Original article

A comparative study of efficacy and safety of esmolol versus dexmedetomidine for attenuation of cardiovascular response to laryngoscopy and endotracheal intubation

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Abstract:

Introduction- Laryngoscopy and intubation procedure enhance sympathetic activity that causes rise of heartrate (HR), blood pressure and occasional disturbance in cardiac rhythm. This hemodynamic changeshave detrimental effects to patients. We try to comparethe role of dexmedetomidine and esmolol for prevention of this response.

Methods- A total84 patients between 18-45 years of either sex with weight 50-90 kgs, had ASA (American Society of Anaesthesiologists) physical status I or II, scheduled to have elective surgery under general anaesthesia were included in this study. Patients were randomly allocated into two groups, and received either dexmedetomidine 1 microgram /kg (group D) or esmolol0.5 mg/kg (group E).

Efficacy parameters - Heart rate , systolic blood pressure, diastolic blood pressure, and mean arterial pressure were recorded prior to intubation , at time of intubation and 1, 3, 5, and 10 minutes after intubation.

Observations and results –Ingroup D, there was no statistically significant increase in HR, systolic, diastolic, mean blood pressure at any time period during the study, whereas in group E, there was a statistical significant increase in diastolic blood pressure, and mean blood pressure after intubation. No adverse effect was observed in both group.

Conclusion: Dexmedetomidine 1 μg/kg is more effective than esmolol 0.5 mg/kg for attenuating the hemodynamic response to laryngoscopy and intubation in elective surgical patients.

Key words *:* dexmedetomidine ,esmolol , intubation

Introduction

Although new airway devices are available,but rigid laryngoscopy and tracheal intubation still remain the gold standard in airway management during general aneaesthesia. [1] Laryngoscopy and endotracheal intubation violate the patient's protective airway reflexes, which increase the release of catecholamines by stimulating the sympathetic nervous system - results hemodynamic changes associated with increased heart rate (HR), increased blood pressure (BP) and occasional disturbance in cardiac rhythm. [2,3 , 4, 5]

These hemodynamic changes are maximum at 1 minute after intubation and lasts for 5-10 minutes.[6]

The rise in the HR and BP is usually transient, variable and unpredictable. Usually these changes are well tolerated by healthy individuals. But in patients with cardiovascular diseases this hemodynamic changes may lead to life threatening complications (myocardial ischemia, acute heart failure and

cerebro-vascular accidentsetc). Convulsions may be precipitated in pre-eclamptic patients. [1]

Several strategies have been used to blunt this hemodynamic response, but each method has its own advantages and disadvantages. Many drugs have been used to attenuate hemodynamic responses to laryngoscopy and intubation. Lidocaine, α and β adrenergic blockers, calcium-channel blockers, sodium nitroprusside, nitroglycerine and opioids have been used to prevent those responses, but their side effects like increased sedation, difficulty in coughing and swallowing, limit their use. [1, 4, 7, 8]

Searching a better drug that will be more efficacious and better tolerated, is a continuous process in medical science. Research is still going on for attenuation of pressor response to laryngoscopy and intubation. Among beta blockers, esmolol is an ultra-short acting, β-1 adrenergic blocker. It has rapid onset and short duration of action. In clinical trials, it is seen that, esmolol is a suitable drug to attenuate the hemodynamic responses to laryngoscopy and intubation without several side effects. [4, 9] Clonidine is an alpha (α)‑2adrenoreceptor agonists inhibitscentral sympathetic outflow and decreases hemodynamic response to stressful events like laryngoscopy and endotracheal intubation. [10, 11]

Dexmedetomidine is anewer highly selective α-2adrenergic receptor agonist (α2 : α1 - 1620: 1), is more effective α-2agonist than clonidine (α2: α1 - 220: 1). In addition, dexmedetomidine is faster acting than clonidine. Some studies have reported that dexmedetomidine reduces hemodynamic changes during anesthetic induction and surgery. [5, 12]

However, there is lack of clinical trials showing comparison between esmolol and dexmedetomidine as attenuating agent for cardiovascular response due to laryngospopy and endotracheal intubation. On this background, the study was conducted to compare the efficacy and safety of esmolol versus dexm-edetomidine for attenuation of cardiovascular response to laryngoscopy and endotracheal intubation.

