ORIGINAL ARTICLE

A prospective, randomized, double-blind entropy-guided approach to evaluate the efficacy of different doses of dexmedetomidine with propofol versus fentanyl with propofol for ProSeal laryngeal mask airway insertion

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Abstract

Background: Airway management with Proseal™ Laryngeal Mask Airway (PLMA) is increasingly being used. PLMA insertion requires adequate jaw relaxation and depth of anesthesia while maintaining hemodynamic stability. Opioids including fentanyl and alpha-2 agonists like dexmedetomidine are increasingly being used with propofol for the same. *Aims and Objectives:* To assess efficacy of different dexmedetomidine doses in providing optimal conditions for insertion of PLMA, compare with that of fentanyl, and correlate with Entropy. *Material and Methods:* Prospective double-blind, randomized study was conducted on 120 individuals between 18 - 65 years of ASA I /II and had been randomized into 4 groups: Group 1 - Dexmedetomidine 0.5 µg/kg, Group 2 - Dexmedetomidine 0.75 µg/kg, Group 3 - Dexmedetomidine 1µg/kg and Group 4 - Fentanyl 2µg/kg. Standard anesthesia monitors with entropy sensors were attached. Study drug was administered over 10 minutes, followed by a propofol bolus; once the State Entropy was less than 50, PLMA was inserted after assessing jaw relaxation. *Results:* Both groups were similar in demographic data and insertion conditions. Systolic blood pressure, mean arterial pressure, and diastolic blood pressure reductions were larger in group fentanyl. Apnea time was more infentanyl group than the dexmedetomidine group but was not statistically significant. *Conclusion:* Different doses of dexmedetomidine in conjunction with propofol provide identical PLMA insertion settings as fentanyl propofol combination, better maintenance advantage of hemodynamics, and less apnea incidence with adequate depth of anesthesia.

Keywords: ProSeal Laryngeal Mask Airway, dexmedetomidine, fentanyl, entropy

Introduction

Laryngeal Mask Airway (LMA) is a Supraglottic Airway (SGA) device which secures the airway by using an inflated cuff to create low-pressure seal over laryngeal inlet which is an alternative to both face masks and Endotracheal Tubes (ETT). When properly positioned, ProSeal Laryngeal Mask Airway (PLMA), an SGA device, creates more efficient seal than traditional LMA with a gastric drainage tube that makes this easier for a gastric tube to pass through for protection against regurgitation and avoids gastric insufflation. Adequate mouth opening, jaw relaxation, with obtundation of airway reflexes like coughing, gagging, or laryngospasm are necessary for LMA implantation [1-2]. Because inhalational anaesthetics take longer to administer the LMA, intravenous agents were chosen. Propofol has been the most preferred intravenous agent as it suppresses upper airway reflexes, provide sufficient laryngeal reflex depression, resulting in less gagging, coughing, and laryngospasm than thiopentone [3-4].

Propofol when administered in bolus at the time of induction of General Anesthesia (GA), larger doses are required which could lead to an excessive sedation depth, clinically significant cardiovascular and pulmonary depression, or insufficient deep sedation leading to delayed recovery in short procedures. If administered in low doses it may be associated with intraoperative recall. Hence analgesics alongside sedatives have been used in conjunction with propofol for the purpose of anesthesia induction. The co-induction of GA with multiple drugs is typically planned by studying the potential interactions, particularly synergism, between the drugs to be used, mostly benzodiazepines, opioids, and propofol [5-7].

Fentanyl is a strong agonist at the μ-opioid receptors. It has been strong depressant of upper airway reflexes; fentanyl pre-administration may make it easier for inserting LMA with propofol [8-9].

Propofol dosages are decreased during induction as well as maintenance by dexmedetomidine, an extremely selective α2-adrenergic receptor agonist having sedative as well as analgesic effects. It has been determined that dexmedetomidine is clinically safe for respiratory use when administered at supramaximal plasma levels. Additionally, it has been demonstrated to reduce circulatory and airway responses throughout extubation along with intubation [10-11].

