

A COMPARATIVE CLINICAL STUDY BETWEEN IV ESMOLOL AND IV FENTANYL ON ATTENUATION OF HAEMODYNAMIC RESPONSES TO LARYNGOSCOPY AND INTUBATION

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ABSTRACT

INTRODUCTION

Laryngoscopy and intubation is an integral part for providing general anaesthesia to patients undergoing various types of surgery. It also plays an important role in critical care units viz. for providing mechanical ventilation. It is a very essential tool in the hands of anaesthesiologist in maintaining airway. The present study is undertaken to determine and compare the efficacy of single bolus dose of IV esmolol 1 mg/kg and IV fentanyl 2 mcg/kg in attenuating the haemodynamic responses to laryngoscopy and tracheal intubation and to ascertain the effectiveness of esmolol hydrochloride and fentanyl citrate in suppressing sympathetic responses.

MATERIAL & METHODS

The study was conducted under the Department of Anaesthesiology and Critical Care, Assam Medical College and Hospital, Dibrugarh, during the period July 2013 to June 2014. For this purpose, 150 patients of either sex between 20-50 years of ASA I & II physical status were selected after obtaining informed and written consent and were divided into two groups namely, Group E receiving IV esmolol (1 mg/kg) and Group F receiving IV fentanyl (2 mcg/kg).

RESULTS

Inj. fentanyl 2 mcg/kg IV administered 5 minutes before laryngoscopy and intubation was able to prevent adverse haemodynamic changes better than Inj. esmolol 1 mg/kg IV administered 3 minutes prior to laryngoscopy and intubation during elective surgeries under general anaesthesia.

CONCLUSION

Hence, from the findings of this study we can conclude that IV bolus dose of fentanyl 2 mcg/kg administered 5 minutes before laryngoscopy and intubation can attenuate the sympathetic response to laryngoscopy and intubation without any side effects of the drug in healthy patients undergoing elective surgeries under general anaesthesia.

KEYWORDS

Fentanyl, Esmolol, Laryngoscopy, Intubation, Haemodynamic, Attenuation.

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INTRODUCTION: Airway management is prime to the practice of anaesthesia. In order to understand airway management fully, the anaesthesiologist must be well conversant with the anatomy of the region and with its innervations and possible physiological and pathological conditions and also with the consequences and complications of airway manoeuvres.¹

Laryngoscopy and endotracheal intubation are very essential tools in the hands of anaesthesiologist in maintaining airway. It involves manipulation of the airway. The sensory part of airway is of concern during cardiovascular responses to laryngoscopy and intubation.²

The development of tracheal intubation as we know it today dates from about 1900.³ Reid and Bruce (1940) and King, Harris (1951) described the circulatory response to laryngeal and tracheal stimulation following laryngoscopy and tracheal intubation as reflex sympathoadrenal stimulation.^{4,5} Although increase in heart rate and blood pressure due to sympathoadrenal response are short-lived, these may have detrimental effects in high-risk patients, especially those with cardiovascular diseases, increased intracranial pressure or anomalies of cerebral vessels.⁶

Laryngoscopy and tracheal intubation induced pressor responses have been associated with increase in catecholamine levels like norepinephrine and epinephrine. Rise of these catecholamines are associated with elevation of blood pressure and heart rate.^{7,8,9}

Some authors consider the intubation period one of the greatest risk in surgical patients with coronary artery diseases. Although the responses may be transient, it is invariably significant, often persistent, and of great concern. Therefore, it is important to find an effective means of

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attenuating the sympathetic responses to laryngoscopy and intubation.

Many strategies have been advocated to minimise the haemodynamic adverse responses and aimed at different levels of the reflex arc.¹⁰

For Example:

- Blockade of the peripheral sensory receptors and afferent input by topical application and infiltration by local anaesthetics of superior laryngeal nerve.
- Blockade of the central mechanisms of integration of sensory input by using fentanyl, morphine, droperidol etc.
- Blockade of the efferent pathway and effector sites by using IV lignocaine, β -blockers, calcium channel blockers, hydralazine, etc.

But no single drug or technique is satisfactory.¹⁰

Among the recommended procedures, IV lignocaine, fentanyl, esmolol, clonidine, dexmedetomidine and calcium channel blockers appear to fulfil the above-mentioned criteria.