Aims and objectives

Primary objective

 To assess the efficacy of esmolol in comparison to dexmedetomidine for attenuation of cardiovascular response to laryngoscopy and endotracheal intubation.

Secondary objective

 To assess the safety of esmolol in comparison to dexmedetomidine for attenuation of cardiovascular response to laryngoscopy and endotracheal intubation.

Methodology

A Prospective, interventional, parallel, randomized, double-blinded, unicentric clinical trial was conducted from July, 2014 to August 2014 in general surgery operation theatre of a tertiary teaching hospital. The study was conducted as student STS (short term studentship) project of Indian Journal Medical Research ,2014.

The study protocol, informed consent form (in Bengali, Hindi & English) and case report form (CRF) were submitted to the Institutional Ethics Committee (IEC) of College of Medicine & JNM Hospital, Kalyani for approval.

After obtaining institutional ethics committee's approval, total 84patients between 18-45 years of either sex with weight 50-90 kgs, had ASA (American Society of Anaesthesiologists) physical status I or II, scheduled to have elective surgery under general anaesthesia were included in this trial. On the other hand known hypertensive patients (BP> 140/90 mm Hg), patients with difficult airway;

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laryngoscopy and intubation time more than 15 seconds, or requiring more than two attempts,patients with history of cardiovascular illness, neuromuscular or hematological disorders , history of other systemic illness (hepatic or renal disease, respiratory illness, diabetes mellitus, diabetic neuropathy, etc.) , patients on beta blockers, alfa-2 agonist or in chronic medication , allergy to study drugs and pregnant mothers were excluded from the study.

After obtaining written informed consent, the patients were randomly (computer generated randomization schedule) allocated into one of the two groups. Blinding was done using the SNOSE (sequentially numbered opaque sealed envelope) technique. Patients were received either esmolol 0.5 mg/kg body weight diluted with 0.9% normal saline to 10 ml intravenously (I.V.) [**Group E**] or dexmedetomidine 1mcg/kg body weight diluted with 0.9% normal saline to 10 ml I.V. [**Group D**].

Patients were fasting for 8 hours prior to surgery, and did not receive preanaesthetic medication.

In group E, 10 ml of 0.9% saline was infused for 10 minutes (infusion being started at 1st minute). After 7 minutes of infusion, 0.5 mg/kg of esmolol (at 7th minute; diluted with 0.9% saline to 10 ml) was given in 30 seconds.

In group D, 1 mcg/kg body weight dexmedetomidine (diluted with 0.9% saline to 10 ml) was administered for 10 minutes (infusion being started at 1st minute). After 7 minutes of infusion, 10 ml of 0.9% saline was administered in 30 seconds.

Patients were pre-oxygenated with 100% 0_2 by a facemask for 3 minutes. Induction was done with sleeping dose of inj. thiopentone at 8^{th}minute and muscle relaxation was achieved by succinylcholine at a dose of 1-2 mg/kg at 9^{th}minute. 60seconds later the patient was intubated using a Macintosh laryngoscope (at 10^{th} minute). All intubations were done by the same experienced anaesthesiologist.

Anaesthesia was maintained with nitrous oxide: oxygen= 2:1 and vecuronium 0.1mg/kg.

Noninvasive blood pressure (NIBP), attached for monitoring the Heart rate (HR), systolic, diastolic, and mean arterial blood pressure (SBP,DBP,MAP) prior to induction, at time of intubation and 1, 3, 5, and 10 minutes after intubation. Electrocardiography (ECG) and pulse oximetry were attached to monitor ECG changes and oxygen saturation (SpO2).

Assessment parameters

Efficacy parameters –HR**,** MAP, SBP, DBP

Safety parameters- ECG, any adverse events like bradycardia, hypotension, arrhythmias etc.

Statistical Analysis

Statistical analysis was done only after the completion of case report form of the last subject.

Data were represented as mean ± S.E.M (standard error mean). Categorical data were compared between groups by Chi-Square ($\chi 2$) test. Baseline parameters between the groups are assessed by unpaired t test. As the data could not pass the normality test, numerical data between the groups were analyzed Mann-Whitney U test (nonparametric) test, whereas within the group were analyzed by Friedman's ANOVA (nonparametric) followed by Dunn's Multiple Comparison test as post hoc test. All analyses were two-tailed and $p < 0.05$ was taken to be statistically significant. The analysis was performed by using graph pad-instat-3 software.

