Original Article

Dexmedetomidine with propofol versus fentanyl with propofol for insertion of Proseal laryngeal mask airway: A randomized, double-blinded clinical trial

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Abstract

Background and Aims: Successful insertion of the proseal laryngeal mask airway (PLMA) requires much greater doses of propofol as compared to classic laryngeal mask (CLMA). Dexmedetomidine and fentanyl are equally effective adjuvants for CLMA insertion. We designed this study to compare the efficacy of these two drugs as sole adjuvant in PLMA insertion.

Material and Methods: Seventy four American Society of Anesthesiologists (ASA) I and II patients were randomly allocated to receive either dexmedetomidine 1 μg/kg [Group PD] or fentanyl 1 μg/kg [Group PF]. Study drugs were diluted in 10 ml NS and administered over 10 min prior to induction of anesthesia with 2.5 mg/kg propofol. PLMA insertion condition was measured according to the Muzi scoring system. Score ≤2 was considered optimal for PLMA insertion. Patient's cardio-respiratory parameters, emergence time, and postoperative pain were also recorded.

Results: In our study 83.8% patients in the group PF and 91.9% in the group PD achieved optimal insertion condition (not significant). Hemodynamic stability was maintained in both the groups but the incidence of apnea was significantly higher in the PF group ($P = 0.011$). We also observed that emergence time was prolonged but postoperative pain scores were significantly lower in the PD group ($P < 0.001$).

Conclusion: We conclude that both dexmedetomidine and fentanyl in a dose of 1 μg/kg when used before induction with propofol provide comparable conditions for successful PLMA insertion. Dexmedetomidine has additional advantage of preserving spontaneous respiration and providing better analgesia.

Keywords: Dexmedetomidine, fentanyl, proseal laryngeal mask airway

Introduction

Propofol is the most preferred agent for the laryngeal mask airway (LMA) insertion.[1,2] Propofol requirement for the proseal laryngeal mask airway (PLMA) insertion is significantly higher as compared to the classic laryngeal mask airway (CLMA).[3,4] Also after induction of anesthesia with 2–3 mg/kg propofol, CLMA has been found to be easier and quicker to insert in the first attempt as compared to PLMA.[5]

The anesthetic requirement for different supraglottic airways devices are dissimilar due to their structural differences. Therefore use of adjuvants may not only improve first attempt PLMA insertion conditions but also reduce the propofol requirement and associated adverse effects.

Different adjuvants such as opioids, benzodiazepines, muscle relaxants, ketamine, dexmedetomidine have been advocated to facilitate smooth insertion of CLMA. Previous studies have shown that dexmedetomidine and fentanyl in a dose of 1 μg/kg are equally effective and safe adjuvants for insertion of

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CLMA.[6,7] However we found very few studies comparing the efficacy of these commonly used adjuvants for PLMA insertion which requires greater depth of anesthesia. The primary objective of our study was to compare the effects of single intravenous dose of dexmedetomidine and fentanyl administered prior to propofol on the PLMA insertion conditions as per the Muzi scoring system.[8] Changes in hemodynamic and respiratory parameters, time required for emergence from anesthesia, and postoperative pain scores were compared between the two groups as secondary outcome variables.

Material and Methods

This prospective, randomized, double-blinded, parallel group clinical trial was conducted after obtaining the ethical approval from our institutional clinical research ethics committee. Seventy four American Society of Anesthesiologists (ASA) physical status I–II patients, aged 18–60 years, weighing between 35 to 80 kg scheduled for elective urosurgical procedures lasting <120 min were enrolled for the study. Patients with anticipated difficult airway, morbid obesity (BMI >35), or those at risk of gastric aspiration were excluded from the study. Written informed consent was obtained from each patient. The patients were randomized to one of the two groups based on computer-generated random number to receive: 1 μg/kg dexmedetomidine [Group PD] or 1 μg/kg fentanyl [Group PF]. Randomization and study drug preparation were done by an anesthesiologist not involved in the study. Study drug was prepared by diluting 1 μg/kg of dexmedetomidine and fentanyl with normal saline up to a total volume of 10 ml. It was labeled as "study drug" for both the groups.

