Intubating Conditions with Varying Doses of Propofol Without Muscle Relaxants in Paediatric Patients

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ABSTRACT

Background: Propofol has been widely used in anaesthetic practice as an induction agent, with certain advantages over other agents such as thiopental and etomidate, including a rapid recovery and antiemetic action. These characteristics have made Propofol the agent of choice for short surgical procedures especially in outpatient surgery. The first stage of the elimination half-life of Propofol is lower in children thus ensuring rapid recovery after short surgical procedures. It can be used for intubation without muscle relaxant in children helping in avoiding side effects.

Aim: To compare the frequency of acceptable intubating conditions with 3.0mg/kg and 3.5mg/kg doses of Propofol without muscle relaxant in paediatric patients undergoing elective surgery.

Methods: This was a Randomized Controlled Trial conducted at Department of Anaesthesiology, Mayo Hospital Lahore. After informed consent from parents of the patients and IRB approval, 400 patients planned to undergo elective surgery were included in the study. Patients were randomly divided into 2 groups of 200 patients each using lottery method. Group I received Inj. Propofol 3.0mg/kg body weight while Group II received Inj. Propofol 3.5mg/kg body weight. Patients were intubated 90seconds after injecting Propofol. For study purpose, single successful intubation attempt was considered and acceptable intubating conditions were labelled (as per operational definition). Data entry and analysis was done by using SPSS 18 according to the approved analysis plan.

Results: Mean age of patients in Group-I and in Group-II was 7.36±2.50 and 7.14±2.00. Mean weight of patients in Group-I and in Group-II was 28.51±7.04 and 29.47±5.35. In Group-I mean duration of laryngoscopy was 18.36±3.47 and in Group-II mean duration of laryngoscopy was 17.78±3.42 minutes. Acceptable intubation was achieved in 154(77%) patients in Group-I while in Group-II acceptable intubation was achieved in 186(93%) patients. (P value=0.000).

Conclusion: According to the results of this study acceptable intubating conditions is higher with Group-II [3.5mg/kg: (93%)] as compared to that of Group-I [3.0 mg/kg : (77%)] without muscle relaxant in paediatric patients undergoing elective surgery. So in our clinical set up a dose of 3.5mg/kg propofol is effective for acceptable intubating condition in paediatric population without muscle relaxant.

Keywords: Acceptable intubating conditions, Propofol, Muscle relaxant, Paediatric patients.

INTRODUCTION

Endotracheal intubation is the most important and crucial step during the administration of general anaesthesia. Vast majority of drug combinations are designed to provide better analgesia, good depth of anaesthesia and the ease of airway manipulation. Use of sedatives and opioids to induce apnea and adequate intubating conditions has been favoured over time1.

Propofol is one such drug vastly used for rapid sedation and induction. Propofol is the most frequently used IV anaesthetic today. Work in the early 1970s on substituted derivatives of phenol with hypnotic properties resulted in the development of 2,6-diisopropofol. Because of its profound depressing effect on airway reflexes it has a quick and smooth induction2, 3.

Paediatric patients are more susceptible to adverse effects of short acting muscle relaxants such as succinylcholine. Although premedication with anticholinergic such as Atropine tends to avoid bradycardia associated with succinylcholine but it augments the pressor response to intubation. In certain patient groups these can have devastating end results. Also calculated doses of muscle relaxant show variable results due to unpredictable nature of metabolism, receptor development and body fat to muscle ratio4,5.

Due to anatomical features and friability of structures paediatric age group presents with relatively difficult to manipulate airways. Finding a properly fitting face mask for bag mask ventilation as well as ventilation with face mask may prove to be quite challenging in this group. Difficulty to ventilate and inability to intubate pose an eminent threat if standard induction with a muscle relaxant is done6. A study has shown acceptable intubating conditions
in 80% children with 3.0mg/kg Propofol which was significantly lower than acceptable intubating conditions achieved in 90% children with 3.5mg/kg Propofol (P-value=0.0238). But a similar study found no significant difference in the intubating conditions produced by these two doses.

