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Comparative Evaluation of Different Doses of Propofol without Muscle Relaxants for Intubation

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Abstract : *It has been proved that Propofol is sufficient to intubate patients without muscle relaxants, because of its property to suppress airway reflexes better than any other agents . Therefore we evaluated intubating conditions with different doses of Propofol without muscle relaxants on 90 patients of ASA Grade I and II posted for elective surgery requiring general anaesthesiainto group I (Propofol 2mg/kg);group II (propofol 2.5mg/kg)group III (Propofol 3mg/kg).Pre medicationwith inj. Glycopyrrolate, inj. Ranitidine, inj. ondensetron, inj. Midazolam and inj. Fentanyl as slow iv given. After 5mins, Inductionof anaesthesia was done with inj. Propofol followed by inj. Lignocaine (preservative free)1.5mg/kg as IV bolus, 90 seconds after completion of Propofol, intubation was performed. Intubating conditions were assessed at various level. Ideal conditions for intubation without muscle relaxants were possible with 3 mg/kg Propofol, 2 µg/kg fentanyl & 1.5 mg/kg lignocaine. The stress response to laryngoscopy and intubation attenuated well.*

Keywords: *Airway reflexes, fentanyl, intubation, propofol, without Muscle relaxants.*

I. Introduction

Since very long time various induction agent with minimal side effects have been tried . So far the Thiopentone has remained the only intravenous induction agent in spite of many induction agent have been introduced . Presently Propofol is most commonly used anesthetic agent in general anesthesia and has been accepted as an effective alternative to time tested Thiopentone for intravenous induction in recent years . Since 1988 anaesthesiologist have proved that induction dose of Propofol is sufficient to intubate patient without muscle relaxants . Propofol is unique in having property to suppress airway reflexes better than any other agent . Therefore it was undertaken to evaluate clinically acceptable intubating conditions with different doses of Propofol without muscle relaxants[1].

Propofol is an ideal induction agent as it produces reliable sedation, good operating condition and haemodynamic stability. The administration of Fentanyl with Propofol decreases the hypertensive response to intubation . Use of depolarizing muscle relaxant like Suxamethonium may be associated with postoperative myalgia , prolonged paralysis , increase intraocular pressure and hyperkalaemia[2] . Tracheal intubation was successful in 95% of patients receiving Fentanyl- Propofol and 100 % of patients receiving Propofol Suxamethonium . Fentanyl Propofol provided better haemodynamic stability than Propofol Suxamethonium[3] .

II. Patients And Methods

All the patients and their attendants were explained , in detail , about the procedure and kept nothing by mouth after 10 p.m. in the previous night of surgery . They were randomly divided into three groups of 30 patients each .

Group I (n = 30) injection Propofol 2 mg\kg IV
Group II (n = 30) injection Propofol 2.5 mg\kg IV
Group III (n = 30) injection propofol 3 mg\kg

Criteria for choosing patient include age between 20 to 50 years , ASA grade I and II patients posted for abdominal , orthopaedic , gynecological , ENT surgeries requiring general anaesthesia. Patients with history of hypertension , asthma , Ischemic heart diseases, TB, Diabetes Mellitus , COPD previously documented difficult intubation Patients undergoing neurosurgical and ophthalmic operations Elderly and debilitated patients , impaired liver and renal functions excluded from the study.

Pre –anaesthetic assessment was done prior a day and proper advise was given . In the operation theater after proper identification of patients , written informed consent was taken . Preoperatively pulse and BP were recorded. After applying monitors and starting IV line with 18 G cannula and the ringer lactate 10 ml\kg was given 10 minutes before induction . Premedicated with inj. Glycopyrrolate 5mcg\kg IV , inj. Midazolam 0.02mg\kg IV and inj. Fentanyl 2mcg\kg IV one after other as slow iv bolus in the

same order were given to all patients . After giving inj. Fentanyl patients were watched for apnea , oxygen saturation and were given 100 % oxygen by mask , as Fentanyl takes 5 -7 minutes for its plasma concentration to equilibrate with that of brain concentration .

