Comparison of Bilateral Infraorbital Nerve Block with Lidocaine Hydrochloride (Xylocaine) Or Bupivacaine Hydrochloride (Marcaine) With Intravenous Pethidine for Postoperative Pain Management of Pediatric Patients of Cleft Lip Surgery (Cheiloplasty): A Prospective Double Blind Randomized Clinical Trial

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Abstract

Introduction: Post-operative pain relief is one of the major practices in anesthesiology. The different pharmacokinetic and sensitivity of children to different classes of anesthetics drugs, especially opioids, make the clinical judgment of pediatric anesthesiologist harder.

Materials and Methods: After getting ethical approval, all the patients who underwent surgery for cleft lip surgery with pain management at Mofid Children's Hospital were contacted, and in case of any long-term complications, parents were invited to visit the hospital.

Results: The average duration of analgesia in the X, M and P group were 18.48± 2.45, 17.62± 2.96, and 17.56± 3.16 hours, respectively. The duration of analgesia in the group X was superior to the other groups; however, there was not any meaningful different between the duration of analgesia between the 3 groups (p>0.05).

Conclusion: the present double-blind clinical trial disclosed that the preoperative bilateral infraorbital nerve block induced an anesthetic effect prolonged as the duration induced by the opioid infusion.

Keywords

- infra orbital block
- cleft lip surgery
- bupivacaine
- lidocaine
- petidine
- pain managment

Introduction

Pain management in pediatric patients is a double-edged sword for anesthesiologists. In other words, prescription of anesthetic and induction drugs which induce a bunch of alteration of physiological changes in their body systems; especially the opioid drug classes, that predispose children to respiratory depression, affects the anesthesiologist's clinical decision of making the drug of choice. However, postoperative pain being usually undertreated in children, influences the quality of post-op care of these group of patients.

Cheiloplasty, the cleft lip repair surgery, is a common surgery among children particularly the infants across the globe. Cheiloplasty is always associated with dramatic pain post operation. Therefore, adequate post-op pain management increases the quality of patients care with decrement of oxygen consumption, reduction of cardio-pulmonary demands leading to prompt ambulation and recovery of the patients.[1]

Regional nerve block in combination with general anesthesia (GA) is an effective method of reducing drug demand with adequate pain relief of patients intra- and post- operation.[2] Bilateral infraorbital nerve block is accompanied with sensory blockade of the upper lip, lateral sides of the nose, mucosa of the nasal vestibules and the inferior eyelids area.[3]

The advantage of opioid analgesic for cheiloplasty post-op pain management is evident in the literature. Less crying on extubation, fewer airway trauma and decrement of post-op bleeding are the advantages of the opioids[4] Postoperative sedation and respiratory depression due to various pharmacokinetics of opioid drugs in pediatrics are disadvantages of administration of them, necessitating their prescription under supervision of an expert pediatric anesthesiologist.[5-8]

Despite the above-mentioned advantages of the infraorbital nerve block in cheiloplasty, lack of enough evidence of their efficacy in comparison with opioid is obvious. The aim of the present double-blind clinical trial was to compare the effectiveness of infraorbital nerve block with lidocaine or bupivacaine, with intravenous pethidine to assess the pain management of our patients after cheiloplasty procedure.

Materials and Methods

Forty-five patients aged between 3 moths to 36 months were randomly allocated from the cheiloplasty waiting list of Mofid Children Hospital in September, 2023. Patients with hypersensitivity with local anesthesia or opioids, with known bleeding diathesis or other co-existing complications, that would prolong their surgery duration, were excluded. Then, the included patients were randomly assigned to each group of Lidocaine hydrochloride (X), bupivacaine hydrochloride (M), or pethidine hydrochloride (P) with computer generated randomization logic with 15 members per group.

Ketamine 5 mg/kg IM, and intravenous ringer lactate were used as premedication. Continuous monitoring was simultaneously applied. Following 3 minutes of pre-oxygenation, induction with midazolam 0.05 mg/kg, fentanyl 1 mcg/kg, Suxamethonium chloride 1.5 mg/kg were done. Maintenance with N_20:O_2 50:50 and Vecuronium bromide 0.1 mg/kg were carried out for all patients.

In groups X and M, 0.75^{cc} of lidocaine 2% and bupivacaine 0.5%, respectively, were diluted in 1.5 ^{cc} normal saline and applied 1^{cc} on each side for nerve blockade of infraorbital region. In the group P, 0.25 mg/kg pethidine was administrated intravenously.

