79.71 ± 30.34	482.50 ± 38.62	260.00 ± 31.62	< 0.001*	< 0.001*	< 0.001*	< 0.001*
Time to feed (h)		10.27 ± 1.72	5.53 ± 1.74	7.17 ± 1.91	< 0.001*	< 0.001*	< 0.001*	0.002*

Data presented as mean ± SD or patient number (%). P presented the comparison among the three groups. P1 presented the comparison between the C group and the M group. P2 presented the comparison between the C group and the P group. P3 presented the comparison between the M group and P group.
* P < 0.05 denotes statistical significance.

bilateral GPN block in pediatric patients undergoing palatoplasty provided better intraoperative analgesia as compared to bilateral SMB. The difference of these results as compared to our findings may be explained by the fact that Botros et al. performed a blind block of the maxillary nerve. This is different from the ultrasound-guided technique used in our study that might have improved the accuracy of SMB and hence its analgesic efficacy. In addition, another difference with our study includes the higher age group (6 months- 5 years) investigated in their

Table 3
Children and Infants Postoperative Pain Scale (CHIPPS) score.

	Control group (C)	Maxillary group (M)	Palatal group (P)	P value	P1	P2	P3
On admission	3 (2–3)	1 (1–2)	1.50 (1–2)	< 0.001*	< 0.001*	< 0.001*	0.846
1 h	4 (3–4)	1 (1–2)	2 (1–2)	< 0.001*	< 0.001*	< 0.001*	0.301
2 h	3 (2–4)	1 (1–2)	1.5 (1–2)	< 0.001*	< 0.001*	< 0.001*	0.115
4 h	4 (3–4)	1 (1–2)	2 (1–2)	< 0.001*	< 0.001*	< 0.001*	0.093
6 h	3 (2.75–3)	2 (1–2)	2.5 (2–3)	< 0.001*	< 0.001*	0.015*	0.018*
8 h	3 (3–4)	1.5 (1–2)	2.5 (2–3)	< 0.001*	< 0.001*	< 0.001*	< 0.001*
12 h	3 (3–3)	2 (1.75–3)	3 (2–3)	0.001*	< 0.001*	0.165	0.189
18 h	3 (2–3)	2 (2–3)	2.5 (2–3)	0.170			
24 h	2 (2–3)	2 (2–3)	2 (1.75–3)	0.848			

Data presented as median (interquartile range). P presented the comparison among the three groups. P1 presented the comparison between the C group and the M group. P2 presented the comparison between the C group and the P group. P3 presented the comparison between the M group and P group.
* $P < 0.05$ denotes statistical significance.

Table 4
Adverse events and patient satisfaction:

		Control group (C)	Maxillary group (M)	Palatal group (P)	P value	P1	P2	P3
Satisfaction	Satisfied	11 (36.7%)	25 (83.3%)	23 (76.7%)	0.002*	0.001*	0.007*	0.768
	Fair	15 (50%)	4 (13.3%)	5 (16.7%)				
	Unsatisfied	4 (13.3%)	1 (3.3%)	2 (6.7%)				
Complications	Hematoma	0 (0%)	2 (6.7%)	1 (3.3%)	0.355			
	Nausea& vomiting	3 (10%)	5 (16.7%)	6 (20%)	0.553			

Data presented as patient number (%). P presented the comparison among the three groups. P1 presented the comparison between the C group and the M group. P2 presented the comparison between the C group and the P group. P3 presented the comparison between the M group and P group.
* $P < 0.05$ denotes statistical significance.

study compared to our study (3 months- 2 years).

Our results showed a significant reduction in time to feed following extubation in both maxillary and palatal blocks compared to control group.

Infants show poor tolerance for long fasting periods. Therefore, early resumption of oral feeding is recommended. Decreased time to tolerate oral feed indirectly indicates infant comfort. Gunawardana and Ratnayaka [16] reported that early reestablishment of milk feeding may have a calming effect after repair of cleft lip mediated via endogenous opioids system.

As regards palatal block, our results showed better postoperative analgesia in PB group compared to control group. The palate receives sensory innervation from naso palatine, greater and lesser palatine nerves. Blocking these nerves provides adequate palatal analgesia.

Jonnavithula et al. [9] evaluated 45 children undergoing CP repair. They compared PB using 0.25% of bupivacaine versus a placebo and reported that PB provided adequate postoperative analgesia but with no anesthetic sparing effect. They also added the benefit of lowering the risk of systemic toxicity or tissue distortion due to the relatively low volume of local anesthetic required for the block.

During their pilot study and other studies [17–19] significant but inconsistent analgesia was reported with saline injection. This could be explained by the mechanical pressure applied on the nerve and not its block [17,18].

Jonnavithula et al. [9] proposed that PB can reduce the metabolic and endocrine responses to surgery. They reported the additional benefit of smooth emergence on reducing airway trauma and thus less postoperative bleeding.

Kamath et al. [20] compared PB to IV pethidine in 50 patients undergoing CP repair and reported statistically comparable pain scores, yet, fewer analgesic doses in PB group.

Alternatively, Muthukumar et al. [21] investigated local infiltration of lidocaine in cleft lip and/or palate repair. Lower pain scores were limited to the first two postoperative hours, while, less rescue analgesic request was only noted in the immediate postoperative period. They attributed their results to rapid systemic absorption of local anesthetics through palatal mucosa. Also, 20% of patients were operated only for cleft lip repair.

Limitations of our study included the relatively small number of patients enrolled in the research as well as the lack of blinding since performing sham blocks wasn't feasible.

5. Conclusion

Both ultrasound-guided bilateral suprazygomatic maxillary block and palatal block decreased postoperative pain score compared to control group. However, SMB provided superior postoperative analgesia and decreased rescue analgesic consumption as well as time to tolerate oral feeding compared to PB without increased side effects.

6. Funding

The study was funded by departmental resources.

7. Conflict of interest

The authors declare that there is no conflict of interest.

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