

ORIGINAL RESEARCH

Nalbuphine-Propofol versus Butorphanol-Propofol for insertion of Proseal Laryngeal Mask Airway: A randomized prospective study**Dr. Hitesha Gurttoo¹, Dr. Neha Sharma², Dr. Ajay Gupta³**^{1,2,3}Department of Anesthesiology and Critical Care, GMC Jammu, India**Corresponding Author**

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Abstract

Background: A second-generation supraglottic airway called the Proseal Laryngeal Mask Airway (PLMA) is made to better seal with the digestive and respiratory tracts. Propofol works well for PLMA insertion because it reduces airway reflexes and has good jaw relaxing qualities. The objective of the present paper is to compare the proseal-laryngeal mask airway insertion conditions and to assess the hemodynamic response of patients using either propofol-nalbuphine or propofol-butorphanol combination. **Methods:** This study has been conducted in the Department of Anaesthesiology and Intensive Care, Govt. Medical College, Jammu. After obtaining the approval from the Hospital Ethical Committee, an informed written consent was taken from patients of either gender, ranging from 20-60 years of age, belonging to ASA grade 1 & 2, scheduled for surgeries under general anaesthesia. A total of 60 patients were randomly allocated into 2 groups with 30 patients in each group. **Results:** The present study revealed a significant difference between the groups with respect to swallowing, Coughing or Gagging and movement with a p-value of 0.007*, 0.028* and 0.046* respectively. The average proseal LMA score in group N was significantly better (17.3 ± 0.94) compared to group B (15.7 ± 1.67). SBP, DBP, MAP, EtCo₂ and SPO₂ were comparable between the groups but group N had significantly smaller average apnea duration compared to group B (121.3 vs 142.7) seconds with a p-value of <0.001*. **Conclusion:** In conclusion, compared to butorphanol-propofol, nalbuphine-propofol can provide better insertion conditions with stable hemodynamics during PLMA insertion.

Keywords: Proseal laryngeal mask, nalbuphine, propofol, butorphanol

Introduction

A second-generation supraglottic airway called the Proseal Laryngeal Mask Airway (PLMA) is made to better seal with the digestive and respiratory tracts. The device's second tube enables a second sealed junction against the upper esophageal sphincter, providing continuity with the digestive system and separating it from the airway. Although PLMA insertion requires a specific degree of jaw relaxation and anaesthesia depth, as a secure and effective airway technique, PLMA can take the place of endotracheal intubation. If sufficient jaw relaxation and inhibition of airway reflexes are not achieved, undesirable effects as gagging, swallowing, coughing, laryngospasm, and movements of the head and limbs may occur during inserting PLMA.¹ Propofol works well for PLMA insertion because it reduces airway reflexes and has good jaw relaxing qualities. Propofol must be used in much higher doses for effective insertion when taken alone, which could lead to unfavourable cardio-respiratory

depression.^{2,3} To help in the smooth insertion of CLMA, various adjuvants including opioids, benzodiazepines, muscle relaxants, ketamine, and dexmedetomidine have been recommended. Dexmedetomidine and fentanyl in a dose of 1 g/kg are both equally efficient and secure adjuvants for CLMA insertion, according to prior research.^{4,5} Nevertheless, there are surprisingly few studies comparing the effectiveness of these often employed adjuvants for PLMA insertion, which necessitates a deeper level of anaesthesia. Drugs like butorphanol and nalbuphine are synthetic mixed agonist antagonist opioid analgesic. These medications benefit from being easily accessible and have fewer side effects in terms of nausea, vomiting, respiratory depression, and addiction. Additionally, no pruritus nor urine retention are brought on by these mixed agonist antagonists. These medications offer appropriate analgesia with little or minimal cardiovascular effects.⁶⁻⁷

The objective of the present paper is to compare the proseal-laryngeal mask airway insertion conditions and to assess the hemodynamic response of patients using either propofol-nalbuphine or propofol-butorphanol combination.

Material and methods

This study has been conducted in the Department of Anaesthesiology and Intensive Care, Govt. Medical College, Jammu. After approval from the Hospital Ethical Committee, an informed written consent was taken from 60 patients of either gender, ranging from 20-60 years of age, belonging to ASA grade 1 & 2, scheduled for surgeries under general anaesthesia. A detailed history, thorough physical and systemic examination and all routine and relevant investigations were recorded. Demographic profile including age, sex, height and weight was recorded. Body Mass Index was calculated. Airway examination was carried out a day before surgery.

