

Comparative Evaluation of Effective Dose 50 (ED 50) of Propofol in Adult Patients with Saline-Propofol, Dexmedetomidine-Propofol and Fentanyl - Propofol for Laryngeal Mask Airway Insertion

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ABSTRACT

Introduction: Propofol a short acting intravenous anaesthetic is widely used with various adjuncts to facilitate improved insertion conditions of Proseal Laryngeal Mask Airway (PLMA). We compared the median effective dose (ED 50) propofol requirement and insertion conditions of PLMA with saline - propofol, dexmedetomidine - propofol and fentanyl - propofol.

Material and Methods: This was a prospective randomized double blind study conducted in 100 adult patients of American Society of Anaesthesiology (ASA) class I/II scheduled to undergo elective surgical procedures. They were randomly allocated into four groups of 25 each - Group N normal saline, Group F1 fentanyl 1 mcg/kg, Group F2 fentanyl 2mcg/kg and Group D dexmedetomidine 1mcg/kg. The study drug was diluted in 50ml saline and infused over 10 minutes followed by a predetermined dose of propofol as per Dixon's up and down method. The ease of PLMA insertion was assessed as per Muzi mouth opening score. Hemodynamic parameters were observed starting from baseline (T0), at 10 min post test drug infusion (T1), post propofol injection (T2), 1min post LMA insertion (T3) and till 3 minutes post LMA insertion (T4).

Results: The ED50 of propofol for the insertion of PLMA with normal saline, fentanyl (1mcg/kg), fentanyl (2 mcg/kg) and dexmedetomidine (1mcg/kg) as adjuncts were found out to be 3.25mg/kg, 2mg/kg, and 1.67mg/kg and 1.92mg/kg respectively. PLMA insertion conditions and hemodynamic parameters were comparable between the four groups. Least incidence of apnoea was noted in group D with only 8 patients requiring assisted ventilation.

Conclusion: Dexmedetomidine significantly reduces the requirement of induction dose propofol for PLMA insertion while providing stable hemodynamic and excellent insertion conditions.

Keywords: Dexmedetomidine, Fentanyl, Propofol, Proseal Laryngeal Mask Airway.

hypotension and transient respiratory depression. Separate clinical trials have shown that propofol in doses of 2.5–3 mg/kg or plasma concentrations of 7–9 µg/ml cannot provide adequate depth for LMA insertion.³ Fentanyl is a short acting opioid. Addition of opioids has been shown to improve the overall insertion conditions with an overall success rate of 85-95%. Unfortunately these medications also increase the incidence and duration of apnoea.⁴ Dexmedetomidine is a potent and highly selective α_2 -adrenoreceptor agonist. In 1999, FDA approved the use of dexmedetomidine infusions (0.1-1 mcg/kg/hr) for up to 24 hours as a sedative and analgesic for adult patients in ICU on mechanical ventilation.⁵ Dexmedetomidine has sedative, analgesic, sympatholytic and anxiolytic effects without causing significant respiratory depression. Dexmedetomidine diminishes airway and circulatory responses during intubation and extubation.⁶ In this study, we compared the ED50 of propofol and LMA insertion conditions by using dexmedetomidine (1 mcg/kg) and two different doses of fentanyl (1 and 2 mcg/kg) when combined with propofol to propofol alone. ED50 of propofol was defined as the dose of intravenous propofol required for the successful first attempt insertion of LMA in 50% of the patients.

MATERIAL AND METHODS

After due clearance from Institutional Ethics Committee, (Registration number in case of a clinical trial - CTRI/2014/08/004921, ICMR National Institute of Medical Statistics) this prospective randomized double blind study was conducted in 100 adult ASA I and II patients of either sex scheduled to undergo elective surgical procedures

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INTRODUCTION

The ProSeal Laryngeal Mask Airway (PLMA) is a second generation supraglottic airway device with modified cuff and drainage tube, designed for better seal of both the respiratory and gastrointestinal tracts.¹ Propofol is a short-acting intravenous anesthetic that can effectively reduce laryngeal responses and is widely used to induce anesthesia for laryngeal mask placement.² However, anesthetic induction using propofol alone often requires large doses to achieve enough depth of anesthesia for LMA insertion, resulting in

under general anaesthesia using PLMA from January 2014 to January 2016. Patients with history of gastroesophageal reflux disease, cervical spine disease, cardiovascular diseases, upper respiratory tract infection in last two weeks potentially difficult airway (Mallampati score >2), mouth opening less than 2.5cm, ASA grade III & IV patients and obese patients with BMI of more than 30kg/m² were excluded from our study.

