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Pre-emptive epinephrine nebulization prior to nasotracheal intubation for mandibular fracture fixation surgeries: Does it really differ? A randomised controlled clinical trial

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ABSTRACT

Introduction: Isolated mandibular fractures as any other fracture are associated with pain and inflammation which possess difficulty for both laryngoscopy and intubation. Nasotracheal intubation is relatively more efficient in individuals with isolated mandibular injuries. Epistaxis is the most common complication of nasal intubation. This study aimed to highlight the role of preoperative usage of epinephrine 1:1000 combined with lidocaine as a nebulization session before induction of anaesthesia as a method to spread vasoconstriction and analgesia.

Methods: The patients were randomly assigned to one of two equal groups; nasal Lidocaine drops followed by Oxymetazoline nasal drops (OL as control group) or Epinephrine mixed with Lidocaine as nebulization session (EL as the study group). Our primary measures were to estimate the degree of epistaxis and its effect on intubation time.

Results: Lidocaine with epinephrine as a nebulization session prior to NTI has statistically significant less intubation time (37.8 ± 6.32) versus (42.16 ± 5.1) in the control group with *p*-value (0.000028). This correlates with higher incidence of moderate nasal bleeding in OL group (7/60 = 11.66%) versus (4/60 = 6.66%) in EL group and *P*- value = 0.01. EL mixture has a higher priority of decreasing surgical blood loss. Mean± SD measures were (406.86 ± 89.6) and (468.6 ± 139), p-value = 0.00026*in EL and OL groups respectively.

Conclusion: Despite being time consuming measure. Yet, lidocaine epinephrine nebulization session can be considered as an efficient method for prophylaxis against nasotracheal intubation induced epistaxis, to control intraoperative field bleeding, acts as an adjuvant to control intraoperative pain and protects against postextubation nasal complications.

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1. Introduction

Maxillofacial fractures are relatively prevalent in the Middle East and North Africa (MENA) area and are often due to RTAS, particularly among young men. It has become increasingly prevalent due to high-speed travel, the accelerating pace of contemporary life, the increased frequency of violence, the severity of traffic accidents, crowded societies, sports injuries, industrial traumas, and military injuries [1]. Despite being the strongest as well as the largest bone of the facial skeleton, the mandible is the second most frequently broken bone, following the nasal bones. The most often broken anatomical location is the parasymphysis, followed by the condylar region [2] and [3]. Isolated mandibular fractures, like any other fracture, are associated with pain and inflammation, which pose difficulties for both laryngoscopy and intubation. Bilateral fractures specifically are associated with extensive oral edema and lacerations, which possess surgical and intubation difficulties [4]. Nasotracheal intubation (NTI) is relatively more efficient in individuals with isolated mandibular injuries. Epistaxis is the most common complication of nasal intubation, occurring in 18% to 66% of the instances when the nasal tube destroys the nasal mucosa along its passage [5]. Intravenous steroids and locally administered vasoconstrictors are frequently used to reduce the likelihood of tissue oedema and the possibility of epistaxis [6] and [7]. The use of a method to spread analgesia and vasoconstriction to prepare the nasal and oral mucosa during mandibular fixation surgeries is our goal in this study.

2. Study objective

This study aimed to highlight the role of preoperative usage of epinephrine combined with lidocaine as a nebulization session before induction of anesthesia in patients with isolated mandibular fractures undergoing elective fixation with nasotracheal intubation.

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3. Materials and methods

We obtained the approval of Ain Shams University Hospital's Ethical Committee No. (FMASU R 132/2021) ClinicalTrials.gov ID: NCT05738564. The patients were informed about the study's objectives, as well as its benefits and risks, the confidentiality of personal information, the right to withdraw at any time, and the voluntary nature of enrolment. Cases with American Society of Anesthesiologists (ASA) classes I and II, scheduled for elective oral isolated mandibular fracture open reduction surgeries requiring NTI, were selected.

Exclusion criteria included a history of nasal abnormalities (such as polyps, surgery, or nasal trauma), age under 18 years, a history of frequent epistaxis, valvular heart disease, hypertension, ischemic heart disease, or arrhythmias; the use of drugs (anticoagulation therapy, nonsteroidal anti-inflammatory drugs, and oral decongestants); and the use of medications known to alter the parameters under investigation, such as beta – blockers, and calcium channel blockers.

