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Original Contribution

Effects of intravenous administration of fentanyl and lidocaine on hemodynamic responses following endotracheal intubation

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ABSTRACT

Objectives: To compare the effects of intravenous fentanyl and lidocaine on hemodynamic changes following endotracheal intubation in patients requiring Rapid Sequence Intubation (RSI) in the emergency department (ED).
Methods: A single-centered, prospective, simple non-randomized, double-blind clinical trial was conducted on 96 patients who needed RSI in Edalatian ED. They were randomly divided into three groups (fentanyl group (F), lidocaine group (L), and fentanyl plus lidocaine (M) as our control group). M was administered with 3 μgr/kg intravenous fentanyl and 1.5 μgr/kg intravenous lidocaine, F was injected with 3 g/kg intravenous fentanyl and L received 1.5 mg/kg intravenous lidocaine prior to endotracheal intubation. Heart rate (HR) and mean arterial pressure (MAP) were assessed four times with the chi-square test: before, immediately after, 5 and 10 min after intubation. Intervention was discontinued for five people due to unsuccessful CPR.
Results: HR was notably different in F, L and M groups during four time courses ($p < 0.05$). Comparison of MAP at measured points in all groups exhibited no significant difference ($p > 0.05$). In fentanyl group both HR and MAP increased immediately after intubation, and significantly decreased 10 min after intubation ($p < 0.05$).
Conclusions: Overall, the result of this study shows that lidocaine effectively prevents MAP and HR fluctuations following the endotracheal intubation. According to our findings, lidocaine or the combination of fentanyl and lidocaine are able to diminish hemodynamic changes and maintain the baseline conditions of the patient, thus could act more effectively than fentanyl alone.

1. Introduction

Endotracheal intubation is a procedure involving tube placement into the trachea through mouth or nose of a patient, to provide needed oxygen and anesthesia. Previous studies have shown association between endotracheal intubation and hemodynamic changes, such as tachycardia and hypertension due to the stimulation of sympathetic nervous system, which may occur in up to 40% of critically ill subjects [1,2]. These fluctuations can enhance the development of arrhythmia, myocardial ischemia, infarction, and cerebral hemorrhage among susceptible individuals, especially those suffering from coronary artery disease, hypertension or cerebrovascular disorders [3]. This issue has been a controversial topic since 1940, when Reid et al. [4] indicated that stimulation of the upper respiratory system leads to an increase in the vagal activity. A year later, Burstein et al. [5], found that the pressor response was due to elevated sympathetic activity provoked by the stimulation of the epipharynx and the laryngopharynx that was further confirmed by Prys-Roberts [6].

Many drugs can be used prior to endotracheal intubation to blunt such harmful responses, including anti-arrhythmia agents (such as lidocaine), opioids (such as fentanyl) and α- and β-adrenergic blockers (such as esmolol) [3,7-9].

Administrating lidocaine hydrochloride, a local anesthetic and class I B antidysrhythmic drug, is acceptable to reduce cardiovascular response to intubation, cough reflexes, dysrhythmias, and for the attenuation of the rise in intracranial and intraocular pressure [9]. However, previous studies represent diversity of the results regarding the preventive measures against hemodynamic and the catecholamine alterations, following laryngoscopy and intubation. The drugs studied either had limited impacts, or harmful side effects. Furthermore, admixtures (e.g. lidocaine and esmolol) have been proved to be more productive than either drug alone, but none of the combinations was very effective [10].

Furthermore, optimal management for attenuation of hemodynamic responses in patients, and best drug dosage choice are not yet clear [6, 11-16]. Moreover, regional blocks could cause technical problems and other drugs such as opioids have complications or drug allergies [16].

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Although many studies have found effective agents for preventing hemodynamic changes during intubation, very few had compared the influence of lidocaine and fentanyl regarding this issue. Also, medical reports on the effect of lidocaine plus fentanyl are rarely available, and most of the related studies have examined fentanyl or other chemicals. Thus, this study aims to evaluate and compare the efficacy of intravenous fentanyl and lidocaine in attenuating hemodynamic responses to endotracheal intubation, on subjects who have been requiring Rapid Sequence Intubation (RSI) in the emergency department (ED).