AIM: The aim of this study is to evaluate the beneficial effects of single bolus dose of IV esmolol and IV fentanyl in attenuating the haemodynamic responses associated with laryngoscopy and intubation in patients undergoing general anaesthesia with respect to the following features:

1. Heart Rate & Blood Pressure.
2. Pulse Pressure Product.
3. Sedation.
4. Undesirable Effects.

OBJECTIVE: To study the haemodynamic responses to laryngoscopy and intubation with esmolol hydrochloride (1 mg/kg) versus fentanyl citrate (2 mcg/kg).

MATERIALS & METHODS: After obtaining approval from Research and Ethics Committee of Hospital and after having informed consent from each patient, 150 adult patients scheduled for elective surgery under general anaesthesia in Assam Medical College and Hospital, Dibrugarh were selected and were provided general anaesthesia with endotracheal intubations for all the patients.

The patients were selected from different OT's.

Following criteria were adopted for selecting patients:

Inclusion Criteria:

- Patients aged between 20–50 years of both the sexes.
- Patients scheduled for elective surgeries under general anaesthesia.
- Patients with ASA grade I or II.

Grade 1: Normal healthy patients.

Grade 2: Patients with mild systemic disease.

Mallampati airway assessment of grade I.

Exclusion criteria:

- Unwilling patients.
- Emergency surgeries.
- Anticipated difficult intubation.
- Patients with ASA grade III or higher.
- Patients with neurological and other endocrine abnormalities.
- Patients with renal impairment and hepatic disease.
- Patients with cardiovascular diseases, diabetes mellitus, asthma, COPD, etc.
- Patients on beta blockers or calcium channel blockers.
- Patients on psychotropic drugs or history of drug allergies.
- Patients with language or communication difficulties.
- Previous records of failed intubation.

150 cases were divided into two groups with 75 cases in each group by matching patient's age, sex, Mallampati and ASA grading.

Group E (Esmolol group): In this group, patients received 1 mg/kg esmolol IV three minutes before laryngoscopy and intubation.

Group F (Fentanyl group): All the patients in this group received 2 μ g/kg of fentanyl IV five minutes before laryngoscopy and intubation.

Complete pre-anaesthetic evaluation was performed in each patient including detailed history taking, thorough physical examination and routine preoperative investigations including coagulation profile. The nature and procedure of the study was explained to the patients. All patients had routine preoperative fasting for 6 hours before surgery.

STATISTICAL ANALYSIS: Demographic data, parametric variables like Heart Rate (HR), systolic BP, diastolic BP and pulse pressure product (PPP) were tabulated as Mean \pm SD and analysed by unpaired 't' test. Fisher's exact test was used to determine 'p' value of frequency of complications and number of patients in ASA category, p value of less than 0.05 was considered significant.

RESULTS & OBSERVATIONS: The present work is a prospective clinical study comparing the effects of IV esmolol and IV fentanyl on attenuation of haemodynamic parameters during laryngoscopy and intubation in patients undergoing elective operation under general anaesthesia.

P value:

- >0.05= Not significant.
- <0.05 = Significant.
- <0.01= Highly significant.
- <0.001= Very highly significant.
- <.0.0001= extremely significant.

Group	Total Number
Group E	75
Group F	75

Table 1: Table Showing Count Distribution

Age (years)	Group E		Group F	
	Number	% in Group	Number	% in Group
20-30	29	38.67	27	36.00
31-40	33	44.00	35	46.67
41-50	13	17.33	13	17.33

Table 2: Table Showing Age Distribution

Group	Age (Mean±SD)	P value
Group E	32.80±7.0786	0.9721
Group F	32.84±6.8138	

Table 3: Table Showing Age Comparison

The mean age of patients in group E was 32.80±7.078 years and in group F was 32.84±6.81 years with a p value more than 0.05 and hence both the groups were comparable.

Weight (Kg)	Group E		Group F	
	Number	% in group	Number	% in group
40-50	20	26.67	24	32.00
51-60	47	62.67	42	56.00
61-70	8	10.66	9	12.00

Table 4: Table Showing Weight Distribution

Group	Weight in kg. (Mean±SD)	P Value
Group E	53.57 ±5.193	0.8328
Group F	52.39±5.537	

Table 5: Table Showing Weight Comparison

The mean weight of patients in Group E was 53.57±5.193 kg and in Group F was 52.39±5.537 kg with p

