

## To Assess the Ease of LMA Insertion with Ketofol versus Propofol in Paediatric Patients

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### Abstract

**Aim:** The aim of this study was to compare the effect of the ketamine-propofol mixture (ketofol) and propofol on the insertion conditions of laryngeal mask airway in pediatrics.

**Methods:** The Prospective Double Blind comparative study was done in the department of anesthesiology & critical care medicine IGIMS, Patna, Bihar after taking approval from institute ethical committee with CTRI Registration done: CTRI/2020/10/028242. Written informed consent was taken from each participants of the study. The Data was collected between – October 2020 to December 2021. There were total 100 patients in the study and divided into two groups with 50 each.

**Results:** Patients under 2-14 years of age comprised the majority of study population. The P value is 0.524 and there was no statistically significant difference in the age of the patients between the two study groups. Patients under male and female comprised the majority of study population. 80% male and 20% female in Group FP and 88% male and 12% female in Group KP. Patients under ASA Grade I and II. The present study showed 94% patients in Grade I and 6% in Grade II of Group FP and 92% patients in Grade I and 8% in Grade II of Group KP. Patients of LMA size I and II. 84% patients in I and 16% in II of Group FP and 94% patients in I and 6% in II of Group KP. Swallowing/Gagging 90% patients Score 1, 6% patients score 2 and 4% score 3 of Group FP. 94 % patients Score 1, 4% patients score 2 and 2% score 3 of Group KP. The P. value is significant. (P = 0.001).

**Conclusion:** In this study, I conclude that co-induction with Ketamine (1 mg/kg) and Propofol (2.5 mg/kg) for insertion of Laryngeal Mask Airway in children provided better insertion conditions and minimal alteration in haemodynamic parameters than co-induction with Fentanyl (1µg/kg) and Propofol (2.5 mg/kg).

**Keywords:** Ketofol, Laryngeal mask airway insertion, Propofol

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### Introduction

Propofol is the preferred induction agent for Laryngeal mask airway (LMA) insertion which is widely used for providing general anesthesia in children.

Propofol is a nonopioid, nonbarbiturate, sedative-hypnotic agent with rapid induction and recovery times and antiemetic effects. [1] It allows easy

insertion of LMA by depressing airway reflexes. However, adverse effects include dose-dependent cardiorespiratory depression, injection pain, and having no analgesic properties. [2,3] Ketamine causes little or no cardio-respiratory depression and unlike propofol, has pain relieving properties. Ketamine use as a single induction agent, however, is limited by emergence hallucinations, elevation of blood pressure and heart rate due to its sympathomimetic effects, and increased intracranial pressure. [4,5] Effectiveness of the two agents – propofol and ketamine – in combination (ketofol) has been recently demonstrated and may provide a novel induction agent with favorable hemodynamics and reduced side effects attributed to either drugs. [6] To date, ketofol has been used most extensively for procedural sedation in the Emergency Department with encouraging results, [3,7] but has not yet been standardized as an induction agent. Bispectral index (BIS) monitoring has emerged as a convenient and versatile tool to titrate hypnotic agents and to reduce drug consumption. BIS is a dimensionless number scaled from 100 to 0, with 100 representing an awake electroencephalogram and 0 representing electrical silence. [8]

The most important duty of an anesthetist is the management of airway to deliver sufficient ventilation to the patient by securing airway while general anesthesia is administered. As such, no anesthesia is safe unless meticulous efforts are devoted to maintain an intact and functional airway. [9,10] Effective insertion of the LMA entails optimum anesthetic depth to elude undesirable airway reflexes such as swallowing, gagging, coughing or involuntary movements to severe problems such as laryngospasm. [11,12]

Adequate anesthetic induction situations are paramount delivered by propofol compared to other intravenous induction agents. [12] Nevertheless, when propofol is used as a single induction agent without

premedication, doses greater than 3 mg/kg is necessary for smooth LMA insertion. [13,14] On the other hand, increased propofol doses are not required as undesirable cardio-respiratory depression is dose-dependent. [15,16]

Several combinations of pharmacological agents have been introduced to decrease the hemodynamic instability in anesthesia. [17,18] Ketamine is well known for its airway reflexes maintaining activity and sympathetic cardiorespiratory stimulant so as to causes little or no cardiorespiratory depression and unlike propofol has pain relieving properties.

The aim of this study was to compare the effect of the ketamine-propofol mixture (ketofol) and propofol on the insertion conditions of laryngeal mask airway in pediatrics.

### Materials and Methods

The Prospective Double blind Comparative study was done in the department of anesthesiology & critical care medicine IGIMS, Patna, Bihar after taking approval from institute ethical committee with CTRI Registration done: CTRI/2020/10/028242. Written informed consent was taken from each participants of the study. The Data was collected between – October 2020 to December 2021. There were total 100 patients in the study and divided into two groups with 50 each.

