Original Article

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# A Comparison of Dexmedetomidine and Fentanyl as Co-induction Agents to Propofol for Insertion of Proseal Laryngeal Mask Airway: A Randomised Clinical Study

Anaesthesia Section

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## ABSTRACT

**Introduction:** The Supraglottic Airway Devices (SAD) are bridges between a face mask and Endotracheal Tubes (ETT). Various induction agents like sevoflurane and propofol were used till date for smooth insertion. Propofol causes dose-dependent cardiorespiratory depression while opioids may increase the haemodynamic instability.

**Aim:** To investigate the role of dexmedetomidine and fentanyl as co-induction agents to propofol for Proseal Laryngeal Mask Airway (PLMA) insertion conditions.

**Materials and Methods:** The present study was a randomised clinical study in which 60 patients of American Society of Anaesthesiologists (ASA) grade I-II, 20-60 years of age were divided into two groups. Group P+D received 2.5 mg/kg propofol+1 µg/kg dexmedetomidine while Group P+F received 2.5 mg/kg propofol+1 µg/kg fentanyl. A Bispectral Index (BIS) value of 50-45 was taken as desired end point for insertion of PLMA. Induction time, insertion time, ease of insertion, number of attempts, total propofol requirement and various haemodynamic changes were taken into consideration.

**Results:** Mean induction time with dexmedetomidine (8.28±0.81 min) was lower as compared to that with fentanyl (9.28±0.83 min) ($p<0.0001$). Total propofol requirement was also less with dexmedetomidine (93.66±15.64 mg) as compared to that with fentanyl (135.8±10.95 mg). Dexmedetomidine also provided better insertion score for PLMA ($p=0.044$) with less number of attempts ($p=0.044$), when compared with fentanyl.

**Conclusion:** Dexmedetomidine, as an adjuvant to propofol can be considered as an attractive choice for insertion of PLMA.

**Keywords:** Adjuvant, Bispectral index, Cardiorespiratory, Haemodynamic, Laryngeal mask

## INTRODUCTION

For many years, airway management stressed for successful tracheal intubation [1]. However in 1981, by the invention of Laryngeal Mask Airway (LMA), the focus of airway management modified from intubation to oxygenation and ventilation. The SAD are bridges between a face mask and ETT. They provide hands free airway, easier placement even by inexperienced personnel [2], less invasive and are better tolerated by the patients. SAD typically do not require neuromuscular blockade, thereby avoiding any side-effects of the medication or its antagonists. In General Anaesthesia, as the loss of protective airway reflexes and obstruction of the upper airway can be life threatening, these SAD such as the PLMA provide a secured airway and prevents aspiration as they have gastric port for drainage of gastric contents [3].

Various induction agents like sevoflurane, thiopentone sodium and propofol were used till date for smooth insertion of PLMA. Propofol having short duration of action causes dose-dependent cardiorespiratory depression when used alone, so different co-induction agents such as low dose muscle-relaxants, opioids, benzodiazepines, etc., have been used along with it to decrease the unwanted events while inserting PLMA [4]. However, opioids on other hand may increase the respiratory depression and increase the haemodynamic instability [5].

They may even be used as an emergency airway, where a practitioner skilled in intubation is not available (e.g., paramedic crews) or as in "can't intubate, can't ventilate" ventilate situation where timely management of airway is very critical, this type of SAD plays a very important role. So, aiming to fill this vital gap, the present study was conducted to compare dexmedetomidine, a non opioid and a recently introduced highly selective α2-adrenoceptor agonist with analgesic and sedative properties as an attractive alternative to fentanyl, an opioid for smooth insertion of PLMA.The primary objective was to compare induction time, insertion time, ease of insertion and number of attempts, and the secondary objectives were to compare total propofol requirement and haemodynamic responses.