Induction of anaesthesia was done with inj. Propofol either 2mg\kg , 2.5 mg\kg or 3mg\kg IV slowly in precalculated amount , chosen randomly followed by inj. Lignocaine (preservative free)1.5mg\kg as IV bolus. Patients were watched for apnea , oxygen saturation and ventilated with bag & mask with 100 % oxygen . 90 seconds after completion of Propofol injection, laryngoscopy and intubation was performed . For success only one attempt at laryngoscopy and intubation was considered . All male patients were intubated with portex cuffed endotracheal tube No.8.5 and female patients with No.7.5 . Intubating conditions were assessed by scoring system . Clinically acceptable intubating conditions were excellent and good score . Hemodynamic score were recorded by at following stages : - Baseline value , after premedication , at 5 minutes after injection Fentanyl , after giving Propofol and Lignocaine , pre intubation , post intubation , 5 minutes after intubation . Patients those were not intubated they intubated with muscle relaxants.

III. Results

There was no statistical significant difference in age, sex and weight in any group .

In group I clinically acceptable intubating conditions(excellent and good)were present in 59.99 % (60%) patients with failure rate being 40 % while in group II clinically acceptable intubating conditions (excellent and good) were present in 86.66% of patients with failure rate being 13.33% and in groupIII clinically acceptable intubating conditions were present in 93.33% of patients with failure rate being 6.66% .Thus clinically acceptable intubating conditions in groupI were in less patients (60 %) with 40% failure rate in comparision to group II & III , where these were significantly better ($p < 0.05$) in group II & III (86.66% to 93.33 %) with failure rate of 13.33 % & 6.66% respectively .

During laryngoscopy and intubation there was signficant increase in heart rate in all three groups but when compared between group I ,II and III there was no statistically significant difference .

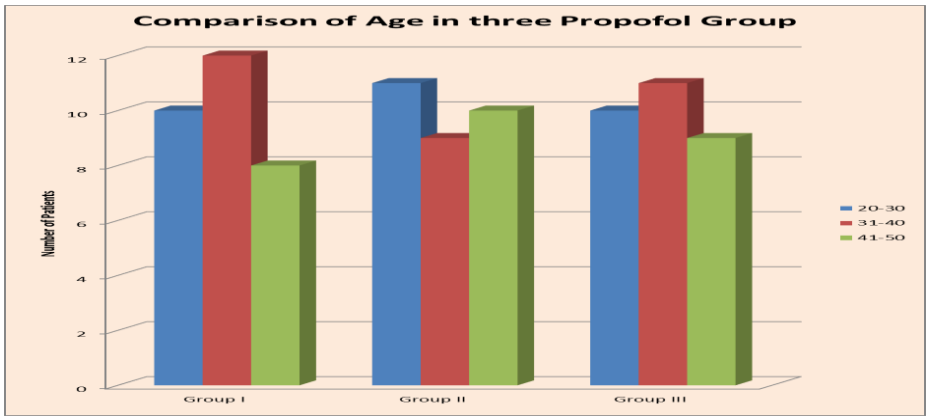
During laryngoscopy and intubation there was significant rise in MAP in groupI ($P<0.05$) not only from the baseline level but also from the level at pre oxygenation . 5 Minutes after intubation the MAP returned almost to baseline level . In group II and III ,during laryngoscopy and intubation there was rise in MAP but it remained below the baseline level and remained same 5 minutes after intubation .

Observations

Table No.1 Comparison of Age (n=30 in each group)

Age (in yrs)	Group I	Percentage	Group II	Percentage	Group III	Percentage
20-30	10	33.33	11	36.66	10	33.33
31-40	12	40	9	30	11	36.66
41-50	8	26.66	10	33.33	9	30

P value= 0.948 Chi-Squire = 0.7 DF =2



Comparison of Sex (n=30 in each group)						
Sex	Group I	Percentage	Group II	Percentage	Group III	Percentage
Male	16	53.33	18	60	13	43.33
Female	14	46.66	12	40	17	56.66

