Original Research Article

Randomised double blinded comparison of efficacy and safety of dexmetomidine - propofol and fentanyl- propofol on the insertion conditions of proseal laryngeal mask airway

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Abstract

Background: During general anaesthesia for surgical procedure associated with loss of airway reflexes requires the airway to be secured for maintaining the patency of airway and ventilation of the patient. Conventionally endotracheal intubation is considered for the same. Over a period of time newer devices have been developed for securing airway, of which supraglottic airway is a major achievement. Newly developed supraglottic airway PLMA, now increasingly being used with added advantages of better glottic seal and provision of drain tube insertion. **Aim and objective:** To compare the efficacy and safety of dexmetomidine –propofol and fentanyl- propofol on the insertion conditions of proseal laryngeal mask airway **Methodology:** In this prospective, randomized, comparative, double blinded study 60 ASA class I and II patients undergoing short surgical procedures with PLMA were allotted in 2 different groups. One receiving Dexmedetomidine (group D-P) and the other receiving Fentanyl (F-P). Comparative analysis was done for insertion conditions, dose of propofol and hemodynamic parameters. **Results and discussion:** The induction dose required for successful insertion of PLMA in first attempt in group D-P was 94.00 ± 27.15 mg (1.92 ± 0.21mg/kg) and in group F-P it was 114.93 ± 22.05mg (1.56 ± 0.24 mg/kg), this higher dose of Propofol required in group F-P is statistically significant. SBP after PLMA insertion (group D-P 111.10 ± 9.80 group, F-P 116.87± 10.18; p= 0.029) and 1 min after PLMA insertion (group D-P 108.63 ± 9.52, group F-P 113.80 ± 9.55; p=0.036) was raised in group F-P and this rise is statistically significant. Diastolic blood pressure and mean arterial blood pressure found to be comparable in both the study groups throughout the procedure. Arterial oxygen saturation was maintained around 98% in both groups and no episode of desaturation was observed throughout procedure.

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INTRODUCTION

Fundamental aspect of anaesthesia practice and emergency critical care lies in the airway management. The gold standard for airway management is endotracheal intubation as it is rapid, simple, safe and a non-surgical technique achieving all the goals of airway management but with its underlying problems. An alternative method to endotracheal intubation, in fasting patients who are breathing spontaneously is the use of traditional facemask with or without oropharyngeal airway. Dr. Archibald Brain, a British anaesthesiologist made a prototype mask using cadaveric pharynx and blindly inserted it under deep halothane anaesthesia with satisfactory lung inflation using gentle positive pressure ventilation. [1] Compared to the facemask it reduced the requirement of fresh gas flow, allowed more effective scavenging, facilitated monitoring of end tidal carbon dioxide(ETCO2) concentration and lastly freed the anaesthesiologist. Though supraglottic airways provide an adequate airway, the risk of aspiration

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always remained. Hence Proseal Laryngeal Mask Airway (PLMA) was introduced.

PLMA consists of softer silicone cuff which reduce the incidence of throat irritation. It has a high seal pressure which provides a tighter seal against the glottic opening without increase in the mucosal pressure. PLMA has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior for a better seal around the glottic aperture with a tighter seal without increasing mucosal pressure and permits high airway pressures without leak. [2] Adequate depth of anaesthesia and suppression of upper airway reflexes are a must for successful insertion of PLMA without any unwanted effects such as gagging and coughing without using neuromuscular blocking agents. [3] 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 Propofol, Thiopentone[, Sevoflurane etc. [3-5] Propofol in a dose of 2.5 – 3.0 mg/kg is considered as the induction agent of choice for PLMA insertion. [6] It is used to facilitate insertion of laryngeal mask airway, because it has a short duration of action and a rapid recovery. Use of Propofol is known to cause dose dependent cardio-respiratory depression, injection site pain, no analgesic property, [5] depresses pharyngeal and laryngeal reflexes.[7] To achieve better insertion conditions with minimal haemodynamic responses and respiratory depression, various adjuvants have been used with Propofol such as Midazolam, Ketamine, low doses muscle relaxants such as Mivacurium , Alfentanyl, Fentanyl.[8-10] Dexmedetomidine has a selective α-2 adrenoceptor agonist action. It has been found to significantly reduce the dose requirement of Propofol for the induction as well as maintenance of anaesthesia. [11-12] Dexmedetomidine has been studied over the last two decades with Propofol as a co-induction agent to assess the haemodynamic response, Propofol dose requirement and overall insertion condition of various types of laryngeal mask airways. [12-14] 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.