Patients were randomly allocated into four groups of 25 each by computer generated numbers. Group N received normal saline, Group D received dexmedetomidine 1mcg/kg, Group F1 received fentanyl 1 mcg/kg and Group F2 received fentanyl 2mcg/kg. An anaesthetist involved in randomization but not involved in airway management administered the study

drugs of respective groups. Muzi mouth opening score⁷ was judged by anaesthetist placing the device. Two independent observers oblivious to the drug being infused observed for 'movement' or 'no movement'.

'Movement' to insertion was defined as: coughing, straining, bucking, laryngospasm or purposeful limb movements at the time of first attempt or within 1 min. This also included persistence of verbal contact and significant resistance to mouth opening. (Muzi score >2)

'No movement' was described as the absence of the above and a Muzi score of 1 or 2.

Written and informed consent was obtained and patients were premedicated with oral ranitidine 150mg and metoclopramide 10mg two hours prior to surgery. Baseline heart rate (HR), mean arterial pressure (MAP), oxygen saturation (SP02) and respiratory rate (RR) were recorded. All patients were administered oxygen at the rate of 6 l/min by venturi mask. The study drug was administered in 50 ml saline over 10 minutes followed by a predetermined bolus dose of propofol intravenously administered over 30 seconds. According to Dixon's up-and-down method, in each group a series of dose levels of propofol with equal spacing between levels of 0.5mg/kg was used. The first patient in each group received propofol 2.5mg/kg based on historical estimate⁸ of ED50 for insertion of PLMA. The dose of propofol for subsequent patients in each group was adjusted according to response of the previous patient. Average dose of six crossover points of a group from movement to no movement was taken as ED50 of that group. Lidocaine was not added to propofol but total dose diluted to a volume of 30ml and no neuromuscular blocking drug was administered. Following loss of verbal contact, the anaesthetist managing the airway continued oxygen administration at 6 l/min via venturi mask and gentle neck extension. Any episode of desaturation, SPO₂ < 94% was treated with gentle manual ventilation. The insertion of PLMA was performed at 90 seconds following propofol administration in all cases by same anaesthetist with experience of at least 50 PLMA insertions using introducer technique. Patients responding by 'movement' hindering PLMA insertion were given a further dose of propofol 0.5mg/kg and insertion reattempted at 30 seconds until patient ceased moving to insertion. After three failed

attempts trachea was intubated. An effective airway was confirmed by absence of gas leak from pharynx following inflation of cuff, normal chest movements, and square wave end tidal capnography (ET CO₂) and peak inspiratory pressures of <20cm of H₂O.

Hemodynamic parameters were recorded before induction (T0), i.e. baseline, after adjuvant drug injection at the end of 10 minutes (T1), after propofol injection (T2), one minute after LMA insertion (T3) and three (T4) minutes after LMA insertion. Adverse effects like hypotension, bradycardia, apnoea were looked for wherein hypotension was defined as MAP < 60mm Hg or a decrease of 30% from baseline values for one minute, managed with intravenous fluids and mephentermine 0.05- 0.1mg/kg. Bradycardia was defined as heart rate below 50 beats per minute or heart rate decrease of more than 30% from baseline value for more than one minute, glycopyrrolate 0.2mg IV was administered in case of persistent bradycardia. Apnoea was defined as absence of respiration for more than 30 seconds; ventilation was manually assisted via facemask or LMA to maintain oxygen saturation above 95%.

Modified Dixon's up-and-down method was used and the study continued until six pairs of successful and failed PLMA insertions occurred. ED50 of propofol for PLMA insertion was defined as the mean of the median cross-over dose. The data was then subjected to probit regression analysis for calculating the ED95 of propofol. Patients characteristic data, predicted ED50 LMA, Hemodynamics, Mean arterial pressure, Heart rate, respiration, oxygen saturation and ET CO₂ were reported as mean ± S.D. and analysed by one-way ANOVA (analysis of variance); p-values <0.05 were considered significant.

