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Original Research Article

The comparative efficacy of two different doses of fentanyl on hemodynamic response to laryngoscopy and tracheal intubation: Prospective, randomized control trail

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ABSTRACT

General anaesthesia with muscle relaxants using controlled ventilation involves laryngoscopy and tracheal intubation, which is associated with haemodynamic changes in the form of tachycardia and hypertension due to increased sympathoadrenal activity and are probably of no consequence in healthy individuals, but they may be hazardous to those with Myocardial Insufficiency and cerebrovascular disease. The objective of the present study was to compare the effect of two different doses of fentanyl with etomidate as an induction agent in attenuating haemodynamic stress response during laryngoscopy and endotracheal intubation. A randomised control trial was carried out on 60 adult patients (ASA I, II, III) undergoing elective surgery under general anaesthesia requiring endotracheal intubation. The patients were randomly allocated into two groups of 30 each i.e. group F2.5 and group F5 receiving fentanyl 2.5μg/kg and 5 μg/kg intravenously five minutes before intubation respectively. The pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and rate pressure product were recorded at various time intervals up to ten minutes after intubation. The study showed that both the doses were equally effective in blunting the pulse rate response, but the 5μg /kg proved significantly effective in blunting the blood pressure response. The rate pressure product, a measure of cardiac O2 consumption was found to be significantly lower in fentanyl 5μg/kg compared to fentanyl 2.5μg/kg. Hence, we conclude that fentanyl in 5 mcg/kg dose is more effective in attenuating hemodynamic responses to intubation as compared to 2.5 mcg/kg.

1. Introduction

Laryngoscopy and tracheal intubation is an intense, noxious stimulation which is associated with hemodynamic changes due to reflex autonomic discharge.[1] There is a necessity to blunt this response to prevent deleterious effects like arrhythmias, myocardial ischemia, increased intracranial pressure, rupture of cerebral aneurysm etc.[2] Various drugs like intravenous lidocaine, adrenergic blocking drugs like alpha blockers and beta blockers, vasodilators like nitroprusside, nitroglycerin, hydralazine and intravenous opioids are used for attenuation of hemodynamic response to laryngoscopy and tracheal intubation. Various studies have already discovered that fentanyl 2mcg/kg is effective in attenuating this cardiovascular responses.[2–7] However, in this studies thiopentone[3] and propofol[6] are used as induction agents. Very few studies have been carried out

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to determine the ideal dose of fentanyl for attenuation of this hemodynamic response with etomidate as an induction agent.[5,8]

Etomidate is a rapidly acting anaesthetic induction agent. It appears to produce hypnosis, amnesia, and inhibition of nociceptive responses, almost exclusively via actions at one class of neuronal ion channels (i.e. γ-aminobutyric acid type A receptors [GABAA receptors].[9,10] It has a very favourable hemodynamic profile on induction, no change in myocardial contractility and cardiac output.[11] But is having some annoying side effects in the form of pain on injection, myoclonus and postoperative nausea and vomiting apart from suppression of adrenal synthesis.[9,12] It does not have any analgesic effect. Therefore, etomidate by itself, even in large doses, produces relatively light anaesthesia for laryngoscopy. Thus marked increases in heart rate and blood pressure may be found when Etomidate is solely used for induction.[13] Pre-treatment with fentanyl can attenuate these side effects during induction with etomidate and also blunt the hemodynamic response to laryngoscopy and endotracheal intubation.[9,10]

Fentanyl is a potent, synthetic opioid agonist with analgesic effect having rapid onset and short duration of action.[14–16] As fentanyl in lower doses is associated with suboptimal attenuation of hemodynamic response and in higher doses is associated with systemic side effects like nausea, vomiting, sedation, pruritus, urinary retention, wooden chest syndrome and respiratory depression[14–16] this study thus aims to compare two different doses of fentanyl (2.5 mcg/kg and 5 mcg/kg) to attenuate the hemodynamic response to laryngoscopy and endotracheal intubation in patients undergoing elective surgeries with etomidate as induction agent. Primary objective of the study is to compare attenuation of hemodynamic response of rise in heart rate, mean arterial pressure and rate pressure product of the two groups. While secondary objective is to compare intraoperative complications in the form of pain on injection, myoclonus, apnea, hypotension, bradycardia and tachycardia.