Aim and objective: To compare the efficacy and safety of dexmetomidine –propofol and fentanyl- propofol on the insertion conditions of proseal laryngeal mask airway

MATERIAL AND METHODS

Present study was a Randomized double blind prospective study carried out at Tertiary care center. Study population was patients undergoing short surgical procedure under general anaesthesia.

Inclusion Criteria: 1. patients undergoing short surgical procedure under general anaesthesia of ASA grade I and II 2. Patients in age group of 18-60 years.

Exclusion criteria: 1. Patients undergoing surgery without general anaesthesia 2. Patients not willing to participate in the study

Study was approved by ethical committee of the institute. A valid written consent was taken after explaining study to them.

This study was conducted on 60 patients. They were divided into two groups using randomisation in a group of 30 patients each by a blinder by chit block method. Group D patients were receiving Dexmedetomidine with Propofol and group F patients were receiving Fentanyl with Propofol. A complete pre-operative assessment was done and checked for patient's fitness. Then patient was taken on the OT table and monitors were attached. Intra-venous (I.V.) cannula was secured and I.V. Ringers lactate fluid was infused. Heart rate, systolic blood pressure, diastolic blood pressure, mean blood pressure, saturation and respiratory rate noted for baseline characteristics. Patient pre-medicated with Inj. Glycopyrrolate 0.004 mg/kg I.V. Among the two groups created, for one group, group D, Inj. Dexmedetomidine was calculated according to 1 mcg/kg dose based on body weight and diluted in normal saline by an anaesthesiology resident not involved in study. This single bolus dose was given to the patient intravenously over 10 min. by an infusion pump. Similarly for group F, Inj. Fentanyl was calculated according to 1 mcg/kg and diluted in normal saline by an anaesthesiology resident not involved in the study. This single bolus dose was given to the patient intravenously over 10 min. by an infusion pump. Inj. Midazolam 0.02 mg/kg was given over 4 min. intravenously in either group. Parameters like heart rate, blood pressure (systolic, diastolic and mean), saturation and respiratory rate was noted after giving premedication. Patient was pre-oxygenated with 100% oxygen over 3 minutes. After 10 min of completion of either Dexmedetomidine or Fentanyl infusion patient was induced with Inj. Propofol 2.5 mg/kg till loss of eyelash reflexes or loss of consciousness. Patients head was placed in sniffing morning air position.Ninety seconds after the administration of Propofol, a blinded investigator who had experience of at least 25 PLMA insertions, inserted a PLMA of appropriate size using the Introducer technique after lubricating the deflated cuff with water based jelly, then the cuff was inflated and adequacy of ventilation was checked, Then the device was fixed and secured and connected to breathing circuit. Following successful insertion of the LMA, its position was assessed by observing chest expansion and capnography during spontaneous breathing. Gastric tube of appropriate size was lubricated and inserted after confirming absence of gas

leak during ventilation. The blinded investigator graded the PLMA insertion conditions according to mouth opening, swallowing, gagging or coughing, head or limb movements, lacrimation, laryngospasm and ease of PLMA insertion. Malpositioned PLMAs were removed. If the first attempt at PLMA insertion was unsuccessful or the PLMA was mal-positioned, we gave a further dose of Propofol 0.5 mg/kg and made another attempt at PLMA insertion 1 min later. Time taken for insertion of PLMA was defined as after induction since taking up PLMA till successful insertion and attaching breathing circuit to anaesthesia machine and confirming the correct positioning. Following successful insertion and correct positioning of the PLMA, anaesthesia was maintained with 2% Sevoflurane, 50% Nitrous oxide in 50% Oxygen. The device insertion was abandoned after 3 unsuccessful attempts. In case of failure patient was withdrawn from the study and muscle relaxant was given and intubated with endotracheal tube. For any bradycardia less than 45 bpm, Inj. Atropine 0.01 mg/kg was given. At the end of 1 min. of PLMA insertion all the parameters were noted again, then the parameters was noted at the interval of 3 min., 5 min., 10 min., 15 min. and 20min. Before end of the surgery, inj. Tramadol 2mg/kg was given for post op analgesia. At the end of procedure device was removed when patient was totally awake. All above parameters was checked at intervals as baseline, before induction, after induction, after PLMA insertion, after 1, 3, 5, 10, 15 and 20min. Data was entered in excel sheet and analysed with SPSS version 20. p value < 0.05 was accepted as statistically significant.