Exclusion criteria

- BMI<35kg/m²
- Patients with known or anticipated difficult airway.
- Any cervical pathology and pathologic abnormality within the oral cavity
- or pharynx,
- Patients with known allergy to study drugs.
- Patients with known h/o seizures, neuromuscular, cardiovascular, hepatic
- or renal disease.
- Surgery whose duration was more than 3 hours.
- Respiratory tract pathology.
- Contraindications to the use of PLMA.

Patient groups

Patients were randomly allocated into 2 groups. Each group included 30 patients. The patients were prepared by overnight fasting and were premedicated with Tab. Alprazolam 0.25 mg and Tab Pantoprazole 40 mg 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. 30 mins before the surgery patient will receive Inj. Pantoprazole 40 mg i/v, Inj. Ondansetron 4mg i/v and Inj. Glycopyrrolate 0.2mg i/m. Monitors like ECG, Non-Invasive Blood Pressure and Pulse-oximeter was attached to the patient. All baseline parameters like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and oxygen saturation were recorded.

- In Group N; Patient received Inj. Nalbuphine 0.2mg/kg i/v (diluted to 10ml) over 10 secs. Then they was preoxygenated with 100% O₂ for 3 mins followed by Inj. Propofol 2mg/kg i/v which was given over 15 secs.
- In Group B; Patient received Inj. Butorphanol 30mcg/kg i/v (diluted to 10ml) given over 10 secs. Then, they was preoxygenated with 100% O₂ for 3 mins followed by Inj. Propofol 2mg/kg i/v which was given over 15 secs.

Ventilation of the patient was assisted for 60secs with 100% oxygen after which PLMA insertion was done. Before insertion, PLMA was prepared by using a water soluble jelly, then an appropriate sized PLMA will then be inserted by an anesthetists. Once the PLMA is successfully inserted, cuff was inflated with air of appropriate volume for that size and was fixed by taping it over the chin. After insertion of PLMA, correct placement was confirmed by bilateral symmetrical chest expansion on manual ventilation, breath sounds on auscultation, waveform on capnography, no audible leak of the gases and no gastric insufflations. In case of PLMA 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 is to be carried out after 2 unsuccessful trials of PLMA insertion and that patient was excluded from the study. An appropriate frenchorogastric tube was inserted into the drain tube of PLMA.

HR, MAP, etco₂ and SPO₂ was recorded immediately after PLMA insertion. Duration of apnea was also noted and ventilation is to be assisted manually until regular spontaneous respiration resumes. Anesthesia is to be maintained with 66% nitrous oxide, 33% oxygen and 0.5-1% Halothane (to achieve MAC1). Muscle Relaxation was achieved with Inj. Atracurium 0.5mg/kg i/v following maintenance with incremental doses of inj. Atracurium 0.1mg/kg. Intraoperatively monitoring was done by recording HR, MAP, etco₂ and SpO₂ at 1 min, 3 mins, 5 mins and then after every 15 mins until the end of the surgery. At the end of procedure, neuromuscular blockade was antagonized by inj. neostigmine 50 microgram/kg and inj. glycopyrrolate 10 microgram/kg. 100% oxygen was given before emergence.

Parameters

Insertion criteria

An insertion criterion was based on six variables on 3 point scales for LMA insertion:

Resistance to mouth opening

- Resistance to insertion
- Swallowing
- Coughing/gagging
- Limb/head movements
- Laryngospasm

A score of 3 was given to Nil, 2 was given to Slight and 1 was given to Gross. Total score of 18 considered as excellent, 16-17 as satisfactory and below 16 as poor.

Duration of apnea:

Duration of apnea in secs was noted following adm. of study drugs.

Hemodynamic Changes:

Hemodynamic Changes: Baseline Heart rate, mean arterial pressure, SPO₂ was recorded after PLMA insertion at 1 min, 3 mins and 5 mins after LMA insertion. Thereafter, it was recorded every 15 mins till the end of surgery.

