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Ultrasound-guided infraorbital nerve block for cleft lip repair in pediatrics: a new technique for an old block

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Abstract

Background: One of the challenges that anesthesiologist faces is the intra- and postoperative analgesia in cases of cleft lip repair in pediatrics. However, the use of ultrasound infraorbital nerve (ION) block has not been evaluated before in pediatric. This prospective randomized double-blinded study was designed to evaluate the analgesic efficacy of ultrasound-guided ION block in infants undergoing unilateral cleft lip repair.

Methods: Sixty infants (ASA status I, II) aged 3–10 months undergoing unilateral cleft lip repair were allocated randomly to two groups ($n = 30$ each). The bupivacaine group (group B) received ION block with 1 ml 0.25% bupivacaine, and the saline group (group S) received 0.9% normal saline 1 ml in each side by the use of ultrasound. Intraoperative measurements included heart rate and mean arterial blood pressure. Postoperative pain score was recorded at 15 and 30 min, then at 2, 6, 10, and 16 h. If the score exceeded 3 points, 25 mg/kg of paracetamol suppository was given, with recording the time of first rescue analgesia and total dose given in each group.

Results: Postoperative pain, using FLACC (Face, Legs, Activity, Cry, Consolability) score the median scores were higher in the saline group than bupivacaine group at 15 min, 30 min, 2 h, 6 h and 10 h. There was significantly longer time in the bupivacaine group than the saline group for first rescue analgesia (476.6 ± 100.7 vs 21 ± 6 min respectively, $P < 0.001$). Whereas more number of paracetamol doses were required in the saline group when compared to bupivacaine group, total dose of paracetamol was significantly lower in the B group than the S group.

Conclusions: Ultrasound-guided bilateral ION block provides a superior postoperative analgesia for infants undergoing cleft lip repair. It is a simple and easy to perform technique, with high success rate and minimal complications.

Keywords: Infraorbital nerve, Ultrasound, Infants, Cleft lip

Background

Surgical repair of cleft lip is a common operation in infants and young children and requires that the child is pain-free during the intraoperative and postoperative periods; if pain control is neglected or inadequate, it will cause major complications such as respiratory dysfunction, delayed wound healing, and emergence agitation (Jonnavithula et al. 2007). Postoperative opioid analgesia

in infants undergoing cleft lip repair is associated with the potential risk of airway obstruction secondary to drug-induced respiratory depression in the presence of post-surgical soft tissue swelling and bleeding (Bouwmeester et al. 2004). The infraorbital nerve (ION) provides sensory innervations to the skin and mucous membrane of the upper lip and lower eyelid, to the skin between them, and to the side of the nose. It has been suggested that ION block is the local analgesic technique of choice for repair of cleft lip (Bösenberg and Kimble 1995). Failure to obtain satisfactory ION block using the traditional methods has been reported to reach 22% (Pascal et al. 2005). One reason for this high percentage is the difficulty to identify the landmarks for

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superficial trigeminal nerve blocks (especially infraorbital) in neonates and young children (Tsui 2009). Ultrasound-guided nerve blocks have been shown to provide better blocks with fewer complications (Jeng et al. 2011). Ultrasound-guided ION block has been reported in many studies in adult age group but not in pediatrics (Lim et al. 2013; Takechi et al. 2015).

The aim of the present study is to evaluate the use of ultrasound-guided ION block in cleft lip repair as a tool of intra- and postoperative analgesia (primary outcome) with recording of its possible side effects.

Methods

After ethical committee approval and written informed consent from the parents, 60 infants were undergoing a repair of unilateral cleft lip, with an age between 3 and 10 months of both sexes, with ASA I–II, and weighing between 5 and 12 kg were included in the study. A modified Millard's rotation advancement repair of cleft lip by the orbicularis oris muscle was the surgical procedure performed and was done by the same surgical team at Ain-Shams University Hospital. Exclusion criteria for the study were patients with redo operation, hemoglobin less than 10 g/dl, local infection, coagulation abnormalities, history of allergy to any of the study drugs, or other major systemic disease.

