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Original Research Article

A Prospective Randomised Study Comparing Proseal-LMA Insertion Conditions Using Fentanyl-Propofol versus Dexmedetomidine-Propofol

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Abstract

Introduction: LMA insertion without use of muscle relaxant requires adequate depth of anesthesia and a certain degree of jaw relaxation. Inadequate depth can lead to coughing, bucking, gagging and laryngospasm. Propofol is commonly used because of its superior jaw relaxation and suppression of airway reflexes. The drawback is apnea due to its respiratory depressant effect and a decrease in cardiac output. A number of adjuvants have been used in an attempt to decrease the dose of propofol and improve LMA insertion conditions.

Aim: The aim of our study was to compare Pro-seal LMA insertion conditions using propofol induction after pre -treatment with either fentanyl or dexmedetomidine. We compared the insertion conditions, the number of attempts needed for successful placement, the dosage of propofol needed and the haemodynamic variables.

Materials & Methods: In this prospective randomized study 320 patients of either sex, ASA I or II, aged 18-60 yr were randomized into two groups: Group FP received fentanyl (2µg/kg diluted in normal saline to a volume of 10ml over 10min) and Group DP received dexmedetomidine (1 µg/kg diluted in normal saline to a volume of 10ml over 10mins). Patients of both groups were given a bolus of Inj. propofol 2mg/kg. Ninety seconds after propofol bolus, jaw thrust was given and LMA Pro-seal insertion was attempted. In case of difficulty, additional bolus of Inj. Propofol 0.5mg/kg was given every 30 seconds till the patient allowed jaw thrust and another attempt at LMA insertion was made. If the placement of LMA was not satisfactory, the LMA was removed, additional propofol bolus of 0.5mg/kg given and insertion reattempted 60 seconds later up to a maximum of three attempts. The overall conditions for LMA insertion were scored as excellent, satisfactory and poor after grading the following: jaw opening, ease of insertion, coughing and gagging, swallowing, patient movement and laryngospasm.

Results: The parametric data like hemodynamic parameters and demographic data were analysed using student's t-test. Non-parametric data such as PLMA insertion conditions and number of attempts were analysed using Chi-square test. $p<0.05$ was accepted as statistically

significant. The Mean insertion score of patients receiving Dexmedetomidine (6.72±0.841) was significantly better than fentanyl (7.08±1.028) (p=.001). There was no significant difference in the number of attempts needed for PLMA insertion. In the fentanyl group, LMA was successfully inserted in first attempt in 148 patients, second in 11 patients and third in 1 patient. With dexmedetomidine, insertion was performed in first attempt in 152 patients, second attempt in 8 patients and no patient required third attempt. The mean propofol dose required in both groups were comparable, fentanyl group (127.75±16.896 mg) v/s Dexmedetomidine group (126±14.845 mg). The difference in the mean heart rate following infusion of study drugs was significant. 76.27±5.123/min in the Fentanyl group v/s 72.7±4.256 /min in the dexmedetomidine group. Immediately after LMA insertion and thereafter at 1,2,3,5,7 and 10min the heart rate in patients, who received Dexmedetomidine was significantly lesser than those who received Fentanyl . The systolic, diastolic, and mean arterial pressures measured at these intervals were also significantly lower in the dexmedetomidine group.

Conclusion: We found the PLMA insertion score to be better with Dexmedetomidine. However, there was no significant difference in the number of attempts of LMA insertion and propofol dose requirement between Dexmedetomidine and Fentanyl groups.

Keywords: Dexmeditomidine Fentanyl, Propofol Pro-seal LMA.

Introduction

The LMA Proseal (PLMA) is a reusable second generation supraglottic airway that is widely used for both spontaneous and controlled ventilation. The depth of anaesthesia needed for LMA insertion is less than that required for endotracheal intubation. [1,2,3] However, a certain amount of jaw relaxation is required for insertion. Sufficient depth of anaesthesia is necessary to avoid coughing, bucking, gagging laryngospasm and haemodynamic perturbations in a non-paralysed patient. Propofol is one of the most useful induction drugs for insertion of LMA because of superior jaw relaxation and suppression of airway reflexes although adjuvants may be needed in many cases [4]. An induction dose of propofol results in a 25-30% incidence of apnoea due to its respiratory depressant effect. Independent of the presence of cardiovascular disease, an induction dose of 2-2.5 mg/kg produces a 25% to 40% reduction of systolic blood pressure. It is associated with a decrease in cardiac output, cardiac index, stroke volume index and systemic vascular resistance.[5] Studies have found that the dosage of propofol needed to achieve conditions satisfactory for LMA insertion was 3.7mg/kg when used alone.[6] In order to decrease the dosage of propofol and improve LMA insertion conditions adjuvants such as opioids, midazolam, ketamine, low dose muscle relaxants, sevoflurane etc have been advocated.[7]

