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ORIGINAL ARTICLE

Randomised Comparative Study of Nalbuphine-Propofol Versus Fentanyl-Propofol For Proseal Laryngeal Mask Airway Insertion

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Abstract

Background: The purpose of the study was to compare the Proseal laryngeal mask airway(PLMA) insertion conditions and haemodynamic changes by using either Nalbuphine-propofol or Fentanyl-propofol. **Material and Methods:**-60 ASA Grade 1 and 2 patients of age group 20-60 years, scheduled for general anesthesia were randomly allocated in two groups of 30 each. Group N received Nalbuphine 0.2mg/kg i.v and Group F received Fentanyl 2mcg/kg. Assessment of LMA insertion was done using 6 variables: resistance to mouth opening, gagging, swallowing, head and limb movements, laryngospasm and resistance to insertion. Incidence and duration of apnea were recorded. Patients cardiorespiratory parameters, postoperative sedation score and complications if any were recorded. **Results:**-The demographic profile was comparable in all the groups . The incidence of coughing /gagging was higher in group F as compared to group N (p=0.031). Swallowing was also statistically significant (p=0.034), being higher in group N as compared to group F. Limb movements followed the same pattern being higher in group F compared to group N (p=0.032). Laryngospasm was not seen in both the groups. The apnea duration was more in group F as compared to group N and was statistically significant (p<0.001). There was statistically significant Rise in heart rate and MAP in group F as compared to group N at 1st and 3rd minute. After PLMA insertion postoperative complications were statistically insignificant.**Conclusion:**-The use of Nalbuphine-Propofol combination provides better PLMA insertion conditions with greater haemodynamic stability as compared to Fentanyl-propofol combination.

Key Words

Nalbuphine , Fentanyl, Proseal laryngeal mask airway(PLMA), propofol

Introduction

The laryngeal mask airway (LMA) has gained widespread popularity for airway management during surgery. [1-4] Proseal laryngeal mask airway (PLMA) is a modification of the classic laryngeal mask airway (CLMA) that incorporates a drain tube ending at the tip of the mask so that there are less chances of aspiration. [5] Use of muscle relaxant is not a must for PLMA insertion although a certain degree of jaw relaxation and depth of anesthesia is required. [6] PLMA can be used as a safe and effective alternative airway device to endotracheal intubation. [7] Propofol is a useful agent for PLMA insertion because of its good jaw relaxation and suppression of airway reflexes. [8] A variety of adjuvants have been tried which can ease LMA insertion e.g Butorphanol [9] , Dexmedetomidine [10] fentanyl [11] , Intravenous lignocaine

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[12], muscle relaxants [13] but none have been found to be ideal. In this study, the combination of propofol and fentanyl was compared to the combination of propofol and nalbuphine to assess PLMA insertion conditions, haemodynamic changes, duration of apnea, complications if any and postoperative sedation score.

Material and Methods

After approval from Hospital Ethical Committee [No. IEC/GMC JAMMU/2019/881 dated 26-12-2019] an informed written consent of 60 patients of either gender,20- 60years of age,ASA grade 1& 2, scheduled for surgeries under general anesthesia were randomly selected and divided into two groups of 30 each. Exclusion criteria included BMI < 35kg/m², Patients with known or predicted difficult airway, cervical pathology, with known allergy to study drugs, with known h/o seizures, neuromuscular, cardiovascular, hepatic or renal disease, respiratory tract pathology and surgery more than 3hours.The patients were prepared by overnight fasting and were premedicated with Tab. Alprazolam 0.25mg orally night before surgery. On the morning of surgery, intravenous line was secured with an appropriate sized venous cannula and Ringer lactate infusion was started. 30mins before the surgery patient received Inj. Pantoprazole 40mg iv, Inj. Ondansetron 4mg iv and Inj. Glycopyrolate 0.2mg im. Baseline parameters like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure , oxygen saturation and end tidal carbon dioxide were monitored continuously.

Patients in group N received Inj.Nalbuphine 0.2mg/kg iv (diluted to 10ml) over 10sec.Patient in group F received Inj.Fentanyl 2mcg/kg iv [diluted to 10ml] given over 10 secs. Then, they were preoxygenated for 3mins followed by Inj.Propofol 2mg/kg iv (with 0.5ml Xylocard) which was given over 15secs.Ventilation of the patient was assisted for 60secs with 100% oxygen after which Proseal LMA insertion was done.Appropriate size LMA was inserted by the anesthetist. In case of LMA malposition or malfunction, it was removed, and a further dose of Propofol (1 mg/kg) was given. 60 secs later reinsertion was attempted. Endotracheal intubation was carried out after 2 unsuccessful trials of Proseal LMA insertion and the patient was excluded from the study. Once the proseal LMA was successfully inserted, cuff was inflated with air of adequate volume and was fixed by taping it over the chin. A 14 french orogastric tube was then inserted into the drain tube of Proseal LMA.