During the preoperative visit, all infants included in the study were assessed clinically and for laboratory results and the parents were clearly informed about the procedure, the study, and the plan for postoperative pain management.

On the day of surgery, all infants were checked again for anesthesia readiness. Infants were taken to operating room without any premedication where basic monitors were applied (ECG, pulse oximetry, and non-invasive blood pressure). Anesthesia was induced inhalationally

with sevoflurane 8% in 100% O₂. After deepening of anesthesia, an intravenous line was secured, atracurium besylate 0.5 mg/kg were injected, and the trachea was intubated with an appropriately sized oral preformed endotracheal tube. Intubation was confirmed by positive capnogram and equal breath sounds by auscultation, then the tube was secured to the midline of the lower lip. If during anesthesia an event of bradycardia (heart rate < 100 beats/min) that necessitated the use of atropine occurred, the case was excluded from the study. As per Surgeon protocol, after intubation, he injected 3–5 mL of local adrenaline of 1/200,000 concentration in the site of surgery before draping.

Then, patients were randomly allocated to one of two groups ($n = 30$ each) according to computer-generated random numbers. All patients received bilateral ultrasound-guided ION block with 1 ml of solution at each side. Bupivacaine group (group B) received block with 0.25% bupivacaine, and saline group (group S) received 0.9% normal saline. The ultrasound approach to achieve the infraorbital foramen in both groups was done by using ultrasound system (Honda electronics; HS-2100, Japan) with a high-resolution (12.5 MHz) linear probe (HLS-513). A disruption in the continuity of bone will appear as scanning will proceed from medial to lateral direction at the level of the foramen (Fig. 1). Use of color Doppler confirmed the presence of infraorbital artery in the foramen; finally, 1 ml of the study solution was injected at the infraorbital foramen using a 23-gauge needle after sterilization of the skin with povidone iodine 10% (Tsui 2009). Then, the procedure was repeated on the other side.

Surgical stimulation was allowed to start after 10 min of the block injection, and skin incision by the surgeon was considered as a test for adequate block. An increased heart rate due to skin incision of more than 20%



Fig. 1 Ultrasound-guided infra-orbital nerve block. **a** Ultrasound imaging with high resolution 12.5 MHz. **b** Injection of local anesthetic

from the basal heart rate of the infant was considered as inadequate block, for which the patient was given fentanyl 1 µg/kg intravenously.

Anesthesia was maintained with 100% O₂ and an inspired sevoflurane concentration of 2–2.5%, maintenance doses of atracurium besylate 0.1 mg/kg, pressure controlled ventilation to maintain end tidal CO₂ at 30–35 mmHg. Fentanyl 1 µg/kg was given in case of tachycardia more than 20% of the base line or increased blood pressure more than 20% of the base line. Intraoperative patient warming was done by Bair Hugger (3M Health Care, St. Paul, USA). Intravenous fluid was maintained at a rate of 10 ml/kg/h of lactated Ringer's solution.

Intraoperative measurements included heart rate and mean arterial blood pressure, recorded just before induction of anesthesia (baseline), 10 min after ION block (with skin incision) and then every 15 min till end of surgery. A temperature probe was applied in the axilla, and temperature was continuously recorded and warming was adjusted to keep infant axillary temperature between 35.7–36.7 °C. Total fentanyl requirements during operation were also recorded. At the end of surgery, the surgeon was asked to rate the bleeding in the operative field according to the 3-grade score of surgeon satisfaction used by Nasreen et al. (grade I, bloodless field not hampering surgery; grade II, mild bleeding requiring minimal suction; grade III, excessive bleeding hampering surgery despite suction) (Nasreen et al. 2009). Surgery time (skin incision-skin closure) and recovery time (sevoflurane off-extubation) were also noted. A well-trained nurse, who was blind to the medication given in the ION block, assessed the infants' postoperative pain using a FLACC (Face, Legs, Activity, Cry, Consolability) pain scale (Table 1) (Merkel et al. 1997).

Postoperative pain score was recorded at 15 and 30 min in the post anesthesia care unit, then at 2, 6, 10, and 16 h in the ward. If the score exceeded 3 points, 25 mg/kg of paracetamol suppository was given, with recording the time of first rescue analgesia and total dose

given in each group. Block-related complications such as hematoma, redness, or edema were noted and recorded.