RESULTS

Patient characteristics were similar in terms of distribution of age, weight, sex, height and BMI in all the groups (Table 1), also induction time from start of test drug infusion till LMA insertion was comparable among the four groups.

Applying Dixon's up and down method the ED50 of propofol in group N, F1, F2, and D was found to be 3.25mg, 2mg, 1.67 and 1.92mg/kg respectively. Subsequent probit analysis showed the ED95 of propofol to be 3.681mg, 2.361mg, 2.360mg and 2.962mg/kg respectively. The response of

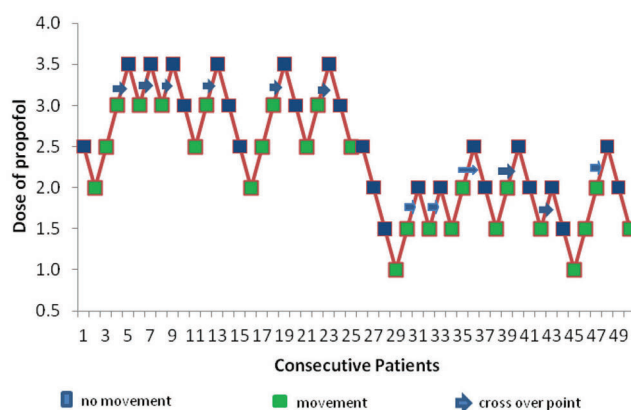


Figure-1: Response in group N and F1

	Group D n=25	Group F1 n=25	Group F2 n=25	Group N n=25	P
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Age(Years)	35.04±8.52	37.52±7.59	37.52±8.39	37.84±8.48	± 0.575
Weight(kg)	63±6.49	65.36±8.52	62.76±7.6	65.36±6.84	±0.425
Sex M/F	13/12	12/13	12/13	10/15	
	±165.12	±167.8	±166.48	±166.4	±0.512
Height(m)	6.67	6.12	5.97	6.11	
BMI(kg/m ²)	23.28 ±2.04	23.12 ±2.06	22.62±2.26	23.21±	±0.347

Table-1: Patient demographics

	Group N	Group F1	Group F2	Group D
DBP T0	84.48 ± 8.13	81.48 ± 7.52	81.96 ± 6.37	83.6 ± 4.15
DBP T1	82.68 ± 6.08	77.76 ± 7.14	78.12 ± 6.6	79.12 ± 4.76
DBP T2	62.08 ± 7.61	69 ± 5.66	71.12 ± 6.82	72.96 ± 9.21
DBP T3	61.84 ± 8.66	62.6 ± 6.56	66 ± 7.26	72.12 ± 9.61
DBP T4	60.52 ± 7.49	58.84 ± 6.74	64.28 ± 8.1	68.76 ± 7.48
HR T0	80.96 ± 7.98	78.36 ± 7.86	75.88 ± 8.78	83.64 ± 17.85
HR T1	80 ± 7.72	77.32 ± 7.36	76.12 ± 11.5	70.44 ± 9.71
HR T2	79.48 ± 8.04	77.44 ± 8.59	75.16 ± 8.67	74.08 ± 10.63
HR T3	79 ± 8.19	75.44 ± 7.47	73.76 ± 7.65	74.44 ± 9.45
HR T4	78.08 ± 8.15	72.88 ± 6.31	71.24 ± 7.62	73.48 ± 10.99
MAP T0	100.76 ± 5.75	97.12 ± 11.67	98.28 ± 8.44	99.28 ± 5.76
MAP T1	97.08 ± 6.73	90.88 ± 8.36	92.4 ± 7.68	91.28 ± 3.79
MAP T2	73.2 ± 7.44	80.84 ± 7.15	82.92 ± 6.31	83.48 ± 9.51
MAP T3	71.8 ± 7.07	73.68 ± 6.24	77.64 ± 7.7	82.08 ± 9.6
MAP T4	70.12 ± 7.78	70.76 ± 5.77	75 ± 7.5	79.52 ± 8.53
SBP T0	131.24 ± 9.45	124.88 ± 14.37	128.48 ± 14.33	130.72 ± 10.81
SBP T1	125.84 ± 10.37	117.56 ± 12.73	120.84 ± 15.26	115.76 ± 7.82
SBP T2	94.52 ± 9.16	101.56 ± 9.26	105.12 ± 11.13	104.76 ± 10.8
SBP T3	94.96 ± 9.48	95.4 ± 5.39	100.76 ± 10.6	102.24 ± 11.21
SBP T4	93.36 ± 8.02	92.16 ± 5.49	95.52 ± 9.8	99.88 ± 9.46

