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A Double-Blinded Randomized Controlled Study on the Effectiveness of Postoperative Analgesia-Comparison Between Ultrasound Versus Anatomical Landmark Technique of Blocking Bilateral Supra Zygomatic Maxillary Nerve in Paediatric Patients Undergoing Cleft Palate Repair

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KEYWORDS
Double-blinded randomised controlled study, Ultrasound, Anatomical landmark technique, Cleft palate repair

ABSTRACT

Introduction: Cleft palate requires surgical correction between 9-18 months of age, often involving palatoplasty techniques. This study aimed to compare the effectiveness of postoperative analgesia between ultrasound-guided suprazygomatic maxillary nerve block and anatomical landmark technique in patients undergoing cleft palate repair.

Methods: This double-blind, randomised controlled study included 70 paediatric patients at the SRM Medical College Hospital between April 2023 and March 2024. The children were randomly assigned to either the US or LM group. Anesthesia was induced, and a suprazygomatic maxillary nerve block was performed using either landmarks or ultrasound. Postoperatively, pain was assessed every 2 h for 24 h using the FLACC score, and intravenous paracetamol was administered if the score exceeded 5.

Results: There were no significant differences in sex, height, weight, airway assessment, ASA of Anesthesiologists status, or surgery duration between groups ($p>0.05$). The US group had a significantly longer block administration time than the LM group did. The US group also showed a statistically significant reduction in the postoperative mean arterial pressure from 1 to 24 h and a lower heart rate. FLACC scores were significantly lower in Group US at 30 minutes, 2, 4, and 8 hours, indicating better pain management and longer block duration (13.08±1.70 vs. 10.80±3.53 hours). Patients in the US group required postoperative rescue analgesics (22.9 vs 45.7%; $p=0.044$).

Conclusion: Children who underwent cleft palate repair experienced superior pain relief with ultrasound-guided suprazygomatic maxillary nerve block, and analgesic efficacy was enhanced by the addition of 0.3 µg/kg to 0.2% ropivacaine.

1. Introduction

According to the World Health Organization's Human Genetics programme (2002), cleft palate, the fourth most common birth abnormality globally, has a prevalence of 0.8 per 1000 live births.[1] The 32% presented as isolated cleft palate, 21% as isolated cleft lip, and 46% as cleft lip and palate. Genetic factors contribute to 25% of these cases.[2,3] Surgical correction of cleft palate, typically performed between 9 and 18 months of age, often involves palatoplasty techniques, such as Furlow Double Opposing Z-Palatoplasty, Veau-Wardill-Kilner Palatoplasty, and Bardach Two-flap Palatoplasty. Nonalveolar moulding, used for unilateral cleft lip and palate, is done by an orthodontist between 1 week and 3 months, while cleft lip repair, commonly utilising the rotation advancement technique, is performed between 3 and 6 months of age.[4-6]

Airway and pain management are major anaesthetic considerations in pediatric surgery, and are crucial for Enhanced Recovery After Surgery (ERAS) pathways. The Copur Index, which incorporates both subjective and objective parameters, is used to assess paediatric airways. Effective postoperative pain control using modalities such as local anaesthetic infiltration, opioids, non-opioids, and nerve blocks is essential. Multimodal analgesia, including regional anaesthesia, reduces opioid consumption and associated side effects and promotes faster recovery. Ultrasound-guided nerve blocks offer practical advantages over traditional surface anatomy-based techniques by providing real-time visualisation.

The FLACC score, which assesses pain through facial and behavioural observations, aids in effective pain management in non-verbal children. Our study compared ultrasound-guided suprazygomatic maxillary nerve blocks with traditional anatomical landmark methods in pediatric cleft palate repair and evaluated the success rates, time to administration, opioid reduction, and postoperative pain relief.

Cleft Lip and Palate (CLP) develops between the 5th and 8th weeks of embryonic development due to the failure of the maxillary processes to fuse with the lateral and medial nasal processes.[7] Facial development begins by the end of the fourth week, with palate development starting at the end of the tenth week. During the fourth week, swelling around the stomodeum was observed in the frontonasal, maxillary, and mandibular processes. By the fifth week, the medial and lateral nasal processes had formed a horseshoe-shaped ridge. The nasal pits rupture, forming a communication between the nasal and oral chambers. The upper lip forms by the seventh week as the maxillary process fuses with medial nasal swelling. The secondary palate, which forms between the sixth and seventh week, grows vertically before shifting to a horizontal position above the tongue. Palatal fusion, from anterior to posterior, involves the uvula, soft palate, and the posterior hard palate. Clefts in the secondary palate can result from failure of the palatal ridges to contact, failure of ridge fusion, unexpected rupture, or defective consolidation of mesenchymal palatine ridges.[8]