Observations and results

Eighty four (42 in each group) patients were randomized during the period of July, 2014 to August 2014. All patients were selected from general surgery only. But 68 patients (34 in each group) were

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completed the study. Eight (8) subjects in each group were not complete the study (difficult intubation and time required for intubation was more than 15 seconds) were declared as dropout.

The subjects of both groups had comparable demographic profile, laboratory parameters and baseline efficacy parameters [table 1].

There was no significant changes of SBP in group D over different time points,compare to the baseline, the same result was seen in group E also [table 2, table 3].

There was also no significant difference of SBP was seen when both group D and group E were compared in different time periods. [table 4]

There was no significant changes of DBP in group D were seen in different time points, compare to the baseline [table 5].But in group E, there was significant rise of DBP during intubation and 1 minute after intubation (compare to the baseline) [table 6].

When both group D and group E were compared in different time periods, there were significant rise of DBP in group E during intubation (p-0.0009),1 minute after intubation (p 0.0014), 3 minute after intubation (p 0.04), 5 minutes and 10 minutes after intubation (p 0.024 , p 0.03 respectively) [table 7].

There was no significant changes of MAP in group D and group E over different time points, compare to the baseline of individual group [table 8, table 9].

When MAP were compared between D and group E in different time periods, there was significant rise of MAP of group E 1 min after intubation [p 0.009]. [table 10]

There was no significant changes of HR in group D and group E over different time periods compared to the individual group [table 11, table 12],there also no significant difference between group D and group E in different time periods [table 13].

There was no adverse effect like hypotension, bradycardia was seen in both groups.

Discussion

Laryngoscopy and endotracheal intubation are associated with rise of HR, BP and occasional disturbance in cardiac rhythm. [2,3] Although in normotensive subjects, these responses of BP and HR are transient and short lived, but they may prove to be detrimental in high risk patients especially in those with cardiovascular disease, increased intracranial pressure and anomalies of the cerebral blood vessels. [13]So, effective attenuation of hemodynamic response to laryngoscopy and tracheal intubation is of great importance in prevention of perioperative morbidity and mortality.

This randomized, double-blind, parallel study was undertaken to compare the efficacy and safety of two drugs - esmolol and dexmedetomidine in attenuation of the hemodynamic responses following laryngoscopy and endotracheal intubation.

The subjects of both groups had comparable demographic profile, laboratory parameters and baseline efficacy parameters.

It was seen that in both group SBP was stable, although there was rise of DBP in group D compared to group E. Significant rise of MAP is also seen in group E (1 min after intubation).

There was no significant changes of HR in group D and group E over different time periodsThere was no adverse effect like hypotension, bradycardia was seen in both groups.

So this study can inform that both dexmedotomidine (Group D) and esmolol (group E) are effective to attenuate the rise of BP and HR during laryngoscopy and intubation without any adverse effect,

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butdexmedetomidine is better choice than esmolol in that context. This result correlate with recently published trials also.

This result correlates with one study which is published in 2014. In that study it is seen that both dexmedetomidine (1 mcg/kg body weight) and esmolol(2 mg/kg body weight) drugs are effective to suppress the pressure response. Of the two drugs administered, dexmedetomidine provides a consistent, reliable and effective when compared to esmolol.[14]

In a studyon comparative evaluation of dexmedetomidine and esmolol on hemodynamic responses during laparoscopic cholecystectomy, it was seen thatdexmedetomidine (loading dose 1 mcg/kg over a period of 15 min and maintenance 0.5 mcg/kg/h throughout the pneumoperitoneum)is more effective than esmolol (loading dose 1 mg/kg over a period of 5 min and maintenance 0.5 mg/kg/h throughout the pneumoperitoneum)for attenuating the hemodynamic response to pneumoperitoneum in elective laparoscopic cholecystectomy.[15]

In another study on Comparative evaluation of esmolol and dexmedetomidine for attenuation of sympathomimetic response to laryngoscopy and intubation in neurosurgical patients,it was observed that dexmedetomidine 1 mcg/kg is is more effective than esmolol 1.5 mg/kg for attenuating the hemodynamic response to laryngoscopy and intubation in elective neurosurgical patients. [16]

Recently in a study, the effect of Dexmedetomidine versus Esmolol on attenuation of stress response to endotracheal intubation in patients undergoing elective off pump Coronary artery bypass grafting, it is observed that Dexmedetomidine (0.5 microgram/kg) provides more sustained hemodynamic stability than Esmolol (2 mg/kg).[17]

The present study had some limitation like, the study did not include placebo group, it is impossible to determine absolute level of efficacy,higher dose groups were not included in this study, drug concentration was not measured, the efficacy parameters were observational, follow up was not done after 10 minutes after intubation.