All patients were fasted for over 6 h and no sedative premedication was prescribed in the morning of surgery. In the operating room, routine monitors including electrocardiogram (ECG), pulse oximeter (SpO_2), non-invasive blood pressure, and end-tidal CO_2 were applied. After securing an intravenous access, study drug was administered over 10 min with a syringe pump. After thirty seconds of administration of the study drugs, propofol was given in a dose of 2.5 mg/kg for induction of anesthesia. Ninety seconds later a lubricated PLMA was inserted by an anesthesiologist having an experience of >50 previous PLMA insertions. PLMA size was chosen according to the patient's weight as per the manufacturer's recommendation. All PLMA insertions were performed by the same blinded anesthesiologist and jaw mobility was graded according to his observation. PLMA insertion condition which was the primary outcome of our study was assessed according to the Muzi scoring system.[8] The following criteria were used for grading the insertion condition: jaw mobility (1: fully relaxed, 2: mild resistance, 3: tight but opens, and 4: closed), coughing or movement (1: none, 2: 1 or 2 coughs, 3: 3 or more coughs, and 4: bucking/movements). Score ≤2 was considered optimal for PLMA insertion. Effective ventilation was confirmed by adequate chest rise and a capnograph trace. Anesthesia was maintained with sevoflurane in 50% oxygen and 50% air maintaining a minimum alveolar concentration (MAC) of 1%. If any patient movement occurred during insertion, propofol 0.5 mg/kg was given before the next attempt. The procedure was abandoned after three unsuccessful attempts and those patients were excluded from the study. Other events such as apnea, breath holding, expiratory stridor, and tearing were also observed.

Manual ventilation was carried out till the return of spontaneous ventilation and apnea time was recorded. Heart rate (HR), systolic blood pressure (SBP), mean blood pressure (MAP), SpO_2, and respiratory rate (RR) were recorded at baseline, pre-induction and 1, 3, 5, 10, 15 min after PLMA insertion. Number of attempts required for PLMA insertion, additional doses of propofol, emergence time, and postoperative pain were also recorded. HR <60 was considered as bradycardia, whereas SBP <90 mm Hg was categorized as hypotension. Emergence time was defined as time period between switching off of sevoflurane to first response to verbal commands. Postoperative pain was assessed in the postoperative anesthesia care unit (PACU) once the patients were completely awake and responding to verbal commands and graded using the visual analogue scale (VAS).

A blinded investigator noted the episodes of coughing, bucking/movement, additional doses of propofol, hemodynamic parameters, apnea time, time required for emergence from anesthesia, and postoperative pain scores.

Jaw relaxation grade 1 as per the Muzi score was used for calculating the sample size. Taking the difference in jaw relaxation grade I between dexmedetomidine and fentanyl groups as 23.4% and using power analysis, 37 patients in each group were calculated considering α error of 5% and power of 80%. The difference of 23.4% between the two groups was based on an institutional pilot sudy conducted by the same authors using the study drugs in the same doses.

The categorical variables are expressed as number or percentage of patients and compared between the two groups using the Pearson's Chi-square test. Continuous variables are expressed as mean ± SD and compared using unpaired *t*-test and Mann–Whitney U test. The statistical software SPSS version 20 was used for the analysis of data. *P* value <0.05; was considered as significant.

Results

A total of 74 patients were enrolled in the study. All the patients completed the study. The two groups were comparable in terms of patient characteristics such as age, sex, ASA grading, Mallampatti grade (MPG) [Table 1].

In group PD three patients had Muzi score >2. Out of which two patients moved and one had mild resistance to jaw mobility. But none had coughing or bucking during the insertion of PLMA. Whereas in group PF, PLMA insertion score in six patients was >2; out of which three patients had coughing and four patients moved during the first attempt of PLMA insertion. One patient out of these had both coughing and movement. In group PF, two patients who had mild resistance to jaw mobility also had cough during PLMA insertion [Table 2]. The number of patients having Muzi score ≤2 was similar in the two groups [Table 2].

Three patients needed second attempt and one needed third attempt in the PF group as compared to two patients who needed two attempts in the PD group. None of the patient's needed more than three attempts for PLMA insertion.

Baseline HR, SBP, and MAP were comparable in both the groups. But there was a significant reduction in HR after administration of the study drug in PD group as compared to PF group and this remained statistically significant at each time period of the study interval [Figure 1]. The reduction in SBP and MAP were statistically significant at 1 min after PLMA insertion (SBP $P = 0.012$, MAP $P = 0.041$). But later the difference was insignificant [Figure 2].

The incidence of apnea was greater in PF group as compared to PD group [Table 2]. But the difference in apnea time was not statistically significant [Table 3]. There was a significant reduction in RR at 1 min of LMA insertion in both the groups. The RR increased and reached close to pre-induction values 5 min after PLMA insertion in PD group but remained significantly lower in PF group [Figure 3].