Time Interval	HR (Mean±SD)	SBP (Mean±SD)	DBP (Mean±SD)	PPP (Mean±SD)
Group E				
T1	83.89±12.31	118.53±5.87	75.48±4.76	9960.48±1640.87
T2	74.89±12.31	105.53±5.87	67.48±4.76	7920.07±1461.59
T3	71.9±12.31	103.53±5.87	66.48±4.76	7459.68±1429.45
T4	90.87 ±14.81	121.21 ±4.94	77.37±5.11	11019.31±1891.04
T5	81.57±10.64	117.99 ±4.57	76.44±3.96	9623.65 ±1302.43
T6	87.73±11.22	117.53 ±4.05	80.35±2.84	10298.76±1278.41
T7	87.49 ±9.12	115.32±5.51	79.77±3.8	10080.13±1078.93
T8	89.19±9.69	114.95±4.61	78.99±3.62	10258.31±1241.71
T9	78.78 ±9.3	109.27±5.69	71.37±3.95	8608.59±1098.76
Group F				
T1	81.33±9.18	117.28±7.09	74.88±6.06	9553.24±1350.04
T2	73.07±6.43	106.97±4.93	66.92±3.81	7842.16±856.19
T3	71.23±6.43	104.97±4.93	73.92±3.81	7485.76±838.13
T4	83.72±6.48	113.69±5.38	74.19±4.41	9531.04±995.14

value of more than 0.05 which is not significant and hence both the groups were comparable.

Sex	Group E		Group F	
	Number	% in group	Number	% in group
Male	30	40	32	42.67
Female	45	60	43	57.33

Table 6: Table Showing Sex Distribution

In this study, 40.0% were males and 60.0% were females in Group E and 42.67% were males and 57.33% were females in Group F. Hence, both the groups had compatible sex distribution.

Group	ASA I	%	ASA II	%	P value
Group E	63	84.00	12	16.00	0.8222
Group F	64	85.33	11	14.67	
Total	127	84.67	23	15.33	

Table 7: Table Showing ASA Physical Status of Patients

In the whole study, 84.67% belonged to ASA I and 23% were having ASA II physical status. In group E, 84.0% were of ASA I as compared to 85.33% in Group F. Patients having ASA II comprised 16.0% in Group E and 14.67% in Group F. The p value is 0.8222 and hence both the groups were comparable with respect to ASA physical status.

Group	Sedation Score (Mean±SD)	P value
Group E	1.200±0.400	< 0.0001
Group F	1.747±0.435	

Table 8: Table Showing Sedation Score

The mean sedation score before induction was assessed by modified Ramsay Sedation Score and was 1.200 for Group E which was less as compared to Group F with a mean score of 1.747. Patients in Group F were less anxious and more co-operative.

T5	75.29±4.17	111.73±4.66	74.39±3.31	8415.71±627.87
T6	72.08±4.57	108.39±5.53	68.32±5.91	7816.75±696.32
T7	75.73±5.23	113.24±6.16	73.63±6.65	8582.45±829.8
T8	77.44±4.97	111.29±4.49	72.6±4.19	8613.44±583.99
T9	76.53±4.96	107.35±5.25	69.85±4.41	8213.77±649.54

Table 9: Table Showing Haemodynamic Parameters

Heart Rate (per mi)	Group E (Mean±SD)	Group F (Mean±SD)	p Value	Significance
T1	83.89±12.31	81.33±9.18	0.105	NS
T2	74.89±12.31	73.07±6.43	<0.001	HS
T3	71.90±12.31	71.23±6.43	<0.001	HS
T4	90.87±14.81	83.72±6.48	<0.001	HS
T5	81.57±10.64	75.29±4.17	<0.001	HS
T6	87.73±11.22	72.08±4.57	<0.001	HS
T7	87.49±9.12	75.73±5.23	<0.001	HS
T8	89.19±9.69	77.44 ±4.97	<0.001	HS
T9	78.78± 9.30	76.53± 4.96	<0.01	S

Table 10: Comparison between Intraoperative Heart Rate Changes

The above table shows intraoperative heart rate changes of patients at various periods of the procedure. In Group F, these were at lower level as compared to Group E except for baseline reading where it was statistically insignificant.

The maximum rise in HR just after intubation in Group E was 18.97/min whereas in Group F was only 12.97/min which was highly significant. The intra-group variation of heart rate were more stable in Group F than Group E which showed wide fluctuation during the whole intraoperative period.