The anesthesiologists were blind to the concept of the research. Hemodynamic parameters were monitored and recorded by a blind anesthesiologic technician.

At the end of the procedure, patients were reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.02 mg/kg and thereafter were extubated.

Their pain score was measured with CRIES[9] questionnaire (cry, requires O2, increased vital signs, expression, sleeplessness) by a blind anesthesiology resident in the recovery room. Their pain score was recorded hourly and the termination of study was considered as the first use of rescue analgesic including acetaminophen syrup 15mg/kg and fentanyl 1mcg/kg or after 24 hours post-op.

All procedures in the present study were approved by the ethics committee of Shahid Beheshti University of Medical Sciences. In addition, all of applicated methods were met by Helsinki 1966 declaration.[10] The informed consent was given from the parents/ legal guardian of all patients.

The sample size of the current study was calculated using the data of previous

similar studies with alpha error of 0.05 and power of study >90%. The comparison between the sex, age and weight of groups was carried out with Chi-square test. One-way ANOVA and Tukey's test was utilized for the duration of analgesia. Kruskal-Wallis Test was done for comparison of groups pain score. P<0.05 was considered as the level of significancy. All data are demonstrated as mean±SD. All statistical analysis was done by Graph Pad Prism 6.

Result

All 45 patients were included and no one was dropped out neither due to failure of nerve blockade nor to low compliance. The demographic data of each group is represented in **Table 1.** No significant difference was detected among the demographics of each group.

The average duration of analgesia in the X, M and P group were 18.48± 2.45, 17.62± 2.96, and 17.56± 3.16 hours, respectively. The duration of analgesia in the group X was superior to the other groups; however, there was not any meaningful different between the duration of analgesia between the 3 groups (p>0.05), **Figure 1**. No statistical difference was achieved from the comparison of the mean CRIES pain score of the 3 groups (p>0.05), **Figure 2**.

Table 1: The demographics of patients; all data are demonstrated as mean±SD; P: pethidine; M: Marcaine; X: lidocaine

	X	M	P	total
sex (F %)	46%	54%	46%	49%
age (months)	8.8±6.5	9.2±6.8	6.9±2	8.3±5.5
weight (kg)	8.4±2.9	8.2±2.5	7.2±1	7.9±2.3

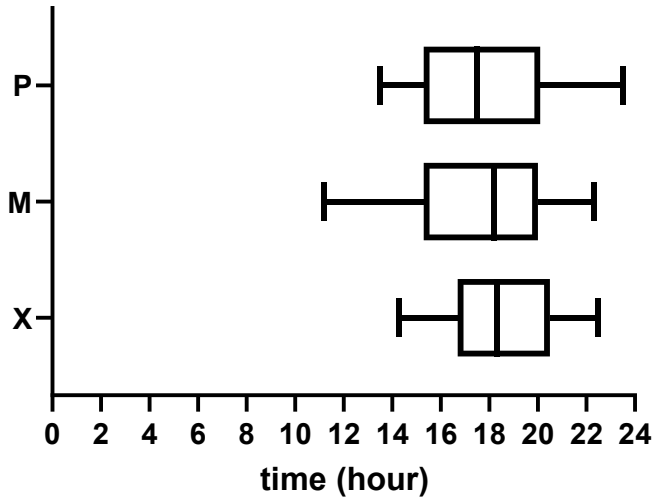

Figure 1: The duration of analgesia in each group; P: pethidine; M: Marcaine; X: lidocaine

