Original Article:

Comparison of dexmedetomidine combined with propofol Vs fentanyl combined with propofol for laryngeal mask insertion

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ABSTRACT

Background: Few studies have assessed adequacy of anaesthesia provided by propofol in combination with dexmedetomidine and propofol in combination with fentanyl for laryngeal mask airway (LMA) insertion for minor to moderate elective surgical procedures.

Methods: Sixty patients admitted for lower abdominal and lower limb surgery were randomized into Group F (n=30) and Group D (n=30). Thirty seconds after the study drug (fentanyl 1 µg/kg in Group F and dexmedetomidine 1 µg/kg in Group D diluted in 10 mL normal saline over 2 min) was administered, induction was done with i.v. propofol 2 mg/kg in both groups. Ninety seconds after propofol injection, jaw relaxation was assessed and LMA of appropriate size was inserted. If the first attempt failed, another attempt was tried after an additional dose of i.v. propofol (0.5 mg/kg). Haemodynamic parameters, namely, heart rate, systolic blood pressure (SBP), mean blood pressure (MBP), diastolic blood pressure (DBP), arterial oxygen saturation measured with pulse oximeter and respiratory rate were recorded before and at the end of 1st, 2nd, 3rd, 5th and 10th minutes after insertion of LMA.

Results: Both the groups were comparable in age weight, sex, age wise distribution and insertion conditions. The reductions in SBP, DBP, MAP were greater in Group F ($p < 0.001$). More patients developed apnoea in Group F than in Group D ($p < 0.05$).

Conclusions: Dexmedetomidine combined with propofol provides the same conditions for LMA insertion as fentanyl-propofol combinations with advantage of better maintainance of haemodynamic parameters.

Key words: *Fentanyl, Dexmedetomidine, Propofol, Laryngeal mask airway*

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INTRODUCTION

The best way of securing airway is by tracheal intubation. Endotracheal anaesthesia is the most commonly used anaesthetic technique for all major surgical procedures. However, it is associated with many complications.[1] For moderate to minor surgical procedures, laryngeal mask airway (LMA) proved to be a useful alternative to provide general anaesthesia.

Laryngeal mask airway is a supraglottic airway, an alternative to both face mask and tracheal tube, is designed to secure the airway by means of a low-pressure seal around the laryngeal inlet by an inflatable cuff.[2] It allows spontaneous ventilation, as well as intermittent positive pressure ventilation with an airway pressure less than 15 cm H_2O.[3]

Insertion of LMA requires lighter plane of anaesthesia than that required for endotracheal intubation.[3,4] However, LMA insertion also requires obtundation of airway reflexes. LMA insertion requires adequate mouth opening and minimal upper airway reflexes such as coughing, gagging or laryngospasm.[5] Because

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of these reasons the search to find the optimum anaesthesia to provide excellent conditions for LMA insertion has been going on.

Since the time required for LMA insertion was longer with inhalational anesthetics, intravenous agents have been preferred. Among the intravenous agents, propofol has been preferred the most because of its potential suppressor effects on upper airway reflexes.[4-6] When used alone without premedication, propofol provides conditions for LMA insertion[7,8] and causes cardiorespiratory depression.[8,9] In order to decrease the adverse effects of propofol, opioids or muscle relaxants were added to reduce the propofol dose requirement.[10-13] Muscle relaxants were not found to be effective[14] and even found to increase the risk of aspiration.[8] Fentanyl[15,16] and alfentanil[17] have also been studied. Unfortunately,these medications increased the incidence and duration of apnoea.

Dexmedetomidine, a highly selective α_2-adrenoceptor agonist, has been shown to have sedative and analgesic properties.[18-20] The α_2-adrenoceptors exert their sedative effects, via the receptors in *locus coeruleus*. Dexmedetomidine, even when used at supramaximal plasma levels, has been found to be clinically safe for respiration.[21] It was also shown to diminish airway and circulatory responses during intubation and extubation.[22-24]

The current study was undertaken to compare the adequacy of anaesthesia provided by propofol in combination with dexmedetomidine with propofol in combination with fentanyl for LMA insertion for minor to moderate elective surgical procedures.