Systolic Blood Pressure (mm Hg)	Group E (Mean±SD)	Group F (Mean±SD)	p Value	Significance
T1	118.53±5.87	117.28±7.09	0.1203	NS
T2	105.53±5.87	106.97±4.93	<0.001	HS
T3	103.53±5.87	104.97±4.93	<0.001	HS
T4	121.21±4.94	113.69±5.38	<0.001	HS
T5	117.99±4.57	111.73±4.66	<0.001	HS
T6	117.53±4.05	108.39±5.53	<0.001	HS
T7	115.32±5.51	113.24±6.16	<0.001	HS
T8	114.95±4.61	111.29±4.49	<0.001	HS
T9	109.27±5.69	107.35±5.25	<0.001	HS

Table 11: Comparison Between Systolic Blood Pressure Changes in Group E and Group F

The table shows intraoperative systolic blood pressure changes of patients of Group F which were at significantly lower level as compared to Group E at various intraoperative periods of the procedure except for the preoperative level. The maximum rise in SBP just after intubation was 17.68 mmHg and 8.72 mmHg in Group E and F respectively. This signifies that fentanyl effectively blunted the rise in SBP as compared to esmolol. The intra-group fluctuations in SBP were more stable in Group F than Group E where it showed wide fluctuation throughout the intraoperative period.

Diastolic Blood Pressure (mm Hg)	Group E (Mean±SD)	Group F (Mean±SD)	p Value	Significance
T1	75.48±4.76	74.88±6.06	0.0785	NS
T2	67.48±4.76	66.92±3.81	<0.001	HS
T3	66.48±4.76	73.92±3.81	<0.001	HS
T4	77.37±5.11	74.19±4.41	<0.001	HS
T5	76.44±3.96	74.39±3.31	<0.001	HS
T6	80.35±2.84	68.32±5.91	<0.001	HS
T7	79.77±3.8	73.63±6.65	<0.001	HS
T8	78.99±3.62	72.6±4.19	<0.001	HS
T9	71.37±3.95	69.85±4.41	<0.001	HS

Table 12: Comparison Between Diastolic Blood Pressure Changes in Group E and Group F

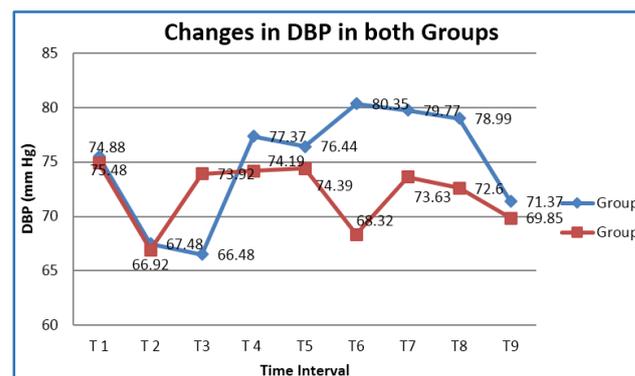


Fig. 1

The figure indicates that intraoperative diastolic blood pressure changes of Group F patients were at significantly lower level as compared to Group E at various intraoperative periods of the procedure except for baseline level.

The maximum difference in DBP after and prior to intubation was 10.89 mmHg and 0.27 mmHg for Group E and F respectively. This shows that hemodynamic response during laryngoscopy and intubation were better maintained in Group F.

PPP	Group E	Group F	P Value	Significance
	(Mean±SD)	(Mean±SD)		
T1	9960.48±1640.87	9553.24±1350.04	0.1536	NS
T2	7920.07±1461.59	7842.16±856.19	<0.001	HS
T3	7459.68±1429.45	7485.76±838.13	<0.001	HS
T4	11019.31±1891.04	9531.04±995.14	<0.001	HS
T5	9623.65±1302.43	8415.71±627.87	<0.001	HS
T6	10298.76±1278.41	7816.75±696.32	<0.001	HS
T7	10080.13±1078.93	8582.45±829.8	<0.001	HS
T8	10258.31±1241.71	8613.44±583.99	<0.001	HS
T9	8608.59±1098.76	8213.77±649.54	<0.001	HS

Table 13: Comparison Between Pulse Pressure Product Changes In Group E and Group F

NS–Not Significant, HS–Highly Significant

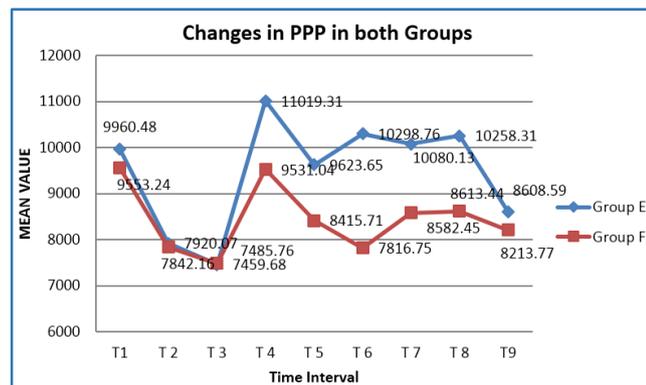


Fig. 2

The figure indicates that intraoperative changes in pulse pressure product of patient of Group F were at significantly lower level as compared to Groups E at various intraoperative periods of the procedure except for preoperative level.

