Original Research Article

Randomized double-blind comparison of Ketamine – Propofol and Fentanyl – Propofol for the insertion of laryngeal mask airway in adults

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Abstract

Introduction: The laryngeal mask airway (LMA) may provide a better airway, concerning ventilation and oxygenation, than a conventional mask and oropharyngeal airway. In addition, the LMA has been successfully used to manage difficult airways as a ventilatory device by itself and as a conduit for tracheal intubation.

Aim of the study: This study compared the ideal insertion conditions for Laryngeal Mask Airway (LMA) with Ketamine versus Fentanyl with Propofol in adults and studies the hemodynamic response with both the drugs.

Materials and methods: The study was conducted in the year 2019-2020 at Madras Medical College. The ideal combination that provides smooth insertion conditions with minimal side effects has not been identified, particularly in children. In this study, 70 adults of age 20-30 years are divided randomly into 2 groups: Group 1 - Group-F - Fentanyl (n=35) received Fentanyl 2µg/kg and Group 2- Group –K- Ketamine (n=35) received Ketamine 0.5mg/kg before induction of anesthesia. Baseline heart rate and arterial blood pressure were measured. Vital parameters (Heart rate and Arterial Blood Pressure) were measured before induction, before LMA insertion, and thereafter at 1, 3, and 5 minutes after LMA insertion. Ideal LMA insertion conditions were evaluated with six variables by a blinded observer: mouth opening, gagging, head and limb movements, laryngospasm, and resistance to insertion. Also, the apnoea time was noted.

Results: The incidence of head/limb movements was statistically significant and Group Propofol–Ketamine showed 22% compared to Fentanyl - Propofol group (2.8%). Coughing/ gagging was seen in 2.86% of both the groups. Resistance to insertion was statistically significant with a p-value of 0.0268 showing more in Propofol + Ketamine. There was no statistical significance in the occurrence of restricted mouth opening, restriction to LMA insertion, and occurrence of swallowing between the two groups. Laryngospasm was absent in either group. The fentanyl group showed the incidence of more apnoea (34.28) compared to the Ketamine group (14.2).The heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) were statistically more with the Ketamine group than the Fentanyl group.

Conclusion: Co-induction with Fentanyl (2µ/kg) before Propofol (2.5mg/kg) induction for insertion of Laryngeal Mask Airway in adults provided better insertion condition with minimal increase in heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure than an admixture of Ketamine (0.5mg/kg) with Propofol.

Key words

Ketamine, Fentanyl, Propofol, Laryngeal mask airway, Comparison.

Introduction

Airway management is one of the most important skills. For securing patients' airways under anesthesia and providing adequate oxygenation and ventilation, various airway devices have become available. Undoubtedly, endotracheal intubation is the definitive way of securing the airway. But this needs the usage of neuromuscular blocking agents and has its side effects [1]. Bag and mask ventilation may be used for providing anesthesia for short surgical procedures. Since the introduction of the Laryngeal Mask Airway (LMA) by Dr. Archiebrain, LMA has gained popularity among anesthetists in securing and maintaining spontaneous ventilation in short surgical procedures bridging the gap between the endotracheal tubes and facemask. It frees the anesthesiologist's hands for performing other important tasks, lesser incidence of airway injury, and minimal cardiovascular and hemodynamic response [2]. Commonly, Propofol is used as an induction agent for LMA insertion. The LMA insertion requires an adequate depth of anesthesia for obtundation of airway reflexes and also it has to be tolerated without undue coughing, bucking, or laryngospasm. Many combinations of drugs have been tried for ideal LMA insertion conditions [3]. Here, we have done a comparative evaluation of the conditions for LMA insertion with Ketamine versus Fentanyl adding Propofol in spontaneously breathing adults undergoing day care procedures [4].

Materials and methods

The study was conducted in the year 2019-2020 at Madras Medical College. The ideal combination that provides smooth insertion conditions with minimal side effects has not been identified, particularly in children.

Inclusion criteria:

- Age 20-30 years. ASA: I & II Elective Surgeries
- Informed consent by the parents or by the relatives of the patients.

Exclusion criteria:

- ASA III & I V
- Patients not satisfying inclusion criteria.
- Patients who are at risk of aspiration.
- Patients with Airway abnormalities
- In patients with an anticipated difficult airway.
- Reactive airway diseases.
- Known asthmatic
- Known drug allergy.
- Seizure disorder
- Neuromuscular diseases.

- Allergy to egg.