Fentanyl (2µg/kg) reduced propofol requirement by 60%, but significantly increased the duration of apnoea [8]. Prolonged apnoea is undesirable if spontaneous ventilation is planned or duration of surgery is short, hence it is important to use a minimum effective dose. Fentanyl in higher doses is known to cause chest wall rigidity. Dexmedetomidine, a highly selective α-2-adrenoceptor agonist has the advantage of providing sedation & analgesia without causing respiratory depression even at supramaximal plasma levels.[9] It was also shown to diminish airway and circulatory responses during intubation and extubation. [10,11] In doses commonly used dexmedetomidine provides haemodynamic stability.

Our study evaluates the difference in PLMA insertion conditions in patients receiving fentanyl -propofol and dexmedetomidine-propofol. Most studies have used fentanyl in the dose of 1µg/kg. Since we did not obtain satisfactory insertion conditions with this dosage during our pilot cases, we decided to use fentanyl 2µg/kg combined with propofol 2mg/kg and compare it with dexmedetomidine 1µg/kg combined with propofol 2mg/kg. We also compared the variations in heart rate, systolic, diastolic, and mean arterial pressures following study drug infusion and PLMA insertion.

Materials and Methods

This study was initiated after obtaining institutional ethics committee approval. 320 patients in the age group of 18-60 years, either gender, ASA I&II, MPC I&II, undergoing elective minor surgical procedures expected to last not more than two hours were included. Patients with anticipated difficult airway, BMI>30kg/m2, pharyngeal pathology, Low pulmonary compliance, ASA Grade III & IV and history of allergy to study drugs were excluded. Detailed Preanesthetic check was performed a day prior to surgery. Patients were asked to remain nil by mouth at least 6 hr before surgery. After obtaining written informed consent, patients were divided into two groups of 160 each using computer generated randomisation tables. Group FP (fentanyl-propofol) and Group DP (dexmedetomidine- propofol). The anaesthesiologist who prepared the study drug infusions according to the group allotted was not involved in data collection. The investigator and patient were blinded. In the OT, standard ASA monitors were attached and baseline heart rate, sPO2, Systolic, Diastolic and Mean Arterial Pressure was recorded. Ringer's lactate 2ml/kg was started after securing a 20G intravenous line and Glycopyrrolate .004 mg given. Group FP received Fentanyl 2 µg/kg diluted in 10ml normal saline over 10min and Group DP received Dexmedetomidine 1µg/kg diluted in 10ml normal saline over 10mins. After 30 seconds of study drugs**,** propofol 2mg/kg was injected in both groups. Ninety seconds after bolus dose of propofol, an anaesthesiologist who had an experience of inserting at least 50 PLMAs inserted the appropriate size PLMA. If difficulty was encountered an additional bolus of Inj. Propofol 0.5mg/kg was given every 30seconds till the patient allowed jaw thrust and another attempt at LMA insertion was made. Proper placement and ventilation were confirmed by chest expansion and capnograph tracing. If the placement of LMA was not satisfactory, the LMA was removed and additional propofol bolus of 0.5mg/kg was given and insertion reattempted 60 sec later. Anaesthesia was maintained with oxygen-air (50:50) and sevoflurane with spontaneous breathing. If after three attempts LMA insertion was not possible, the airway was secured using an endotracheal tube. For analysis however only the conditions at the first attempt were considered. Nasogastric tube was inserted through gastric access channel. Total dose of propofol required and number of attempts were noted.

Ease of PLMA insertion was scored as Excellent, Satisfactory or Poor using the Modified Scheme of Lund and Stovener .[12] The insertion score was a summation of points allotted to the following parameters.