4. Study interventions

One hundred and twenty-six patients were randomized by means of a sealed envelope into one of two equal groups. Six patients were excluded because of failed nasal intubation and conversion to oral ETT. One group of patients received epinephrine mixed with lidocaine as a nebulization session (the EL group, as the study group), and the other group received nasal lidocaine drops followed by oxymetazoline nasal drops (the OL group, as the control group).

Group EL (63 patients): Received a session of nebulization in the pre-induction area, consisting of 1 ml epinephrine (1:1000 Martindale Pharma, an Ethypharm Group company, ampoule 1 mg added to 9 ml of normal saline, then 1 ml of that put in a nebulization cup +2 ml lidocaine 2%), nebulized prior to the induction of anesthesia.

Group OL (63 patients): Received five drops of lidocaine hydrochloride (Xylocaine 2%, 20 mg/ml; AstraZeneca, London, UK) using a prefilled dropper, followed by six drops of hydrochloride Oxymetazoline (Otrivin adult nasal drops 0.1%, 10 ml of 1 mg/ml; Novartis Consumer Health, UK Ltd., 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK) in each nostril in the pre-induction room just before the induction of anesthesia.

In the event of tachycardia (HR > 100 b/min) or hypertension (BP > 160/90 mmHg) prior to anesthesia induction, a beta-blocker (labetalol 20 mg IV was injected slowly over 5 minutes) was administered.

5. Anaesthetic protocol

A preoperative airway evaluation was done. Mouth opening, inter-incisor distance, and the Mallampati score were used to assess the degree of truisms. We examined the nasal cavity by using a light source to select the target nostril; if we could not determine it, we chose the right nostril. No premedication was administered.

Pulse oximetry, non-invasive blood pressure (NIBP), electrocardiography (ECG), and capnography were used to monitor the patients throughout. Both groups were pre-oxygenated with 100% oxygen via face mask for 4 minutes. The patients were subsequently administered intravenous fentanyl (1 µg/kg), lidocaine (40 mg) IV, then rocuronium (0.6 mg/kg), and propofol (1.5 mg/kg). Following the confirmation that the patient had lost consciousness, a water soluble lubricant (K-Y gel) was applied locally via the selected nostril for all patients. A blinded anesthesiologist with experience more than 3 years performed nasal intubation, and reinforced ETT with a taper guard cuff was used for NTI. The size of the ETT was chosen based on these criteria: a 6.5-mm internal-diameter tube for adult females or adult males shorter than 165 cm in height, as well as a 7.0-mm internal-diameter tube for male adults taller than 165 cm. The ETT was gently inserted into the lower airway of the nasal cavity through the targeted nostril. During this phase, when encountering resistance, the ETT was removed and reinserted with gentle cephalad tilting of the tube with or without counter clockwise rotation. When resistance was encountered again, reinsertion into the other nostril was performed using the same method. After placing the ETT into the oropharynx, the ETT was inserted utilizing conventional direct laryngoscopy with or without the use of Magill forceps. Oral packing with wet gauze is done after intubation to avoid the risk of blood aspiration during oral surgery. The degree of epistaxis during intubation was measured, as shown in Table (1) and [8].

Table 1. The degree of epistaxis during intubation was estimated as the following.

The degree of bleeding	Definition	Laryngeoscopic view
None	No bleeding	No interference with the laryngoscopic view
Minimal	Tinge of blood	Just blood-tinged ETT but no blood on the vocal cords or mouth floor
Moderate	Blood on the vocal cords and mouth floor	Interferes with the laryngoscopic view, but is easy to confirm the laryngeal structure
Severe	Blood on the vocal cords and mouth floor	Hard to visualize the laryngeal structure without suction because of bleeding.