Statistical Methods

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 \pm SD and categorical variables were summarized as frequencies and percentages. Graphically the data was presented by bar line diagrams. Student's independent t-test or Mann-Whitney U-test, whichever feasible, 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

Results

We observed that age, gender distribution, weight and ASA status were comparable between the two groups and the difference was not statistically significant. Group N patients ranged from 20 to 60 years with the mean of (41.2 \pm 12.2) years, while age of Group F ranged from 21 to 60 years with an average age of (42.5 \pm 12.82) years. Evidently, both the groups were statistically comparable with a p-value of 0.682. The proportion of males was slightly higher in both the groups. However, statistically both the groups were comparable with a p-value of 0.598. The average weight of studied patients in group N was higher compared to group B patients (64.2 \pm 10.16) kg vs. (63.4 \pm 9.55) kg. However, both the groups were comparable with a p-value of 0.763. Around 73.3% of patient in group N had ASA I status compared to 76.7% of group B patients. In group N, 26.7% of the patients had an ASA II status, compared to 23.3% in group B. However, statistical comparisons between the two groups revealed an insignificant difference.

Table 1: Comparison based on proseal LMA insertion conditions in two groups						
Proseal LMA insertion conditions		Group N		Group B		P-value
		No.	%age	No.	%age	
Resistance to mouth opening	Nil	29	96.7	26	86.7	0.353
	Slight	1	3.3	4	13.3	
	Gross	0	0.0	0	0.0	
Resistance to placement	Nil	28	93.3	25	83.3	0.374
	Slight	1	3.3	4	13.3	
	Gross	1	3.3	1	3.3	
Swallowing	Nil	27	90.0	16	53.3	0.007*
	Slight	3	10.0	13	43.3	
	Gross	0	0.0	1	3.3	
Coughing or Gagging	Nil	24	80.0	14	46.7	0.028*
	Slight	5	16.7	13	43.3	
	Gross	1	3.3	3	10.0	
Movement	Nil	27	90.0	19	63.3	0.046*
	Slight	3	10.0	10	33.3	
	Gross	0	0.0	1	3.3	
Laryngospasm	Nil	30	100	30	100	1.000
	Slight	0	0.0	0	0.0	
	Gross	0	0.0	0	0.0	

Proseal LMA insertion conditions were compared between the groups, wherein we observe that both the groups were comparable with respect to resistance to mouth opening, resistance to placement and laryngospasm. However, there was a significant difference between the

groups with respect to swallowing, Coughing or Gagging and movement with a p-value of 0.007*, 0.028* and 0.046* respectively

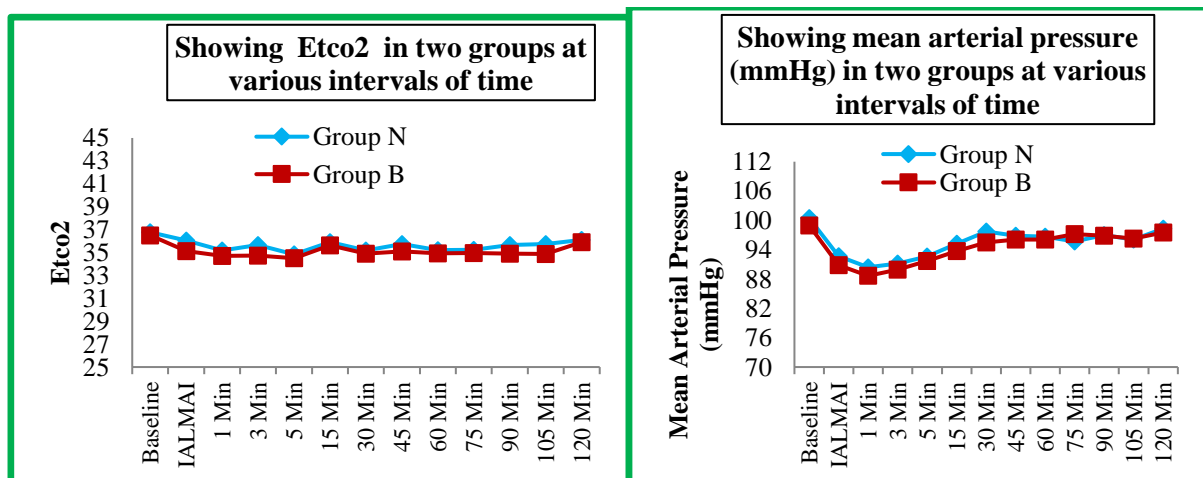
Table 2: Comparison based on proseal LMA insertion score in two groups					
Proseal LMA insertion score	Group N		Group B		P-value
	No.	%age	No.	%age	
Excellent	22	73.3	11	36.7	<0.001*
Satisfactory	7	23.3	12	40.0	
Poor	1	3.3	7	23.3	
Total	30	100	30	100	
Mean±SD	17.3±0.94		15.7±1.67		