## MATERIALS AND METHODS

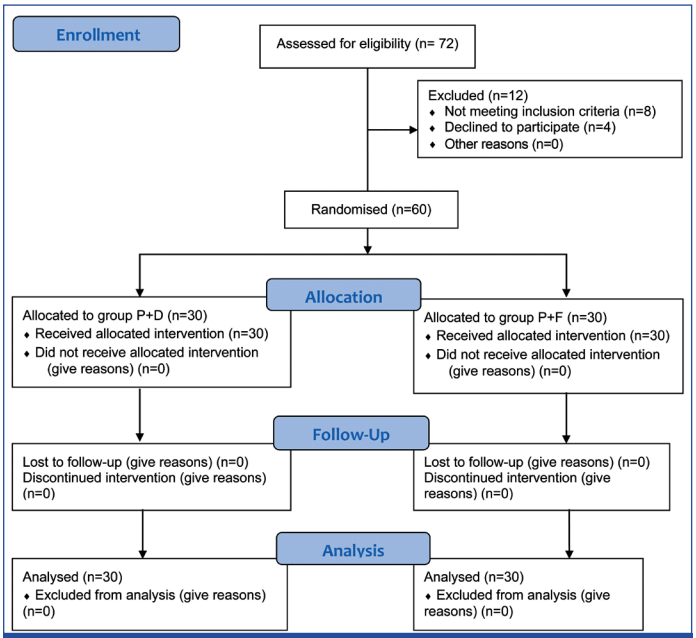
This randomised clinical study was conducted in Department of Anaesthesiology, Mahatma Gandhi Memorial Medical college and M.Y. Hospital, Indore, Madhya Pradesh, India, after approval from Institutional Ethics Committee (IEC) (EC/MGM/Feb-20136) and obtaining informed consent from the participants. The study was conducted for a period of one year from June 2020 to July 2021.

**Inclusion criteria:** ASA I-II patients aged from 20-60 years of either gender were included and divided into two groups of 30 each, scheduled for elective surgery under general anaesthesia.

**Exclusion criteria:** Patients with pre-existing diseases like, cardiopulmonary diseases, hepatic dysfunction, renal dysfunction, psychiatric illness, pregnant and lactating women and patients at risk of aspiration with reduced mouth opening were excluded from study.

**Sample size calculation:** Sample size was calculated using the formula $n_i=2\left(\frac{Z_{1-\alpha/2}+Z_{1-\beta}}{ES}\right)^2$, where $n_i$ is the sample size required in each group (i=1 ,2), α is the selected level of significance and $Z_{1-\alpha/2}$ is the value from the standard normal distribution holding 1-α/2 below it, and 1-β is the selected power and $Z_{1-\beta}$ is the value from the standard normal distribution holding 1-β below it [6]. ES is the Effect Size, The sample size obtained at 95% confidence interval with an 80% power of the study. α (type-I error rate)=0.05, β (power of the study)=0.8. A total of 60 patients were included in the present study.

**Allocation:** A thorough pre-anaesthetic evaluation was performed and patients were randomly allocated (using closed envelop technique) to one of the two groups, comprising 30 patients each. Group P+D received 2.5 mg/kg propofol+1 µg/kg dexmedetomidine while Group P+F received 2.5 mg/kg propofol+1 µg/kg fentanyl [Table/Fig-1].