2. Subjects and methods

2.1. Patients

A prospective, simple nonrandomized, double-blind clinical trial was conducted on 96 patients, aged between 21 and 94-years-old, who needed emergency oropharyngeal intubation in the Edalatian emergency center, Imam Reza Academic Hospital, Mashhad University of Medical Sciences (MUMS), Mashhad, Iran. The study protocol was approved by the Ethical Committee of MUMS (Registration code: MUMS/930268). The trial was registered in the Iranian website (www.irct.ir) for registration of clinical trials (IRCT ID: IRCT2016121514872N5). Besides, written informed consent was obtained from all the patients. Five of them having predetermined sensitivity to lidocaine or fentanyl, crash intubation (Crash intubation was defined as orotracheal intubation, in which no medication was used [17]), and had difficulty with intubation or those who were contraindicated for succinylcholine, were excluded.

The patients were divided into 3 groups. The control group (M) including 32 patients were injected with 3 μgr/kg intravenous fentanyl and 1.5 μgr/kg intravenous lidocaine. A number of 32 patients in the fentanyl group (F) and lidocaine group (L) were given 3 μgr/kg intravenous fentanyl and 1.5 mg/kg intravenous lidocaine before endotracheal intubation, respectively. In addition, 0.3 mg/kg etomidate as a sedative induction agent and 1.5 mg/kg succinylcholine as paralytic agent were administered (more details are presented in Figs. 1 and 2).

Heart rate (HR) and MAP were evaluated 4 times as follows: before intubation, exactly after intubation, and 5 and 10 min after intubation.

2.2. Statistical analysis

For data analysis, we first evaluated the normality of data using Kolmogorov-Smirnov sample test with lilliefor's correct. Then, for normal data, we used student *t*-test and if data were non-normal, we used the Mann-Whitney and Wilcoxon tests. We also used Chi-Square test for analyzing data with nominal scale and Fisher's Exact Test in cases, where >20% of the expected frequencies in tables were <5 [18]. We performed the statistical analysis using the SPSS package (version 16, SPSS, Chicago, IL) and p-value < 0.05 was considered significant.