Conclusion

Although both dexmedotomidine and esmolol are effective to attenuate cardiovascular responses due to laryngoscopy and intubation, but it can be said that dexmedetomidine 1 mcg/kg body weight has been found to provide better hemodynamic stability than esmolol 0.5 mg /kg body weight, when prescribed before laryngoscopy and endotracheal intubation. Both dexmedetomidine(1 mcg/kg) and esmolol (0.5 mg/kg) have no side effect.

Table 1. Comparison of demographic, laboratory and baseline efficacy parameters

PARAMETERS	GROUP D (N= 34)	GROUP E (N=34)	p VALUE
Demographic parameters			
Age (years)	33.44 ± 2.69	41.75 ± 4.42	0.12
Sex (M:F)	7:10	8:9	0.8
Weight (Kg)	52.77 ± 1.64	48.5 ± 2.87	0.19
Height (cm)	160.33 ± 1.9	164.33 ± 1.9	0.82
ASA grade (I : II)	14:3	13:4	0.76

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Laboratory parameters			
Hemoglobin (gm %)	12.03 ± 0.31	11.07 ± 0.33	0.09
Total leukocyte count	6363.22 ± 273.78	7512.5 ± 913.41	0.13
FBS (mg/dl)	92.44 ± 4.1	80.75 ± 4.58	0.11
PPBS (mg/dl)	120.11± 4.99	120.75 ± 3.66	0.93
Urea (mg/dl)	25.44 ± 1.65	26.5 ± 1.7	0.71
Creatinine (mg/dl)	0.53 ± 0.04	0.55 ± 0.09	0.85
Efficacy parameters			
HR (beats/min)	84.11± 2.93	86.5 ± 4.7	0.66
SBP (mm of Hg)	123.11 ± 1.2	125.2 ± 0.96	0.26
DBP (mm of Hg)	82.66 ± 0.91	84.2 ± 0.66	0.27
MAP (mm of Hg)	94.88 ± 3.01	98.5 ± 1.5	0.46
SPO_2 (%)	99.56 ± 0.24	99.75 ± 0.25	0.63

Data are presented as mean ± standard error of mean (SEM).

FBS / PPBS- fasting / post prandial blood sugar.

p value of categorical data (sex, ASA grade) of two groups were by Chi-Square ($\chi 2$) test, whereas p value of other parameters were by unpaired t test, considering $p < 0.05$ is significant.

Table 2: Shows sbp in various time periods of group D

SBP	**Mean ± SEM**	**p value**
Baseline (SBP B)	123.11 ± 1.2	
During intubation (SBP D)	133.11 ± 6.4	p >0.05
1 min after intubation (SBP 1)	135.88 ± 2.84	p >0.05
3 min after intubation (SBP 3)	127.88 ± 3.01	p >0.05
5 min after intubation (SBP 5)	123.55 ± 3.75	p >0.05
10 min after intubation (SBP 10)	121.55 ± 3.11	p >0.05

Statistical analysis for comparisons of SBP within the group (with baseline comparison) were performed by nonparametric Friedman's ANOVA (p value >0.05, so post-hokanalysis by Dunn multiple comparison test was not performed). p value <0.05 considered significant different with baseline.

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Table 3: Shows SBP in various time periods of group E

SBP	Mean ± SEM	p value
Baseline (SBP B)	125.2 ± 0.96	
During intubation (SBP D)	133.8 ± 0.73	p > 0.05
1 min after intubation (SBP 1)	136.2 ± 0.81	p > 0.05
3 min after intubation (SBP 3)	134.4 ± 2.06	p > 0.05
5 min after intubation (SBP 5)	133.4 ± 2.24	p > 0.05
10 min after intubation (SBP 10)	129.4 ± 2.5	p > 0.05

Statistical analysis for comparisons of SBP within the group (with baseline comparison) were performed by nonparametric Friedman's ANOVA (p value >0.05, so post-hokanalysis by Dunn multiple comparison test was not performed). p value <0.05 considered significant different with baseline.