While the degree of epistaxis after intubation and extubation was measured using pharyngeal aspiration with a 14-F, 50-cm-long suction catheter connected to a 2.5-m-long suction tube at −100 mmHg [9]. Based on the amount of blood sucked via the suction tube into the container, the severity of epistaxis was determined: none = no bleeding; mild = blood volume less than 50 cm; moderate = blood volume more than 50 cm and less than 300 cm; severe = blood volume more than 300 cm. The cases that suffered moderate to severe epistaxis were managed by nasal packing with an epinephrine-soaked cotton pack. General anesthesia was continued with sevoflurane at 2% with an injection of rocuronium every 30 minutes. Before the skin incision, patients received a 1 gm paracetamol infusion. An increase in heart rate and/or blood pressure>20% of the pre-surgical incision baseline during the whole operative time was considered a lack of analgesia and was managed by 50 micrograms of IV fentanyl. Intraoperative blood loss was calculated and compensated according to hemodynamic variables. At the end of the surgery, inhalational anesthetic medications were terminated, the oral pack was removed, and extubation was done after full reversal of muscle relaxation with neostigmine 0.05 mg/kg and atropine 0.02 mg/kg. Before discharge from PACU, the patients were interviewed about nasal pain intensity using the visual analogue score (VAS) [9]. Which ranges from 0 to 10, where 0 means no pain and 10 means the most severe pain. Nasal obstruction symptoms (mild, moderate, or severe) were checked. The incidence of post-extubation epistaxis was followed up in PACU and after one hour in the ward.

6. Study measurements

- Epistaxis incidence and degree were measured during the intubation (the primary outcome) and were traced five minutes following intubation, immediately after extubation, and prior to discharge from the post-anesthesia care unit (PACU).
- Intubation time was recorded.
- A need for labetalol was recorded.
- Hemodynamic measures (HR, MABP, and incidence of arrhythmias) were continuously monitored and recorded as baselines immediately following intubation, at 10, 20, and 30 minutes after intubation, and immediately following extubation.
- Intraoperative fentanyl consumption.
- Intraoperative blood loss. The blood loss calculated from whole blood loss in the suction container and soaked gauzes
- The intensity of postoperative nasal pain was recorded in the PACU using VAS.
- Post-extubation nasal obstruction symptoms were recorded.

7. Statistics

The sample size was determined by setting the power (1-) at 0.8 and the type 1 error () at 0.05 in the STATA program. Based on the findings of a prior study (Song, 2017) [8], 85% of XS group cases had minimal epistaxis during intubation, compared to 62% in the EP group, to detect a difference of 23% reduction in minimal epistaxis incidence. Calculations resulted in a sample size of 57 subjects, which is approximately 60 subjects per group to consider for dropout cases.

Data results were recorded and analyzed by computerized statistical methods utilizing Statistical Package for Social Science (SPSS) version 21.0. Microsoft® Excel 2016 (Microsoft, Seattle, WA, USA) and Chicago, Illinois, USA. Qualitative data were expressed in the form of percentages and numbers, whereas quantitative data were expressed as the mean ±standard deviation. The independent-samples t-test was utilized for comparing means in both groups. The Chi-square test was utilized to compare proportions between two qualitative parameters. P-value<0.05 was deemed significant, and $P > 0.05$ was deemed non-significant.

8. Results

No statistically significant intergroup differences were detected in terms of ASA class, body weight, height, sex, and age (Table 2). The parasymphysis region was the most frequently fractured anatomical region,

Table 2. Patient's demographics and surgical data.

Parameters	Group EL No. (60)	Group OL No. (60)	*P*- value
Age, Years (mean± SD)	31.765± 6.8	30.725± 6.0	0.235
Height, cm (mean± SD)	157.980± 3.16	158.216± 3.62	0.442
Weight, Kg (mean± SD)	72.020± 6.12	73.451± 8.92	0.337
Sex	Males: 95% Females: 5%	Males: 96.66% Females: 3.33%	0.647
ASA grade:			0.46
ASA I	36(60%)	32(53.3%)	
ASA II	24(40%)	28(46.7%)	
Type of mandibular fracture	Condylar fracture (28%) Parasymphiseal (72%)	Condylar fracture (35%) Parasymphiseal (65%)	0.432

*Significant difference (p-value <0.05); SD: Standard deviation.

followed by the condylar region, but it was a non-significant difference.Intubation time was a statistically significant result. The mean time and standard deviation were shorter in the EL group than the OL group. (37.8 ± 6.32) (42.16 ± 5.1), p-value (0.000028).The OL group had a higher incidence of moderate bleeding (7/60 = 11.66%) than the EL group (4/60 = 6.66%), with a P-value of 0.01. The bleeding 5 minutes after the intubation was a non-statistically significant result. Moderate bleeding persisted in the EL group (3/60 = 5%) versus the OL group (5/60 = 8.33%), p-value = 0.085 (Table 3).