P value= 0.948 Chi squire =1.692 DF =2

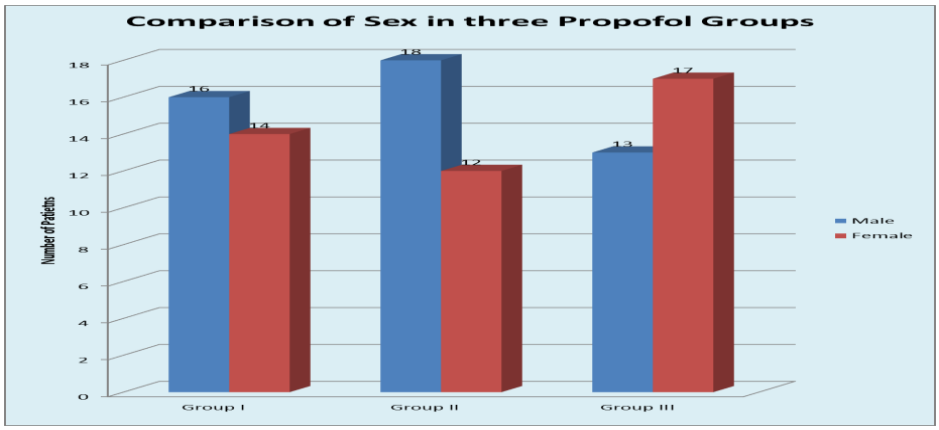


Table No.3(n= 30 in each group)						
Comparison of Weight						
Weight (Kg)	Group I	Percentage	Group II	Percentage	Group III	Percentage
50-60	17	56.66	19	63.33	18	60
61-70	13	43.33	11	36.66	12	40

P value=0.87 Chi squire = 0.278 DF = 2

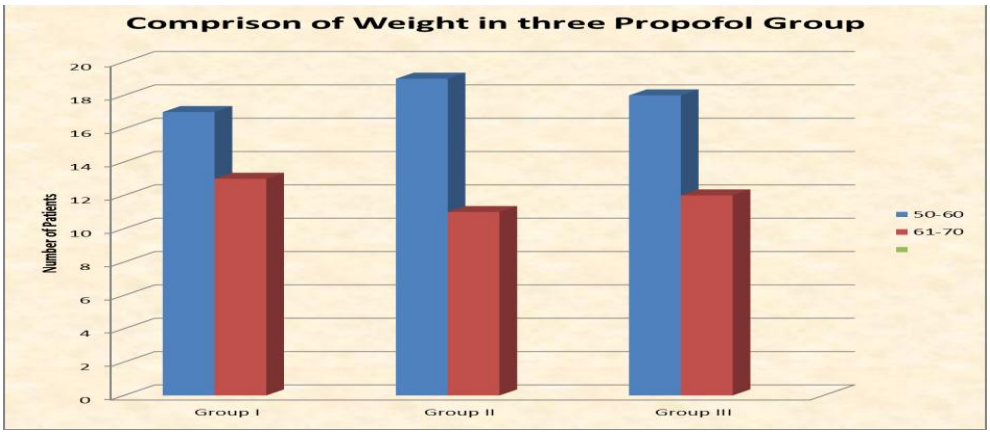


Table No.4						
Comparison of Intubating conditions (n= 30 in each group)						
Grading	Group I	Percentage	Group II	Percentage	Group III	Percentage
Excellent	2	6.66	16	53.33	15	50
Good	16	53.33	10	33.33	13	43.33
Inadequate	12	40	4	13.33	2	6.66