Statistical method

According to our previous postoperative records of unilateral cleft lip repair for infants (without ION block), the mean dose of paracetamol suppository consumption was 249 mg (unpublished data).

Using PASS 13 for sample size calculation, a sample size of 26 patients per group was required to achieve 80% power to detect a reduction of 150 mg paracetamol in the treatment group, with a significance level (alpha) of 0.05 using a two-sided two-sample *t* test. So, 30 patients per group were enrolled for the possibility of dropouts.

The statistical analysis was performed using a standard SPSS software package version 17 (Chicago, IL). Normally distributed numerical data are presented as mean ± SD, differences between groups were compared using the independent Student *t* test, data not normally distributed were compared using Mann-Whitney test and are presented as median (IQR), and categorical variables were analyzed using the χ^2 test or Fisher exact test and are presented as number (%). All *P* values are two-sided. *P* < 0.05 is considered statistically significant.

Results

Sixty infants were included, and all have completed the study. Demographic data of patients and surgery time in the two groups showed no statistically significant differences (Table 2). There was no difficulty to do the block using the ultrasound in both groups. No events of bradycardia occurred in both groups.

Total fentanyl consumption during operation was higher in the group S than in the group B (2.3 ± 0.54 vs 0.36 ± 0.22 µg/kg respectively, *P* < 0.001). The operative field bleeding score was better in the group B compared to the group S. The surgeon reported grade I in 23 cases in the group B versus only 9 cases in the group S; grade

Table 1 FLACC scale (Merkel et al. 1997)

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

Each of the five categories Face, Legs, Activity, Cry, and Consolability is scored from 0 to 2, which results in a total score between zero and ten

Table 2 Demographic and clinical data

	Group B N = 30	Group S N = 30	P value
Age (months)	4.85 ± 1.1	5.36 ± 0.8	0.058
Weight (kg)	6.1 ± 1	6.34 ± 0.9	0.425
Gender (male/female)	18/12	17/13	1
ASA I/II	26/4	27/3	1
Surgery time (min)	76.9 ± 14.75	74.4 ± 18.8	0.437
Recovery time (min)	6.47 ± 2.2	11.3 ± 3.23	< 0.001*
Intraoperative fentanyl consumption (µg/kg)	0.36 ± 0.22	2.3 ± 0.54	< 0.001*
Surgeon satisfaction score	I (I–II)	II (I–III)	
I	23 (76.7%)	9 (30%)	0.001*
II	5 (16.6%)	15 (50%)	
III	2 (6.7%)	6 (20%)	

Values are mean ± SD or numbers (%)

ASA American Society of Anesthesiologists

*Statistically significant P value < 0.05

II was reported in 5 vs 15 cases, while grade III was reported in only 2 vs 6 cases of groups B and S respectively ($P < 0.001$) (Table 2). Also, the recovery time was longer in the saline group than in the bupivacaine group (11.3 ± 3.23 vs 6.47 ± 2.2 min respectively, $P < 0.001$) (Table 2).

Intraoperative hemodynamic were comparable between the two groups except at 10 min after IOB (at skin incision), then at 75 and 90 min (near end of surgery) where the heart rate and mean blood pressure were significantly higher in the saline group than in the bupivacaine group, (Table 3).

As regards postoperative pain, the median scores were higher in the saline group than in the bupivacaine group at 15 min, 30 min, 2 h, 6 h, and 10 h. (Fig. 2). For first rescue analgesia (476.6 ± 100.7 vs 21 ± 6 respectively, $P < 0.001$) (Table 4), whereas more number of paracetamol doses were required in the saline group when compared to the bupivacaine group (Table 4). There were no recorded complications at the site of block in any of the two groups.