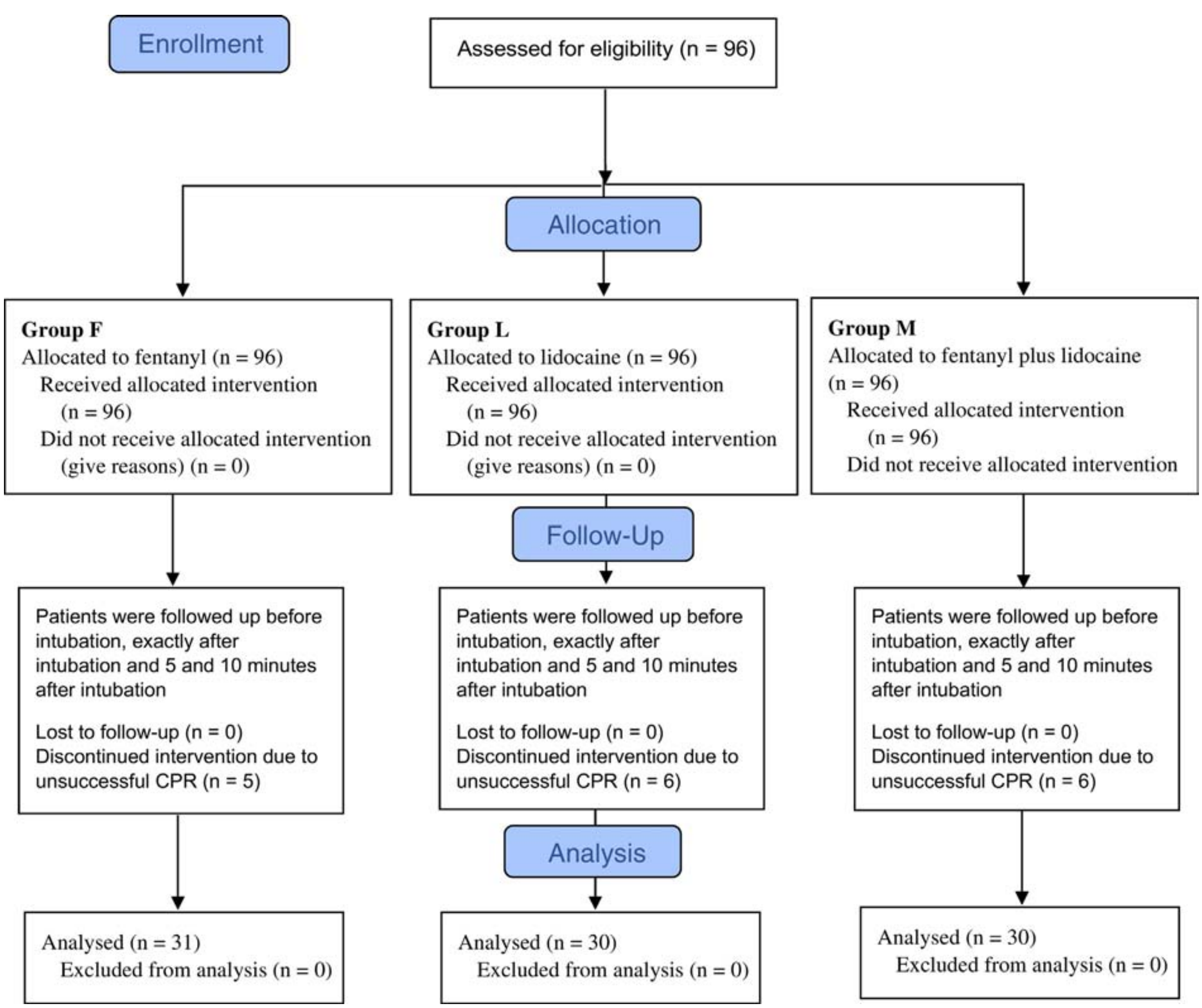

Fig. 1. CONSORT 2010 flow diagram.