P value =0.0002 Chi squire =21.809 DF = 4

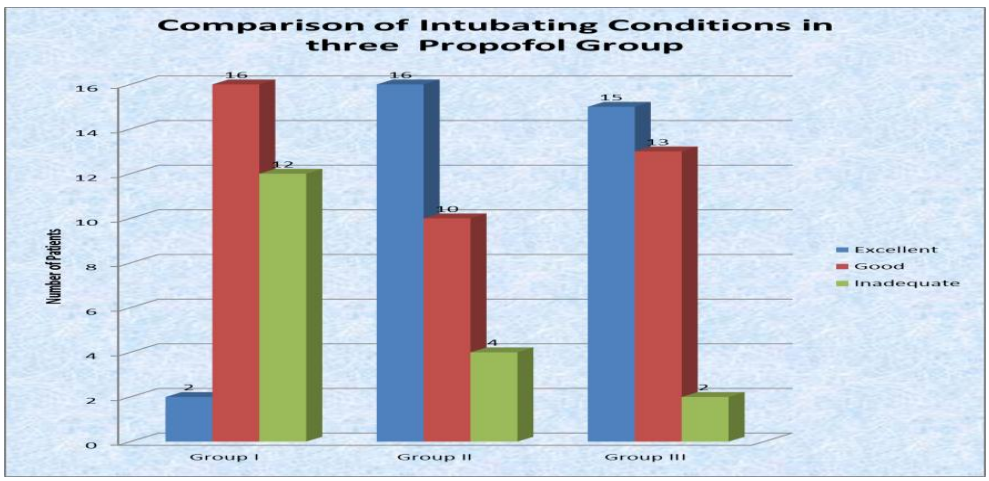


Table No.5					
Comparison of Jaw Relaxation (n=30 in each group)					
S.No.	Group	Jaw Relaxation			
		Full Relaxed	Mild Resistance	Tight but Open	Impossible
1	I (2mg/kg)	2	17	2	9
2	II (2.5 mg/kg)	16	5	5	4
3	III(3mg/kg)	15	13	2	0

P value =0.0001 Chi squire = 28.87 DF = 6

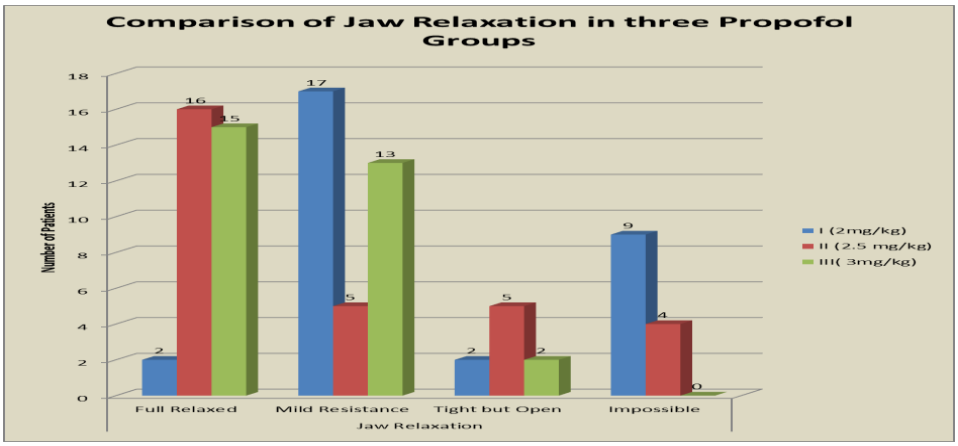


Table No.6					
Comparison of Vocal Cord Position (n=30 in each group)					
S.No.	Group	Vocal Cord Position			
		Widely Open	Mid Position	Moving but Open	Closed
1	I (2mg/kg)	2	13	3	11
2	II (2.5 mg/kg)	17	5	4	4
3	III(3mg/kg)	16	12	2	0