Cleft Lip (CL) is traditionally corrected between 3 and 6 months, but neonatal surgery is increasingly common. Cleft Palate (CP) correction is recommended at 9-18 months.[6] Surgical timing depends on the surgeon's preference, the need to address speech impairments, minimise facial growth distortion, and optimise associated abnormalities, with postoperative pain treatment tailored to the patient's age and comorbidities. Some anaesthetists prefer the Colorado Pediatrics Airway Score (COPUR) to the Mallampati score for predicting difficult airway management in children because of its precise scoring methodology.[7] The COPUR score, incorporating multiple parameters and a combination of subjective and objective assessments, is more sensitive and specific and provides comprehensive airway evaluation. Scores above 12 suggest difficult intubation (Cormack and Lehane grades 3 and 4) and recommend levels of care for airway management, including awake or fibreoptic intubation.[9]

Aim

This study aimed to compare the effectiveness of postoperative analgesia between ultrasound-guided suprazygomatic maxillary nerve block and anatomical landmark technique in pediatric patients undergoing cleft palate repair.

2. Materials and Methods

This double-blind randomised control study included 70 pediatric patients undergoing cleft palate repair at SRM Medical College Hospital, Kattankulathur, from 2023 to 2024.

Inclusion criteria

Pediatric patients undergoing cleft palate repair, aged 9 months to 7 years, both sexes, ASA I and II, elective surgeries, and willing parents were included in this study.

Exclusion criteria

Pediatric patients with bleeding disorders, infection at the injection site, allergy to a local anaesthetic drug, or associated syndrome-producing facial anomalies with difficult intubation were excluded from the study.

Methods

This study included 70 paediatric patients divided into two groups: 35 in Group US, children receiving ultrasound-guided SZMN block, and 35 in Group LM, children receiving anatomical landmark-guided SZMN block.

Conduct of anaesthesia

The child underwent a preoperative anaesthesia assessment the day before surgery, and the parents were informed of the anaesthetic procedures. According to ASA guidelines, the NPO instructions were as follows: 6 h for solid meals and formula milk, 4 h for breast milk, and 2 h for clear liquids. In the preoperative holding room, the child was premedicated with oral triclofos (50 mg/kg, maximum 10 ml) 20 minutes before induction. In the operating theatre, monitoring included pulse oximetry, ECG, and blood pressure measurement. Induction was done with 4-8% sevoflurane in 6 L oxygen. After securing IV access, sevoflurane was reduced to 2%, and glycopyrrolate (10mcg/kg) and fentanyl (2-3mcg/kg) were administered. Propofol (2–3 mg/kg) and atracurium (0.5 mg/kg) were used for the induction and muscle relaxation, respectively. The child was preoxygenated for 3 minutes and intubated with an appropriately sized Oral RAE tube. Anesthesia was maintained using 50:50 oxygen and air and 2% sevoflurane, monitored with a BIS between 40 and 60. The child was then handed over to the anesthesiologist for block administration according to the group allocation**.**

Conduct of nerve block under anatomical landmark technique

After positioning the child supine with the head turned to the opposite side, bilateral nerve blocks were performed by senior anesthesiologists with over 10 years of experience in the ultrasound-guided block. The needle entry point was at the angle formed by the superior edge of the zygomatic arch and posterior orbital rim. A 22–25-gauge needle was inserted perpendicular to the skin, advanced 10-15 mm to reach the greater wing of the sphenoid, and then redirected caudally and posteriorly for an additional 35-45 mm to reach the pterygopalatine fossa. Following a negative blood aspiration test, 5 ml of 0.2% ropivacaine (2 mg/kg) with Dexmedetomidine (0.3 mcg/kg) was injected on each side. Surgery commenced 15 min after the nerve block.

