FREQUENCY OF EXCELLENT LARYNGEAL MASK AIRWAY INSERTION CONDITIONS IN CHILDREN UNDERGOING ELECTIVE SURGERY: A COMPARISON OF PROPOFOL WITH KETOFOL.

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ABSTRACT: Objectives: The laryngeal mask airway is used for provision of anesthesia for various surgical procedures as well as in emergency management of airway. It is a useful rescue tool in cases of failed intubation. Its insertion is associated with lesser complications. With advancement in medical equipment new versions of LMA with additional benefits are available. In this study evaluation of frequency of excellent LMA insertion conditions with use of ketofol or propofol as induction agent has to be evaluated. Purpose of the study is to identify which agent will provide favourable conditions for insertion, with least complications. Study Design: Randomized control trial. Setting: Departments of Anesthesia and Intensive Care Allied Hospital and Aziz Fatimah Hospital, Faisalabad. Period: From 01-01-2017 to 30-06-2018. Material & Methods: Approval from ethical review committee was obtained. 230 children presenting for elective surgery were enrolled into study using non-probability consecutive sampling. Two groups consisting of 115 each were generated by randomization. Group P received propofol and Group PK received 2:1 propofol ketamine mixture. Ease of LMA insertion was assessed on the basis of degree of muscle relaxation and adverse reactions to LMA insertion. Data was collected and analysed using SPSS version 18. Results: Results were presented in terms of frequency of excellent LMA insertion conditions. It showed that ketofol provides better LMA insertion as compared to propofol alone with p value of 0.007, which is significant. Conclusion: The study concluded that use of ketofol provides excellent insertion conditions for LMA insertion in children presenting for elective surgery. Key words: LMA, Laryngeal Mask Airway, Propofol, Ketofol.

INTRODUCTION
Securing and maintaining a patent airway are the corner stones of the anesthesia care, though health care providers other than anesthetists should master this skill as well. In order to provide adequate ventilation and thus oxygenation a good airway control is mandatory and it is part and parcel of safe anesthesia practice.¹ With the advancement in anesthesia care certain new devices and techniques for securing airway have been introduced, among these are the supraglottic airway devices such as laryngeal mask airway, I-gel etc. As compared to the technique and advanced level of clinical skill required for endotracheal intubation these devices can be inserted with less level of training.²

LMAs have been used widely during general anesthesia, they have certain benefits over conventional bag mask ventilation in terms of freeing anesthetist’s hands and lesser complications.³ Rather than crossing the vocal cords like endotracheal tube it sits over the cords. It is equally useful both in elective and emergency surgeries as well in adults and children.⁴ As evidence based practice, supraglottic airway devices are now part and parcel of difficult airway management protocols which are in practice all over the world.⁵

Propofol (2,6 di isopropylphenol ) is a central nervous system depressant acting through GABA₆ receptors and inhibition of NMDA receptors. It provides sedation hypnosis and also

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Propofol (2,6 di isopropylphenol ) is a central nervous system depressant acting through GABA₆ receptors and inhibition of NMDA receptors. It provides sedation hypnosis and also
a neuromodulator. Its emulsion preparations contain preservatives. It is used widely in operation theatres and in ICUs.\textsuperscript{6}

Ketamine is a racemic mixture that exerts its effects via NMDA receptors. Its degradation produces an active end product. These days its clinical uses range from anesthesia, analgesia to procedural sedation. However its psychological side effects are undesireable.\textsuperscript{7}

Ketofol is a mixture of ketamine and propofol in different ratios. This combination allows reduction in total dose of propofol administered. It has a better safety profile in terms of cardiorespiratory complications.\textsuperscript{8} In small doses along with other sedative hypnantics as used in ketofol it causes minimal hallucinations.\textsuperscript{9}