P value=0.0001 Chi squire = 30.52 DF = 6

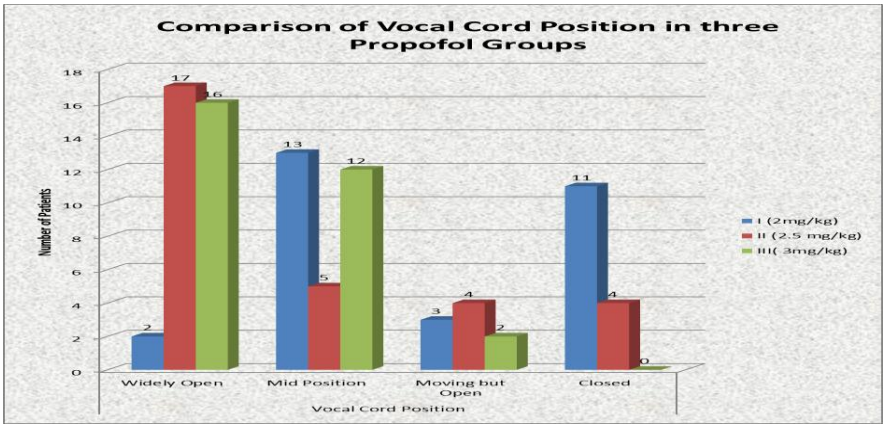


Table No.7					
Comparison of Intubation Response (n= 30 in each group)					
S.No.	Group	Intubation Response			
		None	Diaphragmatic Movement	Slight Coughing	Severe Coughing
1	I (2mg/kg)	2	2	15	11
2	II (2.5 mg/kg)	21	5	0	4
3	III(3mg/kg)	15	13	2	0

P value =0.0001 Chi squire =60.407 DF =6

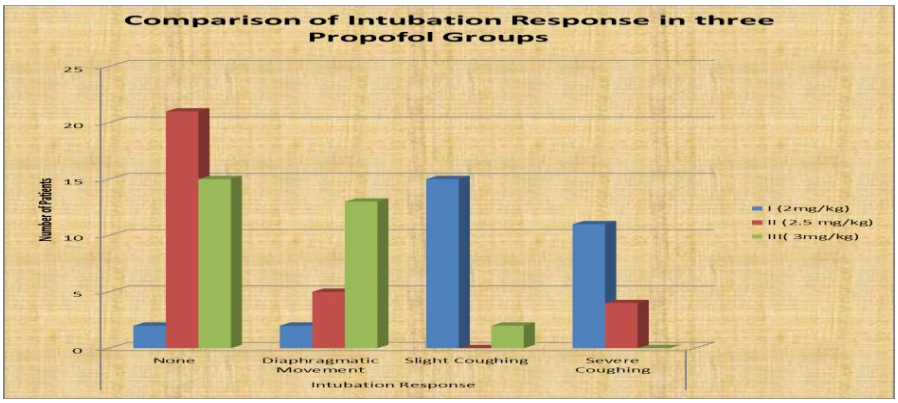


Table No.8			
Comparison of Heart Rate			
Time	Group I	Group II	Group III
Pre Operative	77.06±5.20	77.2±5.26	77.23±4.98
After pre medication	75.1±5.49	75.56±5.22	75.6±4.84
After propofol	75.43±4.44	75.73±4.52	75.8±4.48
Pre Intubation	75.83±4.45	75.96±4.65	75.96±4.65
Post Intubation	81.83±3.83	81.83±3.83	81.53±4.26
5 min after intubation	76.96±5.95	77.23±5.90	77.46±5.66

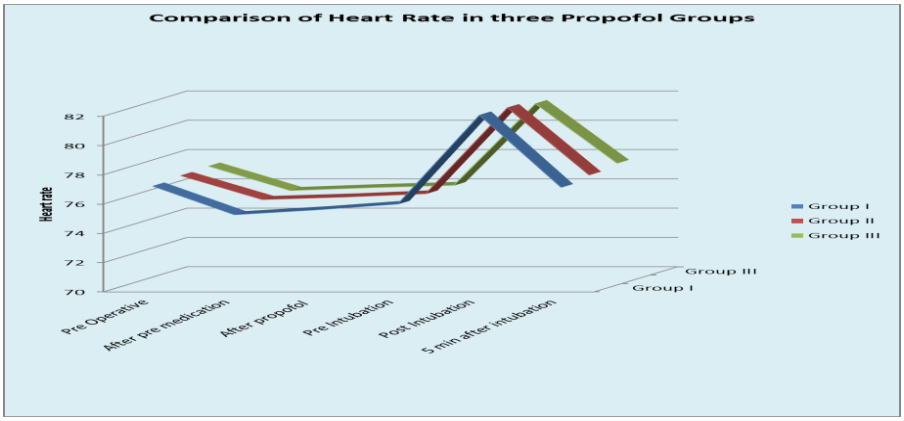


Table No.9				
Comparison of Mean Arterial Pressure in three Propofol Groups				
S.No.	Time	Group I	Group II	Group III
1	Pre Operative	91.46±4.70	91.13 ± 3.13	91.93 ± 2.47
2	After pre medication	88.56 ± 4.52	88.3 ± 2.97	89.46 ± 1.68
3	After propofol	81.03±5.19	80.53±2.60	81.83±1.57
4	Pre Intubation	80.2 ± 4.42	80.83 ± 3.05	81.46 ± 1.56
5	Post Intubation	90.8±4.79	89.13±3.40	88.46±4.03
6	5 min after intubation	87.03 ± 5.45	88.06 ± 2.69	83.96 ± 1.81