Jaw opening: full -1 partial -2 nil -3
Ease of insertion: easy-1 difficult-2 impossible -3
Coughing & Gagging: Nil-1 Mild-2 Severe-3
Swallowing: Nil-1 Slight-2 Gross-3
Patient movement: Nil-1 Slight-2 Vigorous-3
Laryngospasm: Nil-1 Mild-2 Severe-3

The overall conditions for LMA insertion were scored as:

Excellent: 6
Satisfactory: 7-10

Poor: >10

Heart rate (HR), Systolic (SBP), Diastolic (DBP) and Mean Arterial (MAP) blood pressure were recorded at following intervals: Baseline, after injection of study drugs, Prior to LMA insertion after drug injection, following insertion of LMA immediately and at intervals of 1, 2,3,5 7 and 10minutes. A similar study by Pal et al reported significant difference in the number of attempts and ease of LMA insertion[13](P=0.044). Considering α error of 5% and power of 80%, the sample size calculated was 150 patients in each group. We included 160 patients taking into consideration dropouts.

Results

Mean and standard deviations of all values were calculated and compared between the two groups. The parametric data like hemodynamic parameters and demographic data were analysed using student's t-test. Non-parametric data such as PLMA insertion conditions and number of attempts were analysed using Chi-square test. Statistical analysis was done using SPSS ver.16 software. P<0.05 was considered as statistically significant.

The two groups were comparable with respect to demographic variables. (Table 1) There was no significant difference in the number of attempts required for successful PLMA placement between the two groups. (Table 2). The LMA insertion score was significantly better in the dexmedetomidine group (6.72±0.841) as compared to fentanyl (7.08±1.028) (P .001) (Table 3).

There was no significant difference between the two groups in the mean propofol dose required for PLMA insertion i.e 127.75±16.896 mg in the fentanyl group versus 126±14.845mg in the dexmedetomidine group. (p=0.326). (Table 3)

The mean baseline HR of patients in the two groups was comparable. There was significant difference after infusion of study drugs. It was 76.27±5.123 /min in the fentanyl group and 72.7±4.256 /min in the dexmedetomidine group. Immediately following LMA insertion as well as 1,2,3,5,7 and 10min post insertion, patients who received fentanyl had a significantly higher heart rate than those receiving dexmedetomidine. (Fig-4)

The mean baseline SBP of patients was comparable. Prior to PLMA insertion, there was significant difference, 111.16±4.497 mmHg in the group given fentanyl and 108.13±5.06 mmHg with dexmedetomidine. Significantly higher mean SBP values were found in the fentanyl group immediately following LMA insertion as well as 1,2,3,5,7 and 10min post insertion. (Fig-5)

The mean DBP of patients was comparable. Prior to LMA insertion, there was significant difference, 72.96±4.42 mm Hg in the group given fentanyl and 69.54±4.107 mmHg with dexmedetomidine. Significantly higher mean DBP values were found in the fentanyl group immediately following LMA insertion as well as 1,2,3,5,7 and 10min post insertion (Fig-6). The MAP in both groups was comparable at baseline and showed a similar trend.(Fig-7).

Table 1: Demographic distribution of patients

	Group Fentanyl-Propofol	Group Dexmeditomidine Propofol	P value
Age (yr)	31.14 ±7.424	30.14±7.32	0.198
Sex M/F	81/79 (50.6%/49.4%)	79/81(49.4%/50.6%)	0.823
Body Mass Index	23.103 ±1.956	23.095 ±1.928	0.969
ASA I/II	137/23(85.6%/14.4%)	144/16 (90%/10%)	0.232
MPC I/II	113/47(70.6%/29.4%)	123/37(76.9/23.1%)	0.204

Data are Mean ±Standard deviation for age and BMI. Absolute numbers with percentage for BMI, ASA and MPC.

Table 2: Number of attempts needed for successful PLMA placement. No significant difference between the groups.

Number of insertion attempts	Group Fentanyl-Propofol	Group Dexmeditomidine-Propofol	P value
1	148(92.5٪)	152 (95.0%)	0.466
2	11(6.9%)	8(5.0%)	
3	1(0.6%)	0	

Table 3: PLMA insertion score expressed as Mean±Standard deviation (SD) significantly better (t -test applied) with dexmedetomidine

	Group Fentanyl-Propofol Mean ±SD	Group Dexmeditomidine-Propofol	P value
PLMA insertion score	7.08±1.028	6.72±0.841	.001
Propofol dosage(mg)	127.75±16.896	126±14.845	0.326