**[Table/Fig-1]:** CONSORT flow chart.

## Procedure

On arrival to operating room, intravenous line was secured and baseline vital parameters like Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Respiratory Rate (RR), oxygen saturation ($SpO_2$) and End Tidal $CO_2$ ($ETCO_2$) were recorded. Patients were premedicated with Inj. glycopyrrolate 0.004 mg/kg intravenously and inj. midazolam 0.05 mg/kg intravenously. After preoxygenation for 3 minutes with 100% oxygen on mask, study drugs were administered intravenously over 10 min with a syringe. Thirty seconds after administration of the study drugs, propofol was administered intravenously in a dose of 2.5 mg/kg mixed with 1 mL of 2% lidocaine for induction of anaesthesia in a titrated manner to achieve a BIS value of 50-45 [7] as desired end point for insertion of PLMA. Ninety seconds later a lubricated PLMA was inserted using standard or classical insertion technique and cuff was inflated to the pressure just to seal adequately and patient was connected to breathing circuit [8,9]. After ensuring the correct placement of PLMA, Ryles tube was advanced from the gastric port and its position was ensured by insufflating some air and auscultating over the epigastrium. Patients were kept on assisted spontaneous ventilation and anaesthesia was maintained with $N_2O$:$O_2$=50%:50%, and sevoflurane (1-1.5%).

If mouth opening was not adequate or excessive cough or gag reflexes prevented proper placement of PLMA, anaesthetic depth was further increased by giving an additional dose of propofol 0.5 mg/kg. The second attempt for PLMA insertion was taken and if not successful, the case was excluded from the study. Other events such as apnoea, breath holding, expiratory stridor, and tearing were observed. HR, SBP, DBP, MAP, RR, $SpO_2$ and $ETCO_2$ were recorded at preinduction and 1, 3, 5, 10, 15 min after PLMA insertion. Induction time, insertion time, ease of insertion, number of attempts required for PLMA insertion and additional doses of propofol were also taken into consideration and noted down. The period of observation for the study ended when the patient was considered to have reached adequate depth of anaesthesia and was well settled after insertion of PLMA.

Induction time was defined as the time interval between the administration of induction agent and loss of consciousness to reach a BIS value between 50-45 which is the appropriate level for general anaesthesia. Insertion time was defined as the time interval from the moment the tip of PLMA crossed the incisors till the confirmation of its placement by waveform capnography, which is a gold standard parameter.

**The following criteria were used for grading the insertion condition [10]:**

**Scores for jaw mobility:** Score 1 for fully relaxed jaw, score 2 for mild resistance of jaw opening, score 3 for tight but opened jaw and score 4 for closed jaw.

**Scores for coughing/bucking:** Score 1 for no coughing, score 2 for 1-2 coughs, score 3 for ≥3 coughs and score 4 for bucking.

A combined score of ≤2 was considered optimal (easy) for PLMA insertion, scores between 3-5 considered as 'difficult' to insert and score of 6-8 considered as 'impossible' to insert.

## STATISTICAL ANALYSIS

The data was initially entered into the Microsoft excel from the customised proforma for analysis. Statistical Software Mini Tab Version 17.0 was used for calculating the p-values. Comparison of means between the two groups was done using unpaired 't' test, association between two non parametric variables was done using Pearson's Chi-square test and comparison of proportions was done using Fisher's-Exact test. A p-value of <0.05 was taken as statistically significant.

## RESULTS

Both the groups were comparable demographically [Table/Fig-2]. The induction time was statistically lower in the P+D group than with P+F group. However, the difference in insertion time was not significantly different. The mean total propofol requirement was statistically lower in P+D group than in P+F group [Table/Fig-3].

| Parameters | P+D Group | P+F Group | p-value |
|---|---|---|---|
| Mean age (years) | 32.22±10.851 | 34.03±10.952 | 0.5227 |
| Sex | 56.7% (M), 43.3% (F) | 53.3% (M), 46.7% (F) | 0.7952 |
| Weight (kg) | 57.64±4.2 | 58.9±3.81 | 0.2280 |
| Mallampatti grading I/II | 25/5 | 26/4 | 0.7176 |

**[Table/Fig-2]:** Distribution of patients according to demographic data. Unpaired 't' test applied

| Variable | P+D Group | P+F Group | p-value |
|---|---|---|---|
| Mean Induction time (min) | 8.28±0.81 | 9.28±0.83 | <0.0001 |
| Mean Insertion time (sec) | 11.23±0.47 | 11.37±0.68 | 0.357 |
| Total propofol requirement (mg) | 93.66±15.64 | 135.8±10.95 | <0.0001 |