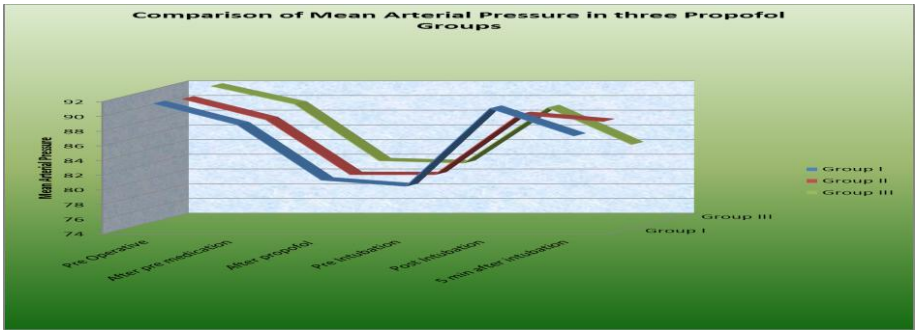
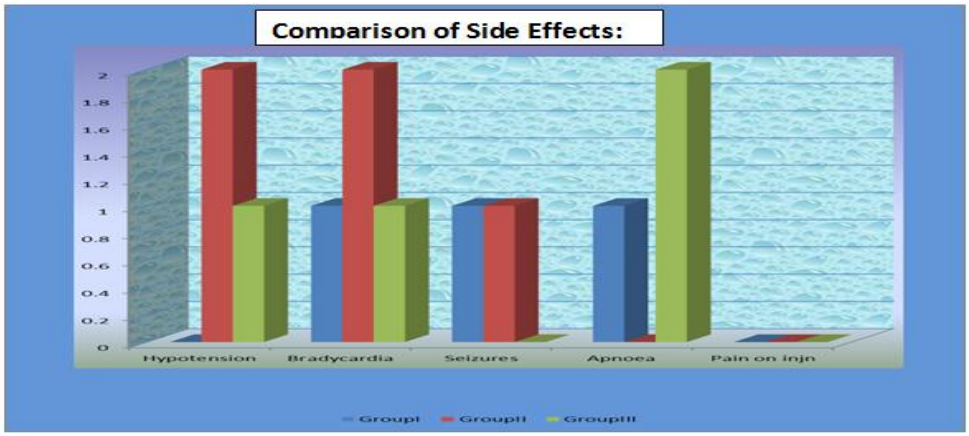


Table No.10 Incidence of side effects

Side effects	Group I	Percentage	Group II	Percentage	Group III	Percentage
Hypotension	0	0%	2	6.66%	1	3.33%
Bradycardia	1	3.33%	2	6.66%	1	3.33%
Seizures	1	3.33%	1	3.33%	0	0%
Apnoea	1	3.33%	0	0%	2	6.66%
Pain on injection	0	0%	0	0%	0	0%



IV. Discussion

Anaesthesia provides relief from pain and suffering during surgery with simultaneously providing good operating conditions. Previously the methods which were used to anaesthetize the patients, were associated with various side effects and some of which were life threatening. Now due to improved anaesthetic techniques surgery has become easy with good and smooth outcome .Induction of anaesthesia is one of the important events in the conduct of general anaesthesia. Prior to the introduction of intravenous anaesthetic agents ,induction of general anaesthesia necessarily required inhalation of gases or vapours which was an unpleasant experience to most of the patients . However intravenous agents are also not free from side effects. Presently among inravenous agents Propofol is commonly used drug which shows various haemodynamic changes during induction. Propofol also used for intubation. Keaveny JP and Knell PJ (1998)[1] were amongst the first workers to propose the concept of intubation with only Propofol without muscle relaxants .This was the beginning for the thought of elimination of muscle relaxants for intubation .