The LMA is most commonly placed using propofol as only anesthetic drug, it provides adequate muscle relaxation required for insertion. Use of propofol is associated with some adverse effects, most important being cardiorespiratory i-e hypotension, cough, laryngospasm, prolonged apnea. Pain at injection site is also common.\textsuperscript{4} These hemodynamic effects become more marked during LMA insertion as dose required for relaxation is often greater than the recommended dose for inducing anesthesia.\textsuperscript{10} Adverse effects associated with deeper levels of anesthesia achieved with some induction agents especially propofol can lead to fatal events in pediatric population. On the other hand minimizing induction dose as a protective strategy can itself trigger coughing, gagging and/or laryngospasm.\textsuperscript{11} This necessitated either switching to another induction agent or addition of an adjunct which can counter these unwanted effects in children.\textsuperscript{12} For this sake different co-induction agents have been used with propofol, these include ketamine, fentanyl and butorphanol.\textsuperscript{13}

Ketamine has multidimensional clinical effects. It has gained its place as a co-induction agent. It is a sympathomimetic agent leading to increased heart rate and blood pressure. In addition ventilatory drive is minimally effected, and airway reflexes are preserved but at the same time muscle tone and secretions are increased. Its analgesic properties are very useful.\textsuperscript{14}

Considering the pharmacological characters of these two drugs, it has been observed that their combination results in a balanced profile regarding cardiorespiratory complications in the patients.\textsuperscript{15}

It is the first study of its kind in this institute. Aim of this study is to identify better drug among propofol and ketofol in terms of ease of laryngeal mask airway insertion in pediatric patients.

MATERIAL AND METHODS
This randomized control trial was conducted at the departments of anesthesia and intensive care Allied Hospital and Aziz Fatimah Hospital from 01-01-2017 to 30-06-2018.

Consecutive non-probability sampling technique was used. A total of 230\textsuperscript{16} (by using WHO sample size calculator for 2 proportions; $P_1=68\%$, $P_2=52\%$, power of study= 80\%, level of significance=5\%) ASA I and ASA II patients (children), presenting for elective surgery to be done under General anesthesia using LMA, ranging from 1 to 12 years and weighing 5 -30 kg, Mallampati class I and II were enrolled in the study. Informed consent was duly signed by the parents. Patients with difficult airways, those having allergies to propofol, ASA class III and IV, risk of regurgitation, presenting for emergency surgery were excluded from the study.

Children were divided into two groups using randomization method. Each group consisted of 115 patients. Group P received propofol alone and group KP received ketamine and propofol combination.

Intravenous induction agents were prepared in 10 ml syringes, for group (P) 1 \% Propofol was mixed with 20 mg lidocaine hydrochloride and for group (KP) propofol and ketamine 2:1 ratio mixture was prepared. Basic monitors applied to the patients and intravenous fluid started. All patients were pre-oxygenated and Intravenous injection atropine 0.01mg/kg and injection nalbuphine 0.2
mg/kg were given before induction agent. Both induction agents were administered in incremental doses till the loss of verbal contact with patients. Appropriate size LMA was administered 60 seconds later. Additional boluses of the induction agent were administered in 0.5 ml aliquots to deepen the anesthesia whenever required.

Excellent LMA insertion conditions were assessed in terms of jaw relaxation and adverse response to airway manipulation.

Following scoring system was used.\textsuperscript{17}

| Variables                        | Score 0 | Score 1    | Score 2 | Score 3 |
|----------------------------------|---------|------------|---------|---------|
| Jaw relaxation (mouth opening)   | Unable  | Minimally  | Half    | Fully   |
| Coughing and gagging            | Severe  | Moderate   | Mild    | Nil     |
| Involuntary limb movements      | Severe  | Moderate   | Mild    | Nil     |

Adverse response to airway manipulation is graded as
- **Mild**: Transient and minimal lasting $\leq 5$ seconds
- **Moderate**: Lasting $>5$ seconds but resolved spontaneously within 20 seconds
- **Severe**: Sustained $>20$ seconds or required additional boluses of drugs

The numerical insertion score was obtained by summing up the scores assigned to the factors: jaw relaxation, coughing and gagging and involuntary limb movements. The maximum score is thus 9 while the minimum score is 0.