Group N= Saline + propofol; Group F1= fentanyl (1mcg/kg)+ propofol; Group F2= fentanyl (2mcg/kg) + propofol; Group D= dexmedetomidine (1mcg/kg)+ propofol; DBP = diastolic blood pressure (mm Hg); HR= heart rate (/min); MAP= mean arterial blood pressure (mm Hg); SBP systolic blood pressure (mm Hg); T0= baseline, T1= post test drug infusion; T2= after propofol injection; T3= one minute after LMA insertion; T4= 4 minutes after LMA insertion.

Table-2: Trends in hemodynamic parameters

		Group N (n=25)	Group F1 (n=25)	Group F2 (n=25)	Group D (n=25)	P value
Ease of LMA insertion	Resistance	10(40.00%)	11(44.00%)	10(40.00%)	9(36.00%)	0.954
	Relaxed	15(60.00%)	14(56.00%)	15(60.00%)	16(64.00%)	

Table-3: Ease of LMA insertion

		Group N (n=25)	Group F1 (n=25)	Group F2 (n=25)	Group D (n=25)	P value
Apnoea	Absent	4(16.00%)	11(44.00%)	8(32.00%)	17(68.00%)	0.002
	Present	21(84.00%)	14(56.00%)	17(68.00%)	8(32.00%)	

Table-4: Incidence of apnoea in various groups

studied patients to the first attempt of LMA insertion with varying doses of propofol in group N, F1, F2, and D is shown in Fig 1 and 2.

All groups showed comparable jaw relaxation (Muzi score=1) group N (60%), F1 (54%), F2 (60%) and D (64%) (p value=.954). Overall ease of LMA insertion was better in group D; however the same is statistically not significant.

(p=0.954) (Table 3) Limb movement was the most common observation seen in our study. Incidence of apnea was found to be statistically significant between the groups, with minimum incidence in group D. p value (0.002) (Table 4). In groups N, F1 and F2 there was no clinically significant variation in heart rate post test drug infusion at T1, however clinically and statistically significant decrease in heart