We in our study have compared different doses Propofol with lignocaine and fentanyl to obtain clinically acceptable intubating conditions without using muscle relaxants .Attenuation of pressor response and haemodynamic changes were also observed during the study .

Anaesthesiologists have tried to formulate combination of drugs which will help us to intubate patients without coughing or bucking in absence of muscle relaxants.

Age and Weight distribution

Age of patients in three groups varied between 20-50 years. There was even distribution of age in all three groups .

A random allocation of patients was done in different groups. To judge the clinical significance , observations for the age distribution were subjected to chi-squire test and mean age difference was statistically not significant ($p > 0.05$) . Gore MS and Harnagale KD (2011)[4] ,Enas AEM and Alaa ED (2011)[5]have also studied with same age group which concide with our study.This has helped us to judge the clinical significance of our study as if the distribution, metabolism, excretion and action of the drug are undoubtedly varied in different age groups . Therefore , clinically insignificant variations in age group simply helped to alleviate these confounding factors .

Weight distribution

There was even distribution of weight in all the three groups .The variation in the distribution of patients according to weight in different groups was not significant ($p> 0.05$). This also helped in, alleviating a point of controversy because obesity as well as cachexia has clinically significant effect on the clinical action of drug. Mean weight of the patients in present study was 61.5 ± 5.18, 60.13 ± 4.81, 60.5 ± 4.43 in Group I, II and III respectively.

Sex distribution

To know the statistical significance of male : female ratio chi-squire test was applied .The male female ratio was almost equal in all four groups showing no statistical significance (p>0.05) .Gore MS and Harnagale KD (2011)[4], Lallo A et al (2009)[6] have also used the inclusion and exclusion criteria which coincides with our study.

Intubating conditions

In our study in Group I (Propofol 2mg/kg) we found that 6.66 % of patients had excellent and 53.33% patients had good intubating conditions. Thus 59.99% patients had clinically acceptable intubating conditions (excellent and good) .However 40% patients could not be intubated and had to be given muscle relaxants to achieve it .Gore MS and Harnagale KD (2011)[4]found better results than us with 2mg/kg propofol. They found acceptable (excellent and good) intubating conditions in 66.70% patients with failure rate 33.30%. Better intubating conditions with 2mg/kg of propofol have been reported by Erhans E et al(2003)[5] achieved along with remifentanil 30µg/kg. Scheller M et al (1992)[7] achieved 100% success rate with 2mg/kg propofol and 40µg/kg Alfentanil as optimum dose They observed that when dose of Alfentanil was increased to 50µg/kg success rate dropped to 93% and with 60µg/kg it further dropped to 86% which author could not be able to explain the reason.

However **Saarnivara L and Klemola VM** (1991)[8] achieved only 16% success rate with 2 mg/ kg propofol and 30 µg/ kgAlfentanil.

Compared to our study the higher success rate achieved by **Grant S** et al (1998)[9] and **Scheller M et al(1992)[7]** might be due to use of Remifentanil and Alfentanil.

In our study in group II with propofol 2.5 mg/ kg we found that excellent intubating conditions were present in 53.33% of patients and good intubating conditions were present in 33.33%. Thus 86.66% patients had clinically acceptable intubating conditions and only 13.33 % of patients could not be intubated and were given muscle relaxants for achieving it . The results found better in study conducted by Gore MS and Harnagale KD (2011)[4] where they found excellent intubating conditions in 66% patients and good incubating conditions in 36.70% patients with 2.5mg/kg propofol .Thus they found clinically acceptable intubating conditions in 96.70% patients and failure rate was 3.30% ,which is better than us.

The result obtained in our study are significantly better than **Leitaud T** et al(2003)[10] who found clinically acceptable intubating conditions in only 35% of patients with propofol 2.5 mg /kg (like us) and Fentanyl 3 µg /kg(higher than us). In their study authors performed Laryngoscopy and Intubation 3 mins after Fentanyl injection whereas we did Laryngoscopy, Intubation at 7 mins after Fentanyl injection. The peak action of Fentanyl comes after 7 mins and the smaller time lag after Fentanyl injection might be the cause of their poor success.