The qualitative insertion scores are as follows\textsuperscript{17}:

| LMA insertion conditions | Score |
|--------------------------|-------|
| Excellent                | 7-9   |
| Good                     | 4-6   |
| Poor                     | 0-3   |

Anesthesia was maintained with N\textsubscript{2}O /O\textsubscript{2} in a ratio of 50:50% and isoflurane (1.3%) in both groups. Continuous monitoring of vital signs done throughout the procedure. After recovery patients were observed in post anesthesia care unit before shifting to the ward till Modified Aldrete score is 9/10.

**Data Collection**
LMA insertion conditions in terms of jaw relaxation and adverse response to airway manipulation (coughing and gagging, involuntary limb movements) were recorded and score assigned as per designed scoring system. Insertion of supraglottic device was done by a trained anesthesiologist who was blinded to the drug preparation. Similarly anesthesiologist who collected data was also blinded to the drug used. Data was collected on a specified proforma.

**Data Analysis**
All the collected data was entered into SPSS version 20 and analyzed. The qualitative data like gender, ASA grade, Mallampati class and excellent LMA insertion conditions were presented as frequency and percentage. Quantitative data like age, weight and total score was presented as means and standard deviations. Chi-square test was applied to compare excellent LMA insertion conditions between two groups. Effect modifiers like age, gender, weight, ASA grade and Mallampati class controlled by stratification. Post stratification chi-square test was applied. P value $<0.05$ was taken as significant.

**RESULTS**
Mean age was calculated as $6.96\pm2.02$ years in Group-P and $7.14\pm2.13$ years in Group-KP (Table-I).

| Age (in Years) | Group-A (n=115) | Group-B (n=115) |
|----------------|-----------------|-----------------|
|                | No. of Patients | %               | No. of Patients | %               |
| 1-6            | 54              | 46.96           | 49              | 42.61           |
| 7-12           | 61              | 53.04           | 66              | 57.39           |
| Total          | 115             | 100             | 115             | 100             |
| Mean SD        | $6.96\pm2.02$   | $7.14\pm2.13$   |

Table-I. Age distribution (n=230)

Weight in Group-P was calculated as $21.48\pm5.69$ kgs and in Group-KP as $21.94\pm6.00$ kgs (Figure-I).
53.04% (n=61) in Group-P and 35.65% (n=41) in Group-KP did not show excellent conditions for LMA insertion. Whereas 46.96% (n=54) in Group-P and 64.35% (n=74) in Group-KP had excellent LMA insertion conditions. p value was calculated as 0.007 showing a significant difference (Figure-2).

The results of our study are also comparable to another done for insertion of laryngeal tubes under propofol or ketofol anesthesia. They showed significant results with p<0.05 with better insertion of laryngeal tube with minimal adverse airway responses and complications under ketofol (Group K ) induction as compared to propofol (Group P).17

Goel S. also showed better insertion of LMA in Group PK (ketofol) and Group PM (propofol+midazolam) than in Group P (propofol)19 which is also confirmed in our study.

Another study by Abbera B. et al did not elicit preference of one drug over other in terms of LMA insertion conditions. P value calculated for their study was 0.681 which was insignificant. Though in terms of mean arterial blood pressure and duration of apnea ketofol was better than propofol.20 Another study showed results contrary to ours with no significant difference between two groups for jaw relaxation and adverse airway reflexes in elderly patients.21

Gupta A et al also showed PK (propofol-ketamine) group with least success in n= 12 (40%) patients as compared to 13 (43.33%) patients in Group PF (propofol- fentanyl) and in 26 (86.67%) patients in Group PB (propfol- botarphanol).12

CONCLUSION
The results of this study concludes that use of ketofol provides excellent insertion conditions for LMA insertion in children presenting for elective surgery.

Current study covered only LMA insertion conditions under two different induction agents. It did not include haemodynamic variations associated with propofl and ketofol. Another study which covers these two aspects in children should be conducted on our population.
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