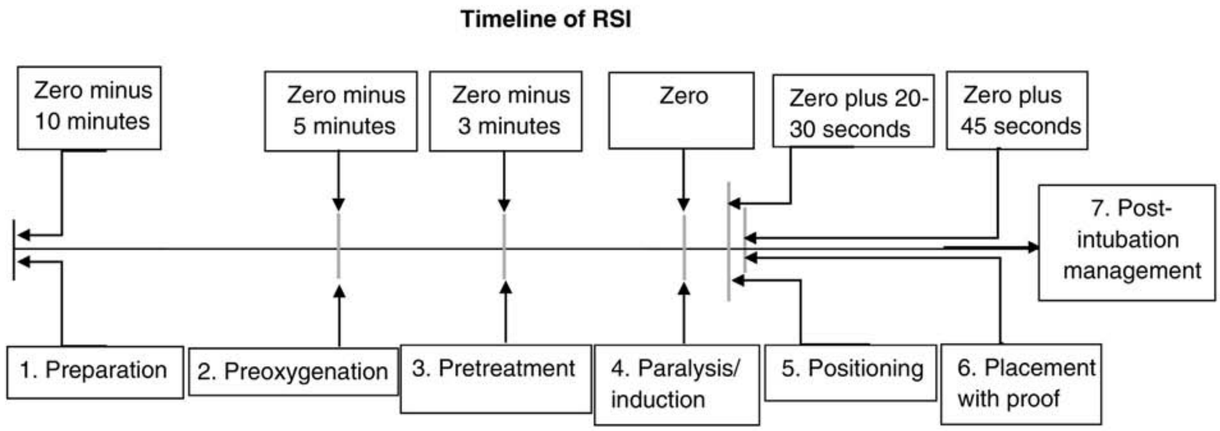

Fig. 2. Rapid Sequence Intubation (RSI): medications, dosages and recommendations. 1. Preparation - assemble all necessary equipment, drug, etc. 2. Preoxygenation - replace the nitrogen in the patient's functional reserve with oxygen –"nitrogen wash out - oxygen wash in" 3. Pretreatment - ancillary medications (e.g., 3 μgr/kg fentanyl, 1.5 μgr/kg lidocaine) are administered to mitigate the adverse intubation 4. Paralysis with induction - administer sedative induction agent (e.g., 0.3 mg/kg etomidate) via IV push, followed of paralytic (e.g., 1.5 mg/kg succinylcholine) via IV push 5. Positioning - position patient for optimal laryngoscopy; Sellick's maneuver, if desired, is applied now 6. Placement with proof - asses mandible for flaccidity; perform intubation, confirm placement 7. Post-intubation management - long-term sedation/analgesia/paralysis as indicated.

3. Results

Five out of 96 patients were withdrawn from the study because of protocol violations. We examined 91 patients, including 55 (60.44%) males with the mean age of 68.74 ± 17.40 years. Chi-square test presented no significant difference regarding sex, age, background history, disorders leading to intubation and corrected Q-T interval (QTc) between groups (Table 1). The baseline hemodynamic characteristics were similar between the three groups ($p > 0.05$) (Table 2).

We evaluated MAP and HR before intubation, immediately after intubation and 5 and 10 min after intubation. MAP and HR were significantly different in group F ($p < 0.05$). These variables increased immediately after intubation, but then decreased even less than primary level. MAP oscillation amplitude in L and M groups were irregular and more limited than group F. Alteration of HR and MAP were not significant when were evaluated between different states in the L group, and also was not notably different in group M ($p > 0.05$). MAP showed no significant difference between the four states in all groups compared with the control group ($p > 0.05$). On the other hand, comparing HR between different states in all groups to the control group, showed significance changes ($p < 0.05$). MAP and HR fluctuations in both F and L demonstrated no substantial differences compared with the baseline ($p > 0.05$).

Table 1
Baseline data of the three groups fentanyl (F), lidocaine (L), and fentanyl plus lidocaine (M).

Characteristics	Group F (N = 91)	Group L (N = 90)	Group M (N = 90)
Age[a] (years)	70.76 ± 15.43	68.90 ± 13.86	66.53 ± 17.72
Gender	31 (34.07%)	30 (32.97%)	30 (32.97%)
Male (%)	20 (64.51%)	16 (53.33%)	19 (63.33%)
Female (%)	11 (35.48%)	14 (46.67%)	11 (36.67%)
PMH[1]			
Diabetes	4	5	6
Cardiovascular diseases	6	3	5
Hypertension	4	5	4
Chronic pulmonary disease	2	3	2
Cancer	1	2	2
Stroke	1	1	2
Liver cirrhosis	1	1	0
Chronic kidney disease	0	1	0
Clinical disorders leading to intubation			
Respiratory distress	10	10	12
Aspiration	2	2	1
Decreased consciousness	16	14	9
Pulmonary edema	3	4	3
QTc[a,2] (s)	0.36 ± 0.16	0.42 ± 0.13	0.40 ± 0.11

No statistically significant difference was found between the groups' baseline characteristics using the Chi-square test. $p < 0.05$ denotes significance.
[a] Data are expressed as mean ± standard deviation (SD).
[1] PMH: Past Medical History.
[2] QTc: Corrected Q-T Interval.

4. Discussion

This nonrandomized, double-blind clinical trial set out to evaluate and compare the efficacy of intravenous fentanyl and lidocaine in minimizing undesirable hemodynamic stress responses (MAP and HR) following endotracheal intubation.

Our findings indicate that fentanyl (3 μgr/kg) caused more variations in MAP and HR and showed more vigor to decrease during four distinct time courses. Nevertheless, lidocaine (1.5 mg/kg) showed more ability to control the hemodynamic changes and prevent HR and MAP from exorbitance increase.