Discussion

The results of our study showed that preoperative ultrasound bilateral ION block with bupivacaine 0.25% (group B) provided superior postoperative analgesia in infants undergoing unilateral cleft lip repair. This was evident by the lower postoperative paracetamol doses, lower pain scores, and longer times for first rescue analgesia, unlike infants who received a placebo normal saline injection instead (group S). Good postoperative pain control is an integral part of perioperative management with better outcome. Inadequate postoperative analgesia often results in agitated combative child with a vigorous cry that is difficult to handle and may lead to wound dehiscence in such delicate surgical procedures.

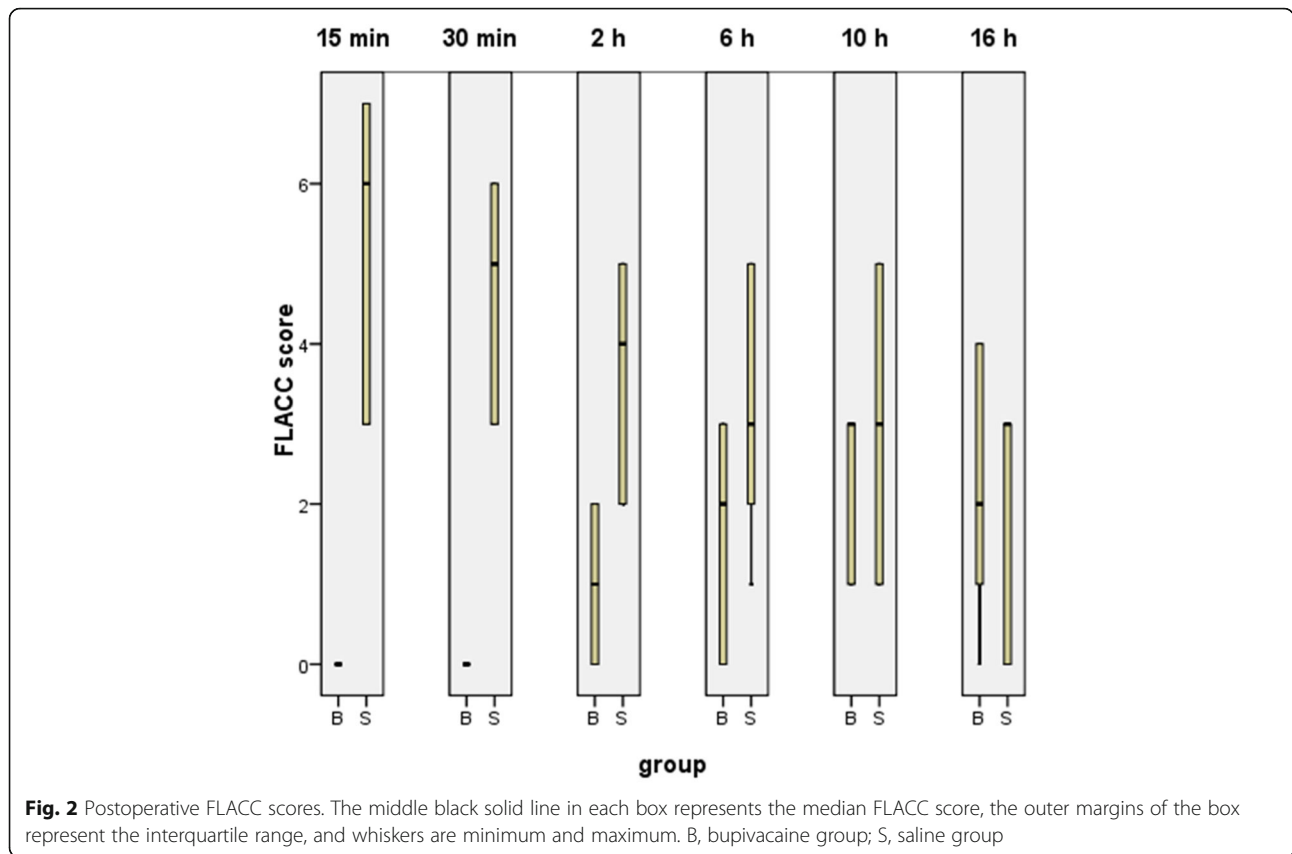
Table 3 Intraoperative hemodynamics

	Group B N = 30	Group S N = 30	P value
Baseline			
HR (BPM)	125.6 ± 13.75	126.7 ± 14.3	0.53
MAP (mmHg)	70 ± 6.41	73.5 ± 9.33	0.52
10 min after IOB (at skin incision)			
HR	123.93 ± 16.94	144.6 ± 22	< 0.001*
MAP	74.43 ± 7.86	81.13 ± 11.83	0.012*
15 min after IOB			
HR	119.87 ± 11	121.6 ± 17.6	0.795
MAP	71.07 ± 8.11	74.5 ± 8.93	0.099
30 min after IOB			
HR	121 ± 14	127 ± 17	0.74
MAP	67.9 ± 7.44	73.07 ± 8.26	0.103
45 min after IOB			
HR	120.23 ± 15.6	129 ± 18.2	0.08
MAP	69.37 ± 10.14	74 ± 6.8	0.097
60 min after IOB			
HR	118.7 ± 21.7	129.43 ± 22.58	0.066
MAP	66.77 ± 10.14	72.13 ± 11	0.056
75 min after IOB			
HR	121.8 ± 12.54	133.9 ± 17.54	0.003*
MAP	71.27 ± 7.09	77.27 ± 11.8	0.009*
90 min after IOB			
HR	121.5 ± 11.9	134 ± 18.8	< 0.001*
MAP	72.23 ± 6.64	77.67 ± 9.76	0.04*

Values are mean ± SD

HR heart rate, MAP mean arterial pressure, BPM beats per minute, IOB infra-orbital block

*Statistically significant P value < 0.05



The use of ultrasound facilitates the precise location of the ION during block injection; hence, we did not report any failure rate of the block. Pascal et al. in 2007 found that failure to obtain satisfactory block of the ION from the traditional methods reached up to 22% (Pascal et al. 2005).

Moreover, the ION block provided better anesthetic quality in the group B, in terms of lesser total intraoperative fentanyl doses, more stable hemodynamics, and shorter recovery times. This was attributed to the success of the block in the B group with bupivacaine that gives effective intraoperative analgesia, while in the S

group we observed a higher need for intraoperative fentanyl analgesia. Our results differ in intraoperative use of analgesia than that of Ahuja et al. that in their study they gave the block at the end of operation, so there was no monitoring of intraoperative use of narcotics (Ahuja et al. 1994).