In this study, 70 adults of age 20-30 years were divided randomly into 2 groups who were undergoing a short surgical procedure. Group 1-Group-F-Fentanyl (n=35) received Fentanyl 2µg/kg and Group 2-Group –K- Ketamine (n=35) received Ketamine 0.5 mg/kg before induction of anesthesia. Baseline heart rate and arterial blood pressure were measured. Vital parameters (Heart rate and Arterial Blood Pressure) were measured before induction, before LMA insertion, and thereafter at 1, 3, and 5 minutes after LMA insertion. Ideal LMA insertion conditions were evaluated with six variables by a blinded observer: mouth opening, gagging, head and limb movements, laryngospasm, and resistance to insertion. Also, the apnoea time was noted.

Statistical analysis

Descriptive statistics were done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analyzed with the help of an unpaired t-test. Categorical variables were analyzed with the help of the Chi-Square Test and Fisher- Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using SPSS version 16 and Microsoft Excel 2007.

Results

Majority of the Ketamine + Propofol Group patients belonged to the 20-30 years age class interval (n=25, 71.43%) with a mean age of 22.8 years. In the Fentanyl + Propofol Group patients, the majority belonged to the 20-30 years age class interval (n=19, 54.29%) with a mean age of 25± 5 years. The association between the intervention groups and age distribution was considered to be not statistically significant since $p>0.05$ as per the 2 tail unpaired t-test. The majority of the Ketamine + Propofol Group patients belonged to the ASA1 class interval (n=27, 77.14%). In the Fentanyl + Propofol Group patients, the majority belonged to the ASA 1 class interval (n=25, 71.43%). The association between the intervention groups and ASA physical classification was considered to be not statistically significant since $p > 0.05$ as per the Chi-squared test (**Table – 1**).

Table – 1: ASA classification.

ASA Physical Classification System	**Ketamine +Propofol Group**	**%**	**Fentanyl + Propofol Group**	**%**
ASA1	27	77.14	25	71.43
ASA2	8	22.86	10	28.57
Total	35	100	35	100
P value Chi Squared Test			0.2991	

Table – 2: LMA Insertion Ease.

LMA Insertion Ease	**Ketamine + Propofol Group**	**%**	**Fentanyl+ Propofol Group**
21	60.00	33	94.29
14	40.00	2	5.71
35	100	35	100
P value Fishers Exact Test			0.0007

In patients belonging to Ketamine + Propofol Group, the satisfactory LMA insertion procedure was 60% (n=21). In Fentanyl + Propofol Group, the satisfactory LMA insertion procedure was 94.29% (n=33). The increased percentage of satisfactory LMA insertion procedure in the Fentanyl + Propofol Group compared to the Ketamine + Propofol Group was statistically

significant as the p-value was 0.0007 as per fisher's exact test indicating a true difference among study groups. The percentage of satisfactory LMA insertion procedure was significantly more in Fentanyl + Propofol Group compared to Ketamine + Propofol Group by 34.29 percentage points. This significant difference of 1.57 times increase in the percentage of satisfactory LMA insertion procedure in Fentanyl + Propofol Group compared to Ketamine + Propofol Group is true and has not occurred by chance. Satisfactory LMA insertion was significantly and consistently more in Fentanyl + Propofol Group compared to Ketamine + Propofol Group when used for Laryngeal Mask Airway insertion (**Table – 2**).

Table – 3: LMA insertion attempts.

LMA Insertion Attempts	**Ketamine + Propofol Group**	**%**	**Fentanyl + Propofol Group**	**%**
One	29	82.86	32	91.43
Two	6	17.14	3	8.57
Total	35	100	35	100
P value Fishers Exact Test			0.3139	

Table – 4: Problems during LMA insertion.

LMA Insertion Problems	**Ketamine +Propofol Group**	**%**	**Fentanyl + Propofol Group**	**%**	**P value Fishers Exact Test**
Nil	21	60.00	33	94.29	REF
Limb Movements	8	22.86	1	2.86	0.0148
Resist to Insertion	5	14.29	0	0.00	0.0268
Gagging	1	2.86	1	2.86	0.9999
Total	35	100	35	100	

Table – 5: Systolic blood pressure.

Systolic Blood Pressure		**Baseline**	**Pre Ind**	**Pre LMA**	**1 min**	**3 Mins**	**5 Mins**
Ketamine + Propofol Group	N	35	35	35	35	35	35
	Mean	101.06	109.03	92.94	91.40	90.83	92.60
	SD	8.80	8.60	10.97	7.03	8.92	10.49
Fentanyl + Propofol Group	N	35	35	35	35	35	35
	Mean	103.40	98.60	84.46	85.69	88.00	88.26
	SD	9.04	10.36	9.02	8.23	9.45	9.10

Table – 6: Diastolic BP.