Dexmedetomidine causes a dose-dependent decrease in median effective concentrations of BIS and propofol. Compared to higher doses, a loading dose of 0.5 μg/kg of dexmedetomidine had been linked to lower bradycardia incidence along with significant decrease in median effective concentration of propofol alongside BIS value of 0.75 μg/kg and 1 μg/kg [12]. When determining SGA placement depth, entropy is a reliable indicator. Entropy exhibits high specificity degree in evaluating consciousness [13].

In our literature search, we didn't come across any study that evaluated the ease of insertion of PLMA with different doses of dexmedetomidine and fentanyl by correlating with entropy. With the background of previous studies, hypothetically dexmedetomidine is better than fentanyl and provide ideal insertion conditions for PLMA insertion.

Our primary research objective was to assess effectiveness of 3 different dexmedetomidine doses with propofol to provide optimal settings for insertion of PLMA and compare with that of fentanyl with propofol. Entropy changes and hemodynamic changes were assessed as secondary objectives.

Material and Methods

Approval from the Institutional Ethics Committee was obtained for this study involving 120 patients, conducted over a period of 18 months. Written informed consent was obtained from each participant in a language they best understood. Adults aged 18 to 65 years of either gender, scheduled for elective surgery, were randomly assigned to four groups of 30 participants each using a computer-generated randomization method.

Group 1 Dexmedetomidine$_{0.5}$: Individuals were administered dexmedetomidine 0.5 μg/kg over 10 min.

Group 2 Dexmedetomidine$_{0.75}$: Individuals were administered dexmedetomidine 0.75μg/kg over 10 min.

Group 3 Dexmedetomidine$_{1}$: Individuals were administered dexmedetomidine 1 μg/kg over 10 min

Group 4 Fentanyl: Patients received fentanyl 2μg/kg over 10 min.

Patients with American Society of Anesthesiologists (ASA) grade III and IV, anticipated difficult airway, BMI of more than 30 kg/m^2 were excluded from this study. Patients were pre-medicated with alprazolam 0.5 mg and ranitidine 150 mg orally previous night before surgery. After confirming nil by mouth status on day of surgery, patients were allocated into 4 groups as shown above.

After shifting the patients to the Operating Room (OR), entropy sensor was applied on the forehead after cleaning with spirit. The following parameters were monitored, and baseline values were recorded: Electrocardiogram (ECG), Heart Rate (HR), Arterial Oxygen Saturation by Pulse Oximetry (SpO_2), Noninvasive Blood Pressure (NIBP), and Entropy™. Aestiva or Avance CS^2 GE Healthcare, Finland (Datex-Ohmeda) anesthesia workstation delivered anesthesia in all patients and GE healthcare module used Entropy to measure depth. An Intravenous (IV) line had been secured using appropriate cannula, alongside IV lignocaine 40 mg had been administered after applying a venous tourniquet, which was kept for 90 seconds, and IV fluid started at the rate of 15 ml/min.

Every research drug (fentanyl along with dexmedetomidine) had been prepared in 20 ml syringe with Normal Saline (NS) by an individual who was not involved in individual's assessment / administering anaesthesia. Soon after, the patients received investigation drug over 10 min utilizing a syringe pump according to their group allocation.

After administering the study drug, HR, NIBP, SpO_2, Respiratory Rate (RR), Response Entropy (RE) along with State Entropy (SE) were documented. Following this, IV propofol 1.5 mg/kg was administered by hand held syringe to all the patients along with 100% O_2 at 6L/min via a tight-fitting face mask and circle system. Before induction, we utilized IV lignocaine (20 mg) for eliminating pain related to propofol injection. An episode of apnea (cessation of respiration for more than 10 s) was noted.

As soon as the SE was less than 50, jaw relaxation was evaluated by 4 point Muzi score [14] (1 – fully relaxed, 2 – mild resistance, 3 – resistance but jaw can be opened, 4 – resistance requiring extra propofol to open), along with motor response's absence to jaw thrust was confirmed. PLMA of appropriate size was inserted using introducer approach, and cuff inflated with the appropriate amount of air. In case of motor response to jaw thrust, additional propofol dose 0.5 mg/kg was administered and ventilation was either assisted or controlled as required. Thirty seconds later, the next attempt was made. A maximum of three attempts were only done. If third attempt also failed, individual was excluded from research and managed further as per the decision of the attending anesthesiologist. Jaw relaxation was assessed and absence of motor response to jaw thrust was confirmed before each attempt.