RESULTS

To start with the study both the groups, group D-P and group F-P were comparable in demographic and baseline hemodynamic parameters. In group D-P it's 1.56 ± 0.24 mg/kg and in group F-P its 1.92 ± 0.21 mg/kg. The induction dose in the F-P group is significantly higher than in the D-P group. Group D-P required 94 ± 27.15 mg and group F-P required 114.93 ± 22.05 mg of Inj. Propofol for induction. According to Mann Whitney test Group F-P required induction dose of Propofol significantly higher than group D-P. Propofol required after considering the repeated attempts in group D-P is 96.03 ± 28.96 and in group F-P is 119.08 ± 26.58. Statistically the total dose of Propofol in the F-P group is significantly higher than in the D-P group calculated by Mann Whitney test. (table 1) In group D-P, two patients required second attempt while in group F-P, four patients required second attempt. Statistically on Chi square test these two groups were comparable. (table 2) Average time required for insertion of PLMA in group D-P is 28.27 ± 12.26 sec while in group F-P is 33.83 ± 16.95 sec. According to Mann Whitney test this data is comparable in two groups with p value 0.078 which is statistically not significant. The insertion conditions assessed were comparable on the basis of findings of Jaw relaxation, coughing and gagging, limb and head movements, laryngospasm and lacrimation, though the coughing and limb movements observed more in group F-P. Jaw relaxation (Young criteria) was comparable in both the groups though statistically not significant. (table 3) We assessed the overall insertion conditions according to modified scheme of Lund and Stovener, table 4 shows 28 patients out of 30 in group D-P had excellent insertion conditions while 24 patients out of 30 in group F-P had excellent insertion condition. According to Chi-square test the insertion conditions were comparable in both the groups and statistically not significant (p value 0.255). Clinically in group F-P, 9 patients out of 30 had apnoea for > 30 sec while in group D-P only 1 patient had apnoea more than 30 sec. Statistically this is significant (p value 0.015) calculated by Chi square test. Considering hemodynamic parameters, the heart rate was comparable at baseline, which was comparable till 20 min after PLMA insertion. Though the trend was decreasing in both study groups, mean heart rate was lower in group D-P. (graph 1) Systolic blood pressure was comparable in both groups till the time of induction. SBP after PLMA insertion (group D-P 111.10 ± 9.80 group, F-P116.87± 10.18; p= 0.029) and 1 min after PLMA insertion (group D-P 108.63 ± 9.52, group F-P 113.80 ± 9.55; p=0.036) was raised in group F-P and this rise is statistically significant. (graph 2) Diastolic blood pressure and mean arterial blood pressure found to be comparable in both the study groups throughout the procedure. (graph 3) Arterial oxygen saturation was maintained around 98% in both groups and no episode of desaturation was observed throughout procedure. (graph 4) At the end of procedure one patient in group F-P we observed the cuff was blood stained in group F-P, this may be due to individual variations between investigators introducing PLMA. There was no evidence of trauma to lip, tongue and teeth; also there was no evidence of gastric contents regurgitation seen on the cuff of PLMA. From our study we came to conclusion that though the insertion conditions were comparable statistically with the use of either Dexmedetomidine or Fentanyl as an adjuvant with Inj. Propofol (up to 2.5mg/kg) for the use of PLMA in short surgical procedures, Dexmedetomidine (1 mcg/kg) can be used with more favourable overall insertion conditions and less chances of coughing and movements; also lower incidence of apnoea than Fentanyl (1mcg/kg). Use of Dexmedetomidine also reduces the requirement of induction and incremental doses of Inj. Propofol. Attenuation of hemodynamic responses is also better along with better insertion conditions with the use of Dexmedetomidine as an adjuvant to propofol as compared to use of Fentanyl as an adjuvant to Propofol.