Postoperative nasal obstruction was a highly significant measure, with a lower incidence in the EL group. Only one patient (1.66%) in the EL group experienced moderate nasal obstruction, compared to 8/60 (13.33%), p-value = 0.015 in the OL group. The other postoperative nasal complications, such as nasal pain and the incidence of bleeding, were all non-statistically significant results. (Table 5)

9. Discussion

Isolated mandibular fractures are associated with inflammation and pain, which cause muscle spasm, decreasing the mouth opening and posing difficulty for intubation. Intraoral mucosa is mostly lacerated; angioedema occurring with these fractures cannot be predicted, so rapid diagnosis and intervention are essential [10]. NTI is mainly encountered during elective mandibular fracture fixation surgeries. Epistaxis is the most common risk, which may be a life-threatening complication in some cases. Blood in the airway may worsen conditions that obscure the laryngoscopic view, and it is possible for blood to aspirate into the lungs [11].

Table 3. Intubation measures and incidence of epistaxis in the studied groups.

Intubation Measures	Group EL No. (60)	Group OL No. (60)	P- value
Intubation time in seconds (mean± SD)	37.8±6.32	42.16±5.1	0.000028*
Severity of bleeding during intubation by percentage			0.01 *
Nil	45/60=75%	29 /60=48.33%	
Mild	11/60=18.33%	24/60= 40%	
Moderate	4/60=6.66%	7/60=11.66%	
Severe	0.00%	0.00%	
Severity of bleeding 5 minutes after the intubation by percentage			0.085
Nil	48/60=80%	37/60=61.66%	
Mild	9/60=15%	18/60=30%	
Moderate	3/60=5%	5/60= 8.33%	
Severe	0.00%	0.00%	

*Significant difference (*p* value <0.05); SD: Standard deviation.

Hemodynamic variations measured over different intervals were all non-significant results except for the mean blood pressure, which was measured 10 minutes after the intubation. Two of the patients in the inhalation group suffered sinus tachycardia associated with elevated mean blood pressure. In that group, 3.33% of the patients required labetalol treatment. The mean and standard deviation measures were higher in the EL group than the OL group, (86.27± 11.5) and (84.62 ± 7.2), respectively; p-value = 0.029. The intraoperative blood loss was a highly significant statistical measure, showing a higher priority for the EL group in decreasing intraoperative blood loss. The mean ± SD measures in the EL and OL groups were (406.86± 89.6) and (468 ± 139), respectively, with a p-value of 0.00026*.Epinephrine mixed with lidocaine administered by inhalation was beneficial in reducing intraoperative opioid consumption. The mean ± SD measures of intraoperative fentanyl consumption were 144.13± 9.2 and 166.66± 58.3, respectively, with a p-value of 0.005 in the EL and OL groups, respectively (Table 4).

Table 4. Intraoperative measures in the studied groups.

HR and mean BP Measures	Group EL No. (60)	Group OL No. (60)	P- value
Basal HR	88±8.5	86.471± 10.4	0.27
Basal mean BP (mean± SD)	77.8±10.1	79.235±8.7	0.45
HR just after the intubation	92.41±7.4	91.6±7.33	0.25
BP just after the intubation (mean± SD)	86.92±6.8	88.4±8.1	0.36
HR 10 minutes after the intubation	90.4±13.3	89.23±8.4	0.36
BP 10 minutes after the intubation (mean± SD)	86.27±11.5	84.62±7.2	0.029*
HR 30 minutes after the intubation	84.29±10.1	85.05±12.6	0.33
BP 30 minutes after the intubation (mean± SD)	81.58±6.8	82.58±9.4	0.228
HR after the extubation	96.78±7.2	94.94±9.2	0.224
BP after the extubation (mean± SD)	98.07±8.5	98.7±9.7	0.266
Patients who needed labetalol	2/60= 3.33%	0/60	0.78
Intraoperative fentanyl consumption (mean± SD)	144.1±39.2	166.66±58.3	0.005*
Intraoperative blood loss (mean± SD)	406.86±89.6	468.6±139	0.00026*

*Significant difference (*p* value <0.05); SD: Standard deviation.