One of the important issues during operation of cleft lip repair is minimization of bleeding in the surgical field to improve the visualization of tissues to facilitate surgery, decrease blood loss, and also shorten the operation time. In the present study, the surgeon satisfaction score about the operative field conditions was significantly higher (better) in the B group than the S group. Surgeon satisfaction score was used in many studies to show the importance of bloodless field in small field operations like ear surgery (Nasreen et al. 2009; Marchal et al. 2001).

In the present study, intraoperative hemodynamics were comparable between two groups except at 10, 75, and 90 min after ION block where heart rate and mean blood pressure were higher in saline group when compared to the bupivacaine group; this was due to the lack of use of opioids at induction of anesthesia in both groups; at 10 min after ION block (when skin incision was allowed), the local anesthesia in the bupivacaine group started its analgesic effect whereas in the saline

Table 4 Postoperative analgesic requirements

	Group B N = 30	Group S N = 30	P value
Paracetamol (no. of doses)			
0	8 (26.7%)	0	< 0.001*
1	22 (73.3%)	5 (16.7%)	
2	0	18 (60%)	
3	0	7 (23.3%)	
Total dose (mg)	101 ± 37	298 ± 40.1	
Time of first rescue dose (min)	476.67 ± 100.74	21 ± 6.013	< 0.001*

Data are numbers (%), mean ± SD
*Statistically significant P value < 0.05

group there was no effect of the injected saline. While at 75 and 90 min after ION block, surgery was finishing with suturing the skin so the analgesic effect was apparent in the bupivacaine group while no effect in the saline group. Our results were different from results of Prabhu et al. 1999 who found that in comparison of two groups of children undergoing cleft lip repair, one group used ION block but with bupivacaine 0.125% only and the other group local infiltration by the same solution. There was a significant rise in the heart rate and blood pressure that accompanied tracheal intubation in both groups which suggested that while both methods of analgesia may be adequate to prevent responses to skin incision, they do not substitute for adequate systemic analgesia during the operation. In the present study, we used bupivacaine 0.25% in the B group while in the S group, only normal saline so the significant higher hemodynamic were in the S group in spite of use of fentanyl analgesia (Prabhu et al. 1999).