Conduct of nerve block under USG guidance

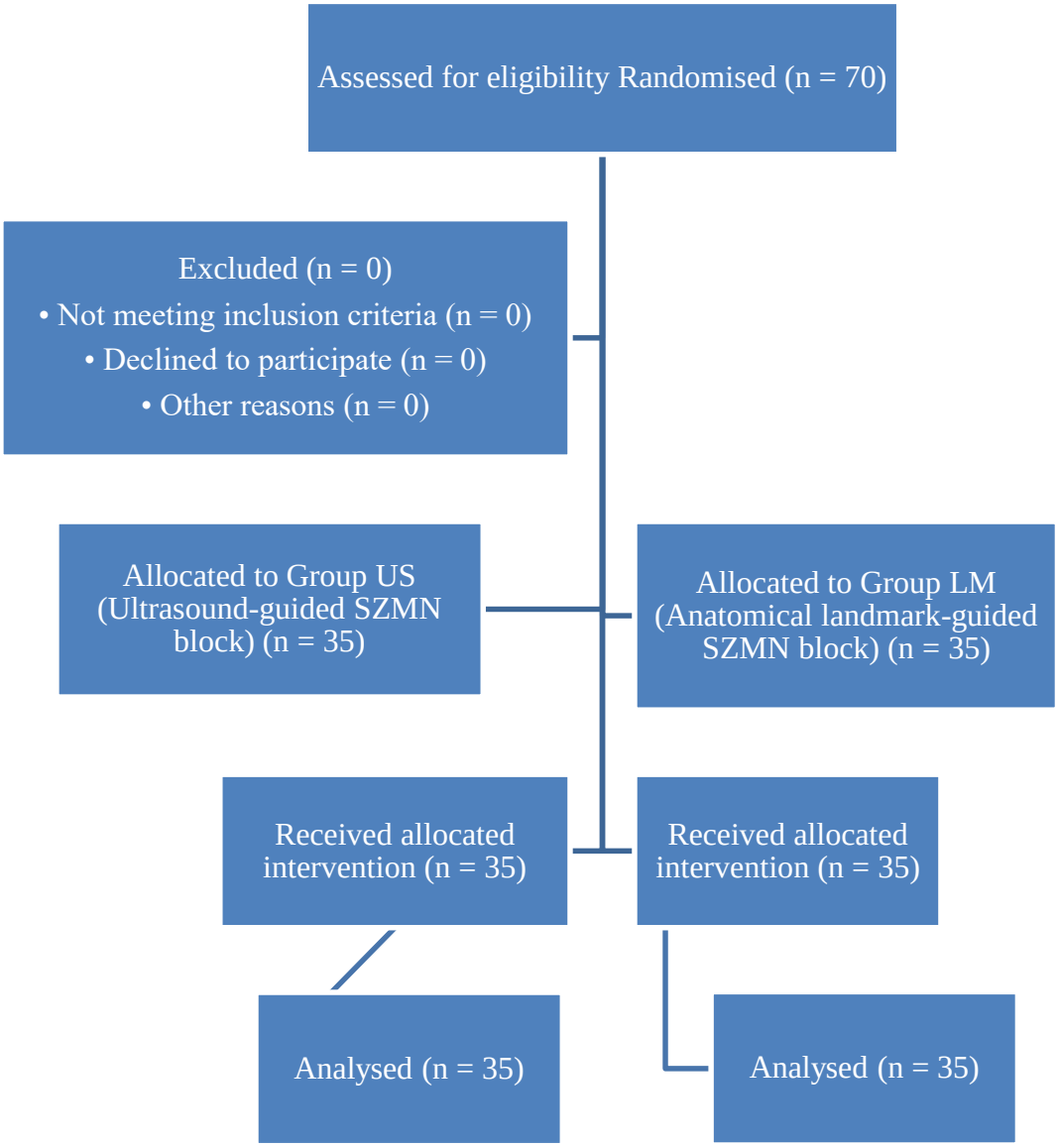
The linear probe was placed between the zygoma and the angle of the mandible, and the pterygopalatine fossa was located between the greater wing of the sphenoid and maxilla. Using an out-of-plane approach, a 22–25-gauge needle was used to deposit the local anaesthetic, which was visualised using ultrasonography. Surgery was performed without local drug infiltration near the molar tooth, and anaesthesia was maintained with 50:50 oxygen and air, 2% sevoflurane, and atracurium with BIS monitoring. Postoperatively, the child was reversed with neostigmine and glycopyrrolate and extubated after regaining muscle power. Intraoperative fentanyl use and postoperative pain were assessed using the FLACC score, with paracetamol administered for scores of > 5.

Ethical approval:

The study was approved by the local institutional ethics committee (SRMIEC-ST1122-238) and the trial was registered at the CTRI (CTRI/2023/03/050425). Informed consent was obtained from all patients.

Statistical analysis

Data analysis was performed using MS Excel, continuous variables were evaluated using an independent t-test, and categorical data were analysed using the chi-square test. Statistical significance was set at a p-value < 0.05.