IV atropine 0.6 mg was utilized for treating any bradycardia episode (HR < 45b/min), while IV ephedrine 6 mg was utilized in treating any decline in mean arterial Blood Pressure (BP) > 20% from baseline.

Proper PLMA placement was verified by bilateral chest expansion alongside square wave capnogram. Individual had been permitted to breathe spontaneously/ventilation had been either controlled/assisted with 100% O_2 as per the need. After successful insertion of PLMA, propofol infusion was initiated at 100 µg/kg/min rate using syringe pump and maintained for 5 min. Conditions for

PLMA insertion were assessed and recorded. RE, SE, HR, Mean Blood Pressure (MBP), SpO_2, RR were recorded just before and soon after the successful insertion of PLMA, and subsequently at 1, 2, 3, 4 and 5 min. Subsequent anesthetic management had been left at the discretion of the attending anesthesiologist. The anesthesiologist and the person recording the observations were blinded to group allocation. Group allocation had been done by a computer assisted randomized technique.

Parameters observed

Apnea time(s): The interval between the last spontaneous breath and the subsequent spontaneous breath following propofol administration was recorded. RR, HR, NIBP, SpO_2, SE along with RE were recorded on arrival to OR, following the study drug's administration, just before and soon after PLMA insertion and subsequently at 1, 2, 3, 4 and 5 min. Individual's reaction to PLMA insertion including gagging, coughing, bronchospasm, laryngospasm/motor response were observed. We evaluated using scoring system that Muzi and colleagues had modified for assessing tolerance of PLMA insertion [14].

Scoring system to grade jaw mobility:

1--------Fully relaxed

2--------Mild resistance

3--------Tight but opens

4--------Closed

Scoring system to grade coughing/movement

1--------None

2--------One or two coughs

3--------3 or more coughs

4--------Bucking/movement

For every category, score < 2 had been accounted optimum for PLMA insertion.

Other events: Spontaneous ventilation, breath holding, inspiratory stridor, laryngospasm, bronchospasm, and lacrimation were also monitored.

Sample size had been computed based on formula

$$N = (Z_\alpha + Z_\beta)^2 (S_1^2 + S_2^2) / (X_1 - X_2)^2$$

In accordance with above formula, total sample size in our study was 120. Parametric data was analyzed using unpaired t-test / ANOVA (Analysis of variance) and stated as mean (standard deviations). Non-parametric data were analyzed using Chi-square test and stated as numbers (percentages). Value of $p < 0.05$ was considered as statistically significant.

Results

One-twenty patients' data were analyzed. Every groups' demographic information was similar (Tables 1 and 2). In all 4 groups, majority of the individuals were females since most of the cases included were laparoscopic sterilization. PLMA insertion was successful in the first attempt in all individuals who were provided with dexmedetomidine 1μg/kg. The fentanyl group had less number of failures in the initial attempt of PLMA insertion in comparison to other dexmedetomidine groups, as shown in (Table 3). Apnea time had been greater in fentanyl group over dexmedetomidine group, but it was insignificant statistically (Table 4). None of our individuals had any saturation drops even after having apnoea, hence didn't need manual ventilation prior to LMA insertion. Adequate jaw relaxation had also been more in fentanyl group, however difference had been statistically insignificant. Mild jaw resistance was seen in 16.67% of Group 1 patients (Table 5). Motor response to insertion of PLMA was more in Group $D_{0.5}$ in comparison to other groups and needed propofol's additional dosage. Motor response had been less in the fentanyl group, moreover it was statistically insignificant (Table 6).

The SE values had been comparable in all groups and had been less than 50 throughout the study period which concluded that awareness was negligible in all the 4 groups ($p > 0.05$). There was an increase in SE value after PLMA insertion, especially in group 4 (Figure 1) but it had been insignificant statistically ($p = 0.5669$). HR remained almost same for the first five minutes after insertion of PLMA and the difference in 4 groups was not statistically significant (Figure 2).