In this study we aimed to compare the frequency of acceptable intubating conditions with 3.0mg/kg and 3.5mg/kg doses of Propofol without muscle relaxant in paediatric patients undergoing elective surgery. In literature there is a controversy in results regarding dose of propofol which is effective in blunting pressor response without causing cardiovascular depression while managing the airway. Therefore we compared the effect of varying induction doses of Propofol without muscle relaxant in paediatric population on provision of clinically acceptable and easy intubating conditions.

The objective of the study was to compare the frequency of acceptable intubating conditions with 3.0mg/kg and 3.5mg/kg doses of Propofol without muscle relaxant in paediatric patients undergoing elective surgery.

**OPERATIONAL DEFINITION**

Acceptable intubating condition: Intubating condition will be considered acceptable if duration of laryngoscopy is <20seconds and tracheal intubation is performed in a single successful attempt.

**Hypothesis:** Intubating conditions are better with 3.5mg/kg dose of Propofol as compared to 3.0mg/kg without muscle relaxant in paediatric patients undergoing elective surgery.

**MATERIAL AND METHODS**

This Randomized Controlled Trial was carried out in Department of Anaesthesiology, paediatric operation theatre Mayo Hospital Lahore over a period of six months. Using Non-probability, purposive sampling, a sample size of 400 cases was calculated (80% power of test, 5% level of significance and taking expected percentage of acceptable intubating conditions i.e. 80% with 3.0mg/kg Propofol and 90% with 3.5mg/kg propofol without muscle relaxant in paediatric patients undergoing elective surgery). After informed parental consent and IRB approval, patients aged 5-12 years of either sex, belonging to ASA class I or II Undergoing minor elective surgery under General Anesthesia were selected. Patients Who were in the lower weight percentile for age, those with congenital physical or mental challenges like cerebral palsy (through physical and clinical examination) and children with bleeding disorders like thalassemia or deranged clotting profile (INR>2) were excluded from the study.

**Data Collection** After arrival in the operation theatre patients were randomly allocated to two study groups I and II using lottery method. Relevant demographic data like name, age, sex and group was recorded on the predesigned Proforma. Patients were pre-medicated with I/V Midazolam 0.02mg/kg and Nalbuphine 0.05mg/kg. After applying monitors patients were pre-oxygenated with 100% oxygen using face mask. Patients in Group I received Inj. Propofol 3.0mg/kg body weight while those in Group II received Inj. Propofol 3.5mg/kg body weight. Patient were ventilated with 100% O2 and intubated 90 seconds after injecting Propofol. Single successful intubation attempt was considered and acceptable intubating conditions were labelled (as per operational definition). All this information was recorded on Proforma.

**Data Analysis:** Age and weight were described as mean and standard deviation whereas gender, ASA status and acceptable intubating conditions were presented as frequency and percentage. Acceptable intubating conditions were compared in both groups by using chi-square test taking P value equal to or less than 0.05 as significant.

**RESULTS**

Mean age of all 400 patients was 7.25±2.26 years. Minimum and maximum age of patients was 5 and 12 years. Mean age of patients in Group-I and in Group-II was 7.36±2.50 and 7.14±2.00. Minimum and maximum age of patients in Group-I and in Group-II was 5 and 12 years respectively. In Group-I there were 128 male and 72 female patients. While in Group-II there were 121 male and 79 female patients respectively. Minimum and maximum weight of Group-I patients was 15 and 42 Kg. While in Group-II minimum and maximum weight was 20 and 43 Kg respectively. In Group-I 199 patients were ASA I and only 1 patient was ASA II. While in Group-II all patients were ASA I. In Group-I there were 154 patients in which laryngoscopy was done in 1st attempt. There were 25 patients in which laryngoscopy was done in second attempt and in 21 patients laryngoscopy was done in third attempt. While in Group-II there were 185 patients in which laryngoscopy was done in 1st attempt. There were 10 patients in which laryngoscopy was done in second attempt and in 5 patients laryngoscopy was done in third attempt.(Table-1)