Similar results of intubating conditions with Propofol 2.5mg/kg and alfentanil 10µg/kg have been found by Davidson JAH et al (1993)[11] and Alcock R et al (1993)[12] as clinically acceptable intubating conditions in 93% and 86% respectively but in contrast to these better results Mulholand D et al(1991)[13] and Hovorka J et al(1991)[14] found clinically acceptable intubating conditions in 66% and 46% which might be due to that they did not used any opioids in premedication resulting poor success. Erhans E et al (2003)[5] have also noticed better intubating conditions in their study.

In our study with 3 mg /kg Propofol we got excellent intubating conditions in 50% of patients and good intubating conditions in 43.30% of patients. Thus clinically acceptable intubating conditions were found in 93.33% of patients with only 6.66% failure rate .Our results coincides with the study conducted by Gore MS and Harnagale KD (2011)[4] whoachieved excellent intubating conditions in 56.70% of patients and good intubating conditions in 43.33% of patients .Thus overall clinically acceptable intubating conditions were found in 100% of patients with Failure rate zero, which shows better results .

Shaikh S & Vijaylaxmi PB (2010)[2], Gupta A et al (2006)[15] and Grange CS et al (1993)[16] have also found clinically better acceptable incubating conditions with 3mg/kg Propofol and fentanyl in 95%, 80% and 93% patients respectively which coincides with our study where we used also fentanyl with 3mg/kg Propofol and found acceptable intubating conditions in 93.33% patients . In contrast to these results Khouri SJ et al (2003)[17] found acceptable intubating conditions in 62.5% patients which is little less than our study, might be because they intubated the patients in 90 seconds after fentanyl while we intubated after 7 mins of fentanyl injection.

In another study conducted by Da Silva Braga FS et al (2001)[18] achieved 75% success rate with 3mg/kg propofol and 80% success rate with 3.5mg/kg propofol and this lower success rate might be due to fentanyl was not used .

Cardiovascular system

Attenuation of pressor response and hemodynamic changes were also assessed. For this we took the blood pressure recordings after premedication (midazolam and fentanyl) as the baseline blood pressure for comparison between different propofol groups and found that in all the three groups after premedication there was a fall in MAP compared to baseline level which is not significant.(P >0.5)Our results coincides with the study of Gore MS & Harnagale KD (2011)[4] .

When compared between the three groups there was no significant difference in the fall of MAP with 2, 2.5, 3 mg kg^{-1} of propofol. Similar results of fall in MAP not requiring active management have been reported by Stevens JB et al (1998)[19] and Grant S et al(1998)[9] .

During Laryngoscopy and intubation there was significant increase in Heart rate in all the three groups but when compared between group I, II and III there was no significant difference .

However during Laryngoscopy and Intubation there was a significant rise in MAP in group I. The rise was significant not only from the baseline level but also from the level at preoxygenation. 5 min after Laryngoscopy and Intubation the MAP returned almost to the baseline level.

In group II and III during laryngoscopy and intubation there was rise in MAP but it remained below the baseline level and remained same 5 min after intubation.

There was significant difference in response to larygoscopy and intubation between group I and group II and III. There was good attenuation of response to laryngoscopy and intubation in 2.5 mg/ kg and 3 mg/ kg propofol group along with 1.5 mg/ kg Lignocaine and 2 µg /kg fentanyl , which coincides with results of Gore MS and Harnagale KD(2011)[4] who achieved the almost similar results .

Gupta A et al(2006)[16] observed that pressor response was not significantly blunted in Propofol 2.5mg/kg (17% increase in HR) , while effectively blunted in 3mg/kg and 3.5mg/kg propofol. They concluded that propofol 3mg/kg provides acceptable intubating conditions in 80% patients, blunts pressor response to intubation without significant cardiovascular depression.

Thus in conclusion, ideal intubating conditions for intubation without using muscle relaxants are possible with 3mg/kgpropofol with 2µg/kg fentanyl and 1.5 mg/kg lignocaine and the stress response to laryngoscopy and intubation gets attenuated well.

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