Systolic BP had also been similar in all the groups till PLMA insertion ($p > 0.05$). Soon after PLMA insertion, a statistically significant difference among SBP between 4 groups had been noted. There was an increase in SBP soon after the insertion of PLMA in group 1 where movement after PLMA insertion was also high (Figure 3). Diastolic blood pressure and mean blood pressure was similar across every group ($p > 0.05$). The dexmedetomidine group elicited an acceptable drop in BP when compared to fentanyl group. There was no episode of desaturation in all 4 groups though apnea incidence had been more in fentanyl group (Figure 4). There were no incidence of coughing, gagging, bronchospasm, laryngospasm in any of our study group.

Table 1: Distribution of males and females in four study groups

Gender	Group 1	Percentage (%)	Group 2	Percentage (%)	Group 3	Percentage (%)	Group 4	Percentage (%)	Total
Male	2	6.67	2	6.67	6	20.00	5	16.67	15
Female	28	93.33	28	93.33	24	80.00	25	83.33	105
Total	30	100.00	30	100.00	30	100.00	30	100.00	120

Chi-square=3.8862 p = 0.2741

Table 2: Comparison of four groups with mean age and BMI by one way ANOVA

Groups	Age (y)	Height (m)	Weight (kg)	BMI (kg/m^2)
	Mean ± SD	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**
Group 1	35.33 ± 12.13	1.59 ± 0.08	56.40 ± 9.15	22.25 ± 3.60
Group 2	36.30 ± 11.39	1.61 ± 0.06	62.23 ± 10.75	24.02 ± 3.86
Group 3	34.40 ± 9.59	1.62 ± 0.09	60.43 ± 12.88	22.96 ± 3.45
Group 4	34.87 ± 12.28	1.61 ± 0.06	60.27 ± 11.71	23.09 ± 3.77
Total	35.23 ± 11.28	1.61 ± 0.07	59.83 ± 11.27	23.08 ± 3.68
p	0.9281	0.6394	0.2345	0.3226

Table 3: Comparison of four groups with number of attempts

No of attempts	Group 1	Percentage (%)	Group 2	Percentage (%)	Group 3	Percentage (%)	Group 4	Percentage (%)	Total
One	22	73.33	22	73.33	30	100.00	25	83.33	99
Two	7	23.33	8	26.67	0	0.00	4	13.33	19
Three	1	3.33	0	0.00	0	0.00	1	3.33	2
Total	30	100.00	30	100.00	30	100.00	30	100.00	120

Chi-square=3.8862 p = 0.2741

Table 4: Comparison of four groups with mean apnoea time (sec) by one way ANOVA

Groups	Apnoea time (sec)
	Mean ± SD
Group 1	15.00 ± 10.36
Group 2	15.53 ± 5.97
Group 3	18.59 ± 8.25
Group 4	19.88 ± 10.64
Total	17.63 ± 9.13
p	0.2831

Table 5: Comparison of four groups with status of jaw mobility

Jaw mobility	Group 1	Percentage (%)	Group 2	Percentage (%)	Group 3	Percentage (%)	Group 4	Percentage (%)	Total
Fully relaxed	25	83.33	27	90.00	27	90.00	29	96.67	108
Mild resistance	5	16.67	3	10.00	3	10.00	1	3.33	12
Total	30	100.00	30	100.00	30	100.00	30	100.00	120

Chi-square=0.8291; p = 0.6612

Table 6: Comparison of four groups with status of movement

Movement	Group 1	Percentage (%)	Group 2	Percentage (%)	Group 3	Percentage (%)	Group 4	Percentage (%)	Total
None	15	50.00	17	56.67	21	70.00	26	86.67	79
Bucking / movement	15	50.00	13	43.33	9	30.00	4	13.33	41
Total	30	100.00	30	100.00	30	100.00	30	100.00	120