CONSORT flow diagram

3. Results

Table 1: Comparison of demographic details and preoperative variables between groups

	Mean±SD		P value
	Group US	Group LM	
Age in years	2.02±1.69	1.87±1.92	0.718
Height (cm)	80.74±16.17	81.86±19.31	0.794
Weight (kg)	10.26±4.02	9.33±3.73	0.319
MAP (mmHg)	69.83±7.91	69.91±7.15	0.962
HR (per min)	125.60±26.88	122.77±7.15	0.65
SPO2 (%)	99.77±0.65	99.77±0.65	1

	Mean±SD		P value
	Group US	Group LM	
Total fentanyl consumption (mcg)	23.29±7.92	24.2±8.30	0.639
Total muscle relaxant consumption (mg)	8.62±1.82	8.37±1.82	0.58
Duration of surgery	3.12±0.88	3.09±0.61	0.649
Time taken for block administration (mins)	17.14±2.51	9.49±1.22	< 0.0001
Duration of analgesia (hrs)	13.08±1.70	10.80±3.53	0.001

In the US and LM groups, there were no statistically significant differences in age, height, weight, mean arterial pressure (MAP), heart rate (HR), and oxygen saturation (SpO2) ($p>0.05$); therefore, both groups were comparable. The preoperative mean arterial pressure, heart rate, and SPO2 were similar between the US and LM groups, with p-values of 0.962, 0.650, and 1.000, respectively, indicating no significant differences.

There were no significant differences in total fentanyl ($p=0.639$), muscle relaxant consumption ($p=0.58$), or duration of surgery ($p=0.649$) between the groups. However, the time taken for block administration was significantly longer in Group US (17.14±2.51 min) than in Group LM (9.49±1.22 minutes), with a p-value < 0.0001. The mean total duration of block analgesia in Group US was 13.08±1.70 and in Group LM was 10.80± 3.53, which was statistically significant ($p=0.001$) (Table 1).

Table 2: Comparison of sex, COPUR index, and need for rescue analgesics between groups

		Group US (%)	Group LM (%)	P value
Sex	Female	12 (34.5%)	14 (40%)	0.621
	Male	23 (65.7%)	21 (60%)	
COPUR index	6	13 (37.1%)	11 (31.4%)	0.307
	7	18 (51.4%)	15 (42.9%)	
	8	4 (11.4%)	9 (25.7%)	
Need of rescue analgesics (Paracetamol)	No	27 (77.1%)	19 (54.3%)	0.044
	Yes	8 (22.9%)	16 (45.7%	

The percentage of females was 34.5% in the US group and 40% in the LM group. Males comprised 65.7% of Group US and 60% of Group LM, which was statistically insignificant ($p=0.621$). The percentage of COPUR index value 6 in the US and LM groups was 37.1% and 31.4%, respectively. The percentage of patients with a COPUR Index value of 7 was 51.4% and 42.9% in the US and LM groups, respectively. The percentages of patients with a COPUR Index value of 8 were 11.4% and 25.7% in the US and LM groups, respectively. The p-value was 0.307, which was not statistically significant; hence, both groups were comparable in terms of airway assessment. The need for postoperative rescue analgesic injury was 22.9% in the paracetamol group and 45.7% in the control group, which was statistically significant ($p=0.044$) (Table 2).

Table 3: Comparison of intraoperative heart rate, mean arterial pressure, and saturation between group

		Mean±SD		P value
		Group US	Group LM	
Heart rate (hours)	30 mins	138. 80±15.18	139. 54±14.54	0.835
	1	141. 80±21.20	141. 31±20.31	0.922
	1.5	140. 46±13.93	140. 86±15.41	0.91
	2	134. 23±18.39	135. 63±16.82	0.741
	2.5	129. 86±15.85	128. 26±16.38	0.679
	3	125. 86±12.69	125. 31±13.65	0.864
Mean arterial pressure (hours) (mmHg)	30 mins	74.69±12.89	75.97±13.75	0.688
	1	76.11±13.66	75.63±12.53	0.877
	1.5	78.2±15.80	75.82±14.89	0.525
	2	72.2±10.15	69.63±12.52	0.349
	2.5	72.94±9.00	66.51±7.94	0.003
	3	71.77±6.82	69.23±5.98	0.102
Saturation (hours) (%)	30 mins	99.8±0.35	100±0.00	0.039
	1	99.93±0.25	99.7±0.60	0.053
	1.5	99.8±0.41	99.93±0.25	0.133
	2	99.9±0.41	99.97±0.18	0.309
	2.5	99.93±0.25	99.93±0.25	1
	3	99.83±0.23	99.87±0.35	0.723

Intraoperative heart rates at various time points (30 min, 1 h, 1.5 h, 2 h, 2.5 h, and 3 h) were similar between the US and LM groups, with p-values ranging from 0.679 to 0.922. None of these differences were statistically significant. At various intraoperative time points, the mean arterial pressure showed no significant differences between Group US and Group LM, except at 2.5 hours where Group US had a significantly higher mean arterial pressure than Group LM ($p = 0.003$). All other p-values ranged from 0.349 to 0.877, indicating no significant difference. At 30 min, the mean SPO2 was significantly higher in Group LM (100.00±0.00) than in Group US (99.8±0.35), with a p-value of 0.039. At all other time points (1.5, 2, 2.5, and 3 h), there were no statistically significant differences in SPO2 between the two groups, with p-values ranging from 0.053–1.000 (Table 3).