MATERIAL AND METHODS

The study protocol was approved by institutional research ethical committee. Written informed consent was obtained from all the patients. The study was a prospective, randomized single-centre study which included sixty patients admitted for lower abdominal and lower limb surgeries at a tertiary care teaching hospital in Tirupati, Andhra Pradesh, during the period August 2010 to April 2011. By computer generated random number technique, randomization was done before initiating the study. Patients were allocated into two groups, dexmedetomidine group (n= 30; Group D) and Fentanyl group (n=30; Group F).

Sixty patients belonging to American Society of Anesthesiologists (ASA)[25] physical status 1 and 2, aged 18-65 years posted for elective lower abdominal and lower limb surgeries were included in the study. Patient's refusal to participate, presence with infection at the site of spinal injection, patients with ASA physical status 3 and 4, patients with coagulopathies and those with hypersensitivity to local anesthetists were excluded from the study.

Preanaesthetic evaluation was done one day prior to surgery by anaesthesiologist involved in the study. Patients were explained about the anaesthetic technique. Preparation of patients included period of overnight fasting, premedication with single dose of oral alprazolam 0.25 mg and ranitidine 150 mg.

Patients were shifted to the operating room and the following parameters were monitored; electrocardiogram (ECG), arterial oxygen saturation by pulse oximetry (SpO_2) and non-invasive blood pressure monitoring. An intravenous line was secured with 18G cannula under local anaesthesia. Preoxygenationwas done for 3 min with a face mask at 8 L/min of oxygen flow. In Group F, 1 µg/kg fentanyl diluted in 10 ml normal saline (NS) was given over 2 min. In Group D, 1 µg/kg dexmedetomidine diluted in 10 mL NS was given over 2 min. After, 30 sec, inj. propofol 2 mg/kg was administered to both the groups.

Anesthesia was maintained by 50% nitrous oxide and oxygen and 1.5% sevoflurane with a fresh gas flow of 8 L/min and patient was ventilated manually via face mask when required, otherwise, spontaneous ventilation was allowed.

Ninety seconds after propofol injection, jaw relaxation was assessed by a 4-point score[26] and LMA of appropriate size was inserted and cuff inflated with required amount of air. Proper placement was confirmed by capnography. If the first attempt of LMA insertion failed, a second attempt was tried after administering an additional dose of intravenous propofol (0.5 mg/kg). Conditions of LMA insertion were recorded and assessed. Haemodynamic parameters, namely, heart rate, systolic blood pressure (SBP), mean blood pressure (MBP), diastolic blood pressure (DBP), SpO_2 and spontaneous respiratory rate (RR) were recorded and assessed before and after the insertion of LMA, at the end of 1st, 2nd, 3rd, 5th and 10th minute after the insertion.

Statistical analysis

Patient data are summarized as mean and standard deviations (SD). Comparison between two groups with respect to continuous variables such as age, weight, heart rate, systolic blood pressure, diastolic blood pressure, mean blood pressure and apnoea time were compared with student's t-test. Parameters measured over multiple points of time were analyzed using repeated measures ANOVA with Bonfernii post-hoc test. Categorical variables like gender distribution were compared by Chi-square test. All statistical analysis was done by using Statistical Packages for Social Sciences (SPSS) version 17.0. A p-value of < 0.05 was considered as statistically significant.

RESULTS

There was no statistical difference in age, weight, sex, age wise distribution and intubation conditions between the two groups (Table 1). The insertion conditions, such as, jaw mobility (fully relaxed, mild resistance, tight but opens, closed); coughing (none, 1 or 2 bouts of cough, 3 or more bouts of cough, bucking); movements (mild, moderate, severe, none); and number of passes (2 each) were also similar in both groups (Table 2). The apnoea times were significantly shorter in group D than in group F (Table 3). Baseline haemodynamics were comparable in both groups The haemodynamic parameters studied are shown in Table 4.

In group F there was a significant decrease in SBP from baseline after induction with propofol till the end of the study ($p<0.01$). In group D there was an increase in SBP from baseline after administration of dexmedetomidine in combination with propofol and then there was a decrease in SBP from baseline from 1min after LMA insertion till end of the study ($p< 0.0001$).