Diastolic Blood Pressure		**Baseline**	**Pre Ind**	**Pre LMA**	**1 min**	**3 Mins**	**5 Mins**
Ketamine + Propofol Group	N	35	35	35	35	35	35
	Mean	63.20	66.80	58.43	53.60	53.94	55.26
	SD	9.01	8.36	8.80	7.64	8.31	9.61
Fentanyl + Propofol Group	N	35	35	35	35	35	35
	Mean	66.29	61.77	50.46	48.97	51.37	51.00
	SD	10.11	8.62	8.05	6.71	8.08	7.99

Table - 7: Respiratory rate (RR).

Respiratory Rate		Baseline	Pre Induction	Pre LMA	1 Min	3 Min	5 Min
Ketamine + Propofol Group	N	35	34	34	34	35	35
	Mean	18.60	20.50	18.85	24.38	24.11	22.34
	SD	3.47	3.63	5.23	5.81	4.01	3.16
Fentanyl + Propofol Group	N	35	32	32	34	35	35
	Mean	17.83	16.69	14.19	18.15	19.43	18.89
	SD	3.66	3.91	4.46	5.06	5.16	3.79

Table - 8: Apnoea.

Apnoea Time	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%
≤2 minutes	4	80.00	9	75.00
2.01-5minutes	1	20.00	2	16.67
>5 minutes	0	0.00	1	8.33
Total	5	100	12	100

Table - 9: LMA extubation complications.

LMA Extubation Complications	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%	P-value Fishers Exact Test
Nil	31	88.57	35	100	REF
Blood Stain	1	2.86	0	0.00	0.9999
Cough	3	8.57	0	0.00	0.1196
Total	35	100	35	100	

Ketamine + Propofol Group patients had 1 attempt on successful LMA insertion (n=29, 82.86%). In the Fentanyl + Propofol Group patients, majority patients had one attempt on successful LMA insertion (n=32, 91.43%). The association between the intervention groups and LMA insertion attempts was considered to be statistically not significant since p value was greater than 0.05 as per fishers-exact test (**Table – 3**).

In patients belonging to Ketamine + Propofol Group, limb movement was the main LMA insertion problem noted (n=8, 22.86%). In Fentanyl +Propofol Group too, the limb movement was the main LMA insertion problem (n=1, 2.86%). The decreased percentage of limb movement was the main LMA insertion problem in the Fentanyl + Propofol Group compared to the Ketamine +Propofol Group which was statistically significant as the p-value was 0.0148 as per fishers exact test indicating a true difference among study groups. Similarly, the percentage of resistance to insertion was found to be decreased in the Fentanyl + Propofol Group compared to the Ketamine + Propofol Group, which was statistically significant as the p-value was 0.0268 as per fishers-exact test indicating a true difference among study groups. The percentage of limb movement as the main LMA insertion complication was statistically less in Fentanyl + Propofol Group compared to Ketamine + Propofol Group by 22 percentage points. This significant difference of 87% decrease in the percentage of limb movement as the main LMA insertion complication in Fentanyl + Propofol Group compared to Ketamine + Propofol Group was true and has not occurred by chance. The percentage of resistance to insertion as the other LMA insertion complication was statistically less in Fentanyl + Propofol Group compared to Ketamine + Propofol Group by 14.29 percentage points. This significant difference of 100% decrease in the

percentage of resistance to insertion as the other LMA insertion complication in Fentanyl + Propofol Group compared to Ketamine + Propofol Group is true and had not occurred by chance. LMA insertion complications like limb movements and resistance to insertion were significantly and consistently lower in the Fentanyl + Propofol Group compared to Ketamine + Propofol Group when used in the insertion of the Laryngeal Mask Airway (**Table – 4**).

By conventional criteria the association between the intervention groups and SBP status among study subjects was considered to be statistically significance since p< 0.05. In patients belonging to Ketamine + Propofol Group, the mean SBP was 96.31 mmHg. In Fentanyl + Propofol Group the mean SBP was 91.40 mmHg. The increased mean SBP measurement in Ketamine + Propofol Group compared to the Fentanyl + Propofol Group was statistically significant as the p-value was 0.0000, 0.0008, 0.0027, 0.0022, and 0.0488 between preinduction and 5 minutes on induction as per unpaired t-test indicating a true difference among study groups. The mean SBP measurement was statistically more in the Ketamine + Propofol Group compared to the Fentanyl + Propofol Group by 1.05 times with a mean difference of 4.91 mmHg. This difference was true and significant and had not occurred by chance. The mean systolic blood pressure measurement was significantly and consistently higher in Ketamine + Propofol Group compared to the Fentanyl +Propofol when used in the insertion of Laryngeal Mask Airway in Adults (**Table – 5**).