Chi-square= 2.5701; p = 0.2773

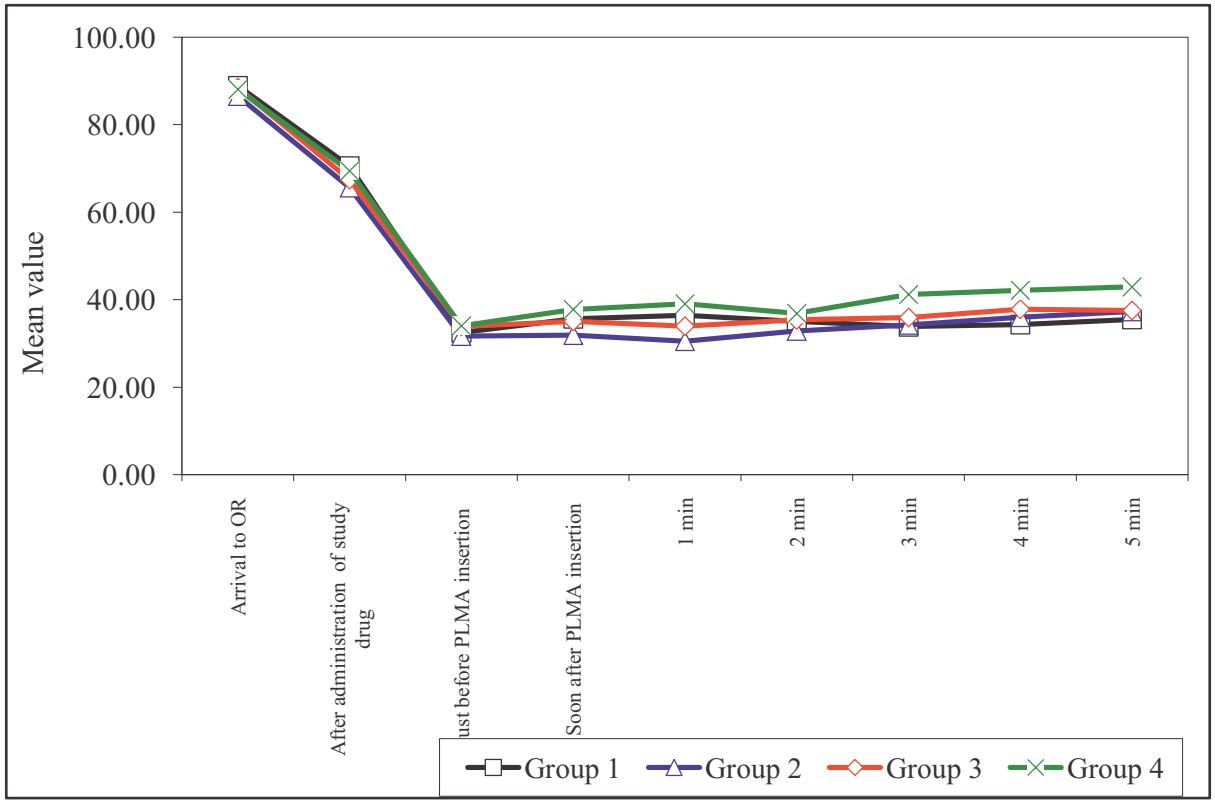

Figure 1: Comparison of four groups with SE scores at different treatment time points by one way ANOVA