Based on six variables on a 3 point scale PLMA insertion criteria were assessed as follows: [14]

1. Resistance to mouth opening: Nil/Slight/Gross
2. Resistance to insertion: Nil/Slight/Gross
3. Swallowing: Nil/Slight/Gross
4. Coughing/gagging: Nil/Slight/Gross
5. Limb/head movements: Nil/Slight/Gross
6. Laryngospasm: Nil/Slight/Gross.

HR, MAP, SPO2 was recorded immediately after LMA insertion. Duration of Apnea was also noted and ventilation was assisted manually until regular spontaneous respiration resumed. Anesthesia was maintained with 66% Nitrous, 33% oxygen and 0.5-1% Halothane (to achieve MAC 1). Muscle Relaxation was achieved with Inj.Atracurium 0.5mg/kg iv followed by maintenance with incremental doses of inj.Atracurium 0.1mg/kg. Intraoperatively monitoring was done by recording HR, MAP and SpO2 at 1 min, 3mins, 5 mins and then after every 15mins uptill the end of the surgery. At the end of procedure, neuromuscular blockade was antagonised by inj.neostigmine 50 mcg/kg and inj.glycopyrrolate 10mcg/kg. 100%oxygen was given before emergence. After removal of LMA, level of sedation was assessed using Ramsay Sedation Score and complications if any were noted.

Statistical Analysis

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were expressed as Mean±SD and categorical variables were summarized as frequencies and percentages. Graphically the data was presented by bar diagrams and line diagrams. Student's independent t-test was employed for comparing continuous variables. Chi-square test or Fisher's exact test, whichever appropriate, was applied for comparing categorical variables. A P-value of less than 0.05 was considered statistically significant. All P-values were two tailed.

Result

Demographic characteristics including age, weight, height, male/female ratio and duration of surgery were not significantly different (P > 0.05) between F and N groups (*Table 1*).

Table 2 shows that the incidence of resistance to mouthopening and resistance to PLMA placement was statistically insignificant in both the groups N and F.

A statistically significant difference was detected between the two groups (P = 0.031) as regards coughing/gagging being higher in the F group compared to the N group.

The incidence of swallowing was significantly (P = 0.034) higher in F group , compared to N group.Limb moving followed the same pattern being higher in the F group compared to the N group. This difference was statistically significant (P = 0.032). Laryngospasm was not seen in

Table 1. Demographic Data of Patients in Two Groups

Parameter	Group N (n=30)	Group F (n=30)	P Value
Age (years)	33.8± 5.87	34.9± 5.4	0.26
Sex (M/F)	16/14	13/17	0.29
Weight (kg)	57.10± 7.99	55.23± 6.90	0.17
ASA Grade (I/II)	13/17	18/12	0.28
Duration of Surgery (min)	76± 0.36	81± 0.36	0.12

Table 2. Conditions during LMA placement in two groups

Conditions during LMA Placement		Group N		Group F		P-value
		No.	%age	No.	%age	
Resistance to mouth opening	Nil	28	93.3	27	90.0	0.641
	Slight	2	6.7	3	10.0	
	Gross	0	0.0	0	0.0	
Resistance to placement	Nil	28	93.3	27	90.0	0.839
	Slight	1	3.3	2	6.7	
	Gross	1	3.3	1	3.3	
Coughing or Gagging	Nil	23	76.7	13	43.3	0.031*
	Slight	6	20.0	14	46.7	
	Gross	1	3.3	3	10.0	
Swallowing	Nil	25	83.3	16	53.3	0.034*
	Slight	4	13.3	13	43.3	
	Gross	1	3.3	1	3.3	
Movement	Nil	27	90.0	19	63.3	0.032*
	Slight	3	10.0	11	36.7	
	Gross	0	0.0	0	0.0	
Laryngospasm	Nil	0	0.0	0	0.0	1.000
	Slight	0	0.0	0	0.0	
	Gross	0	0.0	0	0.0	

Table 3. Comparison based on duration of apnea (seconds) in two groups

Duration of apnea (Seconds)	N	Mean	SD	Range	P-value
Group N	30	123.8	4.65	116-132	<0.001*
Group F	30	209.2	12.96	180-228	

Table 4. Comparison based on intera-operative heart rate (beats/min) in two groups