The maximum elevation in PPP just after intubation in Group E was 3559.63 whereas in Group F it was significantly less with a value of 2045.28. Hemodynamic instability was effectively blunted in Group F during intubation.

Adverse effects	Group E	Group F	P value	Significance
Nausea	2	1	1.000	NS
Vomiting	2	2	1.0000	NS
Bradycardia	5	2	0.4419	NS
Hypotension	0	0	1.0000	NS
Bradypnoea	0	0	1.0000	NS
Shivering	0	0	1.0000	NS

Table 14: Comparison of Adverse Effects in Group E and Group F

The incidence of bradycardia was more in Group E; however, it was not statistically significant. Other adverse effects in both the groups were statistically similar. The incidences of nausea and vomiting were almost comparable in both the groups.

Group	VAS Score (Mean±SD)	P value
Group E	4.12±0.489	<0.0001
Group F	3.04±0.445	

Table 15: Comparison of Visual Analogue Scale Between Group E and Group F

From the above Table it can be deduced that the mean VAS for pain intensity was significantly lower for Group F than Group E. Patients were more comfortable and pain-free in Group F. Fentanyl effectively provided post-operative analgesia.

DISCUSSION & SUMMARY: Laryngoscopy and intubation is an integral part for providing general anaesthesia to patients undergoing various types of surgery. It also plays an important role in critical care units viz. for providing mechanical ventilation.

It is a very essential tool in the hands of anaesthesiologist in maintaining airway. It involves manipulation of the airway. The sensory part of airway is of concern during cardiovascular responses to laryngoscopy and intubation.²

Laryngoscopy and endotracheal intubation is associated with rise in blood pressure, heart rate and cardiac dysrhythmias.¹¹ Though these above-mentioned effects may be short-lived, these may have adverse effects in high risk patients like those with cardiovascular diseases, increased intracranial pressure or anomalies of cerebral vessels.¹²

There are many factors that affect the cardiovascular changes associated with laryngoscopy and intubation. Drugs, age, type of procedures, depth of anaesthesia, hypoxia, hypercarbia etc., influence the haemodynamic response during an operative procedure. Various drugs used during premedication, induction, relaxation and maintenance of anaesthesia influence the sympathetic response to laryngoscopy and intubation.

Laryngoscopy alone may produce most of the cardiovascular responses reported after laryngoscopy and tracheal intubation during anaesthesia.¹³

Various pharmacological agents have been used to obtund this pressor response. Both esmolol and fentanyl have been demonstrated to be efficient in obtunding the

pressor response and in maintaining hemodynamic stability during laryngoscopy and intubation.

This present prospective clinical study was designed to assess and compare the efficacy of Inj. esmolol 1 mg/kg and Inj. fentanyl 2 mcg/kg in maintaining hemodynamic stability during laryngoscopy and intubation.

Laryngoscopy was done using rigid laryngoscope with standard Macintosh blade and intubation was done with appropriate sized disposable, high volume low pressure cuffed endotracheal tube. The patients were then ventilated with 66% nitrous oxide and 33% oxygen with a tidal volume of 8-10 mL/kg and a rate of 12–15 breaths per minute. For maintenance of relaxation, Inj. atracurium was administered according to body weight (0.5 mg/kg). Increase in blood pressure up to 20% of basal BP was managed by increasing isoflurane concentration and more than 20% of basal BP was managed by titrated nitroglycerin infusion. Systolic blood pressure, diastolic blood pressure, pulse pressure product, heart rate were recorded at regular predetermined intervals. Any intraoperative or postoperative complications were noted and were managed accordingly. Level of sedation was assessed before induction by Ramsay sedation scale. Postoperative pain intensity was assessed by VAS score.

The most important laryngoscopic factor influencing the cardiovascular response is found to be the duration of laryngoscopy.¹⁴ A linear increase in heart rate and mean arterial pressure during first 45 seconds has been observed. As duration of laryngoscopy is normally less than 30 seconds, the result of studies in which it takes longer than this have less clinical relevance. The force applied during laryngoscopy has only minor effect.