2. Materials and Methods

The study was carried out during the period of 2020-2021. It was a prospective randomized control trial approved by the Institutional Ethical Committee for Human Research-PG Research (IECHR-PGR).

From the reference study[3] the effect size counted was 0.20 (medium effect), to achieve a power of greater than 80% with α value less than 0.05 (2-sided). A sample size of 60 (30 in each group) was required for to estimate difference of improvement in RPP between two groups as 1355 with standard deviation 1750 (using Med calc statistical software version 20.113).

Patients posted for elective surgery under general anaesthesia expected to last for more than one hour, belonging to American Society of Anaesthesiologists physical status I, II & and III and aged between 20 to 60 years of either sex were included in the study. Patients who refused to give consent, patients having anticipated difficult airway, patients having severe uncontrolled cardiovascular disease, respiratory disease, hepatic disease, central nervous system disease or renal disease that is constant threat to life of the patient and patients having allergy or hypersensitivity to study drug and pregnant or lactating females were excluded from the study.

Detailed preoperative assessment was performed on the previous day of surgery including history taking, general examination, systemic examination, airway assessment. All routine investigations were done. Patients were thoroughly counselled during the preoperative evaluation and were properly explained about the anaesthetic procedure and written informed consent was taken. Patients were kept nil by mouth from 10 p.m. previous night. Tab.Ranitidine 150mg and Tab Diazepam 10 mg orally were given on the previous night of surgery.

Anaesthesia machine, anaesthetic drugs, airway equipments including difficult airway cart, suction apparatus, multipara monitor, and all resuscitation drugs were checked and kept ready. Multipara monitor was attached. Baseline pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, rate pressure product (RPP), arterial oxygen saturation were recorded (Tawake). Intravenous line was taken with 18G cannula in a large forearm vein and secured.

Randomization was done by the sealed envelope method.

Patients were grouped into following two groups.

Group F2.5: INJ fentanyl 2.5mcg/kg IV + INJ etomidate 0.3mg/kg IV.

Group F5: INJ fentanyl 5 mcg/kg IV + INJ etomidate0.3mg/kg IV.

Maintenance fluid ringer lactate was started 2 hrs before surgery according to weight of patients.

All the patients were premedicated with Injection Glycopyrrolate 5mc/kg IV, Injection Ondansetron 0.08mg/kg IV and Injection Paracetamol 100 mg IV infusion. Preoxygenation with 100% O2 was started. Priming dose of Injection Vecuronium i.e. 0.015mg/kg IV was given followed by Injection Fentanyl 2.5mcg/kg or 5mcg/kg over 30 seconds according to group allocation. After 3 minutes of preoxygenation induction with Injection Etomidate 0.3mg/kg over 30 seconds was done. Intubating dose of Injection vecuronium i.e. 0.085mg/kg was given. After 2 minutes of ventilation with 100% o2 and 2% Sevoflurane laryngoscopy and tracheal intubation was performed.

All patients who required the second attempt at intubation were excluded from the study.

Procedures like positioning, epinephrine infiltration, throat packing, Ryle' tube insertion, urinary catheterization

and surgery that might produce hemodynamic response and might interfere with study findings were withheld until the completion of 10 minutes post intubation period.

Anesthesia was maintained with controlled ventilation through close circuit with soda lime with O2:N2O (40:60) in a fresh gas flow of 6L/min, sevoflurane dial concentration 2%. Intermittently vecuronium 0.015mg/kg was given for muscle relaxation. Till 10 min of study duration, fresh gas flow and dial concentration of sevoflurane were not changed and there were not any surgical stimulus. After 10 minutes, fresh gas flow was reduced to 3L/min and sevoflurane was titrated according to hemodynamic response.

Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure (diastolic pressure+1/3pulse pressure), rate pressure product and arterial oxygen saturation were recorded when patient was awake (Tawake), 3 minutes after giving Injection Fentanyl (T3), 1 minute after intubating dose of vecuronium T0 (asleep baseline), at the time of tracheal intubation (Ti), 1 minute, 3 minutes, 5 minutes and 10 minutes after tracheal intubation.

Patients were monitored for complications in the form of pain in injection, myoclonus, chest wall rigidity, respiratory depression, hypotension, bradycardia.

At the end of operation, Nitrous oxide and sevoflurane were stopped. Once the respiratory efforts were observed, the residual neuromuscular blockade was reversed by-IV Inj Neostigmine-50mcg/kg IV and Inj Glycopyrrolate-10mcg/kg.

Patients were extubated once all the criteria for extubation were met. Patients were shifted to recovery room.

Post operative complications in the form of nausea, vomiting and respiratory depression if any were noted.

3. Observations and Result

Out of 69 tested for eligibility, total 60 patients were enrolled in the study.

Both groups were comparable with respect to age, weight, sex, mean awake pulse rate, blood pressure, mean arterial pressure and rate pressure product.

On intragroup comparison, in both the groups, there was no rise in pulse rate from baseline throughout the study period. On comparing both the groups, heart rate remained significantly less in Group F5 ($p<0.01$) as compared to Group F2.5 throughout the study period.

Heart rate remained significantly less in Group F5 as compared to Group F2.5 throughout the study period and in both the groups there was no rise in heart rate from baseline after laryngoscopy and tracheal intubation. In Group F5 there was statistically significant fall in pulse rate at 10 minutes after intubation but did not required pharmacological intervention.

Mean arterial pressure (MAP) (Systolic pressure +1/3 Pulse Pressure) remained significantly less in Group F5 as compared to Group F2.5 throughout the study period. In group F2.5 their was statistically significant rise of MAP at one minute after tracheal intubation. However, their MAP was comparable to baseline at intubation, 3minutes, 5minutes and 10 minutes after intubation in both the groups. In Group F5 there was statistically significant fall in MAP at 5 and 10 minutes after intubation but did not required pharmacological intervention.

Rate pressure product (RPP) is very reliable indicator of myocardial oxygen demand. It is the product of heart rate (HR) and systolic blood pressure (SBP).[17] Rate pressure product (RPP) remained significantly less in Group F5 as compared to Group F2.5 throughout the study period and in both the groups there was no rise in RPP from baseline after laryngoscopy and tracheal intubation.

In both the groups, none of the patient suffered from pain on injection, myoclonus and respiratory depression. The incidence of nausea, vomiting and hypotension was significantly higher in group F5 as compared to group F2.5.

3.1. Data analysis

Data were collected clinically and from multipara monitor. Qualitative data were analysed by Chi-square test. Quantitative data were presented as mean+standard deviation (SD) and they were analysed by students "t" test using med calc software(Version 20.113).

4. Discussion

Fentanyl, a potent rapid-acting synthetic opioid was first synthesized more than 50 years ago and has become the most commonly used opioid for attenuation of hemodynamic changes to laryngoscopy and tracheal intubation since then.[18] The dose of fentanyl for complete sympathoadrenal blockade is greater than 7 mcg/kg.[19] The studies done by Vinod Hosalli et al,[3] Sidharth et al[20] and Babita Bhupendra Singh et al[6] concluded that fentanyl 2mcg/kg was as effective in attenuating hemodynamic response to laryngoscopy and tracheal intubation when compared with fentanyl 5mc/kg, lignocaine 1.5mc/kg along with fentanyl 2mcg/kg and labetalol 0.25 mc/kg respectively. However, they used thiopentone as an induction agent. Yukari et al[7] with target controlled infusion of propofol discovered that fentanyl 2 mcg/kg in patients without hypertension and 4 mcg/kg in those with hypertension are preferable in order to minimize the changes in vital signs and cardiac output associated with tracheal intubation.