Table 4: shows SBP comparison between group D and group E in various time periods

SBP	GROUP D (Mean ± SEM)	GROUP E (Mean ± SEM)	p value
Baseline (SBP B)	123.11 ± 1.2	125.2 ± 0.96	0.26
During intubation (SBP D)	133.11 ± 6.4	133.8 ± 0.73	0.93
1 min after intubation (SBP 1)	135.88 ± 2.8	137.6 ± 0.81	0.67
3 min after intubation (SBP 3)	127.88 ± 3.01	134.4 ± 2.06	0.16
5 min after intubation (SBP 5)	123.55 ± 3.75	133.4 ± 2.24	0.09
10 min after intubation (SBP 10)	121.55 ± 3.11	129.4 ± 2.5	0.11

Statistical analysis for comparisons of SBP between group D and group E were performed by nonparametric Mann-Whitney U test. p value <0.05 considered significant.

Table 5: shows DBP in various time periods of group D

DBP	GROUP D (Mean ± SEM)	p value
Baseline (DBP B)	82.66 ± 0.91	
During intubation (DBP D)	86.55 ± 0.72	p >0.05
1 min after intubation (DBP 1)	87 ± 0.81	p >0.05
3 min after intubation (DBP 3)	85.33 ± 1.58	p >0.05
5 min after intubation (DBP 5)	83.22 ± 1.14	p >0.05
10 min after intubation (DBP 10)	81.55 ± 0.94	p >0.05

Statistical analysis for comparisons of DBP within the group (with baseline comparison) were performed by nonparametric Friedman's ANOVA (p value >0.05, so post-hok analysis by Dunn multiple comparison test was not performed). p value <0.05 considered significant different with baseline.

Table 6: shows DBP in various time periods of group E

DBP	GROUP E (Mean ± SEM)	P value
Baseline (DBP B)	84.2 ± 0.66	
During intubation (DBP D)	95.8 ± 2.59*	p < 0.05
1 min after intubation (DBP 1)	97.4 ± 3.14**	p < 0.01
3 min after intubation (DBP 3)	91± 1.92	p > 0.05
5 min after intubation (DBP 5)	88.6 ± 1.93	p > 0.05
10 min after intubation (DBP 10)	86.2 ± 2.1	p > 0.05

Statistical analysis for comparisons of DBP within the group (with baseline comparison) were performed by nonparametric Friedman's ANOVA followed by post-hokanalysis by Dunn multiple comparison test.
p value <0.05 considered significant different with baseline.

Table 7: shows DBP comparison between group d and group E in various time periods

DBP	GROUP D (Mean ± SEM)	GROUP E (Mean ± SEM)	p value
Baseline (DBP B)	82.66 ± 0.91	84.2 ± 0.66	0.27
During intubation (DBP D)	86.55 ± 0.72	95.8 ± 2.59	0.0009
1 min after intubation (DBP 1)	87 ± 0.81	97.4 ± 3.14	0.0014
3 min after intubation (DBP 3)	85.33 ± 1.58	91 ± 1.92	0.04
5 min after intubation (DBP 5)	83.22 ± 1.14	88.6 ± 1.93	0.024
10 min after intubation (DBP 10)	81.55 ± 0.94	86.2 ± 2.1	0.03

Statistical analysis for comparisons of DBP between group D and group E were performed by nonparametric Mann-Whitney U test. p value <0.05 considered significant different with baseline.

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Table 8: shows MAP in various time periods of group D

MAP	GROUP D (Mean ± SEM)	p value
Baseline (MAP B)	96.14 ± 0.85	
During intubation (MAP D)	103.37 ± 1.62	p >0.05
1 min after intubation (MAP 1)	103.29 ± 1.37	p >0.05
3 min after intubation (MAP 3)	99.52 ± 1.73	p >0.05
5 min after intubation (MAP 5)	99.18 ± 2.98	p >0.05
10 min after intubation (MAP 10)	94.88 ± 1.58	p >0.05

Statistical analysis for comparisons of MAP within the group (with baseline comparison) were performed by nonparametric Friedman's ANOVA (p value >0.05, so post-hokanalysis by Dunn multiple comparison test was not performed). p value <0.05 considered significant different with baseline.

