

A prospective randomised comparative study of efficacy of combination of inj. dexmedetomidine–propofol and inj.fentanyl-propofol for the insertion conditions of proseal laryngeal mask airway

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Abstract

Background: Dexmedetomidine over a period of time has been studied with Propofol as a co-induction agent to assess the haemodynamic response, Propofol dose requirement and overall insertion condition of laryngeal mask airway. **Objective:** To compare efficacy of anesthetic drug with respect to hemodynamic effects during insertion of PLMA. **Methodology:** It is randomised prospective study was conducted on 94 ASA I and II patients satisfying inclusion criteria, aged 18–60 years of either sex. They were divided into two groups using randomisation in a group of 47 patients named as group D, which received Dexmedetomidine with Propofol and group F, which received Fentanyl with Propofol. **Results:** Majority i.e. 35(74.5%) and 39(83%) from group D and F respectively were from ASA I. dose of Propofol required per kg body weight, in group D-P 1.6 mg/kg and in group F-P its 1.9 mg/kg to insert PLMA. Average time required for insertion of PLMA in-group D-P is 33.10 sec while in-group F-P is 35.6sec. Though group F-P shows rise in heart rate at the time of insertion of PLMA, the values are statistically comparable in both the groups. mean systolic blood pressure is significantly higher in group F-P. **Conclusion:** Dexmedetomidine has better potential as a co-induction agent used with Propofol for insertion of PLMA in short surgical procedures in given doses with improved overall insertion conditions and better haemodynamic profile than Fentanyl.

Key Word: Dexmedetomidine–Propofol, Fentanyl–Propofol, Proseal Laryngeal Mask Airway

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INTRODUCTION

Endotracheal intubation, first used in anaesthesia in 1878, is a rapid, simple, safe and non-surgical technique that achieves all the goals of airway management, hence remains the gold standard for airway management with its problems. It often requires neuromuscular blockade, stimulates the unwanted reflex activity and may damage the vocal cords and tracheal mucosa¹. Though supraglottic airways provide an adequate airway, the risk of aspiration always remains. Hence Proseal Laryngeal Mask Airway (PLMA) was introduced. PLMA has a softer silicone cuff reducing the throat irritation. It has a high seal pressure hence provides a tighter seal against the glottic opening.

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PLMA has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior to provide a better seal around the glottic aperture² with a tighter seal without increasing pressure on the mucosa and permits high airway pressures without leak. For the use of PLMA different induction agents used over a period of time for rapid and smooth insertion of PLMA with minimum alteration of haemodynamic responses and insertion conditions are Propofol³, Thiopentone⁴, Sevoflurane³ etc. Propofol is non-opioid, non-barbiturate, sedative-hypnotic agent with rapid induction and recovery time and anti-emetic effect⁵. Propofol 2.5–3.0 mg/kg is considered as the induction agent of choice for PLMA insertion⁶. It is used to facilitate insertion of laryngeal mask airway, because it has a short duration of action and a rapid recovery. In addition, it is known to cause dose dependent cardio-respiratory depression, injection site pain. It has no analgesic property⁵. It depresses pharyngeal and laryngeal reflexes⁷. Propofol decreases blood pressure and heart rate, as it directly suppresses peripheral vascular resistance, decreases myocardial contractility and reduces sympathetic tone⁵. Dexmedetomidine is a pharmacologically active dextro isomer of medetomidine, which displays specific and selective α -2 adrenoceptor agonism. It is found to reduce dose requirement of Propofol to produce unconsciousness and loss of eyelash reflexes^{8,9}. Dexmedetomidine over a period of time has been studied with Propofol as a co-induction agent to assess the haemodynamic response, Propofol dose requirement and overall insertion condition of laryngeal mask airway^{9,10,11}. In this study, we aim to evaluate the effects of Dexmedetomidine versus Fentanyl with Propofol as an induction agent on the insertion conditions, haemodynamic conditions during insertion of PLMA and total and incremental dose requirement of Propofol.

METHODOLOGY

After institutional ethics committee approval, this study was conducted on 94 ASA I and II patients satisfying inclusion criteria, aged 18–60 years of either sex

RESULTS

Table 1: Distribution of cases according to ASA between study groups

ASA	DP		FP		p value
	N	%	N	%	
I	35	74.5	39	83.0	0.313
II	12	25.5	8	17.0	
Total	47	100.0	47	100.0	

Majority i.e. 35(74.5%) and 39(83%) from group D and F respectively were from ASA I. $p > 0.05$ is statistically not significant and the groups are comparable. ASA physical status of the patients selected in this study were comparable ($p=0.313$) and there is no statistically significant difference in both the groups.

scheduled for short surgical procedures under general anaesthesia. It was randomised prospective study. They were divided into two groups using randomisation in a group of 47 patients each by a blinder by chit block method (block of 6). And they were named as group D, which received Dexmedetomidine with Propofol and group F, which received Fentanyl with Propofol. A complete pre-operative assessment was done and checked out for patient's fitness. Patients were assessed for all inclusion and exclusion criteria.