**[Table/Fig-3]:** Comparison of different variables between the groups. Unpaired 't' test applied. A p-value <0.05 was taken as statistically significant

The ease of insertion was better in the P+D group, with more number of patients with 'easy' insertion in this group than that in P+F [Table/Fig-4]. More number of patients could be inserted with PMLA in first attempt, in the P+D group than P+F [Table/Fig-5].

| Ease of insertion | P+D Group, n (%) | P+F Group, n (%) |
|---|---|---|
| Easy | 29 (96.7) | 24 (80) |
| Difficult | 1 (3.3) | 6 (20) |
| Impossible | 0 | 0 |
| p-value | 0.044 | |

**[Table/Fig-4]:** Comparison of ease of insertion of PMLA between the groups. Chi-square test applied. A p-value <0.05 was considered significant

There was significant reduction in mean HR in the P+D group, when compared to P+F group till the end of 15 minutes (A15) after PLMA insertion (p<0.001) [Table/Fig-6].

| Attempts | P+D Group, n (%) | P+F Group, n (%) |
|---|---|---|
| 1 attempt | 29 (96.7) | 24 (80) |
| 2 attempts | 1 (3.3) | 6 (20) |
| p-value | 0.044 | |

**[Table/Fig-5]:** Comparison of mean number of attempts between the groups.
Chi-square test applied. A p-value <0.05 was taken as statistically significant

| Group | P+D Group (Mean±SD) | P+F Group (Mean±SD) | p-value |
|---|---|---|---|
| Mean base line heart rate | 90.43±13.7 | 92.3±13.9 | 0.6004 |
| Mean preinduction heart rate (A0) | 76.9±12.5 | 89.51±14.2 | 0.0006 |
| Mean heart rate at 1 min (A1) | 82.29±13.7 | 95.59±16.69 | 0.0013 |
| Mean heart rate at 3 mins (A3) | 79.25±12.31 | 94.3±15.01 | <0.001 |
| Mean heart rate at 5 mins (A5) | 77.32±11.29 | 93.65±14.19 | <0.001 |
| Mean heart rate at 10 mins (A10) | 76.58±11.6 | 92.13±13.8 | <0.001 |
| Mean heart rate at 15 mins (A15) | 77.29±12.18 | 90.62±11.76 | <0.001 |

**[Table/Fig-6]:** Comparison of mean heart rate between the groups.
Unpaired 't' test applied. A p-value <0.05 was taken as statistically significant

There was statistically significant decrease in mean SBP seen in the P+D group, post-PLMA insertion, starting from 1 min (A1) till the end of 15 minutes (A15); as compared to P+F group with (p value <0.05) [Table/Fig-7]. However, changes in DBP, RR, $SpO_2$, $ETCO_2$ were not significant (p-value >0.05) [Table/Fig-8].

| Group | | P+D Group (Mean±SD) | P+F Group (Mean±SD) | p-value |
|---|---|---|---|---|
| Mean baseline | SBP | 115.46±8.41 | 113.06±8.81 | 0.2849 |
| | DBP | 70.6±6.2 | 72.2±5.2 | 0.2833 |
| At preinduction (A0) | Mean SBP | 104.1±8.5 | 104.76±7. 94 | 0.7572 |
| | Mean DBP | 66.6±5.9 | 70.2±5.2 | 0.707 |
| At 1 min (A1) | Mean SBP | 103.23±8.6 | 110.06±8.52 | 0.0031 |
| | Mean DBP | 67.5±6.1 | 68.9±5.6 | 0.356 |
| At 3 mins (A3) | Mean SBP | 102.46±8.65 | 107.466±9.6 | 0.038 |
| | Mean DBP | 68.1±6.2 | 69.2±5.4 | 0.966 |
| At 5 mins (A5) | Mean SBP | 102.56±7.76 | 108.333±9.4 | 0.0120 |
| | Mean DBP | 66.6±6.02 | 68.6±5.1 | 0.831 |
| At 10 mins (A10) | Mean SBP | 104.26±7.76 | 110.06±9.29 | 0.0111 |
| | Mean DBP | 67.6±6.2 | 68.6±5.2 | 0.572 |
| At 15 mins (A15) | Mean SBP | 105.66±6.9 | 111.6±8.9 | 0.0054 |
| | Mean DBP | 67.4±6.1 | 67.2±5.2 | 0.8918 |

