

## To determine if lower dose of propofol is as good as standard dose of propofol for laryngeal mask airway insertion after pre-medication with midazolam and fentanyl.

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*A Randomized controlled study to evaluate two doses of propofol for Laryngeal Mask Airway insertion in patients pre medicated with midazolam and fentanyl.*

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### **Abstract:**

**Purpose:** To determine if lower dose of propofol is as good as standard dose of propofol for laryngeal mask airway insertion after pre-medication with midazolam and fentanyl.

**Background:** Propofol is routinely used for induction of general anesthesia and facilitating laryngeal mask airway insertion. However, heavy doses may lead to severe complications, whereas lower doses may not be quite as effective.

**Methods:** In a double blind randomized controlled trial, 140 patients undergoing ambulatory surgeries lasting less than 2 hours were recruited to receive intravenous propofol at a dose either 1 mg/kg (Group I) or 2.5 mg/kg (Group II). Intravenous midazolam (0.04 mg/kg) and fentanyl (1 mcg/kg) were used as pre-medication in all patients. After pre-oxygenation with 100% oxygen with appropriately sized facemask, anesthesia induction was initiated. Haemodynamic parameters, LMA insertion score, duration of apnoea, probable complications and number of attempts of LMA insertion were compared between two groups.

**Results:** The systolic blood pressure, diastolic blood pressure, mean arterial pressure was significantly higher in Group I than Group II (p value 0.003, 0.004, 0.03). There was no significant difference in heart rate and saturation via pulse oximetry (p value >0.05). LMA insertion was successful in first attempt in all patients of both groups. The duration of apnoea was significantly higher in group II than group I (p value 0.0001).

**Conclusion:** Propofol in a dose of 1 mg/kg can be safely used for LMA insertion in patients pre-medicated with midazolam and fentanyl. It provides satisfactory LMA insertion conditions. This lower dose is associated with better hemodynamic stability and shorter duration of apnoea.

**Keywords:** Propofol, Laryngeal mask airway, Ambulatory surgeries.

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### **I. Introduction**

The Laryngeal mask airway is commonly used for short surgeries, emergency airway management and in difficult airway<sup>1,2,3,4</sup>. LMA can be used for short procedures in lighter plane of anesthesia. Further, it can be inserted without using muscle relaxants for short procedures providing better safety profile. Propofol is commonly used for induction of anesthesia during LMA insertion<sup>5</sup>. When used alone propofol dose for uncomplicated LMA insertion often exceeds 2.5 mg/kg<sup>6</sup>. This is usually associated with hypotension, respiratory depression and apnea.<sup>6,7</sup> Benzodiazepines and opioids are suggested as pre-medication to overcome these problems. Benzodiazepines such as midazolam reduce upper airway reflexes. It is associated with more jaw relaxation, less coughing, gagging and reduced patient movements<sup>8</sup>. Opioids such as fentanyl in a dose of 1 mcg/kg supplemented with midazolam reduce the propofol dose with minimum respiratory depression and cardiovascular instability<sup>9,10,11,12</sup>. The present study aims to determine if a lower induction dose of 1 mg/kg of propofol when used with standard doses of midazolam and fentanyl is equally efficacious for LMA insertion as the currently administered dose of 2.5 mg/kg. The study further aims to determine the adverse events, hemodynamic changes as well as further supplemental propofol boluses needed during maintenance of anesthesia.

### **II. Materials and methods**

This was a prospective, randomized, double-blind controlled study. After obtaining approval from the ethics committee, this prospective, randomized, double blind, controlled study was carried out at Medanta-The Medicity, Gurgaon, over a period of 04/2015 to 04/2016. Patients, scheduled for ambulatory surgeries lasting less than 2 hours and aged between (18-65 years) were included after taking voluntary, written and informed

consent. Those with surgery on airway, history of gastro-esophageal reflux, full stomach, hiatus hernia or history to propofol, midazolam or fentanyl were excluded from this study

### III. Methods

After obtaining informed consent, subjects were randomized by generating a sequence of 140 random numbers (kept in opaque envelopes), using computer software, to receive either low dose propofol (group I,  $n=70$ ), or standard dose of propofol (group II,  $n=70$ ) during induction of anesthesia.

All standard monitors SpO<sub>2</sub>, ECG, BP were placed.