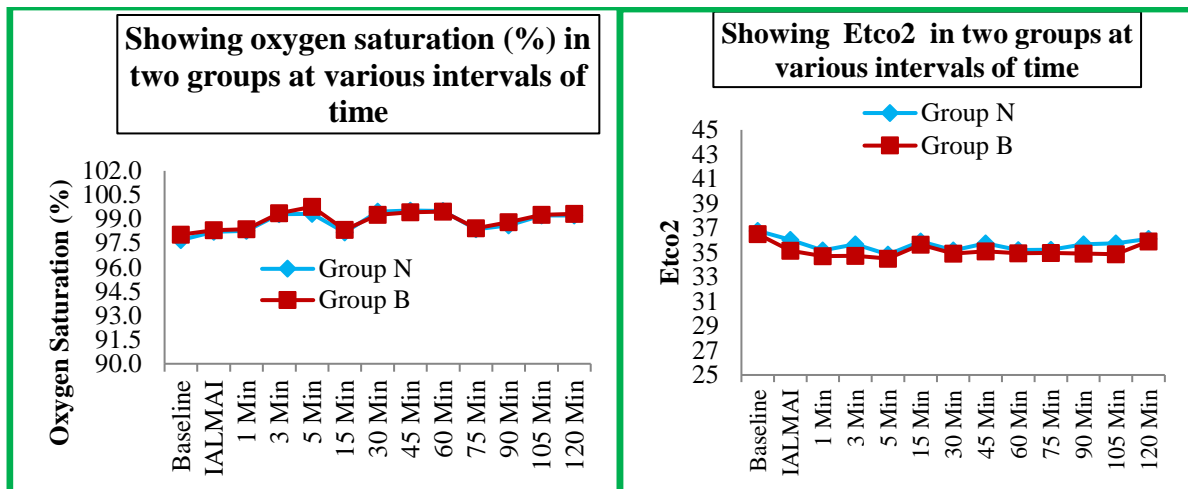
When the scores for proseal LMA insertion were compared between the two groups, it was clear that group N patients had achieved impressive results when compared to group B; excellent responses were seen in 73.3% of group N patients compared to 36.7% in group B, satisfactory responses were seen in 23.3% of group N patients compared to 40% in group B, and poor proseal LMA insertion scores were seen in 3.3% of group N patients compared to 23.3% in group B. Evidently, the average proseal LMA score in group N was 17.3±0.94 compared to 15.7±1.67 in group B

Table 3: Comparison based on duration of apnea (seconds) in two groups					
Duration of apnea	N	Mean	SD	Range	P-value
Group N	30	121.3	7.63	108-135	<0.001*
Group B	30	142.7	7.84	127-153	

Table 3, shows the comparison of duration of apnea between the groups; when the apnea durations of the two groups were compared (in seconds), it was clear that group B had a larger average apnea duration (142.7) seconds than group N (121.3) seconds, with a p-value of <0.001*. Duration of apnea in Group N ranged from 108-135 seconds whereas in Group B it ranged from 127-153 seconds.

When hemodynamic parameters were assessed, we found that heart rate in both the groups decreased immediately after LMA insertion, from the baseline values of (from 85.7 to 76 bpm in Group N) and (from 86.37 to 67.93 bpm in Group B). This decrease in the average heart rate in both groups was statistically significant (p-value<0.001*).





Decrease of average heart rate at 1 min and 3rd minute after LMA was high in Group B as compared to Group N and the difference was statistically significant with p values of $<0.001^*$ respectively. After 5 minutes of LMA insertion, the mean heart rate values in both groups started to recover to baseline and thereafter the difference in average heart rate became insignificant in both the groups till the end of the surgery. These values indicated better control of heart rate in both the groups. No incidence of bradycardia was noted in either of the groups.

