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A CLINICAL STUDY TO COMPARE THE EASE OF INTUBATION WITH COMBINATION OF SEVOFLURANE AND PROPOFOL WITH PROPOFOL ALONE.

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ABSTRACT

Endotracheal intubation is the most important and crucial step during administration of general anaesthesia. Intubation using short-acting hypnotic drug is frequently facilitated by the administration of a depolarizing relaxant such as succinylcholine. However, succinylcholine administration may be associated, with well known side effects. Even the use of non-depolarizing relaxants may be associated with undesirable effects such as prolonged neuromuscular blockage. Propofol is a short-acting intravenous anaesthetic that has been widely used as an induction agent. However, if used alone has been associated with several adverse effects, including hypotension, pain on injection, and excitatory motor movements. Potent inhalation agents can be used as an alternative to facilitate tracheal intubation. Until the introduction of sevoflurane, halothane was the most commonly used agent for inhalation induction. Hence an attempt was made with a combination of Sevoflurane with reduced dosage of Propofol for intubation to evaluate intubation conditions, hemodynamic responses and side effects. **Methodology:** After obtaining a written informed consent and ethical clearance, a prospective study was performed on ASA I patients aged between 20-40 years posted for various surgical procedures. **Result:** Intubating conditions were excellent in combination group ($p<0.001$). There was definite reduction in heart rate and arterial pressure in propofol alone group. Induction time is significantly more in combination group and there was no significant difference in side-effects between the groups. **Conclusion:** we concluded that combination of sevoflurane and propofol is superior to IV propofol alone with respect to quality of intubation. And can also be attempted for anticipated difficult airway intubation.

INTRODUCTION

Endotracheal intubation is the most important and crucial step during administration of general anaesthesia. It helps in maintaining the airway patency, makes procedure safe and also protects the lungs from aspiration.[1] The ease with which endotracheal intubation is achieved depends on technical proficiency, depth of anaesthesia and degree of muscle relaxation. The interplay of these three factors is such that a deficiency of one or two of them can be compensated for by the remaining factors.

Intubation in anaesthesia using short-acting hypnotic drug is frequently facilitated by the simultaneous administration of a depolarizing muscle relaxant such as succinylcholine. However, succinylcholine administration may be associated with well known side effects. Even the use of non-depolarizing relaxants may be associated with undesirable effects such as prolonged neuromuscular blockage, the need to reverse neuromuscular blockade, or the inability to reverse the paralysis quickly if airway management via mask or tracheal intubation is not possible. For these reasons, a method of providing good intubating condition rapidly without muscle relaxants has been sought.[2,3] Propofol in combination with short-acting opioids such as alfentanil and remifentanyl may provide adequate conditions for laryngoscopy and tracheal intubation without using muscle relaxants.[4] Avoiding muscle relaxants when they are not required for the planned procedure may prevent the potential complications of their use, misuse, and antagonism.[5]

Propofol is a short-acting intravenous anaesthetic with high lipid solubility and short elimination half-life. Propofol has been reported to depress pharyngeal and laryngeal reactivity to a greater extent than equipotent doses of thiopental.[6] However, propofol has been associated with several adverse effects, including hypotension, apnea, pain

on injection, and excitatory patient movements. Pain on injection can be avoided if propofol is administered after inhalation induction of anaesthesia.[7]

Potent inhalation agents can be used as an alternative to facilitate tracheal intubation. Until the introduction of sevoflurane, halothane was the most commonly used agent for inhalation induction. Sevoflurane 8% can be used as an alternative to facilitate tracheal intubation, but it is not cost effective.[8] Sevoflurane with its relatively pleasant smell, low airway irritability and low blood-gas solubility allows smooth and more rapid induction and recovery. Sevoflurane as compared with propofol, has the advantage of providing better hemodynamic stability and a smoother transition to the maintenance phase without a period of apnea.[9]

Hence an attempt was made with a combination of lesser percentage of Sevoflurane with reduced dosage of Propofol for intubation with endotracheal tube to evaluate intubation conditions, hemodynamic response during induction and intubation and induction side effects without muscle relaxants in adult patients of age group 20-40yrs undergoing various elective surgical procedures.