The subjects received midazolam 0.04mg/kg and fentanyl 1mcg/kg. They were then pre-oxygenated with 100% oxygen through appropriately sized face mask and a circle system. 1 min after premedication, induction of anesthesia was performed. The induction of anesthesia and the LMA insertion were performed by an anesthetist, with more than 5 years of experience in the speciality.

Group I included those who received propofol at dosage of 1mg/kg body weight intravenously. If required, they received further propofol supplements of 0.25mg/kg.

Group II included those who received propofol at dosage of 2.5mg/kg body weight intravenously. If required, they received further propofol supplements of 0.25mg/kg.

The propofol was prepared by anesthetist who determined the dose after opening the randomisation envelope. They prepared and administered the dose from a syringe labelled with the drug name and concentration. The drug in Group I was mixed with 5% Dextrose to make the insertion volumes equal in both groups and to ensure blinding. The investigator inserting the LMA was unaware of the patient group. The patient continued to inhale 100% oxygen.

After loss of eyelash reflex, an appropriate size LMA was placed and the LMA insertion score determined. In case there was difficulty in insertion of LMA (increased jaw tone), supplemental propofol boluses of 0.25 mg/kg were administered after each attempt. LMA insertion was then reattempted 15 seconds after administration of the supplemental propofol bolus. Number of attempts made at LMA insertion and total propofol boluses were noted.

Once LMA insertion was successful, sevoflurane was added to the breathing gas mixture to maintain a minimum alveolar concentration of 1%. Following LMA insertion, time taken from induction till patient started breathing spontaneously was recorded as 'Apnea time'. In case oxygen saturations fell below 95%, ventilation was assisted. The study period concluded with the return of spontaneous respiration.

A blinded observer recorded all parameters, including heart rate, systolic and diastolic blood pressures & apnoeic episodes in a response sheet. The hemodynamic parameters were recorded at 0 minute (baseline), 1 minute, 5 minutes, 10 minutes and 15 minutes.

All the monitors attached to participants were similar in both the groups.

Any adverse events were recorded. These were defined as any untoward medical event with origins in the study period causing or threatening to cause patient harm, including but not limited to: dental damage, bronchospasm, laryngospasm, bradycardia, airway bruising or bleeding and allergic reactions to study drugs.

#### **Primary objective:**

To compare the LMA insertion scores of propofol in a dose of 1 mg/kg to a dose of 2.5 mg/kg in pre-medicated patients.

#### **Secondary objectives:**

- To compare number of LMA insertion attempts and propofol supplements between propofol doses of 1 mg/kg and 2.5 mg/kg
- To compare the incidence of side effects: Apnea, hypotension, and coughing between propofol doses of 1 mg/kg and 2.5 mg/kg.
- To compare the hemodynamic changes between two doses of propofol. A total of 70 patients in each group were included.

The statistical analysis included profiling of patients for both the groups on different demographic and clinical parameters & co-morbidity etc. Descriptive analysis of quantitative data was expressed as means and standard deviation. Ordinal data was expressed as percentage, median and range.

For quantitative parameters Student t test was used. Repeated measure ANOVA was used to test the difference between the means of hemodynamic parameters measured at different follow up time points. Cross tables were generated and chi square test was used for comparisons & associations. P-value < 0.05 was considered statistically significant. SPSS software was used for analysis.

A simple random numbers list was generated by a statistician not involved in the study. He provided to the guide serially numbered opaque sealed envelopes for allocation concealment. Group allocation was opened just prior to induction of anesthesia. In a study (Dhamotharan S, et al 2014)<sup>68</sup> the decrease in mean arterial pressure