Table 1: Demographic data

Variables	Group F (n=30)	Group D (n=30)	p-value
Age (years)*	39.3 ± 11.7	34.7 ± 12.5	0.1526
Weight (Kg)*	57 ±10.9	61 ± 9.3	0.1422
Gender			
Male	15	16	
Female	15	14	> 0.99
BMI (kg/m^2)	22.4 ± 3.4	23.2 ± 3.4	0.0961

* Data are presented as mean ± standard deviation

ASA = American Society of Anaesthesiologists; BMI = body mass index

Table 2: Comparison of insertion conditions

Parameter	Group F	Group D
Jaw mobility		
Fully relaxed	23	23
Mild resistance	5	5
Tight but opens	2	2
Closed	-	-
Coughing		
None	30	29
1 or 2 bouts of cough	-	1
3 or more bouts of cough	-	1
Bucking	-	-
Movements		
Mild	12	7
Moderate	2	3
Severe	-	-
None	16	20
No. of Attempts of insertion	2	2
Second dose of propofol repeated (No.)	2	6

Group F = fentanyl + propofol; Group D = dexmedetomidin + propofol

In group F there was a significant fall in the DBP after induction till the end of the study ($p < 0.0001$). In group D there was an increase in DBP after administration of dexmedetomidine in combination with propofol followed by a decrease 2 min after LMA insertion till the end of the study ($p< 0.001$).

In group F there was a significant decrease in MAP throughout the study period ($p< 0.0001$). In group D, there was an increase in MAP after induction followed by a decrease that was evident 1 min after LMA insertion and the trend continued till end of the study ($p< 0.001$). (Figure 1). The extent of reduction in SBP, DBP, MAP were greater in Group F compared with Group D ($p < 0.001$).

There was a fall in RR after induction with profol followed by a rise. The magnitude of fall in RR from the base line value to that after induction with propofol was significantly more ($p< 0.05$) in the fentanyl group (69%) than dexmedetomidine group (35%) (Figure 2).

The incidence of apnoea was lower in group D compared to group F (40% vs 67%, $p<0.01$). Baseline pulse rate was similar in both groups. Our study showed that there was a lesser fall

Table 3: Comparison of respiratory depression

Parameter	Group F	Group D	p-value
Spontaneous ventilation			
Present	15	15	
Absent	0	0	>0.99
Apnoea			
Present	22	12	
Absent	8	18	0.018

Group F = fentanyl + propofol; Group D = dexmedetomidin + propofol

Table 4: Trends in haemodynamic parameters

Time	Group F				Group D			
	SBP	**DBP**	**MAP**	**RR**	**SBP**	**DBP**	**MAP**	**RR**
BL	126.4 ± 16.2	77.7 ± 16.7	95.6 ± 14.4	16.3 ± 3.8	131.3 ± 17.9	78.6 ± 12.1	100.3 ± 15.6	16.1 ± 4.6
BI	124.8 ± 14.3	73.0 ± 13	91.6 ± 12.6	15.7 ± 4.0	140.9 ± 18.6	84.1 ± 12.4	106.3 ± 15.5	15.1 ± 6.0
DI	104.3 ± 22.7	60.8 ± 14.2	78 ± 16.9	9.1 ± 8.2	123.6 ± 22.1	76.7 ± 16.1	95.3 ± 16.8	14.3 ± 8.9
AI	111.1 ± 18.6	64.7 ± 13.1	83.0 ± 15.5	10.7 ± 6.5	131.9 ± 22.9	80.5 ± 17.6	102.3 ± 18.2	10.6 ± 7.5
At 1 min AI	104.7 ± 17.7	61.6 ± 13.9	78.4 ± 14.2	16.5 ± 4.9	118.5 ± 23.9	73.8 ± 16.4	92.1 ± 18.9	17.8 ± 7.5
At 2 min AI	103 ± 20.3	59.7 ± 14.9	75.9 ± 16.6	17.5 ± 5.1	114.6 ± 23.2	70.7 ± 15.2	89.2 ± 18.3	18.7 ± 6.9
At 3 min AI	99.4 ± 14.5	57.2 ± 12.7	73.7 ± 12.2	18.1 ± 4.7	112.5 ± 16.4	67.1 ± 12.6	86.4 ± 12.7	18.9 ± 6.3
At 5 min AI	96.8 ± 12.2	56.1 ± 11	72.6 ± 10.6	18.1 ± 4.7	110.0 ± 15.2	65.2 ± 11.9	83.8 ± 10.9	19.1 ± 5.9
At 10 min AI	96.4 ± 13.5	54.4 ± 12.1	71.3 ± 12.8	18.6 ± 4.3	104.2 ± 16.7	63.2 ± 12.5	79.3 ± 13.1	19.9 ± 4.9