Table 1: Comparison of two groups according to doses of propofol

Parameter	Dexmedetomidine-Propofol (30)	Fentanyl-Propofol (30)	Statistical test	P value. Interpretation of P value
Induction Dose of Propofol (mg/kg)	1.56 ± 0.24	1.92 ± 0.21	Mann Whitney test	<0.0001
Induction dose of Propofol (mg)	94 ± 27.15	114.93 ± 22.05	Mann Whitney test	0.002
Total dose of Propofol	96.03 ± 28.96	119.08 ± 26.58	Mann Whitney Test	0.002

Table 2: Comparison of two groups according to attempt of PLMA insertion

Attempts	Dexmedetomidine-Propofol (30)	Fentanyl-Propofol (30)	Statistical test	P value. Interpretation of P value
One attempt	28	26	Chi square test	0.667
Two attempts	2	4		

Table 3: Comparison of two groups according to young's criteria

Young's criteria	Dexmedetomidine-Propofol (30)	Fentanyl-Propofol (30)	Statistical test	P value. Interpretation of P value
Grade I	28	26	Chi square test	0.667
Grade II	2	4		

Table 4: Comparison of two groups according to Modified scheme of Lund and Stovener

Modified scheme of Lund and Stovener	Dexmedetomidine-Propofol (30)	Fentanyl-Propofol (30)	Statistical test	P value. Interpretation of P value
Excellent	28	26	Chi square test	0.255
Good	2	4		