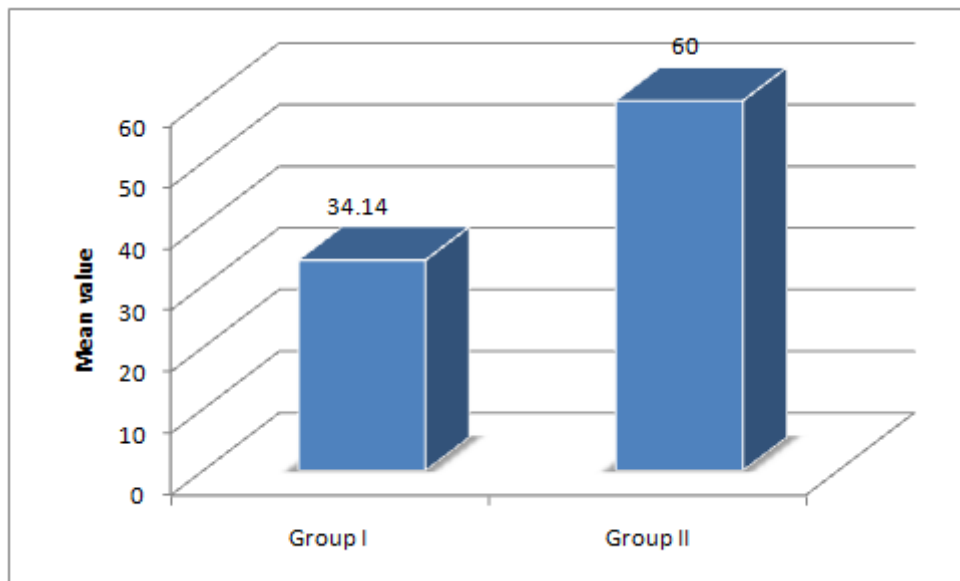
was 8% when compared to the baseline after fixed induction dose of propofol. It was assumed that there would be 25% decrease in MAP in the present study. The sample size was calculated using the following formula (Chan, 2003):

- $n = (Z_{\alpha/2} + Z_{\beta})^2 \times p_1(1-p_1) + p_2(1-p_2) / (p_1 - p_2)^2$
- where n: Sample size in a group
- $p_1$  and  $p_2$  are the proportion estimates
- $Z_{\alpha/2}$ : Significance level,  $Z_{\beta}$ : Power of the study
- Assuming 80% power, 5% significance level with 95% confidence interval, the required sample size per group was calculated 60. Assuming 10% non-response, the final sample size required was 66.

By assuming the excellent insertion condition rate was 50.0% and 66.7% in study & control group. The sample size works out 70 in each group with 95% confidence level and 80% power.

#### IV. Observations & Results

The present study was conducted in the Department of Anesthesia, Medanta-The Medicity. The mean age for Group I was  $47.49 \pm 13.16$  years and in Group II was  $47.33 \pm 12.90$  years and (p value= 0.59), thus showing that both groups were comparable. When comparing the gender, there were 49 males and 21 females in Group I and 46 males and 24 females in Group II (p value= 0.58), thus comparable. The mean weight in Group I was  $73.72 \pm 13.52$  kgs and in Group II was  $73.27 \pm 12.43$  kgs and (p value= 0.83) showing that both groups were comparable. Group I had (41.4%) patients of ASA-I and (54.3%) of ASA-II, while Group II had (40.0%) ASA-I and (58.6%) ASA-II and (p value= 0.56), thus comparable.



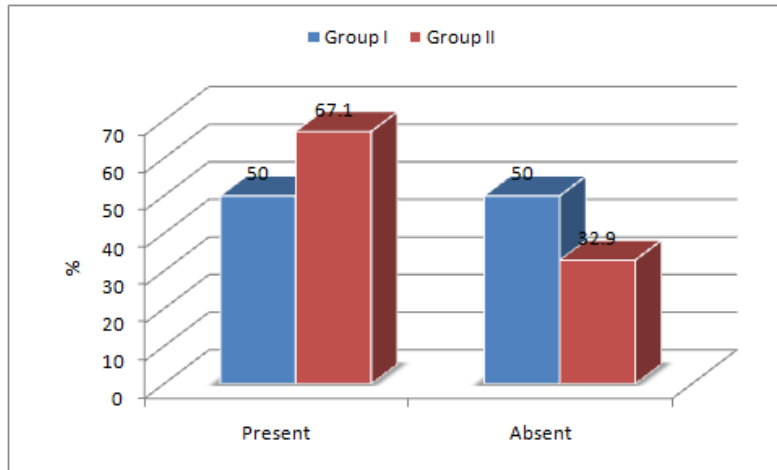
**Fig. 9:** Comparison of duration of apnea at induction between the groups

**Table-9:** Comparison of duration of apnea at induction between the groups

Groups	Duration in seconds	95% CI of mean
Group I	34.14±37.59	25.18-43.11
Group II	60.00±48.13	48.52-71.48
p-value <sup>1</sup>	0.0001*	

<sup>1</sup>Mann-Whitney U test, \*Significant

Fig. 9 & Table- 9 show the comparison of duration of apnea at induction between the groups. The duration of apnea at induction was found to be significantly (p=0.0001) higher in Group II ( $60.00 \pm 48.13$ ) compared to Group I ( $34.14 \pm 37.59$ ).