Group F = fentanyl + propofol; Group D = dexmedetomidin + propofol; SBP = systolic blood pressure (mm Hg); DBP = diastolic blood pressure (mm Hg); MAP = mean arterial pressure (mm Hg); RR = respiratory rate (1 min); BL = baseline; BI= before induction; AI = after induction; DI= during insertion

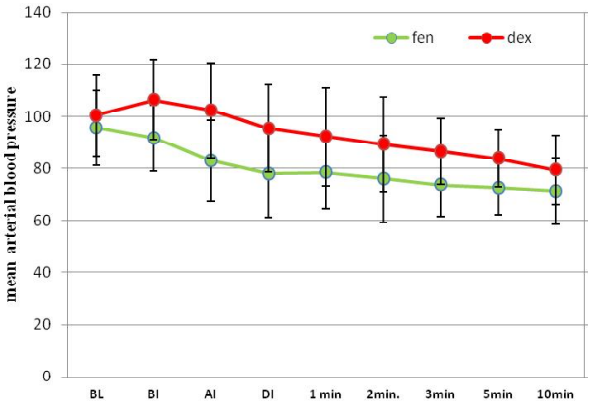

Figure 1: Comparison of mean arterial pressure (mm Hg) BL = base line; BI = before induction; AI = after induction; DI = during insertion; 1 min = 1 minute after insertion; 2 min = 2 minutes after insertion; 3 min = 3 minutes after insertion; 4 min = 4 minutes after insertion; 5 min = 5 minutes after insertion; 6 min = 6 minutes after insertion; 7 min = 7 minutes after insertion; 8 min = 8 minutes after insertion; 9 min = 9 minutes after insertion; 10 min = 10 minutes after insertion

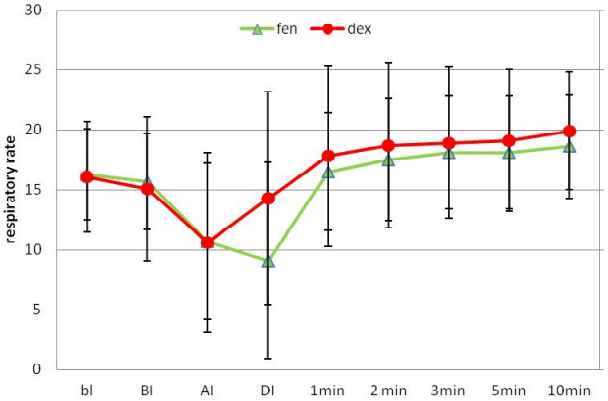

Figure 2: Comparison of respiratory rate (beats/min) BL = base line; BI = before induction; AI = after induction; DI = during insertion; 1 min = 1 minute after insertion; 2 min = 2 minutes after insertion; 3 min = 3 minutes after insertion; 4 min = 4 minutes after insertion; 5 min = 5 minutes after insertion; 6 min = 6 minutes after insertion; 7 min = 7 minutes after insertion; 8 min = 8 minutes after insertion; 9 min = 9 minutes after insertion; 10 min = 10 minutes after insertion

in pulse rate in Group D after study drug when compared to group F (65.9±21 vs 75.6±17.2; p=0.05). Also the magnitude of decrease in pulse rate from baseline to that after the study drug was significantly more in group D than in group F (18% vs 3%; p<0.001). The remaining pulse rate values were comparable in both the groups since the time of induction with propofol to 5 min after LMA insertion. However, towards the end of the study period i.e., 10 min after LMA insertion, there was a significant difference in the pulse rate between the groups (76.8± 14.1 Vs 68.1± 14;p <0.01). The fall in the pulse rate from the baseline towards the end of the study period was not significant in the group F (p=0.32) but significant in group D (p< 0.05).

DISCUSSION

We observed that dexmedetomidine, co-administered with propofol provides successful LMA insertion conditions comparable to performance of the combination of fentanyl and propofol. However, our results showed that the effects on haemodynamics and incidence and duration of apnoea were more desirable in group D than group F. Propofol in combination with fentanyl has been used but its use was associated with occurrence of respiratory depression.

