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EVALUATION OF THE EFFECTS OF PERIOPERATIVE INTRAVENOUS LIDOCAINE INFUSION IN ORTHOGNATHIC BIMAXILLARY SURGERY ON POSTOPERATIVE RECOVERY COMPLICATIONS: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Statement of the problem: The pre-operative or intra-operative administration of intravenous lidocaine has been approved as an accepted medication for postoperative recovery management.

Purpose: The aim of this study was to assess the analgesic, sedative, and anti-emetic effects of intravenous continuous lidocaine infusion in orthognathic surgery.

Materials and Method: Fifty patients were randomly allocated into two groups of 25. The patients in the experimental group received lidocaine 1 mg/kg intravenous bolus dose followed by 2 mg/kg/hr lidocaine dissolved in normal saline as an infusion administered throughout the surgery via an infusion pump. Those in control group received an equal volume of normal saline. Pain, nausea and vomiting, shivering, agitation, and need for opioids were evaluated in recovery room and Oral and Maxillofacial Surgery ward.

Result: After surgery , subjects in the lidocaine group experienced less degree (p=0.038) and incidence (p=0.004) of pain and they required less opioids (p=0.015).The patient's quality of recovery after surgery in lidocain group was better than those in salin group (p=0.006).Compairing the two groups in terms of shivering , post operative nausea and vomiting(PONV) and agitation.The two groups were not significantly different in terms of the three above mentioned indices.

Conclusion: Perioperative intravenous lidocaine infusion reduced postoperative pain and consumption of opioids after bimaxillary orthognatic procedures. The patients' quality of recovery after surgery in lidocaine group was better in recovery room and thereafter.

Keyword: Intravenous lidocaine; Bimaxillary orthognatic surgery ; Postoperative pain ; Recovery complication

INTRODUCTION

Treatment of patients with bimaxillary orthognathic surgery became common since the early 1980s [1, 2]. By that time, the surgeons and orthodontists learned about the three-dimensional nature of facial skeleton and its deformities, which increased their confidence in simultaneous surgery of the two jaws. The main reasons of orthognathic surgeries are esthetic concerns like asymmetry in one or both jaws, and functional considerations such as correction of airway [3]. Swelling, hemorrhage, hematoma,post-operative nausea and vomiting (PONV) , and neurologic problems are among the primary complications of orthognathic surgeries [4]. Rarely does life-threatening hemorrhage occur after such surgeries [5] . Different studies stated the prevalence of severe bleeding to be 1-12.5% after orthognathic surgeries [6, 7, 8].

Perrot *et al.*[9] reported nausea and vomiting as the most common complication of oral and maxillofacial surgeries, the prevalence of which was claimed to be 40% by Silva *et al.* [10].The major risk factors for postoperative nausea and vomiting include female sex, predisposing factors (such as history of vertigo and

migraine headaches) , the surgical site, duration of surgery, use of inhaled anesthetic agents, postoperative opioid analgesia and severe pain after the surgery [10] .

Postoperative pain is among the acute pains, the severity of which depends on the extent of surgical area, the patient's psychological and physiological background, degree of manipulation and the subsequent damage to the tissues on the surgical site [11].A frequent method for postoperative pain control is the prescription of opioid analgesics which can, in turn, be accompanied by some complications, namely, respiratory suppression, itching, nausea and vomiting, urine retention, and constipation [11].

Currently, attempts are focused on improving the patient's postoperative conditions through increasing the quality of analgesia and decreasing the drugs complications. The central effects of intravenous lidocaine decrease the postoperative pain and the need for opioid analgesia [12, 13]. It can also reduce the postoperative vomiting and nausea [14].A number factors may be contributing to the lidocaine mechanism of action; yet, preventing the central hyperalgesia seems to be an important and influential factor. The pain impulses from the injury site are transmitted to CNS via A-delta and C-fiber. Lidocaine prevents the delivery of these messages by blocking the sodium channel[15].

The current study was aimed at evaluating the benefits and risk factors of perioperative intravenous lidocaine on improving the patient's conditions in postanesthesia care unit (PACU) and thereafter.

MATERIALS AND METHOD

This randomized double-blined clinical trial was conducted on 50 adult patients aged 16-40 years old who underwent bimaxillary orthognathic surgery in the Oral and Maxillofacial Surgery ward, Shiraz Chamran Hospital, Iran, in 2014-15.This clinical trial holds Iranian registery number IRCT 201308141674N8 (www.irct.ir) and was approved by the local research ethics committee. The patients' demographic data, medical history, use of analgesic agents, postoperative nausea and vomiting(PONV), shivering,agitation and pain severity were recorded.

