Original Research Paper

Volume-9 | Issue-5 | May-2019 | PRINT ISSN No 2249 - 555X

Anaesthesiology

ASSESSMENT OF INTUBATING CONDITIONS AND HAEMODYNAMIC RESPONSES IN CHILDREN USING FENTANYL AND PROPOFOL AND ITS COMPARISON WITH MUSCLE RELAXANT TECHNIQUE

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ABSTRACT **Background:** Endotracheal intubation is frequently facilitated by administration of a depolarizing muscle relaxant such as suxamethonium during induction of anaesthesia with short-acting hypnotic drugs. However, suxamethonium administration may be associated with side effects such as postoperative myalgia, prolonged paralysis, increase in intraocular pressure and hyperkalaemia1 .Routine use of suxamethonium for tracheal intubation in children is being criticized following some reportsof cardiac arrest and death in young children. For these reasons,a method of providing good intubating conditions rapidly without using muscle relaxants has been sought by a number of investigators.

Aim & Objective: The purpose of the present study will be to assessintubating conditions and haemodynamic responsesin children after induction of anaesthesia usingfentanyl-propofol and to compare the results with those obtained with a propofol-suxamethonium induction sequence.

Material & Methods: This is a prospective study , conducted during (2017-2018) in our institute. 60 patients aged between 4-12yrs, ASA-I &ASA-II belonging to either sex were included in the study.The children who were posted to undergo various elective surgical procedures, for which endotracheal anaesthesia will be planned,were selected.Children with suspected difficult intubation,ASA physical status 3 or 4, havinghistory of allergy to any of the study drugs, undergoing ophthalmic and neurosurgical operations were excluded from study. Patients were randomly grouped into 2 groups of 30 each

GROUP- F:Inj. fentanyl 4 µg/kg + Inj. propofol 3 mg/kg

GROUP- S:Inj. propofol 3 mg/kg + Inj. suxamethonium 1 mg/kg.

The quality of intubation will be graded by using the scoring system devised by Helbo-HansenRaulo and Trap-Anderson. Four variables were assessed

- Ease of laryngoscopy
- Position of vocal cords
- Degree of coughing
- Jaw relaxation

Measurements of heart rate, systolic arterial pressure and arterial O2 saturation were noted at different time intervals (pre-induction, post-induction, postintubationat 0, 1, 3 and 5 minutes) Measurements at 1 minute after injection of atropine were taken as baseline values.Balanced anaesthesia was maintained subsequently as necessary for each case.

Results: Results of present study showed that tracheal intubation was successful in 86.7% of children receiving fentanyl 4 $\mu g.kg^{-1}$- propofol 3 $mg.kg^{-1}$ and 100% of patients receiving propofol3 $mg.kg^{-1}$–suxamethonium 1 $mg.kg^{-1}$. Only 4 out of 30 patients had unacceptable intubating conditions in the fentanyl-propofol group.

Conclusion: Ideal intubating conditions can be achieved without muscle relaxants using fentanyl and propofol and provide an useful alternative technique for tracheal intubation when neuromuscular blocking drugs are contraindicated or should be avoided.

KEYWORDS : Fentanyl,Intubation,Succinylcholine,Children,propofol.

INTRODUCTION

Endotracheal intubation is frequently facilitated by administration of a depolarizing muscle relaxant such as suxamethonium. However, suxamethonium administration may be associated with side effects such as postoperative myalgia, prolonged paralysis, increase in intraocular pressure and hyperkalaemia.[1]

In recent years, several changes have occurred that have reduced or obviated the need for muscle relaxants during paediatric anaesthesia. These include

1-The introduction of newer less toxic, shorter acting anaesthetic drugs and adjuvants (such as propofol, sevoflurane and remifentanil). Since the advent of shorter acting opioid drugs, intubating the trachea has been particularly successful when these drugs are used in combination with propofol. Propofol has been reported to depress pharyngeal and laryngeal reactivity to a greater extent than equipotent doses of thiopental.