We observe that IALMA insertion; SBP, DBP and MAP decreased in both the groups from baseline values; however, we did not see any appreciable differences in SBP, DBP, MAP and EtCO₂ readings and the differences were insignificant between the groups until 120 minutes. Interestingly, SBP, DBP, MAP, EtCO₂ stayed below baseline values in both groups till the end of the surgery. Moreover, SpO₂ in both the groups increased on IALMA insertion, but the difference was not statistically significant until 120 minutes.

Discussion

The proseal laryngeal mask airway (PLMA), a modification of the conventional laryngeal mask airway (CLMA), has a drain tube that finishes at the tip of the mask in order to lessen the possibility of aspiration. PLMA implantation does necessitate some jaw relaxation and a certain level of anaesthesia, though. PLMA is a secure and effective alternative to endotracheal intubation as an airway technique. Propofol is a useful medication for PLMA insertion because it has good jaw relaxing qualities and inhibits airway reflexes. But when administered alone, far greater doses of propofol are required for effective insertion, which could lead to unfavourable cardio-respiratory depression. Many studies have been done employing different supplemental medications, like dexmedetomidine, to help with LMA implantation. In the present study, our main objective was to assess the ease of insertion of proseal LMA during surgeries under general anaesthesia between the drug combinations of (nalbuphine-propofol) vs (propofol-butorphanol). In order to meet the study's objectives, we carefully assessed patient data based on socio-demographic characteristic, clinical parameters. Patients in Group N had ages ranging from 20 to 60, with a mean of (41.2 ± 12.2) years, while those in Group B had ages ranging from 21 to 60, with an average age of (42.5 ± 12.82) years. The age distribution of the patients in both groups was statistically comparable, as shown by the p-value of 0.682. Both groups were comparable in terms of gender ($p=0.598$), weight ($p=0.763$), and ASA status ($p=0.765$). Similar to our study, several studies have reported that demographic parameters like; age, sex, weight, and ASA status were comparable amongst the groups.⁸⁻¹¹ For instance, Nellore SS et al. (2016) stated in their study that the age, gender, weight, and ASA status of their patients were all similar between

the two groups; however, unlike to our study they used dexmedetomidine and fentanyl as adjuvants for co-induction with propofol for PLMA insertion.⁸ Similar to this, Dwivedi S et al(2018) study found no significant differences between the groups in terms of age (p-value: 0.42), gender (p-value: 0.11), weight (p-value: 0.07), and ASA status distribution (p-value;0.34).¹⁰ The ease of insertion score was assessed using a six variable, three point grading methodology. Laryngospasm, limb movement, coughing/gagging, swallowing, mouth opening, and resistance to insertion were some of these factors. Both groups' responses to resistance to mouth opening, placement resistance, and laryngospasm were equivalent when proseal LMA insertion conditions were compared between the groups. However, swallowing (10% vs 46.7%), coughing or gagging (20% vs 53.3%), and movement (10% vs 36.7%) showed a significant difference between the groups with p-values of 0.007*, 0.028*, and 0.046*, indicating that nalbuphine and propofol work well together than butorphanol with propofol during proseal LMA insertion. Both nalbuphine and butorphanol are partial opioid agonist-antagonist with strong κ -receptor agonism and weak μ -receptor agonist and antagonist activity.^{12,13} They have strong analgesic potency and sedative properties with a ceiling effect on μ -receptor activity of respiratory depression.^{14,15} Nalbuphine has the potential to maintain or even enhance μ -opioid based analgesia while simultaneously mitigating the μ -opioid side-effects. In a study by Gupta A et al. (2022) comparing nalbuphine-propofol (group N) with fentanyl-propofol (group F), considerably fewer cases of coughing, gagging, swallowing, and limb movement were reported in group N than in group F.¹¹ In a related study, Salman OH et al. (2015) found that group N experienced considerably less instances of coughing, gagging, and swallowing than group F.¹⁶ These studies' findings agree with those of present study, however, they contrasted fentanyl-propofol with nalbuphine-propofol rather than butorphanol-propofol. It was clear that group N patients outperformed group B when proseal LMA insertion results were compared between the two groups: excellent responses were seen in 73.3% of group N patients compared to 36.7% in group B, satisfactory responses were seen in 23.3% of group N patients compared to 40% in group B, and poor proseal LMA insertion scores were seen in 3.3% of group N patients compared to 23.3% in group B. The average proseal LMA score for group N was evidently 17.3 ± 0.94 compared to 15.7 ± 1.67 for group B. Similar to this, Gupta et al. similarly observed that group N received a higher PLMA score than group F.¹¹ When the apnea durations of the two groups were compared, it was found that Group N's apnea duration ranged from 108 to 135 seconds, whereas Group B's apnea duration ranged from 127 to 153 seconds. Group N had an average apnea duration that was considerably less than group B's (121.3) seconds, with a p-value of 0.001*. The authors of other trials comparing the effects of nalbuphine and propofol and fentanyl and propofol stated that group N's apnea lasted less time than group F's. 62,67,68 The reduced prevalence of respiratory depression in the PN group and the shorter average duration of apnea in group N can both be attributed to the pharmacological properties of nalbuphine. 69 Nalbuphine hydrochloride induces less respiratory inhibition than opioids at the same analgesic dose. Additionally, it has a ceiling effect, thus respiratory depression does not get worse as the dose increases when it is higher than 30 mg. 69-72 For patients undergoing oral surgery, B. Lefevre et al. (1992) suggested using nalbuphine as an alternative to fentanyl because it induces less respiratory depression.¹⁷ According to Chaoyi Deng et al., nalbuphine may also be a suitable replacement for sufentanil in people having a colonoscopy (2017).¹⁸ Nalbuphine can effectively reverse opioid-induced respiratory depression without having a deleterious impact on the endocrine and circulatory systems, and it still has its analgesic effects.¹⁹ Regarding heart rate (beats/min), both groups were compared at the baseline, immediately after LMA insertion (IALMAI), and at 1 minute until 120 minutes. Average heart rate decreased much more in Group B than in Group N at 1 minute and 3 minutes after LMA, and the difference was statistically significant with p values of $<0.001^*$,