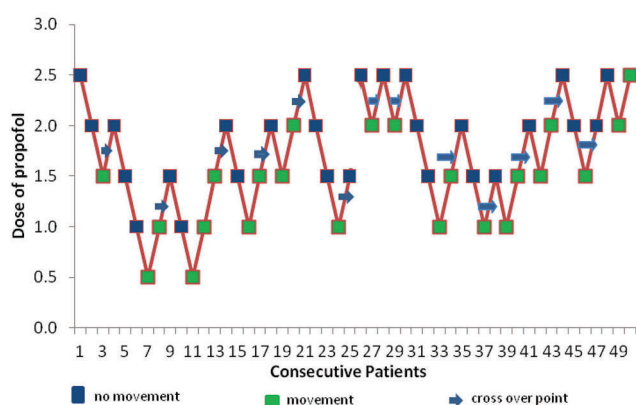


Figure-2: Response in Group F2 and D

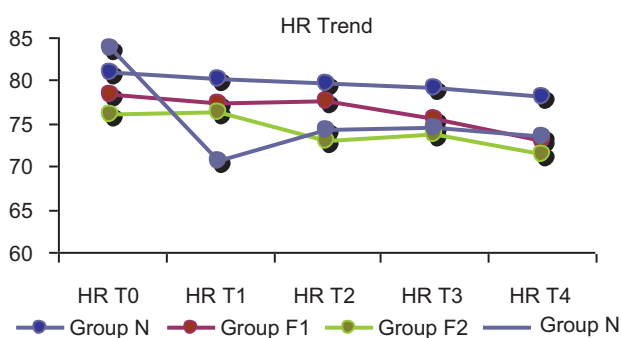


Figure-3: Heart rate trend

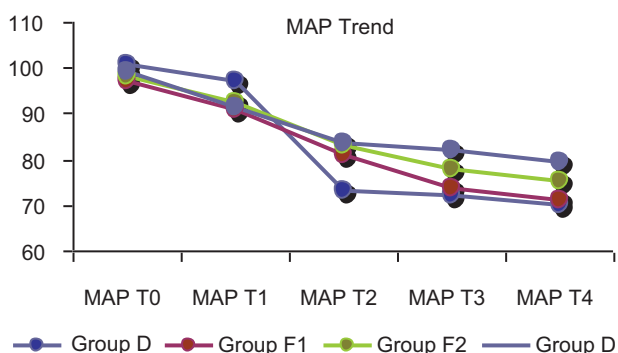


Figure-4: Mean arterial blood pressure trend

rate was observed in group D (T0) to (T1) fall of (14.60% \pm 8.28%) p value of (<0.05). Post LMA insertion and till end of study all four groups showed a decrease in heart rate with a greater fall in fentanyl groups but were not clinically significant (Table2, fig5). Bradycardia not requiring treatment was observed in two patients in group D.

Post test drug infusion MAP showed a comparable fall in all groups. Post propofol injection (T2) maximum fall was seen in group N (27.10% \pm 8.85%) while groups F1, F2 and D showed a fall between 13.30% to 16.70% from baseline (T0). This was in keeping with the mechanism of action of propofol leading to a dose dependent reduction in blood pressures. The trend from T2 to T3 continued from T3 to T4 the final MAP at T4 showing a maximum decrease in group N (30.30% \pm 7.39%) and least in group D (19.80% \pm 8.57%). (Table2, Fig6). Hypotension requiring correction with intravenous fluids and mephentermine 0.05-0.1 mg/kg IV was reported in 12 cases in group N, 5 in group F1, 3 in

F2 and none in group D.

No case of laryngospasm was seen in any of the groups in our study, since adequate time for test drug infusion and post propofol injection was given prior to PLMA insertion.

DISCUSSION

PLMA is a second generation supraglottic airway device and requires adequate depth of anaesthesia for its safe insertion. Propofol a short acting intravenous anaesthetic is widely used with various adjuncts to facilitate improved insertion condition of PLMA. The major finding of this study was that the propofol requirement for smooth insertion of the PLMA with hemodynamic stability was significantly less when dexmedetomidine was used as adjuvant before induction.

In our study the ED 50 of propofol with fentanyl 1mcg/kg was estimated to be 2 mcg/kg which correlates with the study done by Burlacu et al.⁹ In which the ED50 of propofol with alfentanil 5 mcg/kg was 2.33 \pm 0.37 mg/kg. On a milligram basis, clinical potency of alfentanil is approximately one-fourth to one-tenth that of fentanyl when given in single doses so 1mcg of fentanyl would equate to around 4 to 10mcg of alfentanil.

Kodaka et al.¹⁰ using the modified Dixon's method the predicted EC50 LMA of propofol for control, fentanyl 0.5, 1 and 2 mg/kg groups to be 3.25 \pm 0.20, 2.06 \pm 0.55, 1.69 \pm 0.38 and 1.50 \pm 0.54 mg/kg respectively, which correlates with our findings.

Nellore et al.¹¹ estimated a significantly lower mean induction dose of propofol of 1.54 mg/kg with dexmedetomidine (1mcg/kg) and 1.86 mg/kg with fentanyl (1mcg/kg) which could be due to the use of centralisation of pupils as the end point against jaw relaxation.

Nerukar et al.¹² in their study estimated the ED 50 of propofol required for Classic LMA to be 2.7 \pm 0.28 mg/kg with fentanyl 1mcg/kg. This was slightly higher as compared to our estimation which could have been due to the use of Classic LMA in their study.

Similar to the observations in a study done by Yoo et al.¹³ the ED 50 of propofol with dexmedetomidine 1mcg/kg was estimated to be 1.8 to 2.1 mg/kg while in our study it was estimated to be 1.92mg/kg.