2-The introduction of the laryngeal mask airway (LMA) which has replaced the tracheal tube as the method of controlling the airway in many paediatric operations. As the LMA can be inserted easily without the use of a muscle relaxant, its increasing popularity for airway control in children represents a decline in the use of muscle relaxants, which were previously widely used to facilitate tracheal intubation

3-In addition, there have been concerns about the safety of succinylcholine (SCh) in children.

Routine use of suxamethonium for tracheal intubation in children is being criticised following some reports of cardiac arrest and death in young children[2] Even the use of nondepolarizing relaxants may be associated with undesirable effects such as prolonged neuromuscular blockade, 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 conditions rapidly without using muscle relaxants has been sought by a number of investigators. Since the advent of shorter acting opioid drugs, intubating the trachea has been particularly successful when these drugs are used in combination with propofol. Propofol has been reported to possess some characteristics that provide adequate conditions for intubation in combination with fentanyl[3,4] or alfentanil[5,6] or remifentanil[7,8].

The purpose of the present study was

- To compare intubating conditions facilitated by suxamethonium versus fentanyl after induction of anaesthesia using propofol.
- To compare haemodynamic responses in both the techniques

MATERIAL AND METHODS

This was a randomized study of 60 paediatric patient of ASA I and II who were posted for abdominal or ENT surgeries requiring general anaesthesia, in department of Anaesthesiology of a tertiary care hospital for period of 1 yr (JULY 2017 to AUG 2018).

After obtaining approval from institute research and ethical committee and written consent from patient's parent, this study was undertaken.
Inclusion criteria

- ASA I and II
- Schedule for elective surgery
- Either sex between 4year to 12 yr
- Weight 5kg to 30 kg

Exclusion criteria

- Children with suspected difficult intubation,
- ASA physical status 3 or 4,
- History of allergy to any of the study drugs,
- Undergoing ophthalmic and neurosurgical operations Selection of group

Patients were randomized using a random number generator to one of the two group

1. In group F, Inj. fentanyl 4 μg.kg-1 and 5 minutes later Inj. propofol 3 mg.kg-1
2. In group S, Inj. propofol 3 mg.kg-1 followed by Inj. suxamethonium 1mg.kg-1

Preanesthetic check-up was done in the previous evening. A 22- or 24-guage intravenous catheter was inserted in the operating room and an infusion of crystalloid lactated ringer's solution was started according to the 4-2-1 formula(based on bodyweight and hours of fasting). All patients were premedicated with inj midazolam 0.05 mg.kg-1 - and atropine 0.01 mg.kg-1 intravenous (i.v) 10 minutes prior to induction. On arrival in the operative room, each patient received standard anaesthetic monitors, including Electrocardiogram, Non Invasive Blood Pressure Cuff, Pulse Oximeter.

All the baseline parameter including heart rate, blood pressure, and oxygen saturation was recorded. Measurements at 1 minute after injection of atropine were taken as baseline values.

Group F (study group)- Inj. fentanyl 4μg.kg-1 I.V. was given over 30 seconds. After giving fentanyl patients were watched for apnea, oxygen saturation and given 100% oxygen by mask.As fentanyl takes 5-7 mins for its plasma concentration to equilibriate with that of brain concentration,we waited for 5 minutes after which, the children received propofol 3 mg.kg-1 over a period of 30 seconds.Additional bolus of 1 mg.kg-1 of propofol was kept ready if laryngoscopy would not be possible due to muscle spasm, coughing or excessive movements. In those patients where intubation was impossible after two attempts due to any cause, suxamethonium 1 mg.kg-1 was injected and intubation was completed.

Group S (control group)- Anaesthesia was induced with Inj. propofol 3 mg.kg-1 followed by Inj. Suxamethonium 1 mg.kg-1.

Laryngoscopy and intubation was attempted 60 seconds after induction of anaesthesia in both the groups using proper size of laryngoscope . Laryngoscopy and intubation were done in all the patients by a senior consultant anaesthesiologist .The quality of intubating condition was assessed and recorded immediately by the senior intubating anaesthetist and was graded by using the scoring system devised by Helbo-HansenRaulo and Trap-Anderson[9] [Table 1].
During laryngoscopy and intubation, the intubating anaesthesiologist assessed each patient for four variables [Table 1]:
Ease of laryngoscopy
Position of vocal cords
Degree of coughing
Jaw relaxation

The observed conditions with respect to each of the above were allocated scores of 1 to 4. A score of 3-4 was considered excellent; 5-8, good; 9-12, poor; and 13-16, bad. Excellent and good scores were considered as clinically acceptable, and fair and poor scores were considered as clinically unacceptable.