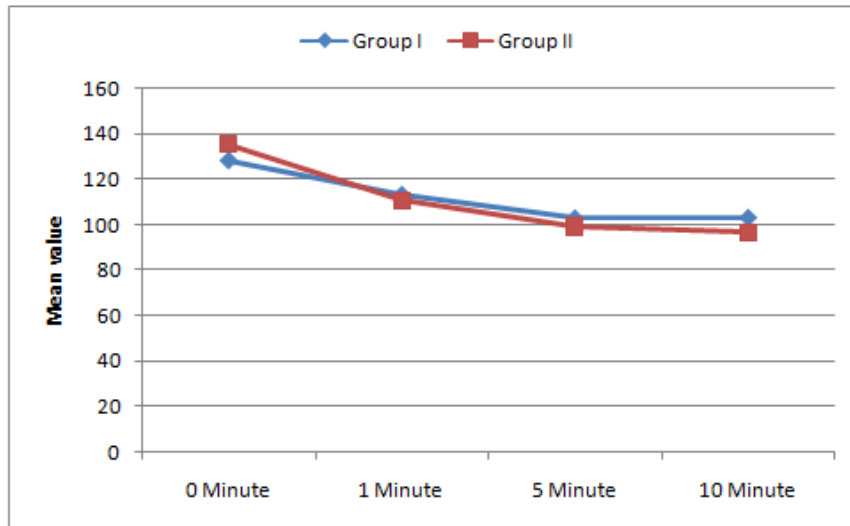
**Fig. 10:** Comparison of hypotension between the groups

**Table-10: Comparison of hypotension between the groups**

Hypotension	Group I (n=70)		Group II (n=70)		p-value <sup>1</sup>
	No.	%	No.	%	
Present	35	50.0	59	67.1	0.0001*
Absent	35	50.0	11	32.9	

<sup>1</sup>Chi-square test, \*Significant

Fig. 10 & Table- 10 show the comparison of hypotension between the groups. The hypotension was present in 50% patients of Group I and in 67.1% of Group II and the difference was found to be statistically significant (p=0.0001).



**Fig. 11:** Comparison of SBP between the groups at different time periods

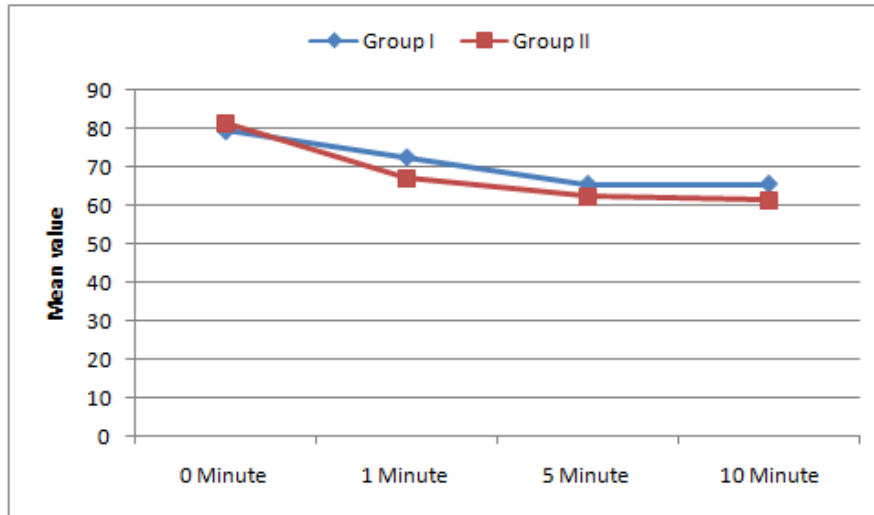
**Table-11:** Comparison of SBP between the groups at different time periods

Time period	Group I	Group II	p-value <sup>1</sup>
0 Minute	128.30±14.85	134.97±16.46	0.06
1 Minute	113.43±14.22	110.49±18.55	0.29
5 Minute	103.17±14.11	99.41±13.38	0.10
10 Minute	103.43±13.47	96.86±11.96	0.003*

<sup>1</sup>Unpaired t-test, \*Significant

Fig. 11 & Table- 11 show the comparison of SBP between the groups at different time periods. The mean baseline SBP was 128.30±14.85 mm Hg in Group I and 134.97±16.46 mm Hg in Group II and (p value= 0.06) was comparable in both groups.