In support of the study done by Uzumcugil et al.¹⁴ we found comparable results in terms of hemodynamic parameters, jaw relaxation and higher incidence of apnoea in fentanyl group.

Similar to our observations Suparto et al.¹⁵ in their study showed a higher fall in heart rate in dexmedetomidine (1mcg/kg) group compared to fentanyl (1mcg/kg) group. A higher reduction in SBP in fentanyl group (19%) vs. dexmedetomidine group (13%) was seen. The author also found a 40% rise in SBP and DBP in fentanyl group and 25%-28% in dexmedetomidine group since their study was post intubation.

Sowmya Jayaram et al.¹⁶ showed similar results in terms of hemodynamic parameter, ease of lma insertion and incidence of apnoea. Contrary to our observation a rise from

baseline in SBP was seen post dexmedetomidine infusion while in our study it decreased. This could be due to rapid administration of dexmedetomidine over 2min in their study leading to the vasoconstrictive effects of dexmedetomidine when stimulating peripheral α_2 receptors.⁵

Akansha Dutt et al.¹⁷ while comparing LMA classic insertion characteristics using fentanyl 1 and 2 mcg/kg with propofol 2.5mg/kg found no significant difference in heart rate between the two groups. This correlates with our findings. Also a significant decrease in MAP was observed in group receiving fentanyl 2mcg/kg which is in contrast to our study where the two groups were comparable. This might have been because of use of premedications and a fixed dose of propofol 2.5mg/kg in their study.

Surabhi et al.¹⁸ in their study observed better jaw relaxation in dexmedetomidine (1mcg/kg) group compared to fentanyl (1mcg/kg) group. This could have been because of them using inj. Midazolam 0.03mg/kg i.v. as premedication.

Burlacu et al.⁹ found a higher incidence of coughing in the LTA group compared to LMA group due to higher stimulation of airway reflexes.

Goh PK et al.⁶ in their study found maximum incidence of apnoea among fentanyl-propofol group compared to saline-propofol and ketamine-propofol. This was in contrast to our findings which could have been because of them using a fixed dose of propofol in saline propofol group.

Kodaka et al.¹⁰ in their study found higher respiratory rates (RR) in control group (propofol alone) compared to fentanyl 0.5, 1 and 2 mcg/kg groups. This observation is in contrast to our study because they administered propofol by TCI pump over 10 min to achieve predetermined propofol target and effect site equilibrium, followed by fentanyl injection and observed RR post 3min for 1min.

In a study done by Ramaswamy et al.¹⁹ wherein they observed 27% decrease in heart rate post dexmedetomidine (1mcg/kg) infusion, in our study a decrease of 14.6% ($p < .05$) was observed, this could be due to dexmedetomidine being infused over 2min compared to 10 min in our study. 92.5% patients in dexmedetomidine group and 87.5% patients in fentanyl group were found to have LMA insertion score of < 2 which were in line with the findings of our study. Similar to our observation a higher incidence of apnoea was observed in fentanyl group (23) than in dexmedetomidine group (14). In a study conducted by Nellore et al.¹¹ similar results for LMA insertion conditions were reported between dexmedetomidine and fentanyl groups with a higher incidence of apnoea in the fentanyl group. Post LMA insertion a greater rise in heart rate in the fentanyl group was observed by them, whereas in our study no clinically significant difference was observed, which could have been due to the use of fixed induction dose of propofol in their study.

Limitations: Target controlled infusion (TCI) system provides for better titration of propofol administration and more accurate dose calculation along with use of Bispectral index (BIS) for monitoring the depth of anaesthesia. However, this was not possible due to non-availability of

both TCI and BIS in our institution at the time when the study was conducted. The study was conducted in non obese ASA I or II adult patients, thus hemodynamic parameters need to be further validated with a study of larger number of patients.

CONCLUSION

Dexmedetomidine (1mcg/kg) can be used as an alternative to fentanyl (1mcg/kg) as an adjuvant to propofol for PLMA insertion. Both of the drugs provide excellent overall insertion conditions and stable hemodynamic profile. Dexmedetomidine decreases the requirement of propofol with the advantage of lesser incidence of respiratory depression.

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