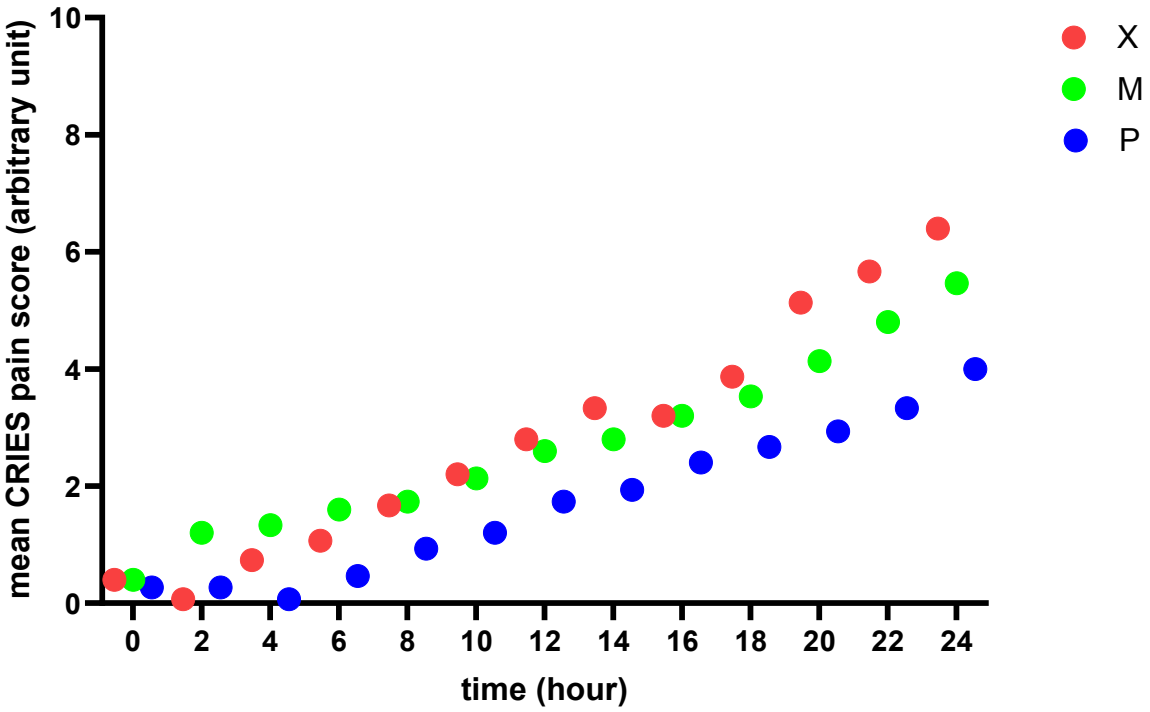

Figure 2: The average of CRIES pain score in each group in 24 hours follow-up; P: pethidine; X: Lidocaine; M: Marcaine

Discussion

The present randomized double-blind clinical trial was designed to compare the duration of anesthesia induced by infraorbital nerve blockade with either lidocaine or Marcaine with intravenous pethidine for pediatric patients' candidate for cleft lip surgery. The duration of anesthesia induced by infraorbital nerve blockade with lidocaine was circa 1 hour more than with the same procedure with Marcaine or IV pethidine. However, the overall trends of our results did not lead to demonstration of statistically significant level.

Pain is perhaps the most annoying sign of any disorder or surgical procedure for all patients in any range of age. Therefore, alleviation of pain is an important field for anesthesiologists. No one can deny the negative short term and long-term effects of pain on children's psycho-somatic health status.[11]

Opioids are well-known anesthetic group; nonetheless, in the pediatric group, due to their different pharmacokinetic response and their increased sensitivity, they are not categorized as a safe anesthetic agent for children undergoing cleft lip surgery.[5-12] Respiratory depression induced by opioids in children suffering from cleft lip make disinclination of their use in cheiloplasty.

Hence, regional anesthesia sounds as a practical method for decrement of opioids adverse reactions. Reduction of required anesthetic agents intra-operatively, with the effective pain relief post-operatively, and returning to pre-operative state rapidly, are counted as its beneficial effects.[13]

There is a bunch of studies in the literature, proved that the adjunctive use of synthetic opioids with regional nerve blockade elongated the anesthetic effect of regional blockade.[14-15] However, as mentioned above, adverse effects of opioid analgesics which threatens the hemodynamic and respiratory state of the pediatric patients; particularly in the general wards, necessitate replacing their single with combined use with infraorbital nerve block, resulting in the increase of the safety of the pain relief. In addition, the outcomes of the present clinical trial revealed that the duration of anesthesia with nerve block was same and, in most patients, more than opioid use.

Moreover, the duration of anesthesia induced by regional nerve block in our trial was consistent with previous studies.[2-14]

Conclusion

the present double-blind clinical trial disclosed that the preoperative bilateral infraorbital nerve block induced an anesthetic effect prolonged as the duration induced by the opioid infusion. The design of more clinical trials with large population of study would demonstrate the statistical meaningfulness of this theory. The authors of the present trial encourage the pediatric anesthesiologists to be more familiar with regional anesthesia as a proper and effective substitute for opioids.

Ethical Consideration

This study received ethical code from the ethical committee of Shahid Beheshti university of medical sciences (IR.SBMU.RICH.REC.1402.030).

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Conflict of interests

There is no conflict of interest

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