Table 5. Post-extubation measurements.

Parameters	Group EL No. (60)	Group OL No. (60)	P- value
Intensity of postoperative nasal pain VAS (mean± SD)	2.96±1.5	3±1.61	0.2
Postoperative nasal obstruction			0.015*
Nil	52/60=86.66%	40/60=66.66%	
Mild	7/60=11.66%	12/60=20%	
Moderate	1/60=1.66%	8/60=13.33%	
Severe	o.0%	0.0%	
Incidence of epistaxis just after extubation	0.00%	0.00%	0.5
Incidence of epistaxis before discharge from PACU	0.00%	0.00%	0.5

*Significant difference (p value <0.05); SD: Standard deviation.

The more extensive the surgical correction, the higher the possibility of postoperative morbidities due to inflammatory tissue edema. Blood loss during the surgery is dependent on many factors, like the surgeon's skills, the extent of the trauma, and the degree of tissue edema. Increased blood loss is associated with a higher possibility of oral tissue edema after the surgery [12].

Topical local anaesthetics, followed by vasoconstrictors, can help reduce mucosal congestion, blood loss, and pain after surgery. Topical vasoconstrictor nasal drops (xylometazoline 0.1%) help to avoid hemodynamic fluctuations and aid in vasoconstriction of the mucosal blood vessels of the nose as well as neighboring regions of the pharynx, thus decreasing mucosal congestion, decreasing the absorption of the applied topical LA, and consequently decreasing the required dose and the incidence of LA toxicity. Nevertheless, oxymetazoline was substantially more potent compared to xylometazoline. Its effect begins within a few minutes and lasts up to 10 h [13] and [14].

Also epinephrine is a commonly used vasoconstrictor [15] and [16]. Epinephrine produces vasoconstriction by stimulating both α- as well as β-adrenergic receptors. Moreover, it substantially lowers blood flow at the capillary level by contracting vascular smooth muscle, thereby shrinking upper respiratory mucosa as well as reducing oedema and the tendency of bleeding [17]. For adult patients, 1 mg of adrenaline in 5 ml of 0.9% sodium chloride administered via a nebulizer was beneficial in certain cases of upper airway obstruction and in adults with asthma. It acts quickly with low side effects as no substantial cardiovascular sequelae, probably since, at the site of obstruction, the mucosal absorption is probably restricted by the produced local vasoconstriction as well as the existence of oedema and turbulent flow with nebulization [18] & [19]. Using lidocaine as a nebulization form is well known to produce local airway anaesthesia to facilitate awake intubation or to relieve post-extubation laryngospasm [20] & [21]. Lidocaine mixed with epinephrine is also used traditionally as jelly nasal packs and as sub-mucosal injections in different concentrations (1:100000 or 1:200000) for nasal surgeries and before nasal intubation [22].

As far as we know, using epinephrine as a nebulizer solution before mandibular fracture fixation surgeries to optimize both intubation circumstances and surgical field has never been studied. In this study, we prepared the airway with a lidocaine 2% mixture with epinephrine 1:1000 as a nebulization session before the induction of anesthesia in one group. The other group is traditionally treated with nasal drops, first with lidocaine 2% drops, then with Oxymetazoline drops. Using lidocaine with epinephrine as a nebulization session prior to NTI in isolated mandibular fracture surgeries resulted in statistically significant less intubation time (37.8 ± 6.32 versus 42.16 ± 5.1), p-value = 0.000028. The OL group had a higher incidence of moderate bleeding (7/60 = 11.66%) than the EL group (4/60 = 6.66%), with a P-value of 0.01. Although intubation time was a statistically significant result, it was not clinically more effective. The difference was just 4.3 seconds (a 10% reduction in intubation time). The priority of using epinephrine with lidocaine as nebulization was to reduce the incidence of mild nasal bleeding. Mild bleeding was reduced by 21.67% in EL group more than the oxymetazoline group.