SBP was higher in Group I, 103.43±13.47 mm Hg than Group II, 96.86±11.96 mm Hg and (p value= 0.003) at 10 minutes.



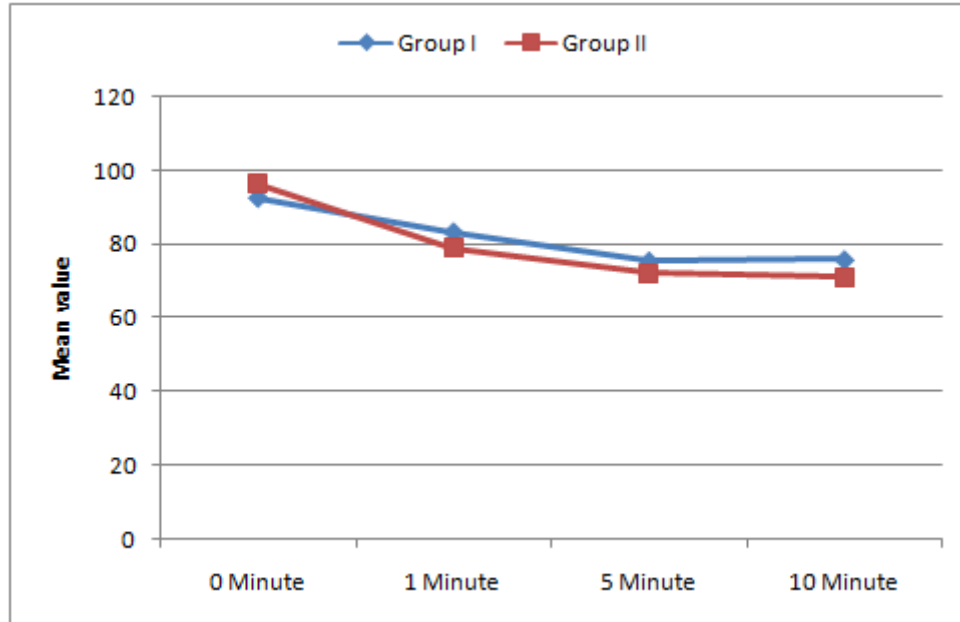
**Fig. 12:** Comparison of DBP between the groups at different time periods

**Table-12:** Comparison of DBP between the groups at different time periods

Time period	Group I	Group II	p-value <sup>1</sup>
0 Minute	79.40±10.39	81.34±11.91	0.30
1 Minute	72.51±12.78	67.00±9.42	0.004*
5 Minute	65.44±11.97	62.19±9.12	0.07
10 Minute	65.51±11.70	61.34±9.01	0.01*

<sup>1</sup>Unpaired t-test, \*Significant

Fig. 12 & Table- 12 show the comparison of DBP between the groups at different time periods. DBP was similar ( $p > 0.05$ ) at 0 min in both the groups. DBP became significantly higher in Group I compared to Group II at 1 min ( $p = 0.004$ ) and 10 min ( $p = 0.01$ )



**Fig. 13:** Comparison of MAP between the groups at different time periods

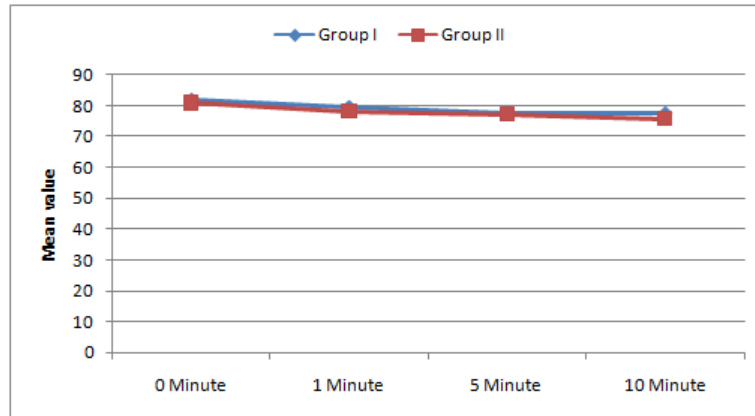
**Table-13:** Comparison of MAP between the groups at different time periods

Time period	Group I	Group II	p-value <sup>1</sup>
0 Minute	92.59±12.47	96.19±13.54	0.10
1 Minute	83.21±12.99	78.89±11.38	0.03*
5 Minute	75.31±13.34	72.14±10.66	0.12
10 Minute	75.64±13.10	71.00±9.99	0.02*

<sup>1</sup>Unpaired t-test, \*Significant

Fig. 13 & Table- 13 show the comparison of MAP between the groups at different time periods.