Table 1: Scoring criteria for intubating conditions

	1	2	3	4
Laryngoscopy	Easy	Fair	Difficult	Impossible
Vocal cord	Open	Moving	Closing	Closed
coughing	None	Slight	Moderate	Severe
Jaw reflex	Complete	Slight	Stiff	rigid

Maintenance of anesthesia was accomplished by Oxygen +N2O and halothane 0.5%. A pediatric circuit or non- rebreathing circuit as per the weight of the patient was used in the surgical procedure.
Pulse, blood pressure, and oxygen saturation were recorded at 6 different time intervals (pre-induction, post-induction, postintubationat 0, 1, 3 and 5 minutes) for both the groups . Any complications were noted and treated immediately.

STATISTICS

The data generated was statistically analyzed . The tools employed for statistical analysis are: Mean, Standard deviation, students t test, Chi-square test.

The description of the data was done in the form of mean± SD for quantitative data. For quantitative data Student's t-test was used to compare between two groups. We considered excellent and good conditions as acceptable whereas fair and poor as non-acceptable. The Chi-square test was used to compare the intubation scores.
Significant figures

- Significant $p < 0.05$
- Strongly significant $p < 0.01$
- Not significant $P > 0.05$

RESULTS

After statistical analysis using chi square test, there was no statistical difference (p>0.05) found between the groups and the sex distribution between the two groups were comparable(Table 2)

Table 2: Sex distribution

Groups	Male n (%)	Female n (%)	P value
GROUP S	18(60)	12(40)	0.386
GROUP F	19(66)	11(34)	

Table 3: Age and weight distribution

GROUPS	AGE(Mean±S.D)	WEIGHT(Mean±S.D)
GROUP S	7.96 ± 1.98	19.85 ± 6.62
GROUP F	8± 2.36	20.15± 6.32
P value	0.94(NS)	0.86(NS)

The age and weight in the two groups were statistically analyzed by student unpaired t test and it was found that there was no statistical difference between the two groups (p>0.05) (Table 3)

The scores observed in each group based on the criteria used to assess ease of intubation are shown in Table 4.

Table 4A: Laryngoscopy score

GROUPS	SCORE 1 n (%)	SCORE 2 n (%)	SCORE 3 n (%)	SCORE 4 n (%)	P value
GROUP S	24(80)	6(20)	-	-	0.582(NS)
GROUP F	23(76.7)	5(16.7)	2(6.7)	-	

None of the patient of either group had a score of 3 or 4 except in 2 patients of fentanyl group (F).Laryngoscopy scores were compared between two groups using chi square test and found statistically not significant .Almost easy laryngoscopy occurred in both the groups.

Table 4B: vocal cord movement score

GROUPS	SCORE 1 n (%)	SCORE 2 n (%)	SCORE 3 n (%)	SCORE 4 n (%)	P value
GROUP S	28(93.3)	2(6.7)	-	-	0.24 (NS)
GROUP F	24(80)	6(20)	-	-	

The position of vocal cords during laryngoscopy was not-significantly different between the two groups (P value 0.24). Though in group F there were more incidence (20% of patient attend score 2) of vocal cord movement than the group S. chi square test was used for comparing the data.

Table 4C : Cough score

GROUPS	SCORE 1 n (%)	SCORE 2 n (%)	SCORE 3 n (%)	SCORE 4 n (%)	P value
GROUP S	25(83.3)	5(16.7)	-	-	0.006 (S)
GROUP F	14(46.7)	13(43.3)	3(10)	-	

After intubation of the trachea and inflation of the tracheal cuff, a small number of patients in each group coughed persistently, more in cases where muscle relaxant was not used. Both groups were compared statistically using chi square and found to be significant with a P value 0.006 which was highly significant. Slight cough was observed in 17% cases in group S ,whereas 53% cases in group F had cough. Moderate cough was observed after intubation in 3 cases of group F, where fentanyl was used .Additional bolus of 1 mg/kg of propofol was used in those 3 cases, to maintain the anesthetic depth and stop cough.