### Inclusion criteria

1. Patients willing to participate
2. Patients between 2-15 year of either sex scheduled for elective surgical procedures under general anesthesia using LMA
3. ASA Physical Status score 1 and 2
4. Patients with MPG score I and II

### Exclusion criteria

1. Patients refusal to participate
2. Patients with hypersensitive airway and anticipated difficult airway

3. Patients with full stomach and emergency surgery
4. Patient with known predictor of difficult airway
5. Patient with hypersensitivity to study drug

### Outcome Parameters

Comparison of ease of LMA insertion and Hemodynamic responses with Fentanyl-Propofol vs Ketamine-Propofol co-induction. Intervention and data Collection Methods: After enrolment in the study the patients assessed preoperatively. In preoperative room baseline parameters were observed and documented. A good intravenous access was secured, Patient was premedicated with Midazolam 0.05mg/kg intravenously and routine monitoring in the form of ECG, SPO<sub>2</sub>, NIBP was instituted. Now patients were randomly divided into two groups based on computer generated random numbers.

- Group FP received Inj. Fentanyl 1mcg/kg and Inj. Propofol 2.5mg/kg
- Group KP received Inj. Ketamine 1mg/kg and Inj. Propofol 2.5mg/kg.

After preoperative preparation and NPO for 8 hours, Patients shifted to the operation room, standard monitoring was applied. Baseline vitals recorded and I.V. fluids administered. Patients were preoxygenated with 100% Oxygen for 3 minutes. Injection glycopyrrolate 0.01mg/kg I.V. was given as the standard of care. The patients were either induced with ketofol (1mg/kg of Ketamine plus 2.5mg/kg of Propofol) or 1mcg/kg of Fentanyl plus 2.5mg/kg Propofol. The drugs were taken in 10ml syringe and normal saline was used to dilute drug to make volume of 10ml and slowly administered. LMA insertion performed 60s after induction of anesthesia. None of the patients were required additional dosage of Propofol in LMA insertion.

Following insertion, the position of LMA was assessed by observing movement of chest and reservoir bag through use of both spontaneous and assisted ventilation. After successful insertion of LMA, Patients were put on mechanical ventilator, and when required additional propofol in the dose of 0.5mg/kg given. For longer surgeries we used relaxant (Atracurium 0.5mg/kg). Thereafter, anesthesia was maintained with sevoflurane 2%, nitrous oxide and oxygen with a flow rate of 3L/min. For intra-operative analgesia we used Paracetamol 15mg/kg and Fentanyl 0.5µg/kg. All patients who was exposed to either Ketamine-Propofol or Fentanyl- Propofol, compared to see different outcomes of both agents as an induction agent on ease of laryngeal mask airway insertion and hemodynamic stability.

Insertion condition was graded by the same anesthetist who performs the procedure as:

- (a) Mouth opening: 1- Full, 2- Partial, 3- Nil
- (b) Coughing: 1- Nil, 2- Slight, 3-Gross
- (c) Swallowing: 1- Nil, 2- Slight, 3-Gross
- (d) Movement: 1- Nil, 2- Slight, 3-Gross
- (e) Laryngospasm: 1- Nil, 2- Mild, 3- Severe
- (f) Ease of LMA insertion: 1-Easy, 2- Difficult, 3- Impossible

### Statistical Analysis

All the data were analyzed using SPSS package (Stata, version 26.0 SPSS INC, Chicago, IL, USA) for windows. The data were presented as descriptive statistics for continuous variables and percentage for categorical variables and was subjected Chi-square test, t test & Anova test. Other values were represented in number, proportions (%) and mean ± SD.

### Results

**Table 1: Age, Gender, ASA Grade and LMA Size wise Distribution of subjects**

Age group (In yrs.)	Group FP		Group KP		P. Value
	N0.	%	N0.	%	
2-3	16	32%	20	40%	0.524
3.5-6	19	38%	12	24%	
7-10	11	22%	17	34%	
≥10	4	8%	1	2%	
<b>Mean±SD</b>	5.52±3.19		5.13±2.82		
<b>Gender</b>					
Male	40	80%	44	88%	1.000
Female	10	20%	6	12%	
<b>ASA Grade</b>					
I	47	94%	46	92%	-
II	3	6%	4	8%	-
<b>LMA Size</b>					
I	42	84%	47	94%	-
II	8	16%	3	6%	-

Patients under 2-14 years of age comprised the majority of study population. The P value is 0.524 and there was no statistically significant difference in the age of the patients between the two study groups. Patients under male and female comprised the majority of study population. 80% male and 20% female in Group FP and 88% male and 12% female

in Group KP. Patients under ASA Grade I and II. The present study showed 94% patients in Grade I and 6% in Grade II of Group FP and 92% patients in Grade I and 8% in Grade II of Group KP. Patients of LMA size I and II. 84% patients in I and 16% in II of Group FP and 94% patients in I and 6% in II of Group KP.