MATERIALS AND METHODS

A prospective randomized controlled study was taken up in our institute over a period of 6 months. The study population consists of 60 ASA I & II, non obese, adult patients aged between 20-40yrs coming for elective surgical procedures under General Anaesthesia and had Mallampatti class I airway anatomy. After approval of the study by our institution ethical committee and obtaining patient's written informed consent, patients were randomized into two groups of 30 each, i.e. Group A and Group B.

Inclusion criteria: 1) Patients belonging to ASA grade I and II undergoing elective surgical procedures of 1-3 hours duration. 2) Patients of either sex, between the age group of 20-40 years.

Exclusion criteria:1) Patient refusal 2) Patients with a history or evidence of a difficult airway. 3) Patients on MAO-inhibitors. 4) Patient had a history of malignant hyperthermia. 5) Patients with previous history of allergy to volatile anaesthetics or propofol. 6) Patients with body mass index more than 1.5 times normal.

A thorough pre-anaesthetic evaluation was conducted on the day before surgery. Detailed history and cardio-respiratory examination was carried out in all patients. All relevant investigations were done. Nil per oral status for a minimum of 6 hrs was advised.

On the day of surgery, after arrival of patient to the operation theatre, pulse-oxymeter, ECG, and non-invasive blood pressure monitors were connected. The baseline heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure were recorded.

After doing a thorough cockpit drill of continuous flow anaesthesia machine and availability of emergency drugs with ET CO_2 monitor, an intravenous line with Ringer's Lactate was secured using either 18G or 20G intravenous cannula.

All patients were premedicated with IV fentanyl 2µg/kg IV midazolam 1mg & IV Glycopyrolate 0.2mg 5min before induction. All patients were pre-oxygenated with 100% O_2 for 3 min. Anaesthesia was then induced in **Group A** patients by 67% N_2O in O_2 and IV propofol 3mg/kg injected over 30 seconds. **Group B** patients were induced by mask with sevoflurane starting at 0.5% and incrementally increased to 4% inhaled concentration with 67% nitrous oxide in oxygen at a total gas flow of 8 liters/min and IV propofol 1.5mg/kg injected over 15 seconds and tracheal intubation was attempted at 240 seconds after the start of induction in both groups. Lignocaine 0.2mg/kg added to propofol to prevent pain on injection.

The heart rate and systolic blood pressure before and after induction and post-intubation at 1, 3 and 5 minutes were recorded. Time to induction in seconds (start of anaesthetic until loss of eye lash reflex), induction side effects like breath holding, cough, excitatory movements, laryngospasm and others (bradycardia, hypoxia, hyperthermia, hypothermia and injection site pain) were noted.

Tracheal intubation was performed using appropriately sized endo-tracheal tube. Intubating conditions were assessed by anaesthesiologist who performed intubation using Copenhagen Consensus Conference (CCC) score which graded the quality of tracheal intubation according to ease of laryngoscopy, position of the vocal cords, cough and movement of the limbs.

Copenhagen Consensus Conference (CCC) intubation score[8]

Laryngoscopy	Easy	Fair	Difficult
Vocal cords position	Abducted	Intermediate	Closed
Vocal cords movement	None	Moving	Closing
Limb movement	None	Slight	Vigorous
Coughing	None	Diaphragmatic movement	Severe coughing
Quality of intubation	Excellent	Good	Poor

Excellent = all scores excellent
Good = all scores excellent or good } Clinically acceptable
Poor = any score poor — Clinically unacceptable

When the trachea could not be intubated, IV succinylcholine 1.5mg/kg was administered intravenously. Following tracheal intubation in all patients, the tracheal cuff was gently inflated after confirming the position of the endo-tracheal tube by auscultation of chest and capnography and anaesthesia was maintained on oxygen, nitrous oxide and sevoflurane for 5min, afterwards sevoflurane was discontinued and muscle relaxants were administered.