Time Interval	Group N		Group F		P-value
	Mean	SD	Mean	SD	
Baseline	87.63	5.130	86.40	5.367	0.381
After LMA Insertion	92.07	5.305	96.23	7.568	0.016*
1 Min	91.80	4.937	95.07	6.433	0.035*
3 Min	90.03	4.727	94.20	6.713	0.007*
5 Min	89.70	4.858	91.37	9.166	0.402
15 Min	88.63	4.553	86.13	9.576	0.208
30 Min	87.57	3.893	85.03	8.915	0.172
45 Min	87.40	3.756	84.07	9.976	0.086
60 Min	87.57	4.166	84.80	9.506	0.217
75 Min	86.11	3.887	85.90	4.711	0.909

either group.LMA insertion score in Group N ranged from 14-18 with a mean SD of 16.7 ± 1.143 and in Group F it ranged from 10-14 with a mean SD of 12.3 ± 1.337.

Table 3 shows duration of apnea was more in Group F as compared to Group N and it was statistically significant.(p<0.001)

Table 5. Comparison based on intera-operative mean arterial pressure (mmHg) in two groups

Time Interval	Group N		Group F		P-value
	Mean	SD	Mean	SD	
Baseline	94.60	4.903	93.20	5.261	0.291
After LMA Insertion	96.20	4.498	100.53	6.318	0.003*
1 Min	95.83	5.038	98.20	3.662	0.042*
3 Min	94.37	3.899	97.13	3.963	0.008*
5 Min	94.10	4.574	95.47	4.416	0.244
15 Min	93.13	5.643	92.80	3.800	0.789
30 Min	93.57	4.133	93.93	4.472	0.743
45 Min	92.57	4.569	93.17	5.173	0.636
60 Min	93.76	4.206	93.60	5.210	0.907
75 Min	93.11	5.110	92.61	6.194	0.836

Duration of apnea in Group F ranged from 180-228 seconds whereas in Group N it ranged from 116-132 seconds.

Table 4 showed that in both the group N and F, heart rate went higher than baseline values immediately after PLMA insertion , at 1st min and 3rd min after PLMA placement, this diffrence was statistically significant. then, gently dropped below baseline values after minute 5 and were statitically insignificant in both the groups.

Table 5 shows variation in MAP.Immediately after LMA insertion, the MAP in both the groups increased from basal values and was statistically significant.(p=0.003). Rise of mean arterial pressure at 1 min. and 3rd minute after LMA was high in Group F as compared to Group N and the difference was statistically significant with p values of 0.042 and 0.008 respectively. 5min after LMA insertion, the mean arterial pressure values in both the groups began to return to the baseline and thereafter,they were statistically insignificant in both the groups till the end of the surgery.

The mean SpO2 in Group N and Group F were statistically insignificant. Total of 18 patients have shown complications post operatively out of 60 patients. In Group N, 10% of the patients had nausea and in Group F 16.7% had nausea. Pain and sore throat was seen only in Group F. These differences were statistically insignificant.

Discussion

The present study was designed to compare the clinical efficacy of Nalbuphine and Fentanyl, when given 3minutes before induction with regards to ease of insertion of PLMA and attenuation of pressor response. Duration of apnea, post operative sedation score, as well as post operative complications, if any, were also studied. The significance of the study lies in selection of the better drug of the two (Nalbuphine or Fentanyl) to achieve the favourable conditions for PLMA insertion.

The following parameters were studied: Ease of insertion of PLMA:-This study showed that the combination of Nalbuphine and propofol is better than the combination of Fentanyl and Propofol for PLMA insertion. The ease of insertion scoring was done using 6 variables 3 point scoring system. These variables were: cough/gagging; swallowing; limb movement; laryngospasm; mouth opening and resistance to insertion.

Coughing and gagging were observed more in Group F as compared to the Group N, the difference was satistically significant (p value=0.031). This observation was in accordance with study conducted by Salman OH *et al*. [15]

Another study by Wong *et al*, [16] demonstrated that higher dose of fentanyl was associated with coughing. Moreover, antitussive action of Nalbuphine might have attributed to the low incidence observed in Nalbuphine compared to Fentanyl group.