Table 4D : Jaw relaxation

GROUPS	SCORE 1 n (%)	SCORE 2 n (%)	SCORE 3 n (%)	SCORE 4 n (%)	P value
GROUP S	23(76.7)	7(23.3)	-	-	0.77 (NS)
GROUP F	21(70)	8(26.7)	1(3.3)	-	

Jaw relaxation was thought to be good in all patients.P value was 0.77 which was not significant. Only in one case jaw was stiff and in the same case laryngoscopy was also difficult with a score of 3.Intubation was achieved using succinylcholine in that patient. No patient appeared to manifest signs of opiod –induced rigidity at any time.

Table 5 : Scoring conditions for tracheal intubation

GROUPS	Score 3-4 (Excellent %)	Score 5-8 (Good %)	Score 9 -12 (Fair %)	Score 13-16 (Poor %)
GROUP S	19(63.3)	11(36.7)	0	0
GROUP F	12(40)	14(46.7)	4(13.3)	0

Excellent intubating conditions (intubation score, 3-4) were achieved in 12 (40%) out of 30 patients in group F and 19 (63.3%) out of 30 patients in group S. Good intubating conditions (intubation score, 5-8) were achieved in 14 (40%) patients in group F and 11(36.7%) patients in group S.

Fair intubating conditions (intubation score, 9-12) were observed in 4 (13.3%) out of 30 patients in group F as compared to 0 in group S [Table 5]. 3 patients were having a score of 9 with fair laryngoscopy, moving vocal cord, moderate cough, only slight jaw relaxation. Only 1patient had a score of 10 with difficult laryngoscopy, stiff jaw, vocal cord moving and slight cough in response to intubation. Poor intubating conditions (intubation score, 13-16) were observed in none among group F or in group S. There was one intubation failure in group F where succinylcholine was used.

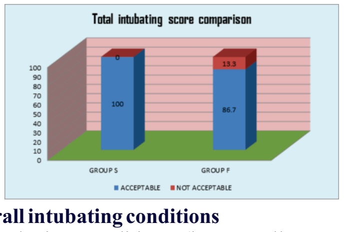


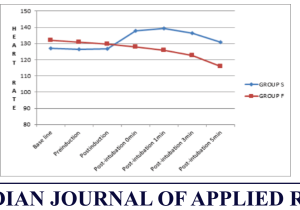
Figure 1: overall intubating conditions

Acceptable intubating conditions (i.e., excellent and good) were observed in 26 (86.7%) out of 30 patients in group F, whereas all (100%) patients in group Shad excellent intubating conditions (not statistically significant).

Unacceptable intubating conditions were observed in 4(13.3%) out of 30 patients in group F and none in group S; this was not statistically significant.

The mean basal heart rate was 127.13±8.97/min in group S and 132.03±10/min in group F, both of which were not statistically significant (P>0.05). There was significant decrease in heart rate in group F after intubation at 0, 1, 3 and 5 minutes when compared with preinduction values (P<0.001),whereas group S showed significant increase in heart rate after intubation at 0, 1, 3 and 5 minutes when compared with preinduction values (P<0.001) [Figure 2].

Figure 2: heart rate changes



The pre-induction systolic blood pressure was 114.6±14.37 mm Hg in group F and 113.87±10.12 mm Hg in group S, respectively, both of which were not statistically significant. The post-induction systolic blood pressures were significantly lower in both the groups (P value 0.001). The systolic blood pressure at intubation did not change significantly (P value 0.285) in group F whereas it showed a sharp rise in group S. The systolic blood pressure decreased significantly after intubation at 3 and 5 minutes in group F when compared with pre-induction values (P<0.001), whereas group S showed significant increase in systolic blood pressure at 0, 1, 3 and 5 minutes (P<0.001) [Figure 3].