Inclusion criteria

- ASA Class I and II
- Age 18-50 years.
- Obesity BMI<30wt/m2
- Mouth opening > 2.5cm
- Mallampatti grade 1 and 2
- GA with short surgical procedure

Exclusion criteria

- Anticipated difficult airway
- Patient undergoing oral and neck surgeries
- Heart rate < 50bpm
- Blood pressure < 90/60mm of Hg
- Allergic to propofol or dexmedetomidine or fentanyl
- Pregnant female
- Known case of asthma, reactive airway, URTI
- Edentulous and patients with dentures

Parameters like heart rate, blood pressure (systolic, diastolic and mean), saturation and respiratory rate was noted after giving premedication.

Statistical analysis: Mean and standard deviation for all the values were calculated and compared between two groups, group D-P and group F-P. For analysis of demographic data either Mann Whitney test or Fisher's exact test were used. Ordinal categorical data such as PLMA insertion conditions and number of attempts were analyzed with either Fisher's exact test or Chi Square test and the haemodynamic parameters were analyzed by using either unpaired T test or Mann Whitney test. A p value < 0.05 was accepted as statistically significant

Table 2: Comparison of mean dose of propofol per kg body weight(mg/kg)

Parameter	DP		FP		p value
	Mean	SD	Mean	SD	
DOSE (mg/kg)	1.6	0.3	1.9	0.3	<0.001*

Note: *means significant at 5% level of significance (p<0.05)

It shows the dose of Propofol required per kg body weight, in group D-P 1.6 mg/kg and in group F-P its 1.9 mg/kg to insert PLMA. According to Mann Whitney test p value <0.0001. The induction dose in the F-P group is significantly higher than in the D-P group.

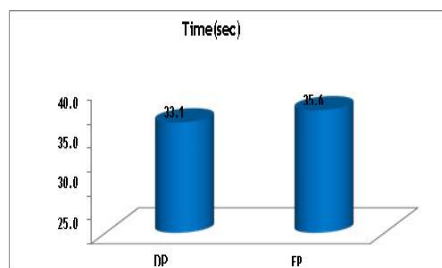
**Figure 1:** Comparison of mean time between study groups

Figure 1 shows comparison time required for insertion of PLMA between two groups D-P and F-P. Average time required for insertion of PLMA in-group D-P is 33.10 sec while in-group F-P is 35.6sec.

Table 3: Change in mean Heart rate according to time between study groups

HR	DP		FP		p value
	Mean	SD	Mean	SD	
Premedication	91.3	12.4	91.1	9.5	0.941
Before induction	93.5	12.4	94.8	9.3	0.575
After induction	97.8	17.4	99.1	10.1	0.665
After LMA insertion	99.7	14.9	104.5	10.5	0.076
1 min after insertion	94.4	13.5	97.6	8.4	0.172
3 min after insertion	88.7	12.7	90.6	7.4	0.384
5 min after insertion	87.2	13.7	86.4	7.6	0.732
10 min after insertion	85.2	14	86	5.9	0.702
15 min after insertion	83.9	11.9	84	6.1	0.965
20 min after insertion	82.4	11.6	81.5	5.6	0.65

Table shows comparison of mean heart rate between group D-P and group F-P. Though group F-P shows rise in heart rate at the time of insertion of PLMA, the values are statistically comparable in both the groups.

Table 4: Change in mean SBP according to time between study groups

SBP	DP		FP		p value
	Mean	SD	Mean	SD	
Premedication	117.7	15.1	116	10.7	0.519
Before induction	117.1	13.8	116.5	9.9	0.817
After induction	108.7	11	112.5	10.9	0.097
After LMA insertion	110.9	11.5	117.7	10.8	0.004*
1 min after insertion	108.3	11.1	114.7	10.2	0.005*
3 min after insertion	107.1	9.1	109.7	8.3	0.159
5 min after insertion	105.6	8.3	108.9	8.5	0.059
10 min after insertion	105.4	7.6	107.9	7.8	0.126
15 min after insertion	108.2	7.2	109.9	6.7	0.227
20 min after insertion	107.4	6.8	109.3	7.1	0.195

Note: *means significant at 5% level of significance (p<0.05)

Table shows comparison of systolic blood pressure between two groups. Mean systolic blood pressure after PLMA insertion in group D-P is 110.9 and group F-P is 117.7, which is calculated by unpaired T test with p value 0.024 and this is statistically significant. Thus mean systolic blood pressure is significantly higher in group F-P. Similarly mean systolic blood pressure 1 minute after PLMA insertion in group D-P is 108.3 and in group F-P is 114.7, which is higher in group F-P.