Observations: The following parameters were studied during the procedure.

1. Time to induction (seconds): start of anaesthetic until loss of eye lash reflex
2. Induction side effects: Breath holding, cough, excitatory movements, laryngospasm and others like bradycardia, hypoxia, hyperthermia, hypothermia and injection site pain.
3. Quality of endotracheal intubation: based on Copenhagen Consensus conference (CCC) scoring system
4. Number of attempts taken for successful endotracheal intubation
5. Supplementation of endotracheal intubation with IV succinylcholine
6. Change in heart rate and systolic blood pressure during induction and intubation.

Statistical analysis: At the end of the study, the data was complied systematically and was subjected to statistical analysis using student 't' test and SPSS version 10.0 for windows. Value of $p<0.05$ was considered significant.

RESULTS

Demographic data:

This shows the distribution of age, sex and weight of the patients

Table I: Age distribution of patients studied

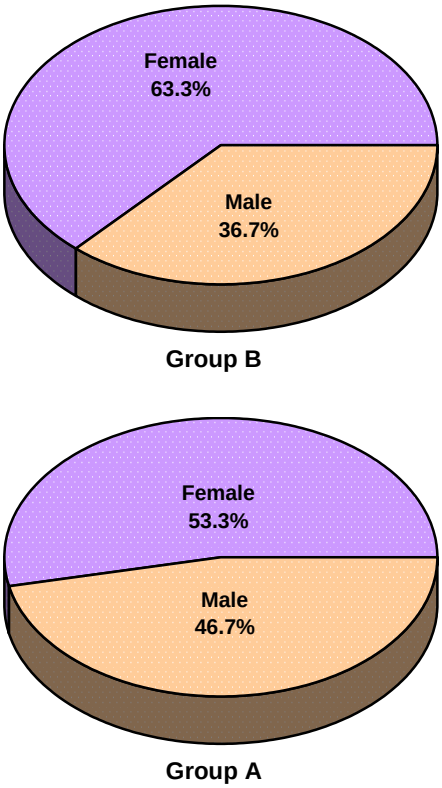
Age in years	Group A	Group B
20-24	9 (30.0%)	9(30.0%)
25-29	11(36.7%)	10(33.4%)
30-34	7(23.3%)	4(13.3%)
35-40	3(10.0%)	7(23.3%)
Total	30(100.0%)	30(100.0%)
Mean ± SD	27.23±5.22	28.67±5.99

Samples are age matched with p=0.327

* Moderately significant (P value: 0.01<P ≤ 0.05)

** Strongly significant (P value: P≤0.01)

Table II: Gender distribution of patients studied



Samples are gender matched with p=0.402

Table III: Weight distribution of patients studied

Weight (kg)	Group A	Group B
38-50	13 (43.3%)	11(36.7%)
51-60	11 (36.7%)	16(53.3%)
61-70	6(20.0%)	3(10.0%)
Total	30(100.0%)	30(100.0%)
Mean ± SD	52.53±7.30	53.10±7.56

Samples are weight matched with p=0.769

Statistical analysis of age, sex and weight distribution was done by using student's unpaired-t test. A p-value of less than 0.05 was regarded as significant. Both groups were found to be statistically similar with respect to age, sex and weight distribution.

Table IV: Time to Induction (seconds)

Time to induction (sec)	Group A (n=30)	Group B (n=30)
1-100	30 (100.0%)	0
101-200	0	29 (96.7%)
>200	0	1(3.3%)
Total	30 (100.0%)	30(100.0%)
Mean ± SD	39.80±8.10	156.07±21.58
Inference	Time to induction in seconds is significantly less in Group A (39.80 vs 156.07) with t=27.629; P<0.001**	

Induction time is significantly less in Group A patients (39.80±8.10) when compared with Group B patients (156.07±21.58), (p<0.001).