Patients in Group N showed less swallowing (p- value= 0.034) and less limb movement (p-value= 0.032) than those in Group F. The difference in both these were statistically significant. Centrally acting drugs such as Fentanyl and Nalbuphine would be expected to affect central respiratory network and consequently may have resulted in a dose related network change of nasopharyngeal airway reflexes. [17,18] Nalbuphine is an agonist on kappa receptors and antagonist on mu receptors, whereas, Fentanyl exerts full agonist activity on mu and kappa receptors which might directly or indirectly participate in less incidence of swallowing and movement. These findings were in accordance with a study conducted by Salman OH *et al*, 2015. [15]

Resistance to mouth opening and placement of LMA was seen more in Group F as compared to Group N but the difference was statistically insignificant. Thus the above variables resulted in a better score for ease of insertion of LMA in Group N than in Group F and the difference was statistically significant (p value<0.001). Duration of apnea:-A significant difference was also detected between the 2 groups as regards higher duration of apnea

in Group F as compared to Group N . This was statistically significant with a p value of <0.001. This is to be expected because intravenous fentanyl is known to cause apnea whereas Nalbuphine has limited respiratory depression action owing to its mu receptor antagonism. Salman OH *et al* 2015[15] did a study comparing Nalbuphine and fentanyl and its results were in accordance to our study.

Effect on heart rate:-In the present study, Nalbuphine and Fentanyl were given 3 minutes before induction. There was statistically significant increase in heart rate in Group F as compared to Group N till 3rd minute after LMA insertion:- Chawda *et al*, 2010 [19] did a study in which he compared Nalbuphine with the placebo group and found that Nalbuphine given 3-5 minutes before laryngoscopy and intubation prevented significant rise in heart rate. The findings of this study is in accordance to our study. Hussain *et al*, 2005 [20] in their study found that fentanyl when given 2 minutes prior to laryngoscopy failed to protect against elevation of both heart rate and systolic blood pressure. As per these studies, Fentanyl should have been given 5 miutes prior to LMA insertion for optimal suppression of cardiovascular response. So, this may be the reason that we have not obtained adequate suppression of cardiovascular response as we have given it 3minutes prior to induction. Kulkarni AG *et al*, [21] did a study with Nalbuphine-Propofol and Dexmedetomidine-Propofol for LMA insertion and hemodynamics and found Nalbuphine to be a better alternative to dexmedetomidine for LMA insertion and providing stable hemodynamics. Ramaswamy AH *et al*, [22] did a comparison between Dexmedetomidine-Propofol and Fentanyl- Propofol and found Dexemedomidine to be superior to Fentanyl for LMA insertion and stable hemodynamic. These studies mentioned above were in accordance to our study. After 5 minutes, the heart rate in both the groups returned to baseline and difference was statistically insignificant.

Effect on Mean arterial pressure:-Mean arterial pressure is a derived value and is important in relation to the auto-regulatory responses of the heart, brain and kidneys. There was significant rise in MAP in Group F as compared to Group N immediately after LMA insertion till 3rd minute. This finding was in accordance with the study conducted by Chawda *et al*, 2010 [19] who found that Nalbuphine in the dose of 0.2mg/kg, 3-5 mins before laryngoscopy and intubation prevented its associated hemodynamic response.

Thus, this can be the reason for inadequate suppression. Channaiah *et al.* [23] noted in their study that inter group MAP yielded significant attenuation in the Fentanyl group for all recorded time periods. This study was in contrast to our study. In the present study, the two study groups were comparable and statistically significant after LMA insertion till 3rd minute and thereafter they were statistically insignificant.

Changes in SpO2:-Mean SpO2 at the baseline were 98.90 and 99.13 % in Nalbuphine and Fentanyl group, respectively and they didnot show any statistical significance at any part of the study.

Ramsay sedation score:-Ramsay sedation score was used for assessment of sedation and analgesia post operatively. Grading was done from GRADE 0 to GRADE 3 .Both the groups usually fell under Grade 0 (Patient was fully awake) and Grade 1 (Patient was drowsy). The difference was statistically insignificant. Though, Patients under Group N showed better Ramsay grading which can be due to long duration of analgesic effect of Nalbuphine (3-6 hrs) as compared to Fentanyl (45-60mins). Khan FA *et al*, [24] compared fentanyl and nalbuphine in TIVA and concluded that nallbuphine provided better post operative analgesia.

Post operative complications:-Nausea, vomiting, pain and sore throat were the main complications encountered but in a very few patients and were statistically insignificant. These can be attributed to the pharmacology of the respective drugs. Pain and sore throat were observed only in Group F which may be due to short duration of action of fentanyl and due to less anti-tussive action of Fentanyl as compared to Nalbuphine.

Conclusion

Propofol-nalbuphine combination is better than propofol-fentanyl combination in terms of ease of insertion of proseal laryngeal mask airway (PLMA) and hemodynamic stability with minimal side effects.

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Conflicts of Interest
There are no conflicts of interest.

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