The study Byung et al.[5] concluded that there was an increases in SBP and HR of more than 30% of the baseline levels when fentanyl 1.0 μg/kg (n = 30) with continuous infusion of 0.1 μg/kg/min was given 1 min before induction

Table 1: Comparison of patient characteristics in two groups

Demographic Data			
	Group F2.5	**Group F5**	**P value**
Patients	30	30	
Age (yr), mean (SD)	50±6.984	53±9.743	0.1757
Sex (F/M)	16/14	15/15	
Weight (kg), mean (SD)	62±3.956	63±5.426	0.4180
Height (cm), mean (SD)	163±9	164±8	0.723
ASA I/II/III	12/15/3	14/11/5	
Heart Rate (per minute) (mean±SD)	86±8.56	83±6.15	0.12
Systolic BP (mm of Hg) (mean±SD)	128±7.43	129±7.15	0.59
Diastolic BP (mm of Hg) (mean±SD)	80±5.32	82±5.236	0.15
MAP (mm of Hg) (mean±SD)	96.16±4.76	98±5.19	0.15
RPP (mean±SD)	11043±1280	10639±936	0.16
SPO2(%) (mean±SD)	99±0.50	99±0.51	1.00

Table 2: Comparison of mean heart rate; HR: Heart rate

Time	**Group F2.5**		**GroupF5**		**Intergroup p value**
	HR (/minute)	**Intragroup P value**	**HR (/minute)**	**Intragroup P value**	
T0*	84±8.992		77±6.807		<0.0001
Ti **	84±8.059	1.000	78±6.886	0.573	<0.0001
T1	86±8.373	0.376	78±7.111	0.580	<0.0001
T3	85±8.152	0.653	78±6.590	0.565	<0.0001
T5	85±7.910	0.649	74±6.866	0.094	<0.0001
T10	84±8.035	1.000	73±7.820	0.038	<0.0001

*(Asleep baseline i.e. 1 minute after full dose of vecuronium), **(At the time of tracheal intubation), T1, T3, T5, T10-1, 3, 5, and 10 minutes after tracheal intubation.

Table 3: Comparison of mean arterial pressure. MAP: Mean arterial pressure

Time	**Group F2.5**		**GroupF5**		**Intergroup p value**
	MAP (mm of Hg)	**Intragroup P value**	**MAP (mm of Hg)**	**Intragroup P value**	
T0*	89.978±5.217		83±4.578		<0.0001
Ti **	90.611±4.959	0.6318	83±4.535	1.000	<0.0001
T1	94.267±4.909	0.0018	83±4.421	1.000	<0.0001
T3	90.778±4.761	0.5374	82±4.3608	0.3899	<0.0001
T5	90.378±4.478	0.7511	79±3.785	0.0005	<0.0001
T10	89.056±4.872	0.4820	78±3.631	<0.0001	<0.0001

*(Asleep baseline i.e. 1 minute after full dose of vecuronium), **(At the time of tracheal intubation), T1, T3, T5, T10-1, 3, 5, and 10 minutes after tracheal intubation.

Table 4: Comparison of rate pressure product. RPP: Rate pressure product

Time	**Group F2.5**		**Group F5**		**Intergroup p value**
	RPP (bpm*mmHg)	**Intragroup P value**	**RPP (bpm* mmHg)**	**Intragroup P value**	
T0*	10021±1206		8096±896.135		<0.0001
Ti **	10073±1126.057	0.8636	8052±847.936	0.8458	<0.0001
T1	10571±1094.772	0.0695	8128±814.021	0.8854	<0.0001
T3	10139±1037.942	0.6861	7969±698.945	0.5409	<0.0001
T5	10094±987.104	0.7984	7545±714.021	0.0108	<0.0001
T10	9981±1109.117	0.8941	7359±828.0222	0.0016	<0.0001

*(Asleep baseline i.e. 1 minute after full dose of vecuronium), **(At the time of tracheal intubation), T1, T3, T5, T10-1, 3, 5, and 10 minutes after tracheal intubation.

with etomidate 0.2 mg/kg. Thus their was need for further evaluation of ideal dose of fentanyl with etomidate as an induction agent.