**[Table/Fig-7]:** Comparison of mean SBP and DBP between the groups.
Unpaired 't' test applied. A p-value <0.05 was taken as statistically significant

| Group | | P+D Group (Mean±SD) | P+F Group (Mean±SD) | p-value |
|---|---|---|---|---|
| Mean baseline | $SpO_2$ | 98.88±0.48 | 98.83±0.461 | 0.6819 |
| | $ETCO_2$ | 37.7±1.8 | 36.7±2.1 | 0.052 |
| | RR | 12.9±0.76 | 12.93±0.73 | 0.87 |
| At preinduction (A0) | Mean $SpO_2$ | 98.76±0.50 | 98.7±0.65 | 0.6901 |
| | Mean $ETCO_2$ | 35.5±1.85 | 34.56±1.8 | 0.053 |
| | Mean RR | 7.13±0.77 | 7.06±0.78 | 0.727 |
| At 1 min (A1) | Mean $SpO_2$ | 98.76±0.56 | 98.76±0.51 | 0.6471 |
| | Mean $ETCO_2$ | 35.16±1.86 | 36.6±1.9 | 0.053 |
| | Mean RR | 7.16±0.69 | 7.26±0.73 | 0.587 |
| At 3 mins (A3) | Mean $SpO_2$ | 98.78±0.45 | 98.88±0.48 | 0.4086 |
| | Mean $ETCO_2$ | 36.2±1.9 | 37.0±2.1 | 0.127 |
| | Mean RR | 8.03±0.764 | 7.9±0.758 | 0.512 |
| At 5 mins (A5) | Mean $SpO_2$ | 98.8±0.57 | 98.76±0.56 | 0.7849 |
| | Mean $ETCO_2$ | 35.31±1.52 | 36.9±1.8 | 0.114 |
| | Mean RR | 8.23±1.67 | 9.4±1.3 | 0.0037 |
| At 10 mins (A10) | Mean $SpO_2$ | 98.92±0.50 | 98.83±0.461 | 0.4710 |
| | Mean $ETCO_2$ | 35±1.92 | 35.7±1.75 | 0.145 |
| | Mean RR | 10.1±0.9 | 9.5±0.9 | 0.012 |
| At 15 mins (A15) | Mean $SpO_2$ | 98.76±0.56 | 98.76±0.50 | 1.0000 |
| | Mean $ETCO_2$ | 35.3±2.16 | 35.5±1.8 | 0.692 |
| | Mean RR | 12.2±0.9 | 11.9±1.06 | 0.24 |

**[Table/Fig-8]:** Comparison of mean $SpO_2$/$ETCO_2$/RR between P+D and P+F groups.
Unpaired 't' test applied. A p-value <0.05 was taken as statistically significant

In P+D group, 29 patients and 24 patients in P+F group had NO adverse events while insertion of Proseal LMA. One patient in P+D group and six patients in P+F group had coughing/bucking/breath holding as side-effects while insertion of PLMA. Thus, the mean adverse effects was found to be statistically significant (p=0.044, Chi-square test applied) between both the groups, showing a lower adverse events in the P+D group than with P+F group.