**Table 2: After LMA Insertion (SBP) , DBP and After LMA Insertion (SPO2) distribution in groups**

After LMA Insertion (SBP)	Group FP Mean±SD	Group KP Mean±SD	't' test	P. Value
0 min	100.34±5.51	100.92±4.58	-0.539	0.592
1 min	103.62±5.17	103.70±4.70	-0.077	0.939
2 min	107.00±4.92	106.44±4.72	0.547	0.587
5 min	110.34±5.05	109.26±4.73	1.018	0.314
<b>After LMA Insertion (DBP)</b>				
0 min	68.84±7.57	67.36±6.63	1.018	0.314
1 min	71.78±6.81	70.04±5.89	1.340	0.187
2 min	74.30±6.23	73.08±5.19	1.042	0.303
5 min	77.16±5.44	75.92±4.39	1.270	0.210
<b>After LMA Insertion (SPO2) distribution in groups</b>				
0 min	98.56±0.76	98.60±0.69	-0.292	0.771
1 min	98.50±0.76	98.42±0.85	0.531	0.598
2 min	98.56±0.70	98.38±0.75	1.353	0.182
5 min	98.48±0.81	98.50±0.78	-0.134	0.894
<b>After LMA Insertion (Heart Rate)</b>				
0 min	93.64±7.88	94.80±8.10	-0.683	0.498

1 min	96.74±7.61	97.82±8.31	-0.635	0.528
2 min	100.22±7.76	100.64±8.15	-0.247	0.806
5 min	103.80±7.26	103.14±8.14	0.407	0.686

The group FP patients had mean SBP from 100.34±5.51mmHg SBP at after LMA Insertion in 0 min and 100.92±4.58mmHg at after LMA insertion in 0 minute of KP group. The SBP increases at 5 minutes of FP group 110.34±5.05mmHg and KP group 109.26±4.73 mmHg. The group FP patients had mean DBP from 68.84±7.57mmHg at after LMA Insertion in 0 min and 67.36±6.63 mmHg at after LMA insertion in 0 minute of KP group. The DBP increases at 5 minutes of FP group 77.16±5.44 mmHg and KP group

75.92±4.39 mmHg. The group FP patients had mean SPO2 from 98.56±0.76 at after LMA Insertion in 0 min and 98.60±0.69 at after LMA insertion in 0 minute of KP group. The group FP patients had mean heart rate from 93.64±7.88 bpm at after LMA Insertion in 0 min and 94.80±8.10 bpm at after LMA insertion in 0 minute of KP group. The heart rate increase at 5 minutes of FP group 103.80±7.26 and KP group 103.14±8.14. There is no significant difference of SBP, DBP, SPO2 and heart rate in group FP and KP.

**Table 3: Comparison of Mouth Opening, Coughing, Swallowing/Gagging, movement of Subjects**

Mouth Opening	Group FP		Group KP		P. Value
	N0.	%	N0.	%	
1 (Full)	38	76%	42	84%	0.085
2 (Partial)	12	24%	8	16%	
3 (Nil)	0	0	0	0	
<b>Coughing</b>					
1 (Nil)	42	84%	44	88%	0.002
2 (Slight)	5	10%	4	8%	
3 (Gross)	3	6%	2	4%	
<b>Swallowing/Gagging</b>					
1 (Nil)	45	90%	47	94%	0.001
2 (Slight)	3	6%	2	4%	
3 (Gross)	2	4%	1	2%	
<b>Movement</b>					
1 (Nil)	35	70%	40	80%	0.052
2 (Slight)	7	14%	6	12%	
3 (Gross)	8	16%	4	8%	
<b>Laryngospasm</b>					
1 (Nil)	47	94%	48	96%	0.013
2 (Mild)	3	6%	2	4%	
3 (Severe)	0	0	0	0	

Mouth opening 76% patients Score 1, 24% patients score 2 and 0% score 3 of Group FP. Patients under Mouth opening 84% patients Score 1, 16% patients score 2 and 0% score 3 of Group KP. Coughing: 84% patients Score 1, 10% patients score 2 and 6% score 3 of Group FP. 88% patients

Score 1, 8% patients score 2 and 4% score 3 of Group KP. Swallowing/Gagging 90% patients Score 1, 6% patients score 2 and 4% score 3 of Group FP. 94 % patients Score 1, 4% patients score 2 and 2% score 3 of Group KP. The P. value is significant. (P = 0.001). Movement: 70% patients

Score 1, 14% patients score 2 and 16% score 3 of Group FP. 80 % patients Score 1, 12% patients score 2 and 8% score 3 of Group KP. Laryngospasm: 94% patients Score 1, 6% patients score 2 and 0% score 3 of Group FP. 96 % patients Score 1, 4% patients score 2 and 0% score 3 of Group KP. The P. value is significant. (P = 0.013).