Assessment of pain in infants and young children is not easy as it has a lot of contents, infants' response to pain was assessed by (behavioral assessment) and physiological changes occurring as a result of pain (physiological assessment). Facial expression, cry, body movement, and general behavioral state such as sleep period have all been used by different workers for pain assessment in infants (Anand and Hickey 1987). In the present study, the use of FLACC score represents the postoperative response of the child to pain as it measure the physiological and behavioral response to pain. The present study showed significant higher pain score of the S group than B group of score at 15 min, 30 min, 2 h, 6 h, and 10 h postoperatively. Our results were like that of Ahuja et al. who found that the pain scores postoperative in patients who received lignocaine in ION block were better than who received saline; however, time of block was short postoperative analgesia as lignocaine is shorter than bupivacaine we used in the present study. In our study, ultrasound ION block nerve block had a very high success rate (Ahuja et al. 1994). The mean (SD) duration of postoperative analgesia with 0.5% bupivacaine with epinephrine 1:200,000 was reported to be 19.4 (5.06) h (Nicodemus et al. 1991), whereas in the present study, we used 1 ml of 0.25% bupivacaine without epinephrine and found the mean (SD) duration of analgesia to be 476.67 (100.74) min, i.e., about 8 (1.6) h (known by time of 1st rescue analgesia).

Time of first rescue analgesia in the S group was not immediately after operation due to the remained effect of intraoperative use of fentanyl, whereas it was longer in the B group due to the effect of block with bupivacaine. The number of postoperative doses of paracetamol used as a postoperative analgesia was significantly higher in the S group than the B group $p < 0.001$

(Table 4). This was due to the analgesic effect of bupivacaine block in the B group. In postoperative pain control in pediatrics, the use of opioids in neonates and infants raises justifiable concerns regarding postoperative sedation, respiratory depression, and consequent airway compromise (Tremlett 2004). In the present study, we did not use opioids as a postoperative tool in controlling postoperative pain. No postoperative complications appear as a result of block in the form of postoperative erythema or swelling. The less incidence of local complications following the block is agreed with higher efficacy that realized using advanced imaging modalities including computed tomography or virtual reality techniques such as US or fluoroscopy (Bhaskar 2012).

The lack of sufficient data from previous studies of using US-guided ION block limits our ability to compare results of the study by others of the same technique in similar age group, so this study open the gate to use US-guided ION block by different concentration of local anesthetics in pediatric age group.

Conclusions

In the present study, we conclude that ultrasound-guided bilateral ION block with 0.25% bupivacaine provides a superior postoperative analgesia for infants undergoing cleft lip repair. It is a simple and easy to perform technique, with high success rate and minimal complications. It provides adequate intraoperative analgesia when performed before surgery and improves operative field conditions.

Abbreviations

ASA: American Society of Anesthesiologists; FLACC scale: Face, Leg, Activity, Cry, Consolability; HR: Heart rate; IOB: Infra orbital block; ION: Infraorbital nerve; IQR: Inter quartile range; MAP: Mean arterial pressure; SD: Standard deviation

Availability of data and materials

Supporting our findings are present in Ain Shams University Hospitals.

Authors' contributions

AAA contributed to the idea of the study, followed up the patients, and participated in the discussion. AEE contributed to the idea of the study, followed up the practical work, and participated in the statistical analysis. KE was responsible for the surgical part of the study, followed up the patients, and collected the scientific data. All authors read and approved the final manuscript.

Ethics approval and consent to participate

There was ethical committee approval from Ain Shams University Hospitals to do this work (the number is not available).

Consent for publication

There was a written informed consent from parents or legal guardians to participate their children in the study. Consent was taken from parents for the publication of personal data of their children.

Competing interests

The authors declare that they have no competing interests.

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