In Group-I mean duration of laryngoscopy was 18.36±3.47 and in Group-II mean duration of laryngoscopy was 17.78±3.42 minutes. In Group-I minimum and maximum duration of laryngoscopy was 14 and 28 minutes while in Group-II minimum and maximum duration of laryngoscopy was 14 and 31 minutes respectively (Table 2).
Acceptable intubation was achieved in 154(77%) patients in Group-I while in Group-II acceptable intubation was achieved in 186 patients (93%) patients, which was significantly higher than Group I (P-value=0.000) (Table 3).

Table 1: Laryngoscopic attempts in treatment groups

<table>
<thead>
<tr>
<th></th>
<th>Group-I</th>
<th>Group-II</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>154(77%)</td>
<td>185(92.5%)</td>
</tr>
<tr>
<td>2</td>
<td>25(12.5%)</td>
<td>10(5%)</td>
</tr>
<tr>
<td>3</td>
<td>21(10.5%)</td>
<td>5(2.5%)</td>
</tr>
<tr>
<td>Total</td>
<td>200</td>
<td>200</td>
</tr>
</tbody>
</table>

Group-I= Inj. Propofol 3.0mg/kg  
Group-II= Inj. Propofol 3.5mg/kg

Table 2: Duration of laryngoscopy (minutes) in treatment groups

<table>
<thead>
<tr>
<th></th>
<th>Group-I</th>
<th>Group-II</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>200</td>
<td>200</td>
</tr>
<tr>
<td>Mean</td>
<td>18.36</td>
<td>17.78</td>
</tr>
<tr>
<td>SD</td>
<td>3.47</td>
<td>3.42</td>
</tr>
<tr>
<td>Minimum</td>
<td>14.00</td>
<td>14.00</td>
</tr>
<tr>
<td>Maximum</td>
<td>28.00</td>
<td>31.00</td>
</tr>
</tbody>
</table>

Group-I= Inj. Propofol 3.0mg/kg  
Group-II= Inj. Propofol 3.5mg/kg

Table 3: Acceptable intubation in treatment groups

<table>
<thead>
<tr>
<th></th>
<th>Group-I</th>
<th>Group-II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>154(77%)</td>
<td>186(93%)</td>
</tr>
<tr>
<td>No</td>
<td>46(23%)</td>
<td>147(7%)</td>
</tr>
<tr>
<td>Total</td>
<td>200</td>
<td>200</td>
</tr>
</tbody>
</table>

Group-I= Inj. Propofol 3.0mg/kg  
Group-II= Inj. Propofol 3.5mg/kg

Chi-Square Test= 20.07  
p-value= 0.000

DISCUSSION

Propofol is an anaesthetic induction agent with a short latency and duration of effect, and is nearly twice as potent as thiopental. The successful use of this drug has been described in adults and children. Numerous studies have stressed the advantages of using Propofol: such as a low cumulative effect which offers a fast recovery of consciousness after surgery, an antiemetic effect, a diminished pressor response to laryngoscopy and tracheal intubation, and a lower incidence of airway complications, in adult and paediatric patients.

Recently, several workers have described the use of Propofol to facilitate laryngoscopy and tracheal intubation without the need for neuromuscular blocking drugs. These studies have shown that adequate relaxation of the jaw and vocal cords is achieved in adult patients when Propofol is preceded by different doses of opioids.

Its rapid redistribution and low elimination half-life (first stage) make it an ideal agent for short surgical procedures, more so in children.

Most of the paediatric ambulatory surgical interventions (minor surgery, dental procedures) do not require intraoperative neuromuscular blocking drugs. Succinylcholine remains the best neuromuscular blocking agent for tracheal intubation in short procedures under general anaesthesia and for rapid sequence induction when there is a risk of aspiration. Undesirable side-effects (increases in intraocular and intracranial pressure, muscle pain, excessive salivation, hyperkalaemia and cardiac dysrhythmias) have limited its use. The incidence of prolonged apnoea, masseter muscle spasm, malignant hyperthermia and even cardiac arrest related to succinylcholine is not insignificant among young children.