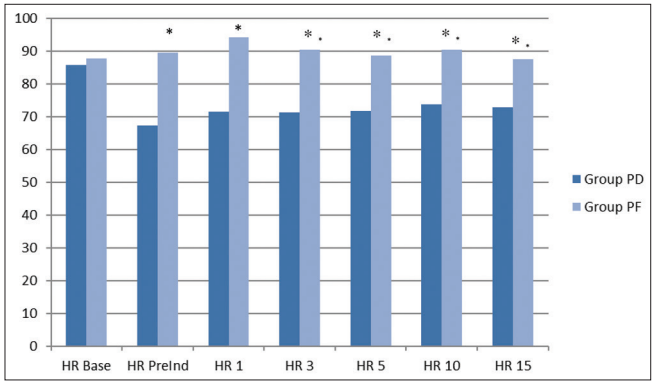

Figure 1: Heart rate in the two groups against time. *Statistically significant difference between the two groups ($P < 0.05$)

Emergence time was significantly longer in PD group as compared to PF group [Table 3]. Postoperative pain as assessed in the PACU showed that VAS values were significantly lower in PD group as compared to PF group [Table 3]. Except for the study drug, the analgesics used in both the groups were similar.

Discussion

The primary results of this study suggest that both dexmedetomidine and fentanyl in a dose of 1 μg/kg are equally

Table 1: Patient characteristics

	PD	PF	*P*
Age	39.2±12.0	41.0±11.7	0.519[a]
Weight	66.9±13.0	66.9±9.8	1.000[a]
Gender	19/18	17/20	0.642[a]
ASA I/II	25/12	22/15	0.469[a]

Data as mean±SD or number of patients. [a]Not significant. SD=Standard deviation, ASA=American Society of Anesthesiologists

Table 2: Parameters for Proseal laryngeal mask airway insertion conditions modified from Muzi and colleagues

	PD	PF	Significance (*P*)
Jaw mobility			
Fully relaxed	36	35	Not significant[a]
Mild resistance	1	2	
Tight but opens	0	0	
Coughing			
None	35	31	Not significant[a]
One or two coughs	0	3	
Three or more coughs	0	0	
Bucking/movement	2	4	
Other events			
Apnea	6	16	*P*=0.001
Breath holding	0	2	
Expiratory stridor	0	0	
Tearing	0	0	
Additional dose of propofol	2	4	Not significant

[a]Criteria for calculating Muzi score

Table 3: Other characteristics (observed parameters for secondary outcome variables)

	PD	PF	Significance
Apnea time	68.8±104.1	123.8±67.7	Not significant
Bradycardia	5	1	Not significant
Hypotension	1	2	Not significant
Emergence time	412.2±77.6	227.3±66.6	*P*<0.001
VAS (0-3)	36	15	*P*<0.001

Apnea time and emergence time measured in seconds (mean±SD), bradycardia, hypotension, and VAS measured as number of patients (mean±SD). SD=Standard deviation, VAS=Visual analogue score

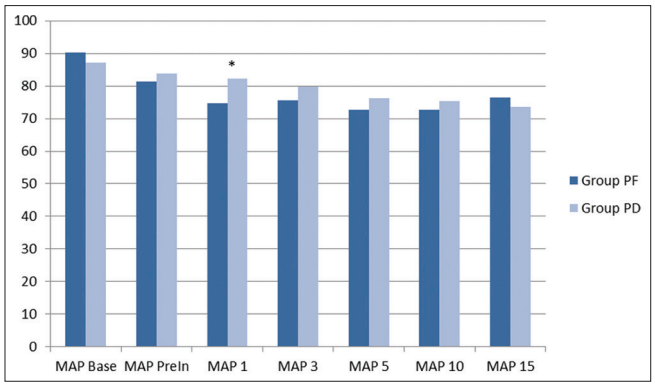

Figure 2: Mean arterial pressure. *Statistically significant difference in the mean arterial pressure observed between the two groups ($P \leq 0.05$)

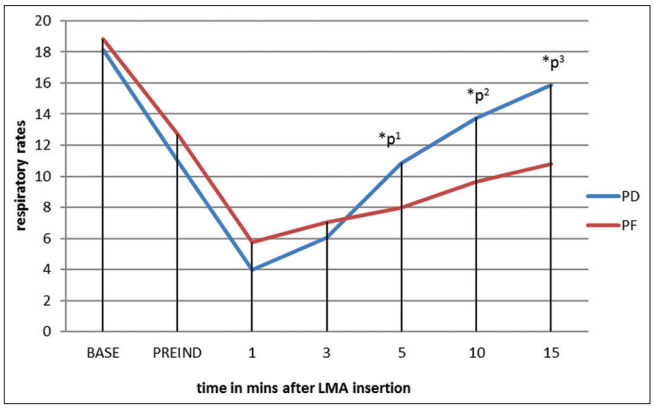

Figure 3: Respiratory rates observed at baseline, pre-induction, 1, 3, 5, 10, 15 min after proseal laryngeal mask airway insertion (breaths/min). *Statistically significant difference in respiratory rates between two groups seen after 5 mins of laryngeal mask airway insertion (p1, p2, p3 < 0.001)