Table V: Both groups were found to be statistically similar with respect to breath holding, cough, excitatory movements, laryngospasm and other induction side-effects.

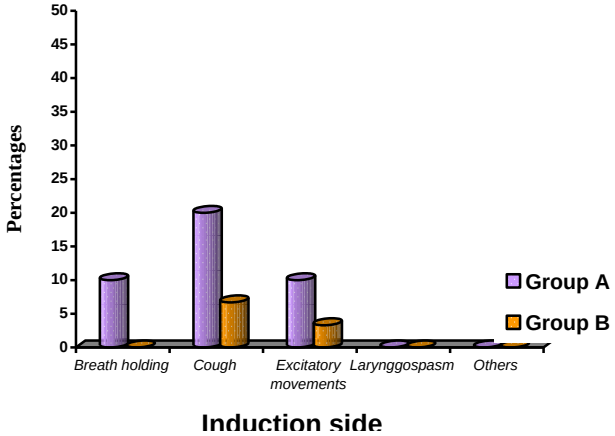


Table VI: Copenhagen Consensus Conference (CCC) intubation score

CCC endotracheal Intubation score	Criteria	Group A (n=30)	Group B (n=30)	P value
Laryngoscopy	Easy	18(60%)	25(83.3%)	0.103
	Fair	10(33.3%)	5(16.7%)	
	Difficult	2(6.7%)	0(0%)	
Vocal cords position	Abducted	20(66.7%)	25(83.3%)	0.202
	Intermediate	8(26.6%)	5(16.7%)	
	Closed	2(6.7%)	0(0%)	
Vocal cords movement	None	20(66.7%)	25(83.3%)	0.201
	Moving	7(23.3%)	5(16.7%)	
	Closing	3(10%)	0(0%)	
Limb movement	None	15(50%)	26(86.7%)	0.010*
	Slight	8(26.7%)	3(10%)	
	Vigorous	7(23.3%)	1(3.3%)	
Coughing	None	17(56.7%)	26(86.7%)	0.037*
	Diaphragmatic movement	9(30%)	3(10%)	
	Severe coughing	4(13.3%)	1(3.3%)	
Quality of Intubation	Excellent	13(43.3%)	25(83.3%)	0.006**
	Good	9(30%)	3(10%)	
	Poor	8(26.7%)	2(6.7%)	

Laryngoscopy was easy in 60% of patients in Group A and 83% in group B. The two groups were comparable with respect to laryngoscopy. (p=0.103, not significant).

Regarding position of vocal cords, they were abducted in 66.7% of patients, intermediate in 26.7% and closed in 6.7% of patients in group A. In group B, vocal cords were abducted in 83.3% and intermediate in 16.7% of patients. The two groups were comparable with respect to vocal cord position. (p=0.202, not significant).

Vocal cords were not moving in 66.7%, moving in 23.3% and closing in 10% of patients in Group A. In Group B vocal cords were not moving in 83.3% and moving in 16.7% of patients. The two groups were comparable with respect to vocal cord movement. (p=0.201, not significant)

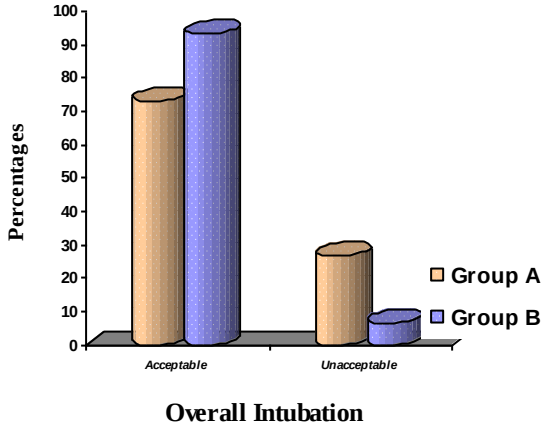
Limb movements were absent in 50%, slight in 26.7% and vigorous in 23.3% patients in group A. In Group B 86.7% patients didn't move, 10% slightly moved, the remaining 3.3% of patients had vigorous movement. Patients in Group A had more limb movements than in Group B, which is significant. (p=0.010, significant).