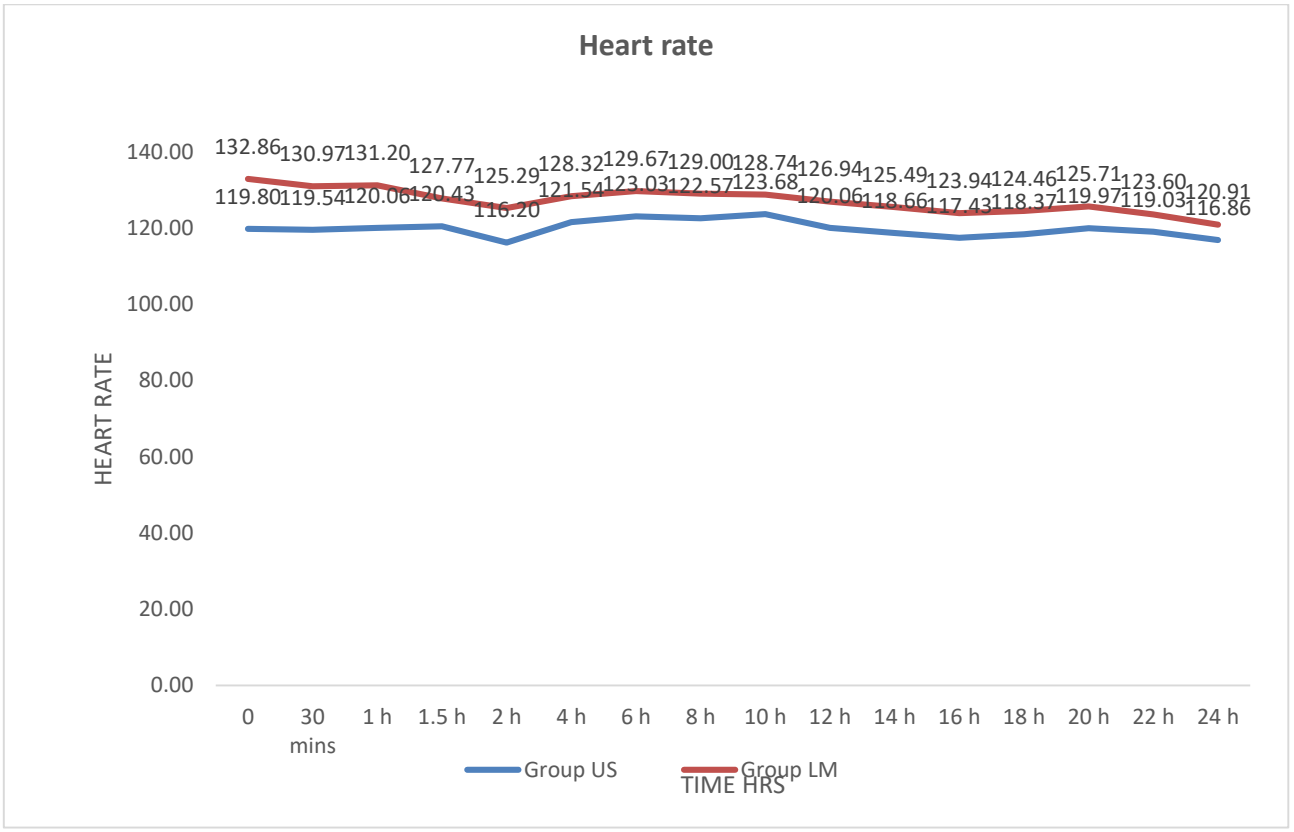


Figure 1: Comparison of postoperative heart rate between the groups

The postoperative heart rates were significantly lower in the US Group LM group at multiple time points. Specifically, significant differences were observed at T 0, 30 min, 1, 1.5, 2, 4, 6, 8, 10, 12, 14, 16, 18, and 20 h, with $p < 0.05$. However, at 22 h and 24 h, the differences were not statistically significant ($p > 0.05$) (Figure 1).