MAP was similar ( $p>0.05$ ) at 0 minute in both the groups. MAP became significantly higher in Group I compared to Group II at 1 minute ( $p=0.03$ ) and 10 minute ( $p=0.02$ ).



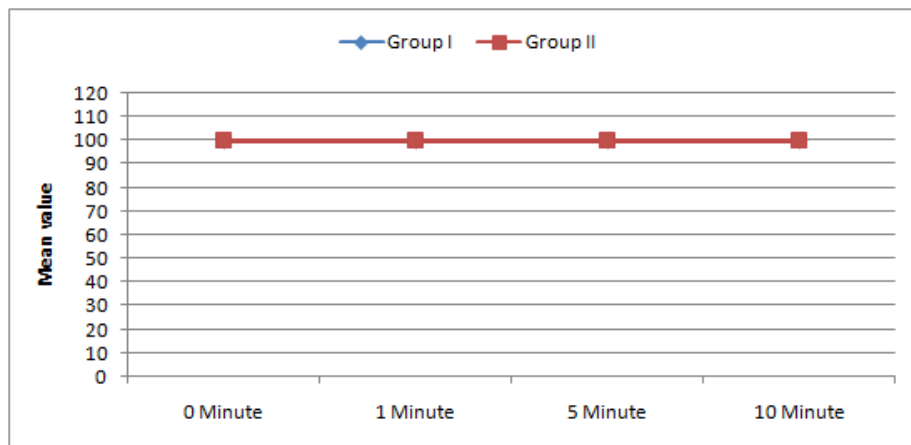
**Fig. 14:** Comparison of heart rate between the groups at different time periods

**Table-14:** Comparison of heart rate between the groups at different time periods

Time period	Group I	Group II	p-value <sup>1</sup>
0 Minute	81.87±14.14	80.86±14.25	0.67
1 Minute	79.69±10.89	78.16±17.05	0.52
5 Minute	77.50±11.57	77.03±13.85	0.82
10 Minute	77.74±12.17	75.80±12.66	0.35

<sup>1</sup>Unpaired t-test

Fig. 14 & Table- 14 show the comparison of heart rate between the groups at different time periods. Heart rate was similar ( $p>0.05$ ) at 0 minute in both the groups. There was no significant ( $p>0.05$ ) difference in the heart rate between the groups at 1 minute, 5 minute and 10 minute. No tachycardia was observed in Group I at 1 minute, 5 minute, and 10 minute.



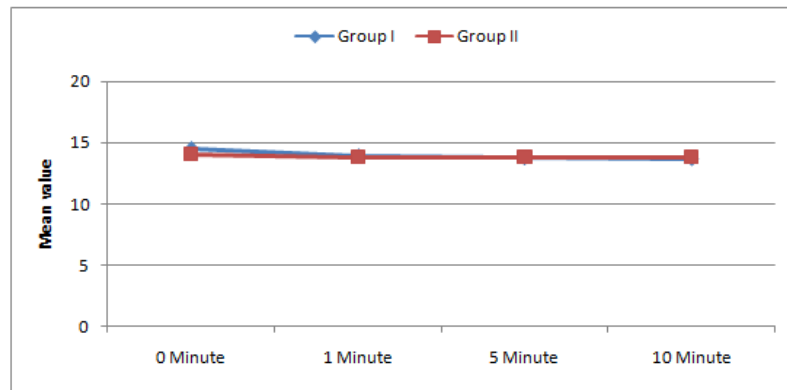
**Fig. 15:** Comparison of SpO<sub>2</sub> between the groups at different time periods

**Table-15:** Comparison of SpO<sub>2</sub> between the groups at different time periods

Time period	Group I	Group II	p-value <sup>1</sup>
0 Minute	99.79±0.56	99.81±0.42	0.73
1 Minute	99.93±0.31	99.86±0.42	0.25
5 Minute	99.91±0.28	99.89±0.49	0.67
10 Minute	99.91±0.40	99.94±0.28	0.63

<sup>1</sup>Unpaired t-test

Fig. 15 & Table- 15 show the comparison of SpO<sub>2</sub> between the groups at different time periods. SpO<sub>2</sub> was similar ( $p>0.05$ ) at 0 minute in both the groups. There was no significant ( $p>0.05$ ) difference in the SpO<sub>2</sub> between the groups at 1 minute, 5 minute and 10 minute.