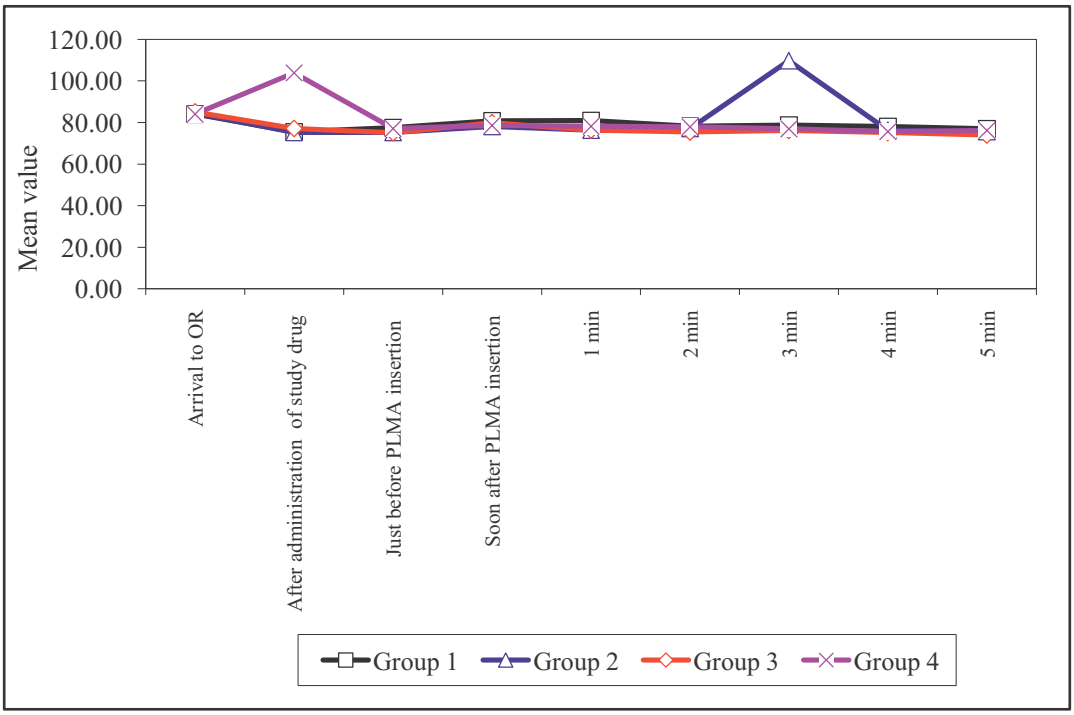

Figure 2: Comparison of four groups with HR scores at different treatment time points by one way ANOVA

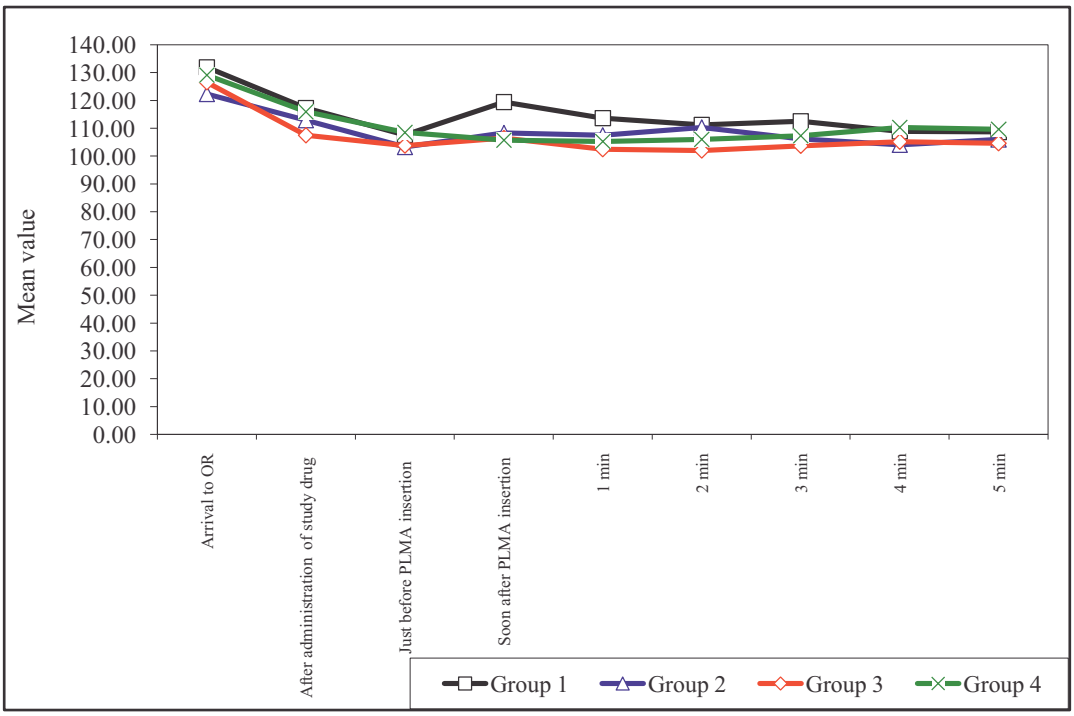

Figure 3: Comparison of four groups with SBP scores at different treatment time points by one way ANOVA