Table 9: shows MAP in various time periods of group E

MAP	GROUP D (Mean ± SEM)	p value
Baseline (MAP B)	97.5 ± 0.61	
During intubation (MAP D)	109.16 ± 1.72	p >0.05
1 min after intubation (MAP 1)	111.33 ± 2.36	p >0.05
3 min after intubation (MAP 3)	105.75 ± 2.13	p >0.05
5 min after intubation (MAP 5)	104.33 ± 2.05	p >0.05
10 min after intubation (MAP 10)	101.16 ± 2.11	p >0.05

Statistical analysis for comparisons of MAP within the group (with baseline comparison) were performed by nonparametric Friedman's ANOVA (p value >0.05, so post-hok analysis by Dunn multiple comparison test was not performed). p value <0.05 considered significant different with baseline.

Table 10: shows MAP comparison between group D and group E in various time periods

MAP	GROUP D (Mean ± SEM)	GROUP E (Mean ± SEM)	P value
Baseline (MAP B)	96.14 ± 0.85	97.5 ± 0.61	0.34
During intubation (MAP D)	103.37 ± 1.62	109.16 ± 1.72	0.05
1 min after intubation (MAP 1)	103.29 ± 1.37	111.33 ± 2.36	0.009*
3 min after intubation (MAP 3)	99.52 ± 1.73	105.75 ± 2.13	0.06
5 min after intubation (MAP 5)	99.18 ± 2.98	104.33 ± 2.05	0.3
10 min after intubation (MAP 10)	94.88 ± 1.58	101.16 ± 2.11	0.05

Statistical analysis for comparisons of MAP between group D and group E were performed by nonparametric Mann-Whitney U test. p value <0.05 considered significant.

Table 11: shows HR in various time periods of group D

Heart Rate (HR)	Mean ± SEM	p value
Baseline (HR B)	84.11 ± 2.93	
During intubation (HR D)	89 ± 3.15	p >0.05
1 min after intubation (HR 1)	96 ± 6.19	p >0.05
3 min after intubation (HR 3)	90.55 ± 6.02	p >0.05
5 min after intubation (HR 5)	90.77 ± 4.47	p >0.05
10 min after intubation (HR 10)	86.66 ± 3.39	p >0.05

Statistical analysis for comparisons of HR within the group (with baseline comparison) were performed by nonparametric Friedman's ANOVA (p value >0.05, so post-hok analysis by Dunn multiple comparison test was not performed). p value <0.05 considered significant different with baseline.

Table 12: Shows HR in various time periods of group E

Heart Rate (HR)	Mean ± SEM	p value
Baseline (HR B)	86.5 ± 4.78	
During intubation (HR D)	95.25 ± 6.93	p >0.05
1 min after intubation (HR 1)	98.75 ± 5.67	p >0.05
3 min after intubation (HR 3)	97.5 ± 8.83	p >0.05
5 min after intubation (HR 5)	89 ± 6.68	p >0.05
10 min after intubation (HR 10)	88.5 ± 5.12	p >0.05

Statistical analysis for comparisons of HR within the group (with baseline comparison) were performed by nonparametric Friedman's ANOVA (p value >0.05, so post-hokanalysis by Dunn multiple comparison test was not performed). p value <0.05 considered significant different with baseline.

Table 13: shows HR comparison between group D and group E in various time periods

Heart Rate (HR)	GROUP D (Mean ± SEM)	GROUP E Mean ± SEM	p value
Baseline (HR B)	84.11 ± 2.93	86.5 ± 4.78	0.66
During intubation (HR D)	89 ± 3.15	95.25 ± 6.93	0.35
1 min after intubation (HR 1)	96 ± 6.19	98.75 ± 5.67	0.79
3 min after intubation (HR 3)	90.55 ± 6.02	97.5 ± 8.83	0.53
5 min after intubation (HR 5)	90.77 ± 4.47	89 ± 6.68	0.82
10 min after intubation (HR 10)	86.66 ± 3.39	88.5 ± 5.12	0.77

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Statistical analysis for comparisons of HR between group D and group E were performed by nonparametric Mann-Whitney U test. p value < 0.05 considered significant.

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