respectively. After 5 minutes of LMA insertion, the mean heart rate values in both groups started to recover to baseline and thereafter the difference in average heart rate became insignificant in both the groups till the end of the surgery. Similar to this, Hazari et al reported a significant difference in HR at minute 15 followed by the mean change in HR from 15 minutes baseline value.²⁰ This could be explained by how analgesics reduce sympatholytic, vagotonic, and baroreflex sensitivity. A significant fall in HR from baseline in group nalbuphine with dexmedetomidine as compared to group dexmedetomidine was also reported by Tungana et al (2020).²¹ Gupta et al (2022) in their study reported that there was statistically a significant increase in heart rate in Group F as compared to Group N till 3rd minute after LMA insertion.¹¹ Both groups' heart rates recovered to baseline after 5 minutes, and the difference was no longer statistically significant. We observed that SBP, DBP, MAP, and EtCo2 readings declined after IALMA insertion in both groups relative to baseline values; however, until 120 minutes, there were no discernible changes in these measurements between the groups. Interestingly, both groups' SBP, DBP, MAP, and EtCo2 levels remained insignificantly below baseline values throughout the whole procedure. Additionally, SpO2 increased in both groups after IALMA insertion, but the difference did not become statistically significant until 120 minutes. Similar to our results, Apte et al (2017) investigated the effects of nalbuphine and pentazocine intraoperatively on SBP and DBP, SpO2, and ECG at 5 minutes and 15 minutes after drug administration. In their investigation, there were no significant differences between the two groups.²² Accordingly, Nellore et al. (2016) also noted a comparable decline in mean arterial blood pressure changes between the two groups (dexmedetomidine-propofol and fentanyl-propofol) following IALMA.⁸ But unlike our work, Gupta et al. (2022) found that both groups (group N and group F) saw an increase in MAP; however, the significant increase in MAP was only seen in the F group.¹¹ An insignificant difference between the groups was observed for ETCO2 and SPO2 in a study by Mostafa et al. (2018) examining the efficacy and safety of dexmedetomidine and nalbuphine, which is consistent with our results.²³

Conclusion

The presents study revealed that group N had significantly larger average proseal LMA score compared to group B. The average heart rate at 1 min and 3rd minute after LMA was high in Group B as compared to Group N and the difference was statistically significant with p values of <0.001* respectively. Although other hemodynamic parameters like; SBP, DBP, MAP, EtCo2 and SPO2 were comparable between the groups but group N had significantly smaller average apnea duration compared to group B (121.3 vs 142.7) seconds with a p-value of <0.001*. In conclusion, compared to butorphanol-propofol, nalbuphine-propofol can provide better insertion conditions with stable hemodynamics during PLMA insertion.

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