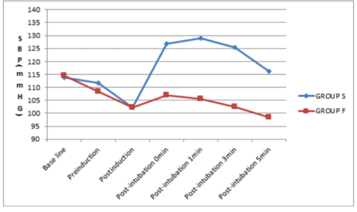


Figure 3:blood pressure changes

There was no significant change in arterial oxygen saturation in group F compared to groups S during the study period.

DISCUSSION

Tracheal intubation without the use of neuromuscular blocking drugs is a technique which has been widely studied and practiced. The present study was carried out in children to assess tracheal intubating conditions and hemodynamic changes after induction of anaesthesia by using fentanyl-propofol without the use of neuromuscular blocking drugs. This was compared with the standard technique of using propofol-suxamethonium. Out of 60 patients, 30 received fentanyl-propofol and 30 received propofol- suxamethonium .

The study showed that healthy pre-medicated children with favourable airway anatomy who are scheduled for elective surgery can be reliably intubated 60 s after co-administration of fentanyl 4 µg.kg^{-1}and propofol 3 mg.kg^{-1}. This may be attributed to propofol as it decreases muscle tone and abolishes laryngeal responses to tracheal intubation or to laryngeal mask insertion [10]. Propofol thus allows ease but the intubating conditions are not optimal. Increasing the depth of anesthesia by administration of fentanyl suppress the hemodynamic response to endotracheal intubation; as it's proved that addition of opioids in general improve intubating condition.

Keaveney and Knell [11]were one of the first workers who reported 95% success rate of intubation without using muscle relaxants by the use of propofol 2.5 mg.kg-1. Andel et al [12] studied the required dose of propofol used in combination with fentanyl for successful tracheal intubation without neuromuscular blocker. They reported that a dose of 2.7 mg.kg-1is needed. Propofol provides better jaw relaxation and attenuation of laryngeal reflexes than thiopental[13] .When used alone for tracheal intubation, propofol 2.5 mg.kg-1 provided satisfactory conditions in 19/20 (96%) patients and ideal intubating conditions in 14/20 (60%) patients[14] .Better intubating conditions with propofol than other hypnotics have been reported by Erhan E et al [15]and Mckeating K et al [16].

Similarly, ***Gupta et al*** [17] ,and ***de Fatima de Assuncao Braga et al*** [18] also concluded that propofol–fentanyl is a good combination for tracheal intubation without significant haemodynamic changes. Gupta and others in their study, on evaluation of different doses of propofol with prior administration (3 minutes before) of 3 µg.kg^{-1} of fentanyl in children in the age group of 3 to 10 years found a dose of propofol of 3.5 mg.kg^{-1}to be effective in producing acceptable intubating conditions. Doses of 3 to 3.5 mg.kg^{-1}of propofol produced good attenuation of haemodynamic responses to intubation.

In light of the above studies, in present study 4 µg.kg^{-1} fentanyl was given 5 minutes before induction, and induction dose of propofol 3 mg.kg^{-1}was used. An additional advantage with fentanyl is the ability to maintain spontaneous breathing in case of intubation failure as a result of airway pathology. Fentanyl was one of suitable opiods used in this study as its short duration of action facilitated prompt recovery from anaesthesia, although duration of apnoea after intubation was not the subject of this study all the patients were breathing spontaneously before the completion of surgery and extubation was not delayed because of apnoea.