In our study acceptable intubation was achieved in 154(77%) patients in Group-I (Propofol 3.0mg/kg) while in Group-II (Propofol 3.5 mg/kg) acceptable intubation was achieved in 186(93%) patients. Difference of acceptable intubation between these 2 groups was statistically significant. (P value=0.000). In Group-I intubation was done in 1st attempt in 77% patients and in Group-B in 92.5% patients were intubated in first attempt.

De Fa’tima de Assunc,ãº Braga et al in their study investigated the use of Propofol given 5 min after fentanyl to permit endotracheal intubation in children. Tracheal intubating conditions were adequate in 20% of the patients in group I (propofol 2.5 mg kg-1), in 75% of the patients in group II (propofol 3.0 mg kg-1) and in 80% of the patients in group III (propofol 3.5 mg kg-1) (P< 0.05 for group I vs. groups II and III). Haemodynamic changes were not significantly different between the groups.

Results of this study are consistent with the results reported by De Fa’tima de Assunc,ãº Braga. However the only difference in both studies was that in our study we had 2 groups and in de Fa’tima de Assunc,ãº Braga had done the comparison in 3 groups. However in this study Group-II (Propofol 3.5 mg/kg) showed acceptable intubation among (93%) patients. Which is higher than that reported by De Fa’tima de Assunc,ãº Braga et al.

Gupta A et al in their study determined the optimal dose of Popofol for successful tracheal intubation and to see its effectiveness in blunting pressor response in children aged 3–10 years. In his results he reported that tracheal intubating conditions were acceptable in 25% of the patients in group I (propofol 2.5mg/Ekg-1), while significantly higher (P< 0.001) in group II (propofol 3.0 mg.kg-1) (80%) and in group III (propofol 3.5 mg/Ekg-1) (90%). The pressor response was not effectively blunted in group I (17%increase in HR), while effectively blunted in groups II and III.

Results reported by Gupta A et al are consistent with the results of this study. However the only
difference observed in his study was that he used 3 different doses of Propofol while we used two different doses of Propofol for acceptable intubation.

While, Robinson et al. comparing a combination of propofol (4 mg.kg-1) with either alfentanil (15μg.kg-1) or remifentanil (1μg.kg-1) without the use of muscle relaxants did not find any significant difference in the overall intubating conditions between the two groups.16 They used a higher dose of Propofol than our study.

Y.K. Batra assessed whether combination of Propofol and remifentanil could be used without a muscle relaxant to facilitate tracheal intubation in children. According to the results tracheal intubation was successful in all patients without requiring neuromuscular blocking agent. Intubating conditions were clinically acceptable in 10 of 20 patients (50%) in Group I (Remifentanil 2 μg/kg or Remifentanil 3 μg/kg) compared with 18 out of 20 patients (90%) in Group II (Propofol 3 mg/kg) (P < 0.05)17.

Due to unique challenges offered by paediatric airway, difficulty to ventilate and inability to intubate pose an eminent threat if standard induction with a muscle relaxant is done.6 Several workers have successfully used a combination of propofol and a short-acting opioid to facilitate tracheal intubation in children. Most of the studies revealed improvement in intubating conditions with increasing dosages of either propofol or opioid. Increasing dose of short-acting opioids may cause muscle rigidity, prolonged apnea and delayed recovery, while increasing dose of Propofol can lead to cardiovascular depression, hence the search for an optimal dose combination.18,19

CONCLUSION

As per results of this study it can be concluded that acceptable intubating conditions can be achieved more with Propofol 3.5mg/kg (93%) as compared 3.0 mg/kg when used as induction agent without muscle relaxant in paediatric patients undergoing elective surgery.

REFERENCES

2. Gore MS, Harnagale KD. Evaluation of intubating conditions with varying doses of propofol without muscle relaxants.