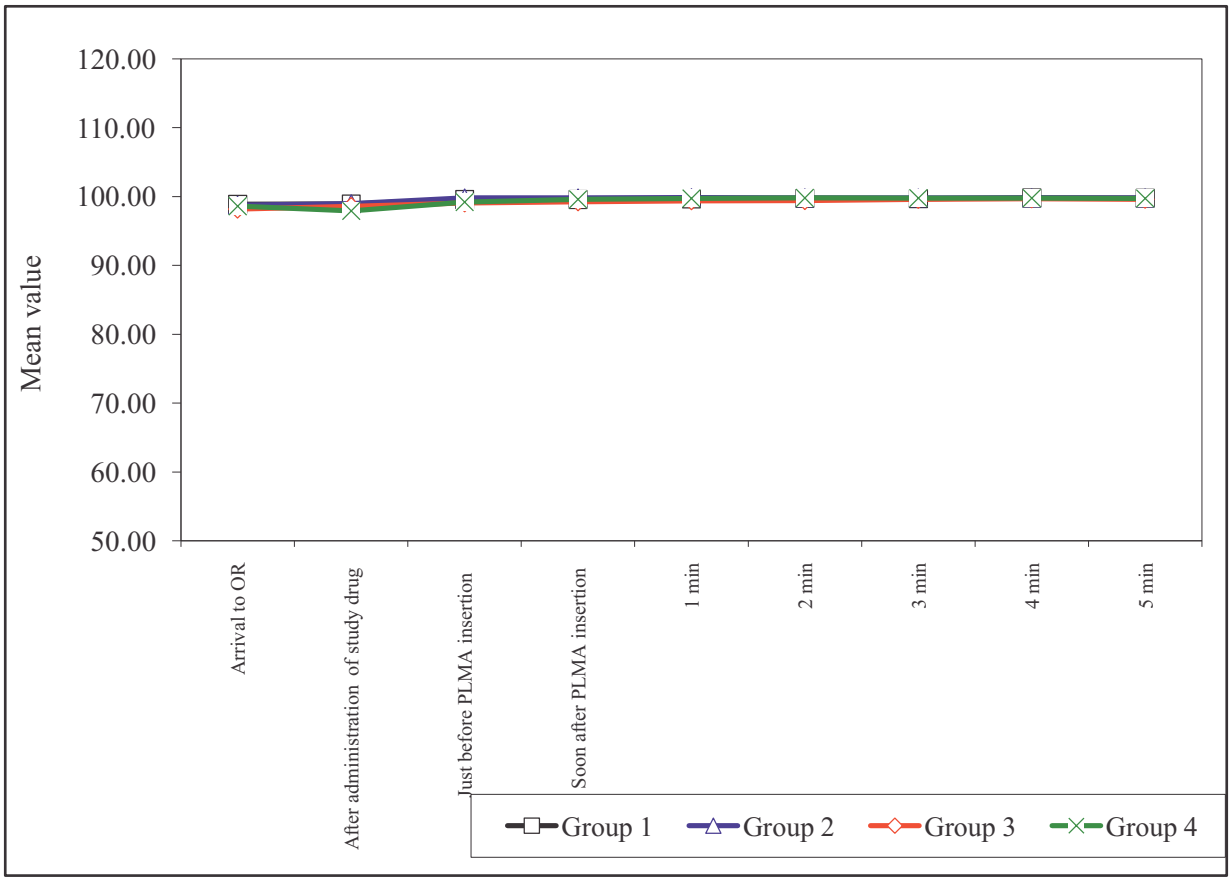

Figure 4: Comparison of four groups with SPO_2 scores at different treatment time points

Discussion

Different doses of dexmedetomidine 0.5 µg/kg, 0.75 µg/kg, 1 µg/kg and fentanyl 2 µg/kg with propofol were used to assess ease of insertion of PLMA without the administration of neuromuscular blocking agent. We also tried to find out the near accurate dose of dexmedetomidine with better hemodynamic stability without having an adverse effect on insertion conditions and on anesthetic depth monitored by Entropy. Three different doses of dexmedetomidine provided suitable PLMA insertion conditions comparable to fentanyl group with less duration of apnea and with stable haemodynamics.

Anaesthetic depth sufficient to obstruct airway reflexes is necessary for PLMA insertion without employing neuromuscular blocking agents. Consequently, propofol is the preferred drug because of its capability of significantly reducing laryngeal with pharyngeal reflexes when compared to thiopentone. Nevertheless, propofol amount necessary to achieve a sufficient anaesthetic depth varies among individuals.