effective in providing optimal conditions for PLMA insertion. Furthermore, both drugs provided stable hemodynamics during PLMA insertion. However, we demonstrated significant differences between the two groups in two secondary outcomes: apnea and postoperative analgesia. Group PD showed significantly lesser episodes of apnea and better postoperative pain scores as compared to fentanyl group.

Uzümcügil *et al*. and Ramaswamy and Shaikh used dexmedetomidine and fentanyl in a dose of 1 μg/kg and concluded that both were equally effective as adjuvants for CLMA insertion when co-administered with propofol.[6,7] Our study was different from these studies as we compared the insertion conditions for PLMA. PLMA needs more attempts and longer duration for insertion as compared to CLMA.[9,10] PLMA insertion difficulty has been attributed to larger, softer, deeper bowl, and the nonlinear leading edge of DT.[4,5] Also, propofol requirements have been shown to be 38–40% greater for PLMA as compared to CLMA.[3,4,11] We conducted this study as the literature regarding the ideal adjuvant for PLMA insertion is still insufficient.

Our findings were supported by a similar study conducted by Nellore *et al.*[12] They reported comparable jaw relaxation ($P = 0.041$) and overall PLMA insertion conditions in both the groups. However, they have given midazolam 0.02 mg/kg in each group 4 min prior to induction of anesthesia which coincides with its peak effect. Midazolam itself reduces upper airway reflexes and has shown to reduce the dose of propofol and improve LMA insertion condition.[13,14] As the aim of our study was to compare the efficacy of the two drugs as sole adjuvants, we omitted all sedative premedications.

Similar to the findings of Uzümcügil *et al.*,[6] we observed a significant decrease in HR in both the groups as compared to the baseline. Group PD showed greater decrease in HR as compared to PF at all the time intervals. However, the episodes of bradycardia and the requirement of atropine were comparable between the two groups.

We recorded a fall in SBP and MAP in both the groups as compared to the baseline. This may be due to effect of induction with propofol. Kunisawa[15] and colleagues demonstrated that dexmedetomidine suppresses the decrease in blood pressure due to anesthetic induction with propofol.

Consistent with previous studies, the incidence of apnea was significantly higher in PF as compared to PD.[6,7] Tan and Wang have shown that fentanyl increases the incidence of prolonged apnea in a dose-dependent manner.[16] Dexmedetomidine itself lacks respiratory depressant effect, and has shown to cause significant increase in RR during its infusion due to its action at multiple sites including locus ceruleus, pulmonary vasculature, and carotid body by stimulating respiratory center.[17] Apnea occurring in few patients in PD group may be due to the effect of 2.5 mg/kg of propofol. However the difference in apnea time was not significant between the two groups as shown in previous studies. Also, we did not find a significant rise in RR from the baseline in PD group as shown by Uzümcügil *et al.*[6] This difference may be due to the fact that our patients did not receive dexmedetomidine infusion but a single pre-induction dose.

Adjunctive use of an intraoperative dexmedetomidine infusion has shown to delay the emergence time i.e., time required for response to verbal stimulus.[6,18] However, we observed significant delay in emergence in PD group with a single pre-induction dose. During this period spontaneous breathing and oxygen saturation were maintained in all patients.

Postoperative pain scores were found to be significantly lower in PD group despite using same analgesics in both the groups. Sedative and analgesic properties of dexmedetomidine are a

result of its action on α 2adrenoceptors in locus ceruleus and dorsal horn of the spinal cord.[19]

Our study had few limitations; we could not compare the depth of anesthesia achieved for PLMA insertion in two groups due to non-availability of BIS monitor. We did not use a control group as propofol alone fails to provide adequate condition for PLMA insertion and may increase the incidence of respiratory morbidities.[1]

Conclusion

We conclude from this study that a single IV dose of 1 μg/kg of both dexmedetomidine and fentanyl administered prior to induction with propofol provide comparable and satisfactory PLMA insertion conditions and stable hemodynamic parameters. Also we found that dexmedetomidine preserved patient's spontaneous breathing and provided better postoperative analgesia.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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