56.7% of patients in group A had no coughing, while 30% patients had diaphragmatic movements and 13.3% had severe coughing after intubation. Group B patients had no coughing in 86.7%, diaphragmatic movement in 10% and severe coughing in 3.3%. Patients in group A had more coughing than in group B, which is significant. (p=0.037, significant)

From the above studies, overall intubating conditions were significantly better in Group B than in Group A.

Table VII: Overall Intubation condition

Intubating conditions were clinically accepted in 73.3% of patients in group A compared to 93.3% in group B, which is highly significant (p<0.001).



Overall Intubation

Table VIII: Number of attempts

Number of attempts	Group A (n=30)	Group B (n=30)
1	23 (76.7%)	29(96.7%)
2	5(16.7%)	1(3.3%)
3	2(6.6%)	0
Inference	Number of attempts were significantly less in Group B when compared to Group A (3.3% vs 23.3%) with P<0.001**	

23.3% patients in group A required 2 or 3 attempts for intubation when compared with 3.3% in group B, which is highly significant (p<0.001)

Table IX: Tracheal intubation supplemented with succinylcholine

Tracheal intubation supplemented with succinylcholine	Group A (n=30)	Group B (n=30)
No	26(86.7%)	30(100.0%)
Yes	4(13.3%)	0
Inference	Tracheal intubation supplemented with succinylcholine is more associated with Group A with p=0.112	

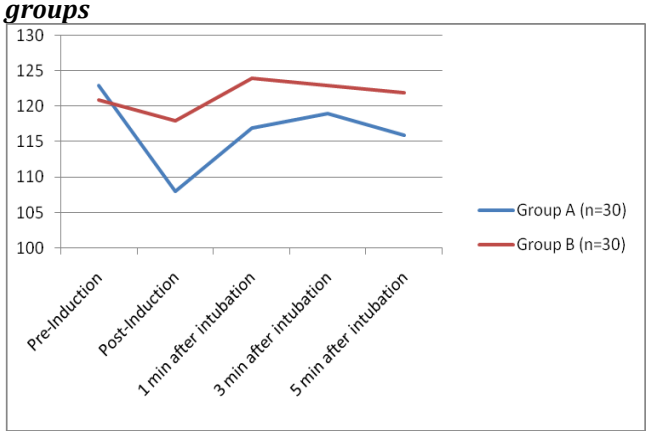
None of the patients in Group B required succinylcholine supplementation to achieve intubation, when compared with 13.3% in Group A, which is not significant (p=0.112)

Table X: Comparison of Heart rate (bpm) between two groups

Heart rate (bpm)	Group A (n=30)	Group B (n=30)	P value
Pre-Induction	90.97±9.86	89.13±13.63	t=0.597;p=0.553
Post-Induction	81.97±8.66	86.73±13.34	t=1.642;p=0.106
1 min after intubation	87.9±8.47	91.43±13.42	t=1.220;p=0.227
3 min after intubation	87.33±7.57	93.67±13.26	t=2.272;p=0.027*
5 min after intubation	87.67±8.1	89.23±13.33	t=0.550;p=0.584

There was no significant difference in heart rate after induction and post-intubation between the two groups except 3min after intubation which was significant (p=0.027)

Table XI: Comparison of SBP (mm Hg) between two groups



There was a significant difference in systolic blood pressure after induction and post-intubation at 1, 3 & 5min between the two groups (p<0.001, p=0.006, p=0.030, p=0.008 respectively)

DISCUSSION

Laryngoscopy and tracheal intubation are essential skills associated with practice of anaesthesia. It is said that for successful intubation it requires patient to be either deeply anaesthetized, paralyzed or anaesthesiologists stronger than patient. The drugs should be combined in such a way that it produces unconsciousness, analgesia and muscle relaxation without compromising hemodynamic stability, at the same time providing best intubating conditions.[3]Usually a combination of hypnotic agent, opioid and a neuromuscular blocking agent is used.