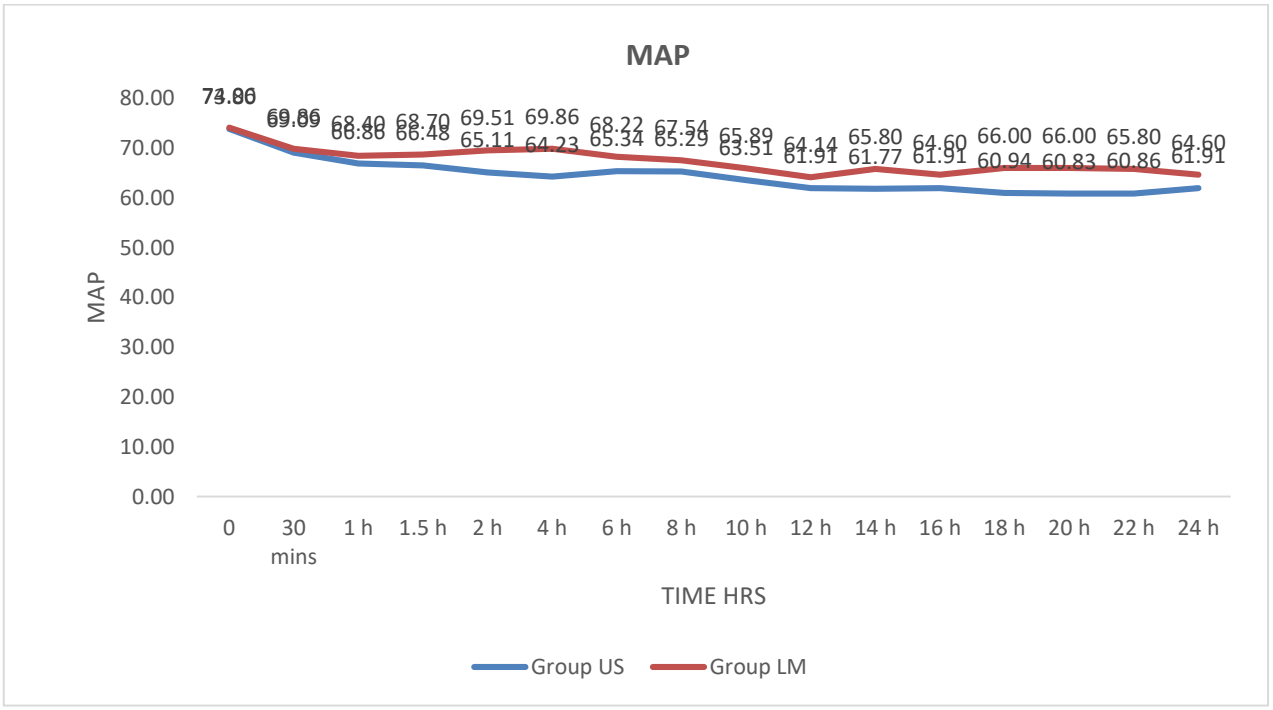


Figure 2: Comparison of postoperative MAP between the groups

Postoperative mean arterial pressures (MAP) were significantly lower in the US Group than in the LM group at several time points. At T 0 and 30 min, the differences in MAP were not statistically significant ($p > 0.05$). However, from 1 h to 24 h, Group US consistently had a lower MAP, with significant p-values (< 0.05) at each time point: 1 h ($p = 0.040$), 1.5 hours ($p = 0.012$), 2 h ($p < 0.0001$), 4 h ($p < 0.0001$), 6 h ($p = 0.025$), 8 h ($p = 0.042$), 10 h ($p = 0.0046$), 12 h ($p < 0.0001$), 14 h ($p < 0.0001$), 16 h ($p < 0.0001$), 18 h ($p < 0.0001$), 20 h ($p < 0.0001$), and 22 h ($p < 0.0001$) (Figure 2).