Method: The patients were randomly assigned into two equal groups. The first group received lidocaine and the second one received normal saline. The surgeon and the nurse who collected the data of pain and drug complications were both blind to the grouping.

Inclusion criteria were Written consent was obtained from the patients willing to

cooperate. The included subjects had no systemic disease or history of taking analgesic agents within the 3 preceding days. They were all candidates of bimaxillary orthognathic surgery without genioplasty.Exclusion criteria were presence of any known allergy to the drug under study, unfavorable reactions to the local anesthetics of amide group, kidney or liver failure, cardiovascular diseases, use of opioid or other analgesics within the three preceding days, and not signing the written consent form.

The patients in the first group (lidocaine group) received an intravenous bolus dose of 1 mg/kg lidocaine within 5 minutes followed by an infusion of 2 mg/kg/hr lidocaine dissolved in normal saline throughout the surgery via an infusion pump. Those in control group (placebo) were administered a bolus dose of equal volume of normal saline for 5 minutes, followed by an intravenous infusion up to the end of surgery. As the intraoperative monitoring, heart rate, non-invasive blood pressure, and arterial blood oxygen saturation were routinely recorded over definite intervals. By the end of operation, the total amount of used analgesia was registered. After the surgery, the patient was monitored in PACU for 4 hours. The pain severity was assessed by a blind operator every half an hour. During the surgery, the amount of analgesic and opioid drugs,incidence of postoperative nausea and vomiting, shivering and agitation were recorded. For the next 12 hours in the Oral and Maxillofacial Surgery ward, opioid medication was prescribed in case of having pain, and the pain was rated and recorded by the nurses.

The pain severity was scored and recorded by using **Wong–Baker Faces Pain RatingScale**.

Similar anesthesia technique was performed on all patients. Intravenous 0.1 mg/kg morphine was administered to induce anesthesia. Induction was achieved with 2.5 mg/kg of propofol, 3 µg/kg of fentanyl, and 0.5 mg/kg of atracurium. Maintenance of anesthesia consisted of 100 µg/kg/min of propofol and 0.1 µg/kg/min remifentanil by infusion. All the subjects received N2O and O2 (50%) during the operation. They were mechanically ventilated to keep the EtCO2 between 35-40 mmHg.

RESULTS

All the obtained data were entered into SPSS software, version 22. The quantitative data were analyzed by using t-test, and the rest of data were statistically analyzed by using chi-square test. P<0/05 was considered to be statistically significant.

No statistically significant difference was noted between the two groups regarding sex (Table 1), age, weight (BMI), and perioperative bleeding (Table 2). The surgery duration in lidocaine group was longer than the normal saline group (p= 0.01).(Table 2).

Five patients of lidocaine group (20%) and 15 subjects of the saline group (60%) experienced a degree of pain, indicating a statistically significant difference between the groups (p= 0.004) which was lower in lidocaine group (Table 3).

Shivering was noted by 4 patients in lidocaine group (16%) and 5 in saline group (20%). PONV was reported by none of the lidocaine recipients (0%), but 2 subjects in saline group claimed to have PONV (8%). The two groups were not significantly different in terms of the two above mentioned indices (Table 3).

Two patients of lidocaine group (8%) and 7 patients of saline group (28%) experienced agitation in PACU, which was lower in lidocaine group. However, the difference was not statistically significant (p= 0.066) (Table 3).

Concerning the need for opioid in PACU and in the ward within the first postoperative 12 hours, 4 patients in lidocaine group (16%) and 12 in saline group (48%) needed opioid agents, indicating a statistically significant decrease in lidocaine group (p= 0.015) (Table 3).

Comparing the two groups in terms of pain severity rated based on Face pain rating scale, the pain severity was significantly lower in lidocaine group (p= 0.038) (Table 4).

In order to evaluate the patient's quality of recovery after surgery and compare the two groups, each postoperative complication including nausea and vomiting, shivering,agitation and need for opioid agents was scored as 0 (absence) or 1 (presence). The pain severity was also scored as 0 (no pain), 1 (mild), 2 (moderate), 3 (severe), 4 (very severe and higher). Accordingly, the patient's quality of recovery after surgery in lidocaine group was better than those in saline group (p= 0.006) (Table 5).