S Vijayaragavan et al[8] concluded that fentanyl 5 μg/kg pretreatment reduces the incidence of increases in heart rate and blood pressure, myoclonus and pain on injection during the induction-intubation sequence in ASA class I and II patients by monitoring heart rate, systemic blood pressure at 3 min after administration of fentanyl, 2 min after administration of etomidate, and 1min after intubation.[16] The trend of hemodynamic fluctuation may not be precisely interpreted with monitoring only 1 time point after intubation, particularly the gap between the drop before intubation and the rise after intubation. Patients could be harmed from the hemodynamic differences. Also, larger doses of fentanyl may produce muscle rigidity. Priming with rocuronium or vecuronium reduced the incidence of difficult ventilation by avoiding the muscle rigidity.[21]

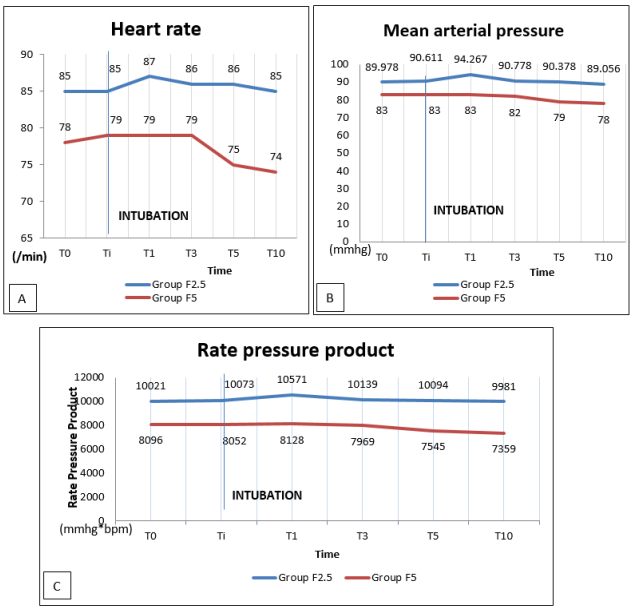

Fig. 1: T0: Baseline parameters after full dose of injection vecuronium; Ti : At intubation; T1, T3, T5 and T10 1, 3, 5 and 10 minutes after intubation

In the present study fentanyl 2.5mcg/kg proved to be as effective as fentanyl 5mcg/kg in attenuation of pulse rate response following laryngoscopy and tracheal intubation, however fentanyl 5mcg/kg in more effective in attenuation of blood pressure response one minute after tracheal intubation. Fentanyl 2.5mcg/kg is as effective as fentanyl 5mc/kg in attenuation of blood pressure response at 3, 5 and 10 minutes post intubation. Mean Rate Pressure Product remained significant lower in fentanyl 5mcg/kg group. Hence, higher dose of fentanyl is required for attenuation of hemodynamic response to laryngoscopy and tracheal intubation despite the use of cardiostable drugs i.e. etomidate and vecuronium. The incidence of postoperative nausea and vomiting was higher in fentanyl 5mcg/kg group.

There are limitations in this study. First, the accuracy of actual BP readings might be vary owing to the improper size of BP cuff and patient mobilisation since noninvasive blood pressure measurement was applied. Moreover, the exact BP value might be lost at the time of intubation due to the delay measurement of non-continuous noninvasive BP cuff.

Second, patients with well-controlled hypertension and poorly controlled hypertension were included hence it may affect the magnitude of hemodynamic changes. The discrepancy of fasting duration may affect the preoperative fluid status and further infuence the hemodynamic parameters.

5. Conclusion

We conclude that Fentanyl Citrate in both the doses are equally effective in attenuating the heart rate response and 5mcg/kg is more effective in attenuating blood pressor response only 1 minute after tracheal intubation in ASA I, II and III patients. Both the doses are equally effective in attenuating blood pressure response at the time of intubation, 3min,5 min and 10 min after tracheal intubation. Rate Pressure Product remains lower in fentanyl 5mcg/kg.

6. Source of Funding

Nil.

7. Conflict of Interest

None.

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