Results of present study showed that tracheal intubation was successful in 86.7% of children receiving fentanyl 4 µg.kg^{-1}- propofol 3 mg.kg^{-1} and 100% of patients receiving propofol3 mg.kg^{-1} –suxamethonium 1 mg.kg^{-1}. Only 4 out of 30 patients had unacceptable intubating conditions in the fentanyl-propofol group. This result is comparable with the finding of ***Gupta A, Kaur R, Malhotra R, et al*** who got acceptable intubating conditions in 80% patients with a combination of Propofol 3 mg.kg^{-1} preceded by fentanyl 3 µg.kg^{-1}.Similar result was found in study of ***De Fátima De Assunção Braga A, Da Silva Braga FS et al*** who got adequate tracheal intubating conditions in 75% of the patients with Propofol 3 mg.kg^{-1}preceded by fentanyl 3 µg.kg^{-1}. A lower success rate than my study might be due to the lower dose of fentanyl used by them. ***Safiya and Vijayalaxmi***[19] reported that tracheal intubation could be accomplished using a combination of fentanyl (4 µg.kg^{-1}) and propofol (3 mg.kg^{-1}) in 95% cases.. This may be attributable to methodologic differences in the two studies, as present study did not include lidocaine in premedication . Their high success rate could be due to the use of lignocaine before intubation Lignocaine has been shown to attenuate the pressor & heart rate response to laryngoscopy and intubation, it abolishes the pain on injection and due to antitussive effects, it improves the intubation scores[20]. ***Bulow and colleagues***[21] used propofol 2.5 mg.kg^{-1}and alfentanil 30 mg.kg^{-1}, and then sprayed the vocal cords with lidocaine 160 mg, 90 s before intubation. Satisfactory conditions were obtained in all 27 patients in this group compared with 73% in the saline group.

Sustained cough is the main encountered obstacle when omitting relaxants. In the present study 4 cases in group F secured an intubation score greater than 9 out of which 3 cases scored maximum due to presence of moderate degree of post intubation coughing. It must be pointed out, though, that unless supplemental anesthesia is quickly administered, some patients will begin to cough or move within a few minutes, particularly in response to surgical positioning or preparation. Thus, when using this technique for tracheal intubation, additional anesthetic drugs such as nitrous oxide, isoflurane, propofol, or thiopental should be administered soon after induction to reliably prevent coughing or movement.

On the contrary, ***Uma Srivastava et al***.[22] ***Mencke Thomas et al***.[23] and ***Samar et al***.[24] have achieved lower success rate despite augmentation of propofol with fentanyl. The result obtained in present study are significantly better than ***Leitaut T et al***[25] who found clinically acceptable intubating conditions in only 35% of patients with propofol 2.5 mg.kg^{-1}and fentanyl 3 µg.kg^{-1}.In their study authors performed laryngoscopy and intubation 3 min after fentanyl injection whereas in present study laryngoscopy and intubation were performed 6 min after fentanyl injection.The peak action of fentanyl comes after 7 min[26,27] and the smaller time lag after fentanyl injection might be the cause of their poor success.

The pattern of haemodynamic response to induction of anesthesia in present study was consistent with other studies. ***Safiya and Vijayalaxmi*** reported that heart rate decreased significantly after intubation in patients who received fentanyl and propofol, whereas heart rate was increased in patients given propofol–suxamethonium. Similar result was seen in present study. In present study there was significant decrease in systolic blood pressure in both groups after induction when compared to pre induction values. The administration of propofol in a dose of 2-2.5 mg.kg^{-1} can lower mean blood pressure by 25% to 40%. This drop is secondary to both the vasodilator and the myocardial depressant effects of propofol. This relative hypotension is always associated with good peripheral perfusion, as evidenced by continuing digital pulse oximetry readings, and is short lived.

Muscle rigidity was not observed during this study. The jaw was judged to be relaxed in all patients and the lungs of all could be easily ventilated via mask.

This study had the limitation of lack of double blinding .Also here it is to be highlighted that, there exists wide subjectivity when assessing individual variables such as coughing , vocal cord movement and jaw relaxation. From a clinical point of view, excellent intubation conditions might be considered by some as the standard, rather than clinically acceptable intubating conditions, which includes both excellent and good conditions.

CONCLUSION

The present study was undertaken to highlight the benefits of avoiding suxamethonium, using only the opioid-propofol technique for routine intubation in paediatric age groups. Results of present study suggest that in premedicated healthy children administration of fentanyl 4µg.kg^{-1} in combination with propofol 3mg.kg^{-1}, after adequate waiting period of 6min, reliably provides good to excellent conditions for tracheal intubation and blunts the pressor response to intubation adequately without significant cardiovascular depression.. Thus ideal intubating conditions can be achieved without muscle relaxants using fentanyl and propofol and provide an useful alternative technique for tracheal intubation when neuromuscular blocking drugs are contraindicated or should be avoided.

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