In those studies, no drugs have been used to prevent sympathetic response following intubation, yet maximum hemodynamic fluctuations are observed which is significantly high in comparison with the preinjection values [6]. Attenuation of such changes in cardiovascular responses is vital in the prevention of the perioperative mortality and morbidity [6,19]. A variety of drugs are used while performing an emergency intubation. However, the selection criteria for the suitable medicine is to inhibit sympathetic response and in any study it must be as follows: Regardless of patient's collaboration, the drug must keep patient from the arousal, prevent the impairment of the cerebral blood flow, and it must be applicable too. On the other hand, drug administration should neither influence the duration or modality of the following anesthesia; nor should it be time consuming. Intravenous fentanyl appears to best fulfil these criteria [6,20]. Intravenous lidocaine blunts the increase of HR and blood pressure associated with laryngoscopy and endotracheal intubation [21,22]. Due to this beneficial property, we examined lidocaine solely, and as a supplement to fentanyl for the attenuation of hemodynamic changes after the intubation. Furthermore, we selected the optimal mean age of 68.74 years. This is due to the fact that HR fluctuations decrease as subjects age, and younger subjects demonstrated more severe changes [6].

The cardiovascular problems which occur pursuant to sympathetic and sympathoadrenal reflexes, they are the common complications of intubation [23]. Different kinds of drugs and chemicals are usually used to decrease these complications. α-2 adrenergic agonists are one of the type, that reduce the hemodynamic changes and decrease the

Table 2
Intergroup and intragroup hemodynamic variables changes between groups fentanyl (F), lidocaine (L), and fentanyl plus lidocaine (M) in four time points.[a,b]

Hemodynamic Characteristics	Groups	Before intubation	Right after intubation	5 min after intubation	10 min after intubation
HR[1] (b.p.m.)	F*	98.16 ± 26.95	106.00 ± 35.55	93.68 ± 28.57	90.65 ± 23.46
	L	94.53 ± 26.74	95.80 ± 30.72	94.50 ± 33.47	93.93 ± 23.52
	M	99.87 ± 34.79	97.03 ± 33.60	96.73 ± 32.21	98.30 ± 28.39
	p-Value**: 0.036				
MAP[2] (mm Hg)	F*	87.97 ± 18.54	91.74 ± 18.95	85.61 ± 14.17	84.74 ± 15.09
	L	88.10 ± 13.86	87.90 ± 12.59	88.33 ± 13.13	88.37 ± 11.49
	M	85.33 ± 20.26	86.40 ± 19.30	83.93 ± 15.97	88.33 ± 13.13
	p-Value: 0.314				

[a] Data are expressed as mean ± SD.
[b] Sphericity assumed test was applied for all comparisons.
* Denotes significance in different states in each group ($p < 0.05$).
** Denotes significance in different states in all groups ($p < 0.05$).
[1] Heart Rate.
[2] Mean Arterial Pressure.

requirement for anesthetics. Admixture of fentanyl and lidocaine is commonly used in emergency intubation [24,25]. Lidocaine (a local anesthetic) acts by blocking the initiation and conduction of pain signals to brain. The mechanism is to close the Na^+ channels and prevent the signals from reaching the postsynaptic cell. This chemical does the same function in the heart and increases the chance of arrhythmia by blocking the sodium channels. In addition, an elevated threshold of airway stimulation causes direct depression of cardiovascular responses, and central inhibition of sympathetic transmission, which apparently suppresses sympathetic response associated with endotracheal stimulation [26]. Lidocaine begins to act a few minutes after the injection and its effects last up to 3 h. Fentanyl (opioid) is one of the other chemicals which is used to suppress the hemodynamic alterations by increasing the depth of anesthesia and diminishing the sympathetic discharge [2,8, 23,27-29].

Similar to our study, some presented that, in subjects whom were administered with fentanyl, the increase in HR was maximum immediately after laryngoscopy and intubation ($p < 0.001$) [6,30,31]. Also, our findings further support the results of several other investigators; who illustrated that lidocaine can solely acts as an effective suppressor of reflex tachycardia and hypertension in response to intubation of patients who have undergone general anesthesia [6,10]. In addition, the present study is in accordance with several previous studies providing that lidocaine (1.5 mg/kg) stabilizes the changes in arterial blood pressure; HR; and cardiac output, while maintaining intraoperative and postoperative hemodynamic changes. These beneficial effects are possibly due to the fact that lidocaine acts as a vasodilator, direct myocardial depressant and influences synaptic transmissions [11,32]. In line with this research, some researchers indicated that intravenous lidocaine in the dosage of 1.5 to 2 mg/kg prevents the rise in HR and MAP following intubation, when injected from the fifth to the second minute before laryngoscopy [26,33,34].