Over past few years, several factors have led researchers to ignore neuromuscular blocking agents for tracheal intubation. The driving force were introduction of propofol, short acting opioids and sevoflurane in clinical practice. Propofol not only suppresses upper airway reflexes and pressor response to laryngoscopy and tracheal intubation[21] but also provides faster recovery of consciousness, possess anti emetic action and reduces incidence of airway complications.[10]

Sevoflurane a new inhalational agent with low blood-gas solubility and a relatively pleasant odour produces rapid induction and recovery. It causes less myocardial depression and cardiac arrhythmias than halothane.[11]

The peak effect of propofol from the time of administration of drug was around 90-100s; **Mc Keating et al** study, showed that it is possible to perform laryngoscopy safely and smoothly at 120s after induction with propofol. Therefore we took 240s as a fixed time interval from the start of induction to intubation in Group A patients (IV propofol 3mg/kg). The use of fixed time interval tests an easily reproducible technique, independent of subjective assessments of depth of anaesthesia.[12]

In Group B patients (inhalational 4%sevoflurane with IV propofol 1.5mg/kg), we chose to evaluate tracheal intubating conditions 240s after the start of induction. The timing of tracheal intubation is complicated by the lack of reliable end points. Depth of anaesthesia is also difficult to assess clinically, with some anaesthesiologists using clinical indications such as constriction and centralization of pupils, and acceptance of face mask, while others have found eye signs unreliable. [13]**Swadia VN et al** had found

significantly greater time for tracheal intubation with sevoflurane i.e. (242.2±52.67s) and (325.93±44.02s) respectively. This difference was not only because of different clinical end points but also a different induction technique in which sevoflurane concentration was increased incrementally and ventilation was not assisted manually.[14]

Addition of 60% nitrous oxide reduces the MAC of sevoflurane by 24%, and fastens the onset of time of induction. 7.5% Sevoflurane in nitrous oxide and oxygen (41s) had reduced induction time by 15% compared to sevoflurane in oxygen alone (48s) using a single breath induction technique.[15]

During induction in Group B patients 6.7% had cough and 3.3% had excitatory movements, which is not significant. Induction time in Group B patients were 156.07±21.58s, when compared with Group A (39.80±8.10). Induction time were significantly more in Group B patients (t=27.629; p<0.001). (Table IV) In **Thwaites et al** study, all children could successfully be intubated with 8% sevoflurane in nitrous oxide and oxygen at 150s. 91% children had excellent intubating conditions and 9% had good intubating conditions. They demonstrated that 8% sevoflurane with nitrous oxide in oxygen can provide acceptable intubating conditions at 150s. In **Swadia et al** study, anaesthesia was induced with 60% nitrous oxide in oxygen and incremental increase in concentration of sevoflurane from 1-7%. Time interval from application of facemask to intubation was 242±52.67s. 80% of children had excellent intubating conditions. None had fair or poor conditions.16% had tachycardia, 8% had bradycardia and 80% had hypotension. Complications like laryngospasm, bronchospasm were not observed.[8,14]

During induction, 10% of patients in Group A had breath holding, 20% had cough and 10% had excitatory movements, which is not significant. Induction time in Group A patients were 39.80±8.10 seconds (Table IV&V). In a study by **Erhan E et al** clinically acceptable intubating conditions were found in 93.3%, 66.7% and 40% in patients receiving propofol, thiopental or etomidate respectively. Patients receiving propofol found to have less severe coughing after intubation when compared to thiopental or etomidate.[5]

In present study (Table VI & VII), tracheal intubation was accomplished in 86.7% of patients in Group A, only 73.3% of those patients had acceptable intubating conditions and remaining 26.7% of patients had unacceptable intubating conditions. Three factors made the intubating scores unacceptable were vocal cords movement (33.3%), coughing (43.4%) and limb movements (50%).Similarly, laryngoscopy was easy in 60%, fair in 33.3% and difficult in 6.7% of patients and vocal cords were moving in 23.4% and closing in 10% of patients, which is not significant. 13.3% of patients required succinylcholine supplementation to achieve intubation because of vocal cords movement, coughing and excessive limb movements. Only 76.7% of patients intubated at first attempt and remaining 23.3% required multiple attempts in group A.