Table 1: Demografic data (sex)

Sex	Lidocaine group	Saline group	P
Male	10 (40%)	9 (36%)	
Female	15 (60%)	16 (64%)	0.771

Table 2: Demografic data and perioperative bleeding

	Lidocaine group	Saline group	P
Age (yr)	23.24 ± 5.29	22.20 ± 5.24	0.489
BMI	21.46 ± 3.07	21.30 ± 2.55	0.840
Surgery duration(hr)	4.56 ± 0.939	3.94 ± 0.666	0.010
Perioperative bleeding (CC)	598 ± 49.28	700.36 ± 59.16	0.190

Table 3: Postoperative variables

	Lidocaine group	Saline group	P
Pain	**5(20%)**	**15(60%)**	**0.004**
Shivering	**4(16%)**	**5(20%)**	**0.713**
Nausea and vomiting	**0(0%)**	**2(8%)**	**0.149**
Agitation	**2(8%)**	**7(28%)**	**0.066**
Need for opioids	**4(16%)**	**12(48%)**	**0.015**

Table 4: Pain severity

		Lidocaine group	Saline group	P
Pain Severity	**No pain**	**20 (80%)**	**10 (40%)**	**0.038**
	Mild pain	**1 (4%)**	**4 (16%)**	
	Moderate pain	**3 (12%)**	**8 (32%)**	
	Severe pain	**1 (4%)**	**3 (12%)**	
	Very severe pain and higher	**0 (0%)**	**0 (0%)**	

Table 5: Quality of Recovery Score

	n	Agitation score	Pain severity score	Need for opioid score	PONV score	Shivering score	Total score	Mean	P
Lidocain group	**25**	**2**	**10**	**4**	**0**	**4**	**20**	**0.8**	**0.006**
Salin group	**25**	**7**	**29**	**12**	**2**	**5**	**55**	**2.2**	

DISCUSSION

The current study assessed the effects of lidocaine on the complications of surgery, the anesthetics and influence on the amount of opioid used in orthognathic surgeries. To do so, the patients in the study group received an intravenous bolus dose of 1 mg/kg lidocaine, followed by infusion of 2 mg/kg/hr lidocaine dissolved in normal saline via an infusion pump throughout the surgery. Systemic lidocaine can cause allergic reactions, arrhythmia, hypotension, and seizure [15]. Most studies showed that a bolus dose of 1.5 mg/kg lidocaine and 2 mg/kg/hr infusion is safe and has no side effect [15].

Lidocaine is the first of amino-amide type local anesthetics with analgesic[16], anti-hyperalgesic[17] and anti-inflammatory[18] effects.Two mechanisms have been investigated to explain the analgesic efficacy of lidocaine : a selective depression of pain transmission in spinal cord and a reduction in tonic neural discharge of active peripheral nerve fibers.[19]

Roland *et al*.[20] showed that the half-life of intravenous lidocaine was 1.5 hour when administered as bolus; but, when administered as infusion, the plasma level could be measured up to 12 hours.

In the studies by Kaba *et al.* [12] and Koppert *et al*[13], lidocaine reduced pain and the need for opioids.

Similar to our study, Farag *et al.* [21] reported that lidocaine reduced the pain and use of opioids in spinal surgery; although, it had no effect on postoperative nausea and vomiting. Kim *et al*.[15] achieved similar results in lumbar surgery.

Unlike the current study, Warner *et al*.[14] detected that lidocaine decreased the nausea and vomiting after strabismus surgery. While, Martin *et al*.[22] noted that pain reduction was insignificant when prescribing 1.5 mg/kg/hr lidocaine in total hip arthroplasty. Apparently, the nature of surgery impacts the outcome of study.

The most important finding of this study was the reduction of pain and need for opioids. Furthermore, the patients'quality of recovery after surgery in lidocaine group was better in recovery room and thereafter.

The main limitation of this study was the small sample size; thus, further studies are suggested to assess a larger sample size. Moreover, we did not check the lidocaine plasma concentration, which may shed light on the relationship between the pharmacokinetics of this medication and its effects.

CONCLUSION

In summary, intravenous lidocaine following general anesthesia reduced postoperative pain and consumption of opioid after bimaxillary orthognatic procedures.thus ,administration of 1 mg/kg lidocaine before induction as bolus followed by 2 mg/kg/hr by intraoperative infusion significantly reduced postoperative pain in the patients undergoing bimaxillary orthognatic surgery whitout any significant increase in the adverse effects.

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