## Discussion

Laryngeal Mask Airway started gaining popularity as an alternative to endotracheal intubation as well as facemask because it causes less hemodynamic changes, associated with negligible raise in intraocular pressure after inserting LMA, causes decreased incidence of sore throat and frees the hands of the anaesthesiologist to perform other important tasks during the surgical procedures. It also provides a beneficial outcome especially in ENT and ophthalmic surgeries where excessive straining is potentially harmful, as it has a low incidence of coughing during emergence.

The frequent variable that we encountered was limb and head movements that too especially limb movements. The higher incidence of head and limb movements in Group Ketamine-Propofol could be due to the combined effects of excitatory movements caused by Propofol and increased muscle tone caused by Ketamine. Also, the incidence of head and limb movements in Group FP (14%) was more compared to Group Propofol + Ketamine (12%) with  $p=0.052$  which is significant. Ranju Singh et al, in their study also found that a statistically highly significant head and limb movements ( $p=0.007$ ) were encountered in Group PK (Propofol + Ketamine) compared to Group PF (Propofol+Fentanyl). [19]

The study done by Goh PK et al, showed greater occurrence of head and limb movement in Ketamine group ( 40% ) than Fentanyl group (16%), the incidence was more than what we noted. [20] There was

no laryngospasm in both the groups in our study. This has been supported by the study done by Ranju Singh et al, which showed nil occurrence of laryngospasm. Group Propofol+ Fentanyl had adequate (100%) jaw relaxation showing nil case of resistance to insertion with 14.29% resistance to insertion in Group Propofol + Ketamine of  $p<0.0268$ . [19] Our results are consistent with the study conducted by Asha Gupta and Sarabjit Kaur in which they compared jaw relaxation according to Young's criteria. Their results showed that the incidence of absolute jaw relaxation was highest in Group PB (Propofol + Butarphanol) - 28(93.33%), intermediate in Group PF (Propofol + Fentanyl) - 53.33% and lowest in Group PK(Propofol + Ketamine) -11 patients (36.66%). [21]

Goh PK et al in his study reported 23% of patients in Fentanyl group required additional bolus dose of Propofol compared to 10% of patients in Ketamine group. [20] Our study showed only 8.5% of patients in Fentanyl group required additional bolus dose of Propofol with second attempt, compared to 17.1% of patients in Ketamine group. The incidence of coughing/gagging between the two groups was significant in our study. There was higher occurrence of coughing & gagging in KP Group (Ketamine-Propofol), of the study conducted by Asha Gupta et al, compared to Fentanyl-Propofol and Butorphanol-Propofol. The overall insertion ease was significantly good with Group FP compared to Group PK ( $p=0.0007$ ). [21] Heart rate was found to be higher in Group KP compared to Group FP in our study. This similar outcome was observed in studies of Asha Gupta et al, Goh Pk et al and Ghatak et al. [20-22]

In our study, pain following Propofol injection was similar in all the groups and was statistically insignificant between two groups. This was analogous to the study done by Ritu Goyal et al. [23] Bah J et al, studied ideal insertion conditions with

different doses of Propofol along with Ketamine + Lidocaine spray for inserting LMA. [24] The study concluded that, dosage more than 3 mg/kg of Ketamine achieved satisfactory degree of jaw relaxation. Kodaka et al noted that a Fentanyl dose of 0.5 µg/kg is adequate to reduce predicted EC-50LMA (the effective concentration for 50% of the attempts to secure laryngeal mask insertion of Propofol using a target controlled infusion with minimum respiratory depression and without a high BIS value.). [25]

Ketamine and Fentanyl group showed a significantly better LMA insertion summed score ( $P < 0.004$ ) and was similar in both the groups than saline group. But the dose of Fentanyl they used was 1 µg/kg. In a study by Gamal T Yousef et al, used Ketofol as induction agent, that lead to adequate jaw relaxation and adequate mouth opening in the KP group i.e., Ketamine + Propofol { $n=45$  (90%)} than in the Propofol group { $n=38$  (76%)}. [26]

Pain while injecting Propofol is considered as a negligible complication, but it might lead to un cooperation and distress to the child. Pain can be due to activation of kininogens or by the free aqueous concentration of Propofol in the emulsion. [27]

### Conclusion

In this study, I conclude that co-induction with Ketamine (1 mg/kg) and Propofol (2.5 mg/kg) for insertion of Laryngeal Mask Airway in children provided better insertion conditions and minimal alteration in haemodynamic parameters than co-induction with Fentanyl (1 µg/kg) and Propofol (2.5 mg/kg).

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