However, tracheal intubation was accomplished in 100% of patients in Group B, 93.3% of those patients had acceptable intubating conditions when compared with 73.3% in Group A, which is highly significant (χ^2=4.320; p<0.001). In Group B, laryngoscopy was easy in 83.3% and fair in 16.7% of patients and vocal cords were abducted in 83.3% and moving in 16.7% of patients, which is not significant. 86.7% of patients had no cough in Group B, compared with 56.7% in group A. Coughing was significantly associated more with Group A (p=0.037). 10% of patients in Group B had diaphragmatic movements and 3.3% had severe coughing. Limb movements were absent in 86.7% of patients in Group B compared to 50% in Group A. Limb movements were significantly more in Group A (p=0.010). 10% of patients in Group B had slight and 3.3% had vigorous limb movements.

None of the patients in Group B required succinylcholine supplementation to achieve intubation. 96.7% of patients were intubated at first attempt in Group B when compared with 76.7% in Group A. Number of attempts were significantly less in Group B (p<0.001). (Table IX)

In present study (Table X & XI), there was definite reduction in heart rate and systolic blood pressure in Group A patients after induction and intubation when compared with pre-induction values. However, there was no significant difference among these parameters when compared with pre-induction values in Group B patients. Thus propofol decreased both heart rate and blood pressure, which indicates there was decrease in cardiac output. So propofol effectively attenuated the hemodynamic response to intubation. Similar results were found in other studies, **Srivastava U et al** found significant decrease in HR and arterial pressure from baseline in children given propofol and fentanyl.[16]

From the above study, it is found that propofol definitely causes reduction in HR and blood pressure following induction and attenuates hemodynamic responses to laryngoscopy and intubation. The decrease in HR and blood pressure in our study was due to synergistic effects of fentanyl and propofol. Fentanyl blunted hemodynamic response to laryngoscopy and intubation whereas propofol decreased sympathetic nervous activity. In **Swadia et al** study, sevoflurane group 16% patients, developed tachycardia, 8% had bradycardia and 80% had hypotension. In **Bithal PK et al** study, HR was significantly high in the sevoflurane group, during post-induction and immediate post-intubation and 1min post-intubation. MAP also increased but slightly from baseline.[1,14]

In our study, there was no significant difference in heart rate after induction and intubation between the two groups, except 3min after intubation, where, heart rate is significantly low in Group A (87.33±7.57) when compared with Group B (93.67±13.26), (p=0.027). There was significant reduction in systolic blood pressure after induction and intubation in Group A patients when compared with Group B patients.

CONCLUSION

A combination of 4% sevoflurane with 67% nitrous oxide in oxygen and propofol 1.5mg/kg preceded by fentanyl 2µg/kg without muscle relaxants had more acceptable intubating conditions compared to propofol 3mg/kg with 67% nitrous oxide in oxygen preceded by fentanyl 2µg/kg in adult patients undergoing various elective surgical procedures under general anaesthesia and there was no significant change in hemodynamic parameters during induction and intubation with respect to combination of 4% sevoflurane with propofol 1.5mg/kg.

Hence, we concluded that combination of inhalational 4% sevoflurane with IV propofol 1.5mg/kg is superior to IV

propofol 3mg/kg with respect to quality of intubation and less significance with respect to hemodynamic response during induction and intubation in adult patients undergoing various elective surgical procedures without muscle relaxants and also this combination is cost effective. This combination can also be attempted for anticipated difficult intubation.

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