In one of the study conducted, it was shown that greater time needed to perform blind oral intubation was not associated with a more pronounced haemodynamic or hormonal stress response. In fact, patients intubated with direct laryngoscopy showed significant response.¹²

There are various measures which can be effective against the haemodynamic and catecholamine responses to laryngoscopy and intubation, but no single anaesthetic technique is perfect in preventing or attenuating these responses. Many techniques have been recommended. The drugs used were either partially effective or had other undesirable effects on the patients. Topical application of local anaesthetics,¹⁵ infiltration or nerve blocks,¹⁵ β -blockers,¹⁶ calcium channel blockers,¹⁷ clonidine,¹⁸ lignocaine, fentanyl, etc. were being used but no single drug or technique was satisfactory.

In various studies conducted throughout the world, esmolol and opioids like fentanyl were found to be the most preferred drug to attenuate the pressor response. Both the drugs fulfil the criteria to be an effective agent to suppress the haemodynamic changes to laryngoscopy and intubation. Hence, this study was undertaken to evaluate the efficacy of IV esmolol and IV fentanyl in maintaining haemodynamic stability by reduction of laryngoscopy and intubation stress response in 150 patients undergoing surgeries under general anaesthesia at Assam Medical College & Hospital divided into

two groups viz. Group E receiving Inj. esmolol 1 mg/kg and Group F receiving Inj. fentanyl 2 mcg/kg.

In this study, 40.0% were males and 60.0% were females in Group E and 42.67% were males and 57.33% were females in Group F. Hence, both the groups had compatible sex distribution. Most of the patients (group E 44.0% and group F 46.67%) in both the groups were aged between 31-40 years. The mean age of patients in Group E was 32.80 ± 7.078 years and in Group F was 32.84 ± 6.81 years with a p value more than 0.05 and hence both the groups were comparable. The mean weight of patients in Group E was 53.57 ± 5.193 kg and in Group F was 52.39 ± 5.537 kg with p value of more than 0.05 which is not significant and hence both the groups were comparable. In the whole study, 84.67% belonged to ASA I and 23% were having ASA II physical status. In Group E, 84.0% were of ASA I as compared to 85.33% in Group F. Patients having ASA II comprised 16.0% in Group E and 14.67% in Group F. The p value was 0.8222 and hence both the groups were comparable with respect to ASA physical status.

Hence all the demographic parameters were comparable in both the groups.

With the present study we summarize that Inj. fentanyl 2 mcg/kg IV administered 5 minutes before laryngoscopy and intubation was able to prevent adverse haemodynamic changes better than Inj. esmolol 1 mg/kg IV administered 3 minutes prior to laryngoscopy and intubation during elective surgeries under general anaesthesia.

LIMITATIONS OF THIS STUDY: This study was done on a small group of 75 patients in each of the groups, all patients belonging to ASA I and II. Most patients were in the young group. Patients with comorbidities like hypertension and diabetes, etc. were all excluded from the study. Hence the advantages of using esmolol or fentanyl in patients having comorbid diseases could not be appreciated. Also various drugs used in the present study are known to influence the haemodynamic changes which were not evaluated. Also patients, who were enrolled in this study were all successfully intubated in the first attempt. Perhaps, the haemodynamic parameters would show a different picture in patients with difficult intubation.

CONCLUSION: Based on the present clinical comparative study, we can conclude that Inj. fentanyl 2 mcg/kg IV administered 5 minutes before laryngoscopy and intubation was able to prevent adverse haemodynamic changes resulting from laryngoscopy and intubation better than Inj. esmolol 1 mg/kg IV administered 3 minutes prior to laryngoscopy and intubation during elective surgeries under general anaesthesia. Also, fentanyl maintained a stable haemodynamic profile throughout the whole intraoperative period and even after extubation. Heart rate, systolic blood pressure as well as diastolic blood pressure were better maintained within normal limits by fentanyl. Patients were sedated and less anxious during the preoperative period, thus, maintaining stable haemodynamic parameters in fentanyl group.

Fentanyl is more effective than esmolol in attenuation of sympathetic response to laryngoscopy and intubation.

Hence, from the findings of this study, we can conclude that IV bolus dose of fentanyl 2 mcg/kg administered 5 minutes before laryngoscopy and intubation can attenuate the sympathetic response to laryngoscopy and intubation without any side effects of the drug in otherwise healthy patients undergoing elective surgeries under general anaesthesia.

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