Local vasoconstrictors such as oxymetazoline, xylometazoline, and epinephrine drops or packs have been studied before for producing nasal mucosa vasoconstriction. On the contrary, according to our study results, oxymetazoline and xylometazoline were superior to epinephrine nasal packs and nasal jelly when studied before. Xylometazoline was more beneficial in reducing severe bleeding and post-extubation bleeding [8] and [23]. In our study, inhalation of epinephrine mixed with lidocaine was superior in decreasing both local nasal bleeding and mucosal surgical bleeding. 48.33% of the patients did not suffer epistaxis during the intubation after using oxymetazoline nasal drops, versus 75% who did not suffer epistaxis after the nebulization session. Total surgical and nasal bleeding decreased by 13.24% with the epinephrine session.

Hemodynamic stability was achieved in most of the readings in both groups. The mean blood pressure was statistically significant ten minutes after the intubation in the EL group. Only two of the patients in the inhalation group (3.33%) required labetalol treatment. Although moderate bleeding was greater in the

oxymetazoline group, there wasn't any hemodynamic instability among the patients that might need specific interference. Preparing the airway mucosa with a nebulization mixture of local anesthetics and vasoconstrictive agents helped reduce intraoperative blood loss and the intraoperative requirements for opioids. Postoperative nasal obstruction was a lesser incidence in the EL group. Only one patient (1.66%) in the EL group experienced moderate nasal obstruction, compared to 8/60 (13.33%), p-value = 0.015 in the OL group. Both methods are effective in decreasing postoperative nasal bleeding and postoperative nasal pain in a comparative manner.

As using epinephrine and lidocaine as nebulization agents to induce mucosal vasoconstriction and local anesthesia prior to awake intubation or nasal surgery is uncommon, it has not been thoroughly studied. A study used aerosolized lignocaine mixed with epinephrine as a clinical technique for making awake nasal intubation without sedation or premedication an easy procedure. That study determined the effectiveness of the technique of administering 2% lidocaine (with 1:200,000 adrenaline) to the pharynx, nose, and larynx by a simple device that was utilized for administering aerosolized lidocaine initially via the nose and then through a nasopharyngeal airway. Ten participants were readily intubated. The average duration from the beginning of lidocaine administration to confirmation of ETT insertion was 12 minutes. Intubation conditions were good, and the technique was well tolerated by all participants. The average dosage of lignocaine was 4.8 mg/kg, and plasma concentrations were much below lethal limits. There was no incident of oxyhemoglobin desaturation, and there was adequate hemodynamic stability. However, this study did not mention the effect on the incidence of epistaxis of using that technique for awake nasotracheal intubation [24].

We recommend using an epinephrine and lidocaine mixture as an inhalation form before oral surgeries requiring nasal intubation and associated with the possibility of tissue edema and pain. This session helped in improving the intubation condition and decreasing the incidence of epistaxis with nasal intubation. At the same time, it improved the surgical field to an acceptable range.

10. Limitations

This study could not measure the plasma level of all medications used to assess the systemic absorption of the studied drugs and the possibility of drug toxicity. We cannot be certain of the cause of the tachycardia and hypertension that occurred in two patients in the EL group. Our center did not have racemic epinephrine. More research is needed to investigate racemic epinephrine rather than L-epinephrine and its effect on postoperative surgical tissue edema.

11. Conclusion

Despite being a time-consuming measure, yet, a lidocaine and epinephrine nebulization session can be considered an efficient method for prophylaxis against nasotracheal intubation-induced epistaxis, to control intraoperative field bleeding, to act as an adjuvant to control intraoperative pain, and to protect against postextubation nasal complications.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Appendix

Appendices:

MENA	Middle East and North Africa
RTA	Road traffic Accident
ASA	American society of anesthesiologists

(*Continued*)

MENA	Middle East and North Africa
RTA	Road traffic Accident
ASA	American society of anesthesiologists
EL	Epinephrine lidocaine group
OL	oxymetazoline lidocaine group
ETT	Endotracheal tube
NTI	Nasotracheal intubation
PACU	post-anesthesia care unit.