Propofol dosage : no significant difference between the two groups

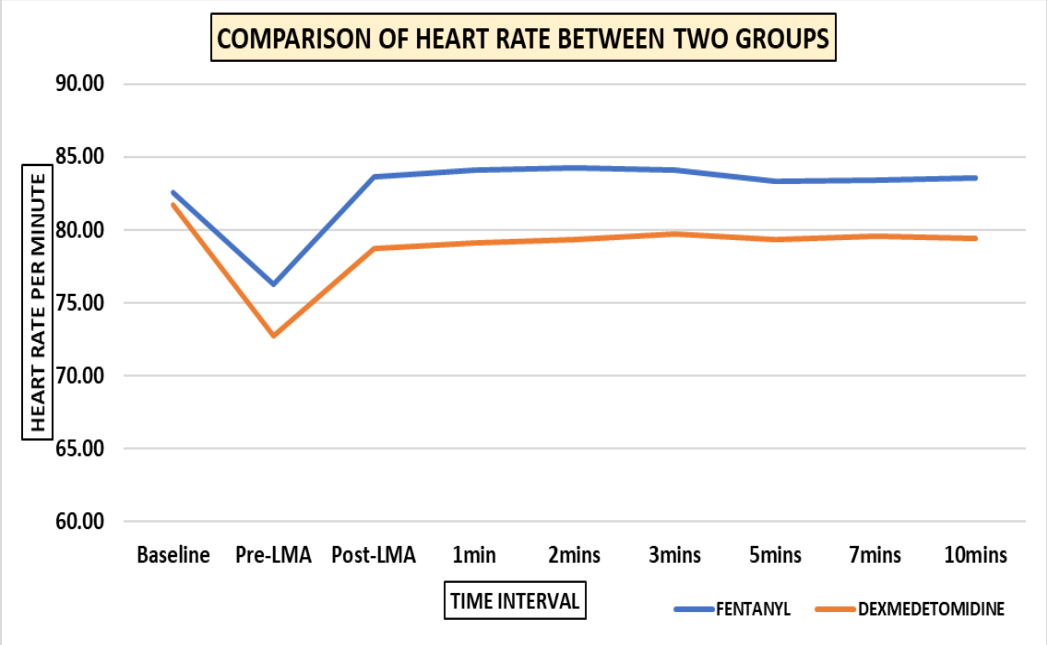

Figure 4: Heart rate recorded at various time intervals

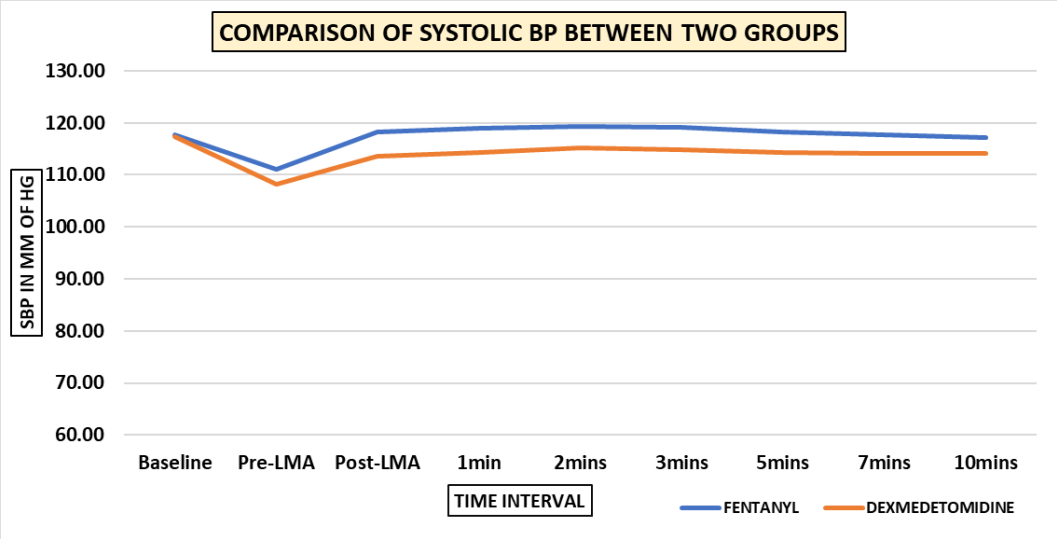

Figure 5: Systolic Blood Pressure recorded at various time intervals

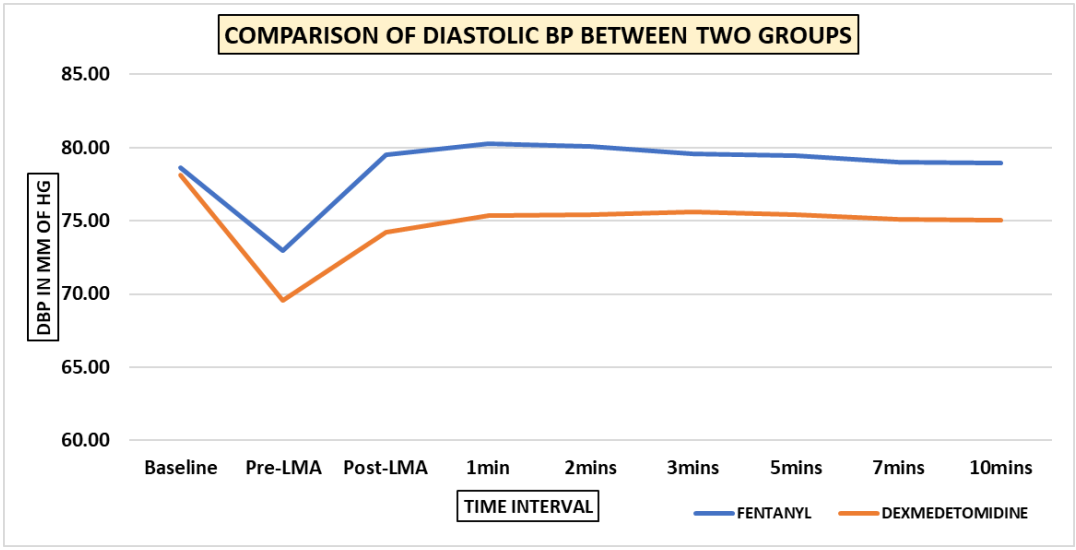

Figure 6: Diastolic Blood Pressure at various time intervals

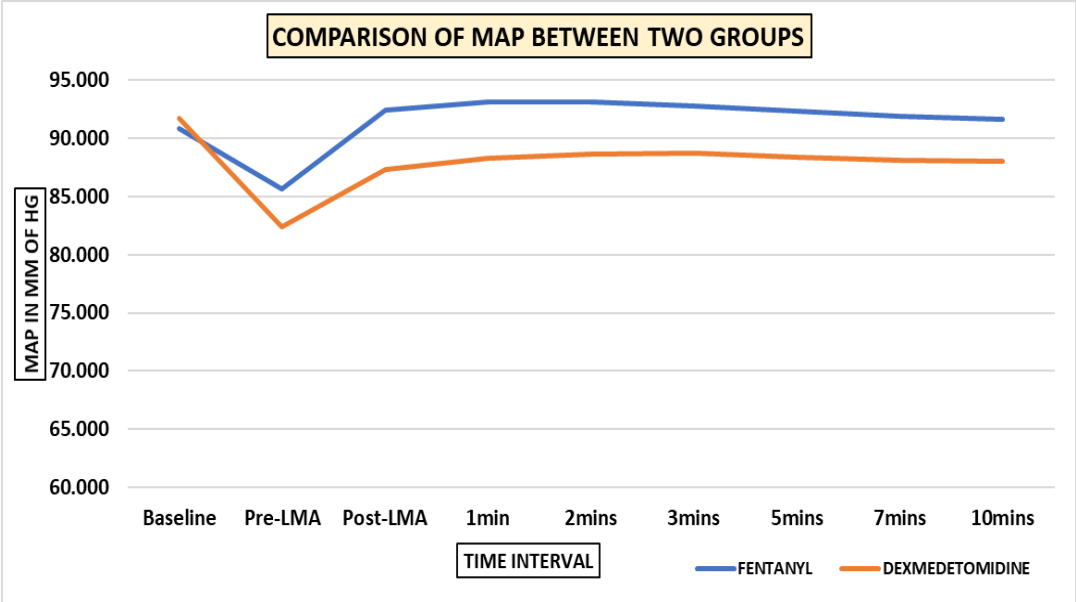

Figure 7: Mean Arterial Pressure recorded at various time intervals.

Discussion

The findings of our study involving 320 patients are that dexmedetomidine 2 µg/kg as pre-treatment before propofol provided better Proseal LMA insertion conditions as compared to fentanyl 2µg/kg. However, there was no difference in the number of insertions attempts or the total dose of propofol needed for insertion. Wong CM et al have studied 0.5, 1.0, 1.5 and 2.0 ug /kg fentanyl with 2.5 mg /kg propofol for LMA insertion [14]. Their results showed that a standard fentanyl dose of 1 ug /kg co-administered with propofol 2.5 mg /kg, provided optimal conditions in 65% of cases only. Optimal dose of dexmedetomidine for attenuating pressor response seems to be 1 µg /kg with lesser doses not being effective.[15] In our pilot study, we found that fentanyl 1µg/kg did not provide suitable insertion conditions, hence we compared fentanyl 2 µg /kg with dexmedetomidine 1µg/kg.