**Fig. 16:** Comparison of respiratory rate (RR) between the groups at different time periods

**Table-16:** Comparison of respiratory rate between the groups at different time periods.

Time period	Group I	Group II	p-value <sup>1</sup>
0 Minute	14.46±1.53	14.07±1.31	0.11
1 Minute	13.87±1.22	13.77±1.32	0.64
5 Minute	13.73±1.07	13.79±1.28	0.77
10 Minute	13.71±1.06	13.77±1.29	0.77

<sup>1</sup>Unpaired t-test

Fig. 16& Table-16 show the comparison of RR between the groups at different time periods. RR was similar ( $p>0.05$ ) at 0 minute in both the groups. The duration of apnea for most patients was between (0-120 sec) and they were ventilated for the remaining period using SIMV mode as per institution protocol. There was no significant ( $p>0.05$ ) difference in the RR between the groups at 1 minute, 5 minute and 10 minute.

## V. Discussion

Doctors and researchers all over the world are channeling their resources towards alleviating the suffering of people. General anesthesia using inhalational and intra-venous agents has become safer and is a preferable option for many short procedures these days.

General anesthesia reduces the incidence of intra-operative patient awareness and recall. It facilitates a complete control of airway, breathing and circulation. Further, it allows complete muscle relaxation for prolonged periods of time and can be adapted easily to procedures of unpredictable duration or extent. It is administered rapidly and easily reversible. With modern advances in monitoring technology, medications, safety systems as well as highly educated and skilled anesthesia providers, many patients prefer general anesthesia over regional anesthesia.

Our study was conducted with the aim to further increase the safety profile of this technique by reducing the physiological fluctuations requiring which are commonly seen with general anesthesia. Our results are promising. ETT is used as a standard in many institutions for airway control in surgeries requiring GA, many advocate the use of supraglottic devices for short procedures in which risk of aspiration is not anticipated and there is no contra-indication for use. The major advantage of using LMA is reduced stress response as compared to laryngoscopy and intubation and during emergence. Further, there is minimal increase in intra-ocular pressure following insertion.

Use of LMA decreases the requirement of neuromuscular blockade and facilitates rapid emergence from anesthesia. It is also tolerated at lighter planes of anesthesia.<sup>5, 6, 12</sup> LMA insertion requires minimal training, especially useful for clinical and para-clinical staff during emergency situations. LMA insertion does not require laryngoscopy or visualization of vocal cords and provides effective ventilation almost similar to ETT. Ambu laryngeal mask (ALM) used in our study, is a sterile, single use product made of polyvinylchloride (PVC), moulded in one piece. It has a built in curve replicating the anatomy of the oropharynx and hypopharynx. In our experience, we observed that in experienced hands, after adequate pre-medication with midazolam and fentanyl, induction using propofol and proper positioning, LMA was inserted in first attempt in all patients.

One of the most common induction agents used to provide general anesthesia is propofol. Propofol effectively obtunds the airway reflexes and relaxes the jaw.<sup>14,15</sup> However propofol when used in standard induction doses of 2-3 mg/kg is commonly associated with hypotension, respiratory depression and apnea.<sup>24,25</sup>

Brown et al<sup>17</sup> also assessed conditions required for LMA insertion in 80 patients following induction of anesthesia. They observed that although propofol is superior to thiopentone as induction agent for LMA insertion, when used alone, propofol provides less satisfactory condition for LMA insertion and causes more cardio-respiratory depression. Midazolam and fentanyl are commonly added to propofol to provide sedation, analgesia, amnesia, for depressing the airway reflexes, improve the conditions for LMA insertion and to provide a more stable hemodynamic profile.<sup>20-23</sup>

Bapat P et al<sup>33</sup> conducted a study in 1996 using midazolam as pre-medication. They demonstrated reduced requirement of propofol and better suppression of airway reflexes when compared to thiopentone for LMA insertion. Our study was done to determine if low dose propofol is as good as standard dose when given at the induction of anaesthesia for laryngeal mask airway (LMA) insertion when used with standard doses of midazolam and fentanyl. Further, the LMA insertion conditions, number of attempts required for insertion, side effects and hemodynamic parameters were also assessed. The results obtained were promising. We studied 140 patients after dividing them into two groups of 70 patients each.