Induction propofol dose 1.5 mg/kg had been decided based on the research by Uzumcugil *et al*., where it was found that dexmedetomidine–propofol combination provided better insertion

condition for PLMA while maintaining respiratory functions to greater extent than fentanyl [15]. Krishnappa *et al*. found that fixed propofol dosage administered rapidly could be excessive/ insufficient, leading to airway complexity alongside hemodynamic disturbances. Titration for achieving appropriate anaesthetic depth for LMA insertion will be more effective when dose is adjusted for targeting clinical response over fixed dose. Consequently, complications incidence will be reduced. Since we were using entropy to monitor the depth of anesthesia that provided satisfactory insertion condition, we decided to use propofol in the 1.5 mg/kg dose [16]. Fentanyl dose (2 μg/kg) had been defined as per the observations made by Goyagi *et al*. The dose of dexmedetomidine (0.5 μg/kg, 0.75 μg/kg along with 1 μg/kg) had been defined as per prior published findings [9]. Fentanyl as well as dexmedetomidine, when administered 30s prior propofol bolus, achieved optimal jaw relaxation along with mouth opening 90s following propofol injection. Predetermined 30s and 90s periods were derived from Goyagi *et al*. Since the study couldn't assess whether anesthetic depth was sufficient, we assessed anesthetic depth by entropy.

Apnea duration had been considerably greater in fentanyl group, in comparison to dexmedetomidine group and might be attributed to respiratory depression induced by fentanyl when administered in conjunction with propofol. These findings are in consonance with Uzumcugil *et al*. [15].

Though PLMA insertion conditions were comparable among four groups, 25/30 patients of Group 1, 27/30 individuals of Group 2 and 3, along with 29/30 Group 4 had fully relaxed jaws. Jaw relaxation was more in fentanyl group. These findings were comparable to Nellore *et al*. [17]. Even motor response during PLMA insertion was more in Group 1; around 50% of patients required additional doses of propofol for PLMA insertion. Gurjar *et al*. compared the midazolam and dexmedetomidine 0.4 μg/kg for assessing PLMA insertion conditions and found that dexmedetomidine 0.4 μg/kg provided better insertion conditions than midazolam. Similarly, in our study, dexmedetomidine 0.5 μg/kg elicited some motor response but provided comparable insertion conditions [18].

The target value for SE for an attempt at PLMA insertion was taken as 50 based on a study by Iannuzi *et al.*, where they concluded loss of consciousness was between 42.2 and 60.4 of SE values. Hence we took the value of SE < 50, as determined by results of our pilot study. For our research, entropy was less than 50 among all the groups at the time of insertion [12].

Our study found that the effects on BP were similar across all four groups. Although there was a noticeable drop from baseline in all measured pressures - including SBP, MAP, and DBP - after administering the investigational drug, the reductions were not statistically significant. An increase in SBP was observed shortly after PLMA insertion in Group 1, which also experienced more movement during the procedure. Additionally, a higher rate of mild resistance during jaw relaxation assessment in Group 1 compared to the other groups suggests that a lower dose of dexmedetomidine may be insufficient, potentially causing an insertion response reflected by the rise in SBP. Otherwise, hemodynamics were stable during the study period. Jayaram and colleagues' research on 60 patients undergoing lower abdominal and lower limb surgeries found that dexmedetomidine as well as propofol combination provided comparable settings for LMA insertion to fentanyl-

propofol combination, with the added benefit of improved haemodynamic parameter maintenance [19].

It was noted that insertion conditions were adequate when dexmedetomidine was administered in conjunction with propofol, a performance that was comparable to that of fentanyl as well as propofol combinations. Outputs also indicated considerable difference between dexmedetomidine and fentanyl groups in terms of hemodynamic stability. Though statistically insignificant, dexmedetomidine groups decreased the incidence of hemodynamic instability.

Conclusion

Different doses of dexmedetomidine in combination with propofol provided identical PLMA insertion and stable haemodynamic conditions as fentanyl-propofol combination, with lesser apnea incidence and adequate depth of anesthesia.

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