The Proseal LMA insertion score calculated by grading parameters i.e jaw opening, ease of insertion, coughing and gagging, swallowing, laryngospasm and patient movement was significantly better with dexmedetomidine as compared to fentanyl. In a similar study

Rustagi PS et al found insertion conditions with i-gel to be comparable between the two groups [16]. They found incidence and duration of apnoea to be higher in patients who received fentanyl 1µg/kg as compared to dexmedetomidine 2 µg/kg. Ramaswamy & Shaikh also found acceptable insertion conditions but significantly longer apnoea duration with fentanyl[17]. Many studies have found the respiratory depressant effect of propofol to be compounded by fentanyl but not dexmedetomidine.

In our study the number of attempts required to insert the LMA were comparable. It was inserted at the first attempt in 92.5% in the fentanyl group versus 95.0% in the dexmedetomidine group. Second attempt was required in 6.9% with fentanyl versus 5.0% with dexmedetomidine. One patient in the fentanyl group but none in the dexmedetomidine group needed a third attempt. Gupta et al compared LMA insertion conditions with ketamine - propofol, fentanyl- propofol and butorphanol-propofol [18]. They found lesser incidence of coughing with butorphanol as compared to ketamine and propofol due to the antitussive action of butorphanol.

We did not find a significant difference in the total dose of propofol used, 127.75±16.896 mg in the fentanyl group versus 126±14.845 mg in the dexmedetomidine group. This was in contrast to the findings of Rustagi et al and Nellore et al who found significantly higher total dose of propofol needed for LMA insertion[16,19]. This was probably because they used a lower dose of fentanyl 1µg/kg while we used 2µg/kg.

Dexmeditomidine exhibits sedative and analgesic properties due to its action on α-2adrenoceptors in locus ceruleus and dorsal horn of the spinal cord. Despite use of same analgesics in both groups, Hall et al found significantly lower postoperative pain scores with dexmedetomidine as compared to fentanyl.[20] Choudhary et al found post operative Visual Analogue Scores to be significantly lower with dexmedetomidine.[21] Although emergence times were longer, spontaneous breathing and oxygen saturation were maintained. We did not study sedation and analgesic requirement.

Dexmedetomidine at lower concentrations decreases blood pressure due to central sympatholytic effects while at higher concentrations, peripheral vasoconstriction causes blood pressure to rise. Transient hypertension during initial infusion can give rise to reflex bradycardia.[22] In adults at plasma concentrations >1-3ng/ml, cardiac output decreased by 35% and heart rate decreased by 16-30%, but stroke volume remained stable at plasma

concentration <5ng/ml. Fentanyl has been widely used to blunt sympathetic response. With doses of 2-5 mcg/kg, heart rate and arterial pressure usually remains stable. Higher doses may be associated with hypotension, bradycardia and reduced systemic vascular resistance.

We found that compared with the baseline, decrease in the heart rate was significant in patients receiving dexmedetomidine as compared to fentanyl. Immediately following LMA insertion and 1,2,3,5,7 and 10min later, patients in the dexmedetomidine group continued to have significantly lower heart rate than those receiving fentanyl. The systolic and diastolic blood pressure values followed a trend like the heart rate.

Choudhary et al found a significant reduction in heart rate at all study intervals in the dexmedetomidine group. The drop in SBP and MAP were statistically significant only at 1 min after PLMA insertion but not thereafter. In contrast to our study Jayaram et al found significantly lower values of Heart Rate, SBP, DBP and MAP (P<0.001) in the fentanyl group throughout.[23] Nellore et al found no difference in heart rate and MAP variations between both groups.

Suparto et al compared fentanyl and dexmedetomidine for attenuating intubation response.[24] While the mean heart rate was 18% higher than baseline in the fentanyl group, it returned to lower than baseline 60 sec after intubation in the dexmedetomidine group. Moreover, the rise in SBP was 40% in the fentanyl as compared to 25-28% in the dexmedetomidine group.

Our study found dexmedetomidine to be a suitable co induction agent with propofol for insertion of Proseal LMA. While dexmedetomidine provided better insertion conditions and hemodynamic stability, there was no difference in the number of insertions attempts and propofol consumption. The limitation of our study is that we included patients with MPC I & II only and ASA I &II. Since we did not have the BIS monitor at the time of our study, depth of anaesthesia was not monitored during LMA insertion.

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