Syedhejazi M et al<sup>62</sup> compared 120 children undergoing out-patient surgeries in a randomized double blind controlled clinical trial and supported that lower dose of propofol is equally effective when used with midazolam and fentanyl for LMA insertion. Our study also showed that despite using a lower dose of propofol, if patient was pre-oxygenated well and standard doses of midazolam and fentanyl were used, none of the patients required supplemental doses of propofol.

Uzumcugil F et al<sup>63</sup> studied 52 ASA-I & II patients scheduled to have minor urological procedures. They observed that to reduce the adverse effects of propofol, opioids or muscle relaxants can be added. However, muscle relaxants increase the risk of aspiration whereas fentanyl suppresses airway reflexes in a dose related manner. Thus, fentanyl seems a suitable agent for having a favorable hemodynamics when propofol is used as induction agent.

Wong CM et al<sup>64</sup> studied 21 male and 54 female healthy Chinese patients requiring anesthesia for minor surgeries and supported the evidence that fentanyl suppresses airway reflexes in a dose related manner. In our study, LMA was inserted in the first attempt in all patients in experienced hands. Also, there was a significant reduction in hypotension and duration of apnea with lower dose of propofol.

The duration of apnea in Group I ( $34.14 \pm 37.59$ ) seconds and ( $60.00 \pm 48.83$ ) in Group II (p value= 0.0001) was statistically significant. Thus, suggesting that there was lower incidence and duration of apnea with lower dose of propofol. On comparing the incidence of hypotension, we found that 50% of the patients showed a decrease in BP in Group I and 67.1% patients in Group II, with (p value= 0.0001). Hence, we suggest use of lower dose of propofol with standard doses of midazolam and fentanyl for decreasing the incidence of hypotension.

Nakazawa K et al<sup>65</sup> studied One hundred and eighty ASA I and II patients to determine the effects of pre treatment with midazolam and fentanyl on ease of LMA insertion using propofol without muscle relaxant. They compared fentanyl in a dose of 1 mcg/kg with midazolam 0.05 mg/kg as a pre medication using propofol as induction agent for LMA insertion. They concluded that pre treatment with midazolam and fentanyl combined with propofol provides satisfactory conditions for LMA insertion.

Ramaswamy AH et al<sup>66</sup> et al observed pre induction vitals including heart rate, systolic blood pressure and SpO<sub>2</sub> and concluded that they were comparable when either midazolam and propofol or only propofol was used. The timing taken for LMA insertion was also same in both groups.

Goel S et al<sup>67</sup> studied 60 children of ASA I and II. They also concluded that midazolam used in sub anesthetic doses reduces the dose of propofol required for induction with synergistic action which improves LMA insertion conditions. They also showed that this combination provided hemodynamic stability without prolonging recovery and is very useful with propofol in day care anesthesia for ambulatory surgeries.

Dhamothran S et al<sup>68</sup> compared 90 patients undergoing minor procedures. Their study showed that midazolam and fentanyl provide a more stable hemodynamic profile when used with low dose propofol for LMA insertion.

Our study also showed that although SBP was comparable in both the groups, DBP and MAP was significantly higher when we used lower dose of propofol along with standard doses of midazolam and fentanyl thus providing a more stable hemodynamic profile. Further, HR was similar in both the groups and no significant tachycardia was observed when lower dose of propofol was used. The RR and oxygen saturation measured via pulse oximetry was also comparable in both the groups.

The LMA insertion score was also similar in both the groups. Thus, based on above observations we suggest that lower dose of propofol can be used along with standard doses of midazolam and fentanyl for LMA insertion for short procedures providing patient with a stable hemodynamic profile and simultaneously reducing side-effects like hypotension and apnea.

## VI. Conclusion



We conclude that propofol in a dose of 1 mg/kg can be safely used for LMA insertion in patients pre-medicated with midazolam and fentanyl. It provides satisfactory LMA insertion conditions. This lower dose is associated with better hemodynamic stability and a shorter period of apnea.

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