By conventional criteria the association between the intervention groups and DBP status among study subjects was considered to be statistically significant since p< 0.05. In patients belonging to Ketamine + Propofol Group, the mean DBP was 58.54 mmHg. In Fentanyl + Propofol Group the mean DBP was 54.98 mmHg. The increase in the mean DBP measurement in Ketamine + Propofol Group compared to the Fentanyl + Propofol Group was statistically significant as the p-value was 0.0157, 0.0002, 0.0089, 0.0140, and 0.0480 between preinduction and 5 minutes on induction as per unpaired t-test indicating a true difference among study groups. The mean DBP measurement was statistically more in the Ketamine + Propofol Group compared to the Fentanyl + Propofol Group by 1.06 times with a mean difference of 3.56 mmHg. This difference was true and significant and had not occurred by chance. The mean diastolic blood pressure measurement was significantly and consistently higher in Ketamine + Propofol Group compared to the Fentanyl +Propofol when used in the insertion of Laryngeal Mask Airway in adults (**Table – 6**).

By conventional criteria the association between the intervention groups and respiratory rate status among study subjects was considered to be statistically significant since p< 0.05. In patients belonging to Ketamine + Propofol Group, the mean RR was 21.47. In Fentanyl + Propofol Group the mean DBP was 17.53. The increase in the mean RR measurement in Ketamine + Propofol Group compared to the Fentanyl + Propofol Group was statistically significant as the p-value was 0.0001, 0.0002, and 0.0000 between preinduction and 5 minutes on induction as per unpaired t-test indicating a true difference among study groups. The mean RR measurement was more in the Ketamine + Propofol Group compared to the Fentanyl + Propofol Group by 1.22 times with a mean difference of 3.94 breaths per minute. This difference was true and significant and has not occurred by chance. The mean respiratory rate measurement was significantly and consistently higher in Ketamine + Propofol Group compared to the Fentanyl +Propofol when used in the insertion of Laryngeal Mask Airway in adults (**Table – 7**).

In patients belonging to Ketamine + Propofol Group, the mean apnoea time was 98.00 seconds. In Fentanyl + Propofol Group, the mean apnoea time was 112.92 seconds. The increased mean apnoea time in Fentanyl + Propofol Group compared to the Ketamine + Propofol Group was statistically significant as the p-value was 0.0025

as per the unpaired t-test indicating a true difference among study groups. Also, only 8.33% of Fentanyl + Propofol showed prolonged apnoea >5 mins which was statistically insignificant. Theme anapnoea time was more in Fentanyl + Propofol Group compared to Ketamine + Propofol Group by 24.92 seconds. This significant difference of 1.25 times increase in mean apnoea time in Fentanyl + Propofol Group compared to Ketamine + Propofol Group was true and has not occurred by chance. The mean apnoea time was significantly and consistently higher in Fentanyl + Propofol Group compared to Ketamine+ Propofol Group when used in the insertion of Laryngeal Mask-Airway in adults (**Table – 8**).

Majority of the Ketamine + Propofol Group patients had a cough as the main LMA extubation complication (n=3, 8.57%). In the Fentanyl + Propofol Group patients, majority patients had no LMA extubation complication (n=35, 100%). The association between the intervention groups and LMA extubation complications was considered to be not statistically significant since p>0.05 as per the Fisher exact test (**Table – 9**).