## DISCUSSION

Various inhalation and intravenous agents have been used to suppress airway reflexes and to achieve good relaxation of jaw muscles for adequate insertion conditions. But patient compliance has been found to be better with intravenous agents. Among them, propofol has been preferred the most, but it also leads to cardiorespiratory suppression [11]. So to avoid this side-effects of propofol, opioids like fentanyl were added to reduce the propofol requirement [12]. Since these drugs increase the incidence of apnoea, another promising adjuvant dexmedetomidine, an α-2 agonist with both sedative and analgesic property has shown to attenuate haemodynamic stress responses more effectively. So, this randomised clinical study has been conducted to compare dexmedetomidine and fentanyl as co-induction agents to propofol for PLMA insertion conditions.

The study findings showed that patient in dexmedetomidine group required less induction time, lower total propofol dose, had better insertion score with less number of attempts as compared to those in fentanyl group. HR and SBP were more stable in dexmedetomidine group as compared to fentanyl group.

Tan ASB and Wang CY [13] reported, that fentanyl produces prolonged apnoea as the dose is increased and they concluded that optimal dose of 1 μg/kg of fentanyl is recommended for LMA insertion along with 2.5 mg/kg propofol, hence 1 μg/kg of fentanyl has been used in present study. The study done by Uzumcugil F et al., concluded that dexmedetomidine, at 1 μg/kg when used before induction, with propofol provided successful laryngeal mask insertion while preserving respiratory function [14]. Thus, in the present study, 1 μg/kg of dexmedetomidine for PLMA insertion was considered.

One of the primary objectives was to compare and evaluate the induction time. Results in the study showed a significant lower mean induction time in the P+D group as compared with in P+F group (p<0.0001) [Table/Fig-2]. This finding was similar to the study done by Ali AR and El Ghoneimy MN, where desired BIS level was achieved earlier in dexmedetomidine group as compared to fentanyl group (p<0.05) [15].

Overall, 29 patients out of 30 had easy insertion score in P+D group as compared to 24 patients in P+F group. Only one patient had difficult insertion score in P+D group in comparison to four patients in P+F group. This finding was similar to the study done by Launde SA et al., where 29 patients out of 30 patients had easy insertion score in dexmedetomidine group, as compared to 22 patients in fentanyl group [16].

The mean insertion time in the dexmedetomidine and fentanyl group of the present study were compatible and showed no statistical significance (p=0.357). Overall, 29 patients out of 30 had single

attempt of in P+D group as compared to 24 patients in P+F group. This finding was similar to the study done by Nellore SS et al., where it was found that 27 patients out of 30 in dexmedetomidine group vs 24 patients out of 30 in fentanyl group required single attempt [17].

Ali AR and El Ghoneimy MN concluded that the propofol requirement was significantly lower with dexmedetomidine group than in fentanyl group during induction and maintenance [15]. The results of the index study coincide with these results, on total propofol requirement [Table/Fig-2].

There was statistically significant decrease in the mean HR in the P+D group, after PLMA insertion starting from preinduction (A0) till the end of 15 minutes (A15) as compared to P+F group [Table/Fig-5]. A statistically significant decrease in mean SBP, also was seen in the P+D group, in post PLMA insertion starting from 1 min (A1) till the end of 15 minutes (A15) in comparison to P+F group [Table/Fig-6]. In a study done by Launde SA et al., the HR and SBP remained stable in dexmedetomidine group as compared to fentanyl group, after LMA insertion [16].

### Limitation(s)

Only fixed doses of both the drugs were used and the desired effect may have been attained in lesser doses in some of the patients. The level of norepinephrine in the blood also could not be measured which could reflect attenuation of stress response.

## CONCLUSION(S)

From the above observation and results, it may be concluded that dexmedetomidine, significantly reduced the induction time, provided greater ease of insertion for PLMA with less number of attempts, less total propofol requirement and few adverse events such as apnoea, breath holding, expiratory stridor, and tearing as compared to fentanyl group. Thus, dexmedetomidine, as an adjuvant to propofol, can be considered as an attractive choice for insertion of PLMA.

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