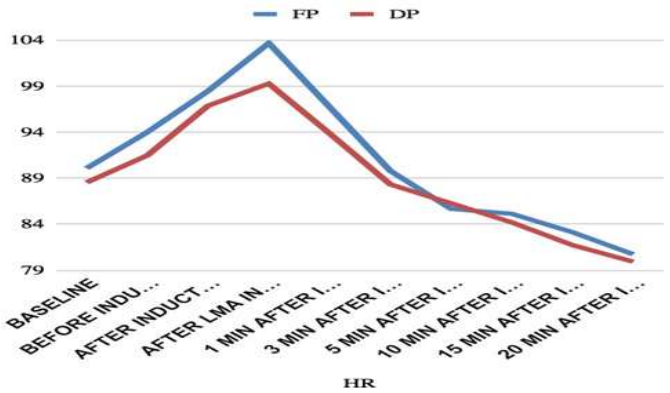

Figure 1: Comparison of heart rate in two groups

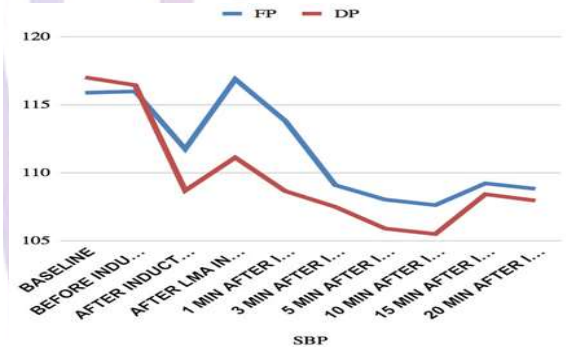

Figure 2: Comparison of Systolic blood pressure in two groups

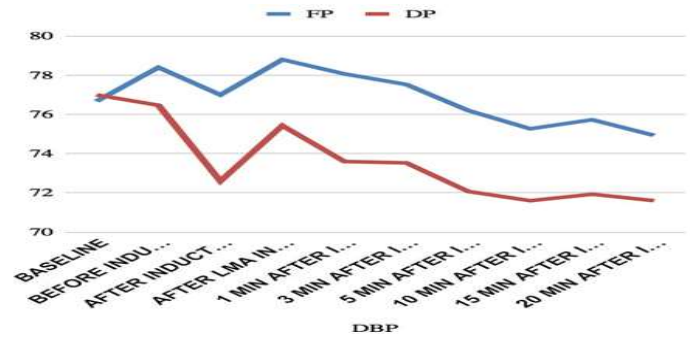

Figure 3: Comparison of Diastolic blood pressure in two groups

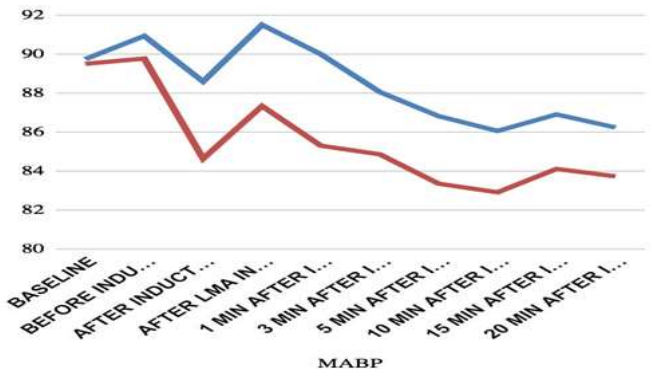

Figure 4: Comparison of Mean Arterial blood pressure in two groups

DISCUSSION

In our study, dose of Propofol required for PLMA insertion in group F-P is significantly higher than group D-P (p value <0.002). This maximum induction dose of 2.5mg/kg of Propofol for PLMA insertion was decided on the basis of previous studies that found this dose to be optimum for jaw relaxation. [8,12,15] We found a reduction in the requirement of induction dose of Propofol below our maximum predecided dose of 2.5 mg/kg following both Fentanyl and Dexmedetomidine. This difference from the earlier studies could probably be because we considered the end point as centralization of eyeballs. Incremental dose of 0.5mg/kg of Propofol was repeated after each unsuccessful attempt at PLMA insertion. The number of attempts required for PLMA insertion after unsuccessful first time insertion, in our study in group D- P 2 (6.6%) patients required second attempt while in group F-P 4 (13.3%) patients required second attempt. These findings are in line with study by Surabhi Lande *et al.* [14] on insertion of LMA they had 1 patient in group D-P and 5 patients in group F-P who required second attempt for insertion of LMA. Though this is clinically significant, statistical significance is not there.

For each second attempt tried an incremental dose of Propofol 0.5 mg/kg was given and patient is allowed to ventilate for 1 minute. Total dose required in group F-P is significantly higher than group D-P. This may either be due to the more number of second attempt required in group F-P or higher induction dose required in group F-P. Insertion condition was 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 Gupta and colleagues. [16] In our study we had 24/30 (80%) patients of F-P group and 28/30 (93.33%) patients in D-P group had absolutely relaxed jaw, though it was statistically not significant. These findings in our study are in line with previous study done by Surabhi Lande *et al.* that stated that group D-P had more relaxed jaw than group F-P. [14] In our study 4 patients out of 30 (13.33%) from group F-P had single episode of mild coughing during insertion of PLMA, while no patient in D-P group had coughing though it is statistically not significant. These episodes of coughing could have been provoked by the intra-venous Fentanyl rather than simply being a response to PLMA insertion. Our results are correlating with study of Asha Gupta [16] where they experienced 13/30 patients (43%) with mild coughing while 1/30 (3.33%) patient had severe coughing in Propofol- Fentanyl group. Wong CM *et al.* [17] in their study stated that a higher dose of Fentanyl notably induces coughing. Apnoea >30 sec is known to occur after Inj. Fentanyl followed by Propofol induction. In our study 9/30 patients (30%) in F-P group and 1/30 (3.33%) patients in D-P group had apnoea. Similarly Sowmya Jayaram *et al.* also found higher incidence of apnoea in F-P group, 22/30 (73.33%) than in group D-P, 12/30 (40%) patients. [9] Bimla Sharma *et al.* [18] 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.* [13]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. Here in our study baseline heart rate was nearly similar in both groups initially. 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.* . [14]

Systolic blood pressure to start with study was comparable in both groups, it was higher in group F-P compared to group D-P throughout study though the difference is statistically not significant. These findings are in concordance with study conducted by Surabhi Lande *et al.*. [14] Diastolic blood pressure in our study had decreasing trend after induction of patient in both groups. Similar trends are found in mean arterial blood pressure, there was a fall in MBP after induction but it was increased after insertion of PLMA and again the trend of MBP was decreasing till the end of study. The Mean blood pressure was higher in group F-P till the end than group D-P, though this data is statistically not significant and with reference to MBP both groups are comparable. Mean arterial oxygen saturation in group D-P is 98.93 ± 0.58 % and group F-P is 98.93 ± 0.70 % and on statistical analysis it's not significant. It can be said that when PLMA, a new supraglottic airway device, is being used for short surgical procedures, the Propofol is a preferred induction agent used. The dose of Propofol when used alone is neither satisfactory for smooth insertion of PLMA nor from haemodynamic point of view.

CONCLUSION

Dexmedetomidine used as a co-induction agent in a dose of 1 mcg/kg gives better insertion conditions and haemodynamic stability compared to Fentanyl used as a co-induction agent in a dose of 1 mcg/kg.

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