Table 5: Change in mean DBP according to time between study groups

DBP	DP		FP		p value
	Mean	SD	Mean	SD	
Premedication	77.1	11	75.7	10.2	0.512
Before induction	76.3	11.3	76.9	10.6	0.778
After induction	72.4	10	76	10.9	0.095
After LMA insertion	75.8	11	77.9	10.2	0.344
1 min after insertion	74	10.9	76.8	8.8	0.18
3 min after insertion	73.4	8.9	76.3	8.5	0.109
5 min after insertion	72.1	8	74.9	8	0.098
10 min after insertion	71.4	8	73.7	7.8	0.163
15 min after insertion	71.6	7.7	73.7	6.8	0.161
20 min after insertion	71	7.8	73	6	0.166

Table 18 and figure 18 shows comparison of mean diastolic blood pressure between groups D-P and group F-P. All the mean values calculated and compared statistically and found to be statistically not significant and mean diastolic blood pressure In both groups is comparable.

Table 6: Comparison of mean spo2% between study groups

	DP		FP		p value
	Mean	SD	Mean	SD	
SPO2%	98.9	0.6	98.8	0.7	0.430

There is no difference in Oxygen saturation of two groups ($p > 0.05$)

DISCUSSION

Insertion conditions were assessed only after the first attempt of PLMA insertion by the Young's criteria, Limb and head movements, coughing and gagging, laryngospasm and lacrimation. These overall conditions were summed up by modified scheme of Lund and Stovener. These parameters were based on study conducted by Asha Gupta¹² and colleagues. In this study 41 patients of F-P group and 34 patients in D-P group had absolutely relaxed jaw. The overall insertion conditions were excellent by modified scheme of Lund and Stovener in which 41/47 patients from D-P group and 34/47 patients from F-P group had excellent insertion conditions. Apnoea >30 sec is known to occur after Inj. Fentanyl followed by Propofol induction. In this study 10/47 patients in F-P group and 2/47 patients in D-P group had apnoea.

Similarly, Sowmya Jayaram *et al*¹³ also found higher incidence of apnoea in F-P group, 22/30 (73.33%) than in group D-P, 12/30 (40%) patients. In this study the average time required for PLMA insertion for group D-P is 33.1sec while for group F-P is 35.5sec. group F-P required more time compared to group D-P, still the data is statistically not significant. Bimla Sharma *et al*¹⁴ showed that the PLMA is a safe airway device in patients undergoing laparoscopic surgery as judged by stable haemodynamics, good oxygenation and adequate ventilation. Suparto *et al*¹⁰ compared Dexmedetomidine and Fentanyl for attenuating sympathetic responses to laryngoscopy and intubation and they found that decrease in heart rate in Dexmedetomidine group is significantly lower than in Fentanyl group ($p < 0.000$). Here in this study

baseline heart rate was nearly similar in both groups initially. Heart rate in group D-P and group F-P was gradually decreased after induction but there was transient rise in heart rate at the time of insertion of PLMA then till the time we recorded the values it was less than baseline heart rate. The rise in heart rate is higher in group F-P than in group D-P, and this finding is similar to study conducted by Surabhi Lande *et al*¹¹. Systolic blood pressure found to rise in group F-P at the time of insertion of PLMA and 1 min after insertion of PLMA and this difference found to be statistically significant with $p < 0.05$. After 1 min of PLMA insertion systolic blood pressure found to be in decreasing trend in both groups though the mean SBP in group F-P was higher than group D-P. These findings are resembling with study conducted by Surabhi Lande *et al*¹¹. Diastolic blood pressure in our study had decreasing trend after induction of patient in both groups. Mean DBP in group F-P was higher in group D-P till the end of study though this difference is not statistically significant. There was a rise in diastolic blood pressure after insertion of PLMA in both groups which was falling after 1 min of insertion till the end of study. Regarding adverse events 4 patients in group F-P had evidence of blood stains around the cuff that was seen after removal of PLMA following the surgical procedure, probably from the oropharyngeal mucosa. There was no evidence of gastric regurgitation in both groups. No trauma to lips, tongue and teeth was found. It can be said that when PLMA is being used for short surgical procedures, Propofol is a preferred induction agent. The dose of Propofol when used alone is neither satisfactory for smooth insertion of PLMA nor

from haemodynamic point of view. Thus the Dexmedetomidine, used in a dose of 1 mcg/kg gives better insertion conditions and haemodynamic stability compared to Fentanyl used in a dose of 1 mcg/kg.

CONCLUSION

Use of Dexmedetomidine also reduces the requirement of induction and incremental doses of Inj. Propofol. Attenuation of haemodynamic responses is also better with use of Dexmedetomidine as an adjuvant, compared to use of Fentanyl as an adjuvant. Thus Dexmedetomidine has better potential as a co-induction agent used with Propofol for insertion of PLMA in short surgical procedures in given doses with improved overall insertion conditions and better haemodynamic profile than Fentanyl.

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