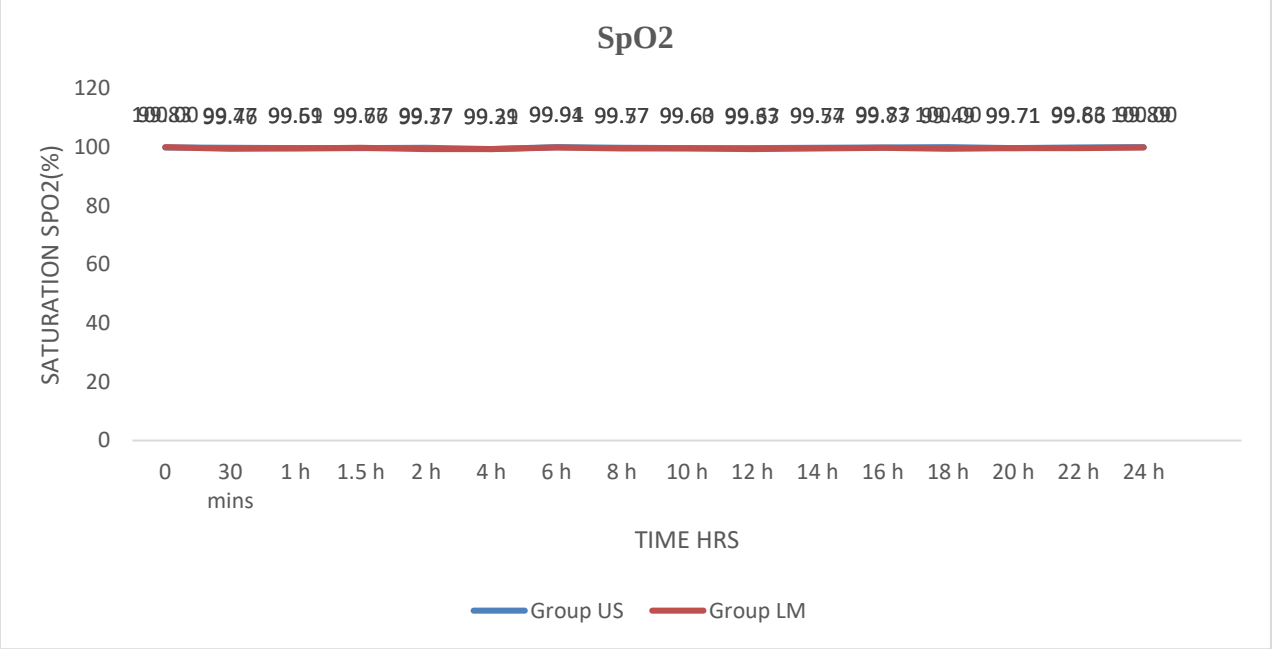


Figure 3: Comparison of postoperative saturation between the groups

Postoperative SPO2 levels were similar between the US and LM groups, with statistically insignificant differences at most time points. Significant differences were found at 30 min ($p = 0.048$) and 2 h ($p = 0.029$), with Group US showing higher SPO2 levels. At other intervals, including 0,1, 1.5, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, and 24 h, the differences were not statistically significant ($p > 0.05$), indicating similar SPO2 maintenance between the groups throughout the postoperative period (Figure 3).

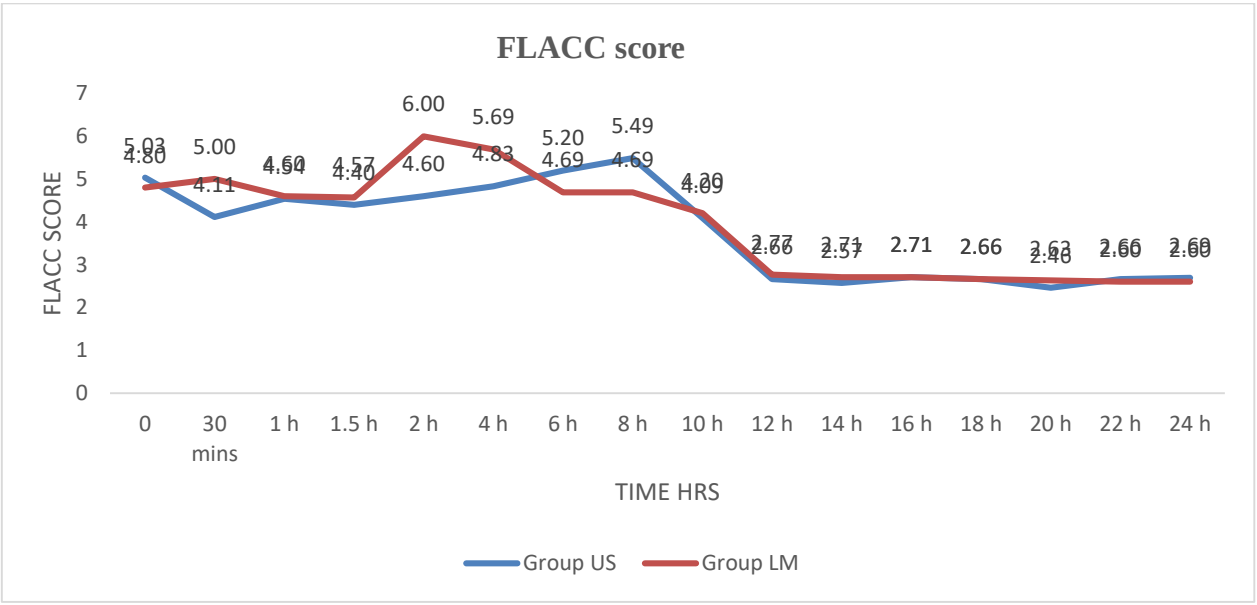


Figure 4: Comparison of FLACC score between the groups

Postoperative FLACC scores between the US and LM groups showed significant differences at 30 min ($p = 0.0001$), 2 h ($p < 0 .0001$), 4 h ($p = 0.008$), and 8 h ($p = 0.009$), with Group LM generally having higher scores, indicating more pain. At 0, 1, 1.5, 6, 10, 12, 14, 16, 18, 20, 22, and 24 h, the differences were not statistically significant ($p > 0.05$), suggesting comparable pain levels between the groups (Figure 4).