To the best of our knowledge, only one earlier study[26] had evaluated dexmedetomidine with propofol to study the conditions of insertion of LMA for minor urological procedures in unpremedicated patients. However, in this study[26] dexmedetomidine was also continued intra-operatively. In our study, we studied patients undergoing not only lower abdominal procedures but also other surgical procedures. Because our study patients required different levels of analgesia and variable duration of anaesthesia, only insertion conditions using propofol and dexmedetomidine were studied.

In our study, the dose of propofol used (2 mg/kg) with either of the study drugs was adequate for LMA insertion in most of the patients. The dosage we had used was less than 2.5 mg/kg used in one study[8] and more than the dosage of 1.42 mg/kg[10] and 1.17 mg/kg[27] used in other studies. Blake et al[28] had assessed four induction doses of propofol (1.5 - 2.5 mg/kg) and reported that insertion was less successful at 1.5 mg/kg. In our study the dosage of

propofol 2 mg/kg for induction purposes (in combination with either fentanyl or dexmedetomidine) was arrived at upon the findings of pilot study. In our pilot study (unpublished data) when propofol was used in a dose of 1.5 mg/kg, we had to administer further increments of 0.5 mg/kg of propofol before achieving a smooth insertion of LMA whereas, when propofol was used in doses of 2 mg/kg, we did not require to give any supplemental doses of propofol before achieving smooth insertion.

Dose of fentanyl (1 µg/kg) was based on observations from one study.[16] The dose of dexmedetomidine (1 µg/kg) was based on prior published observations.[29] Both dexmedetomidine and fentanyl, when used 30s before a propofol bolus, provided optimum jaw relaxation and mouth opening 90 sec after propofol injection. The predetermined periods of 30 sec and 90 sec were derived from earlier published experience.[10,25,27] In our study, we used lignocaine (20 mg) in order to eliminate pain related to propofol injection before induction. Despite having apnoea, none of our patients showed any drop in saturation and so did not require manual ventilation before the insertion of LMA.

After insertion of LMA, intraoperatively-anaesthesia was maintained with sevoflurane, nitrous oxide in oxygen in all the patients. In another study[26] the authors had used dexmedetomidine infusion. We have not used dexmedetomidine intraoperatively but used fentanyl in all these patients for intra-operative analgesia as our patients required different levels of analgesia according to the procedure done.

A limitation of our study was that we did not include a control group in which propofol was used alone. Because propofol was reported several times to be inadequate for LMA insertion when used alone and the doses required to make it adequate were reported to be unsafe for haemodynamics and respiration.

The insertion conditions in our study were similar in both groups (Table 2). The respiratory depression in Group F was found to be greater than that in group D when compared in terms of number of patients developing apnoea (67% Vs 40%; $p<0.01$). The duration of apnoea was also significantly, higher in group F. The significantly longer apnoea times in group F compared to group D could be because fentanyl caused more respiratory depression than dexmedetomidine, when given along with propofol. Our results were similar to that reported in another study[21] with respect to changes in respiration. In our study the respiratory rates were significantly lower in group F compared to group D ($p <0.05$). In other studies[21,30] a statistically significant increase in respiratory rate while using dexmedetomidine was reported. However, when a bolus injection of dexmedetomidine was used[29] a slight decrease in respiratory rate was observed. In our study,we also found that there was a statistically significant decrease in respiratory rates within the both groups compared with the base line after induction and till 1 minute after LMA insertion ($p < 0.01$). After that, the respiratory rates were comparable to the base line within the groups and between the groups. The magnitude of fall in respiratory rate from the base line value to that after induction with propofol was more in the fentanyl group (69%) than dexmedetomidine group (35%) and this was also statistically significant ($p<0.01$).

Our study showed that the effects on haemodynamic parameters with regard to blood pressure were better i.e., more stable in group D than in group F. There was a statistically significant reduction from the base line in all the pressures measured since the administration of study drug namely, MAP, SBP and DBP.

Our study has shown that the combination of propofol and dexmedetomidine group provided

similar conditions for LMA insertion which were comparable to that of propofol and fentanyl group. However, the combination of propofol and dexmedetomidine group caused less respiratory depression and more stable haemodynamics compared to propofol and fentanyl group. Similar observation have been reported in another study.[31] So dexmedetomidine appears to be a potential alternative to fentanyl to co-administer with propofol for LMA insertion.

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