Our results differ from some previous studies. Malde and Sarode [35] carried out a study on 90 patients, aged between 18 and 65 years old. They assessed the difference between the effect of lidocaine (1.5 mg/kg) and fentanyl (2 μg/kg) on hemodynamic stability, and revealed that they both attenuate the rise in HR. However, the effect of fentanyl produced more reliable results. They also demonstrated that lidocaine attenuated the rise in blood pressure while fentanyl inhibits it totally [35]. This result may be explained by the fact that the blocking of the sympathetic response is of dose dependent. Fentanyl at 6 μg/kg, totally abolishes, while at 2 μg/kg, it significantly attenuates the arterial pressure and the HR elevation during laryngoscopy and intubation. Administration of fentanyl at the optimal time diminishes the required dose. The optimal time of fentanyl injection is 5 min prior to intubation, at a dose of 2 μg/kg [6].

In contrast to our study, Splinter et al. studied 150 geriatric cases and observed no difference between lidocaine (1.5 mg/kg) and low-dose fentanyl (1.5 and 3 μg/kg) as suitable adjuncts to anesthesia with thiopentone. This diversity of findings may result from the fact that the optimal time of injection for geriatrics is unknown. However, in younger cases, relatively 3 min before intubation was detected as an advantageous time to inject intravenous lidocaine [11]. In addition, HR fluctuations are less likely to occur with increase in age, while younger patients show more severe changes [6]. Miller et al. [36] showed that lidocaine (1.5 mg/kg) given intravenous within 3 min of laryngoscopy, failed to reduce the cardiovascular responses, following laryngoscopy, and intubation. This practice differs from the findings presented here. Others have found that both 1.5 and 3 μg/kg of fentanyl 4 min before intubation will effectively attenuated both BP and HR increases [11,37]. Sameenakousar et al. allocated 50 patients to receive fentanyl (2 μg/kg) and examined its effects on hemodynamic variables. They found that fentanyl could not notably diminish hemodynamic parameters at 10 min. But with a larger sample size, they might have demonstrated a significant difference [6]. Helfman et al. noticed that only esmolol (2.14 mg/kg) has provided consistent and reliable protection against HR increases. Lidocaine (2.86 mg/kg) and fentanyl (2.86 μg/kg) have failed to protect against HR increases [38].

4.1. Limitations

Our findings may be somewhat limited by the following factors, such as a low number of subjects ($n = 91$) that might have been contributed to the reduced statistical power of some results. Another potential concern is the use of matched controls. Although matched patients were selected with a control group similar in age, gender, and comorbidities to assess a more homogenous population, yet a potential selection bias might have been introduced. This is a multi-operator investigation, whereby the experience of the anesthetists could have affected the process of laryngoscopy and intubation. Furthermore, we evaluated the effect of fentanyl and lidocaine right after intubation, and 5 and 10 min after intubation. However, considering the duration of time within 10 min after intubation would lead to more definite results. The changes in electrical heart function, and also depth of anesthesia weren't assessed. We didn't have a control group receiving no drug due to limitations of research ethics. On the other hand, despite trying to take various exclusion criteria to minimize confounding variables role, lack of cooperation of some patients caused their histories of study to be incomplete. Finally, since this was a single-center study, our results may not be easily applicable to other settings.

4.2. Future studies

It is suggested that future studies, taking the above limitations into account, investigate and review the effects of different doses of fentanyl and lidocaine on hemodynamic stability after intubation, in order to determine the best dosage to administrate.

5. Conclusions

The result of this study shows that fentanyl leads to hemodynamic fluctuations right after intubation, plus 5 and 10 min after intubation. On the other hand, lidocaine effectively prevents MAP and HR fluctuations following endotracheal intubation at these time points. Therefore, lidocaine can terminate hemodynamic changes and maintain the baseline conditions of the patient after endotracheal intubation.

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