4. Discussion

Ultrasound-guided Supratympanic Maxillary Nerve Blocks (SMNB) are used for midface surgeries in both children and adults, particularly in paediatric cleft palate and alveolar bone graft surgeries.[10,11] This technique offers improved accuracy, reduced complications, higher success rates, and enhanced safety compared to anatomical landmark techniques. These benefits include better pain management, increased patient comfort, and reduced postoperative opioid requirements.[12-14]

In our study, ultrasound-guided suprazygomatic maxillary nerve blocks (SMNB) provided real-time visualisation of anatomical landmarks, thereby enhancing safety and accuracy, especially in children with pronounced anatomical variations. The mean time to block administration was significantly longer in the ultrasound-guided group (US group) than in the anatomical landmark group (LM group). Similarly**, Riaz et al.** found that caudal blocks in 240 children aged 2-10 years had a higher success rate on the first attempt with ultrasound guidance owing to anatomical variations, but the procedure duration was also significantly longer.[15]

In our study, postoperative mean arterial pressure (MAP) was monitored at various time intervals. A significant reduction in MAP was noted from 1st-hour till the end to 24 h in Group US compared to Group LM, indicating a statistically significant difference. **Neupane et al.** reported that in their study, no significant difference was observed in the MAP between the two groups who underwent FESS surgery (Group with SZMN block compared with GA alone).[16]

In our study, a significant reduction in postoperative heart rate from 0 to 20 h was observed in Group US compared to Group **Ramasamy et al.**, who reported that aside from a minor decrease in systolic blood pressure at 30 min, heart rate and blood pressure were comparable between groups using local anaesthetic (LA) alone and those with dexmedetomidine and LA in supra zygomatic maxillary nerve blocks, with no hemodynamic complications noted.[17] Similarly**, Neupane et al.** found that the heart rate was significantly lower in the group receiving SZMN blocks than in the group receiving general anaesthesia (GA) alone up to 2 h postoperatively.[16]

In our study, FLACC scores were statistically significant at a few key intervals at 30 min, 2 h, 4 h, and 8 h, with lower scores in the ultrasound group, which mainly determined the duration of the block and the need for rescue analgesics. **Jonnavithula et al.** reported that in their study the average FLACC scores in Group NB (no block) were higher than those in Group S(saline) and Group B (palatal block for cleft palate repair).[18] The mean pain scores were significantly lower in the patients who received a block than in those in Group NB. The number of demands for rescue analgesia was significantly lower in Group B. **Abu et al.** found that, after cleft palate surgery, CHIPPS scores were significantly lower in both the maxillary block (M) and palatal block (P) groups than in the control (C) group at admission and 1, 2, and 4 h postoperatively, with no significant difference between the M and P groups.[19] At 6, 8, and 12 h, the M and P groups continued to have significantly lower CHIPPS scores than the C group, with the M group showing lower scores than the P group at 6 and 8 h, but similar scores at 12 h. No significant differences were noted between the groups at 18 and 24 hours postoperatively.

In our study, the US group required a postoperative rescue analgesic (Inj. Paracetamol) less frequently (22.9%) compared to Group LM (45.7%), and the mean duration of block analgesia was significantly longer in Group US (13.08 ± 1.70 hours) than in Group LM (10.80 ± 3.53 hours). **Ramasamy et al.** similarly found that Group A (SZMN block with LA and dexmedetomidine) had a significantly longer

analgesic duration (12 ± 4.73 hours) compared to Group B (SZMN block with LA alone) which was 5.41 ± 3.9 hours.[17] **Obayah et al.** reported that adding dexmedetomidine to bupivacaine during greater palatine nerve blocks in children extended the analgesic duration by 50%, without significant adverse effects.[20] **Botros et al.** conducted a blind greater palatine nerve block and supra zygomatic nerve block for cleft palatoplasty and concluded that the GPN provided superior intraoperative pain relief. This study differs from our study in that we used an ultrasound-guided technique, which may have enhanced the precision of the suprazygomatic maxillary nerve block (SMB) and subsequently improved its analgesic effectiveness.[21]

5. Conclusion

We conclude that Ultrasound-guided Suprazygomatic Maxillary Nerve block had superior pain relief in children undergoing Cleft Palate repair, in addition to dexmedetomidine 0.3 μg/kg to 0.2% ropivacaine) accentuated analgesic efficacy, with less postoperative supplemental analgesia.

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