Discussion

Endotracheal intubation is a routine procedure to conduct general anesthesia and also a secured way of having control over the airway. But laryngoscopy and tracheal intubation, produce stress response that leads to a reflex surge in sympathoadrenal activity. This causes a rise in heart rate and blood pressure leading to dysrhythmias, which are lethal to cardiac patients. Face masks are routinely used for short surgical procedures during induction and maintenance under TIVA (Total intravenous anesthesia) and volatile induction. But it has the disadvantage of holding the mask continuously in spontaneously breathing patients [5]. Laryngeal Mask Airway started gaining popularity as an alternative to endotracheal intubation as well as face mask because it causes less hemodynamic changes, associated with a negligible rise in intraocular pressure after inserting LMA, causes decreased incidence of sore throat and also frees the hands of the anesthesiologist 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 [6]. Even for the in experienced provider, the LMA acts as an excellent airway device in many clinical areas that include the emergency room, the operating room, and ambulatory care as it is easy to handle even by untrained hands. A nearly 100% success rate for LMA placement occurs in the operating room. A lower rate of achievement for LMA placement may be expected in the emergency setting [7]. The use of LMA in adults is becoming increasingly common. To achieve easy LMA insertion, obtundation of airway reflexes is a must, so that coughing, gagging, head and limb movements, or laryngospasm can be avoided Sufficient depth of anesthesia is needed for adequate mouth opening. Succinylcholine can be used for suppressing these sequelae, but with the disadvantage of muscle pain. Propofol is currently used as an induction agent for LMA insertion, as it depresses airway reflexes more than Thiopentone. However, when Propofol is used alone higher doses are required to reduce pharyngeal and laryngeal reflexes which might cause cardiac depression and also makes LMA insertion conditions unsatisfactory [8]. Combination therapy termed co-induction may provide enhanced effects, more of the desired effect rather than adverse effects, with minimal costs. Recently, in various anesthetic procedures, the concept of co-induction has been proved better. Various combinations of drugs like Propofol - Fentanyl, Propofol - Ketamine, Propofol – Midazolam have been tried [9]. Comparisons have been made between Propofol 2.5 mg/kg with Fentany l2 µg/kg and Propofol 2.5mg/kg with Ketamine 0.5mg/kg concerning ideal LMA insertion conditions [10]. In my study, the insertion conditions of LMA were observed based on 6 variables such as resistance to mouth opening, resistance to insertion,

swallowing, coughing, gagging, limb and head movements, and laryngospasmas proposed in JH Bahk, et al. and Cheam, et al. study. In our study, the patients showed 94.29% satisfactory insertion condition with Fentanyl + Propofol group compared to Ketamine + Propofol with 60%. 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 Propofol + Ketamine 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 PF (2.86%) was less compared to Group Propofol + Ketamine (22.86%) with $p<0.0148$ which is significant [11]. Joseph A, et al., in their study also found that statistically highly significant head and limb movements ($p=0.007$) were encountered in Group PK (Propofol + Ketamine) compared to Group PF (Propofol + Fentanyl) [12]. The study done by M. Kodaka, et al. showed a greater occurrence of head and limb movement in the Ketamine group (40%) than the Fentanyl group (16%), the incidence was more than what we noted. 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 in Group Propofol + Ketamine of $p<0.0268$ insertions summed score ($P<0.004$) and was similar in both the groups than saline group. But the dose of Fentanyl they used was 1µg/kg [13]. Our study showed only 8.5% of patients in the Fentanyl group required an additional bolus dose of Propofol with a second attempt, compared to 17.1% of patients in the Ketamine group. He has also reported that inserting LMA and resistance to mouth opening was found to be higher in the Fentanyl group. The incidence of coughing/gagging between the two groups was not significant in our study. Statistically, a high incidence of apnoea was observed in Group PF with $p<0.0025$ in our study [14]. Supporting our study, the study conducted by Asha Gupta, et al., the incidence of apnoea was greater with Propofol – Fentanyl compared to Propofol-Butorphanol because of Butorphanol receptor specificity and µ antagonism [15]. The apnoea caused by either Fentanyl or Ketamine has little clinical significance and this parameter may allow enough time in checking the LMA position after insertion by manual ventilation. In our study, the baseline parameters like heart rate ($p=0.7$), systolic blood pressure (SBP) ($p=0.264$), and diastolic blood pressure (DBP) ($p=0.182$) were the same for both the groups. Group PK showed a significant rise in systolic, diastolic blood pressure, and mean arterial pressure during pre-induction, pre LMA insertion, 1min after LMA insertion, and 3 mins after LMA insertion [16]. This effect of Ketamine is due to indirect sympathomimetic action on the sinus node. Heart rate was found to be higher in Group PK compared to Group PF in our study. Pain while injecting Propofol is considered a negligible complication, but it might lead to uncooperative and distress. Pain can be due to activation of kininogens or by the free aqueous concentration of Propofol in the emulsion. In our study, pain following Propofol injection was similar in all the groups and was statistically insignificant between the two groups [17, 18, 19, 20].

Conclusion

In this study, we conclude that co-induction with Fentanyl (2µg/kg) before Propofol (2.5 mg/kg) for insertion of Laryngeal Mask Airway in adults provided better insertion conditions and minimal alteration in hemodynamic parameters than co-induction with Ketamine (0.5 mg/kg) and Propofol (2.5 mg/kg). The heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) were statistically more with the Ketamine group than the Fentanyl group.

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