

BIS guided conditions for ProSeal laryngeal mask airway insertion – A comparison of Propofol versus sevoflurane with or without fentanyl

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Abstract

Introduction: Successful insertion of Laryngeal Mask Airway (LMA) ProSeal without any unwanted effects, such as coughing and gagging, requires adequate depth anaesthesia and suppression of the upper airway reflexes. Our prime aim was to study Bispectral Index (BIS) guided conditions for LMA ProSeal insertion comparing Propofol versus Sevoflurane with or without Fentanyl citrate.

Materials and Methods: A randomised prospective study was done on 120 unpremedicated ASA grade 1 or 2 patients which were divided into four equal groups as group P – Propofol intravenous induction, group PF - Propofol intravenous induction with Fentanyl, group S – Sevoflurane gas induction in 60% nitrous oxide and 40% oxygen and group SF -Sevoflurane gas induction in 60% nitrous oxide and 40% oxygen with Fentanyl. The parameters studied were induction time, insertion time, insertion conditions for LMA ProSeal like jaw opening, ease of insertion, coughing, gagging, laryngospasm- airway obstruction and patients movements on a three point scale using six variables.

Result: Excellent and satisfactory conditions were in 100% patients in group SF, 90% patients in group PF and 66.7% in group P and S.

Conclusions: Overall, group PF is better than SF in having shorter induction time and better hemodynamic stability but insertion conditions were better with group SF as compared to group PF though statistically insignificant.

Introduction

Laryngeal Mask Airway (LMA) classic introduced in 1981 has defined airway management in a whole new prospective. But it has many loopholes from airway protection point of view, which were overcome by LMA ProSeal. LMA ProSeal was developed and designed by Archie Brain and co-workers in 1990. The LMA Classic TM was launched in the UK and within 3 years of launch in the UK, the device had been used in at least 2 million.¹ In August 1991 the Food and Drug Administration (FDA) approved the LMA as an alternative to the face mask-but not an alternative to the tracheal tube with features which improved the laryngeal seal without increasing pressure on mucosa so injury to mucosa is less. It provides higher airway seal pressures so chances of cuff leakage are less and provides better conditions for positive pressure ventilation. It has a drainage tube to decompress the stomach, set risk of regurgitation and aspiration of gastric contents is less compared to LMA classic. It is simple, safe, less traumatic and non-invasive method for providing adequate anaesthesia. Over the years, it has been found as an effective device for airway management in surgeries.

Successful insertion of LMA ProSeal without any unwanted effects, such as coughing and gagging, requires adequate depth anaesthesia and suppression of the upper airway reflexes.² Propofol considered the superior intravenous induction agent to achieve the optimum conditions for LMA ProSeal insertion, compared with thiopentone and other intravenous induction agents.³ The conditions for LMA ProSeal insertion after inhalation induction with Sevoflurane are as good as with Propofol.⁴ However, inhalation induction with Sevoflurane, without any co-induction agents produces more excitation before insertion of LMA ProSeal and takes more time to produce jaw relaxation.⁴

The objective of this study was to investigate the conditions for LMA ProSeal insertion in unpremedicated patients using high concentration Sevoflurane, vital-capacity breath induction technique with or without Fentanyl as a co-induction agent, compared with standard Propofol induction with or without Fentanyl taking BIS (Bispectral index) value of 50-45 as a targeted end point for LMA ProSeal insertion. Bispectral analysis is more recent method of EEG analysis.⁵

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Materials and Methods

The present study "BIS guided conditions for ProSeal Laryngeal mask airway insertion, a comparison of Propofol versus Sevoflurane with or without Fentanyl" was conducted in Department of Anaesthesiology after obtaining the approval of institutional ethical committee from July 2014 to June 2015.

Written informed consent was taken from patients prior to enrolment into the study. Details pertaining to patient's clinical history, general physical examination, systemic examination & the following routine investigations like complete haemogram, Blood sugar, Blood urea, Serum creatinine, Bleeding time, Clotting time, ECG & Chest X-ray findings were noted. No premedication was given to patients. Patients were kept fasting for six hours.

One hundred and twenty patients included in the study were randomly allocated to one of four groups of thirty each. Group P-Propofol intravenous induction; group PF-Propofol intravenous induction with Fentanyl 1µg/kg body weight; group S- Sevoflurane gas induction in 60% nitrous oxide and 40% oxygen; group SF-Sevoflurane gas induction in 60% nitrous oxide and 40% oxygen with Fentanyl 1µg/kg body weight. Random allocation was achieved using sealed opaque envelopes, which were opened by the investigator immediately before induction of anaesthesia. The patients were blind to the form of induction they would receive when they gave consent for the study.

The anaesthetic agents were delivered through a circle absorber system with a two litres reservoir bag. The BIS value of 50-45 was considered the desired end point for LMA ProSeal insertion. Induction and LMA ProSeal insertion were done by an experienced anaesthetist with minimum of five years of experience in LMA ProSeal handling. At BIS value of 50-45 LMA ProSeal insertion was

done. If mouth opening was not adequate, excessive cough or gag reflex has prevented proper placement of LMA ProSeal then further anaesthetic depth was increased by giving a bolus dose of Propofol 20-40mg in group P and group PF while 8% Sevoflurane was further extended for few tidal breaths in group S and group SF provided the systolic blood pressure was above 90 mm of Hg, heart rate was above 60 beats per minutes and reinsertion attempted irrespective of the BIS value. Even if the second attempt for LMA ProSeal insertion was not successful then the case was excluded from the study.

After insertion of LMA ProSeal anaesthesia was maintained with 60% nitrous oxide in 40% oxygen and Sevoflurane in all the four groups. Concentration of Sevoflurane was titrated to desired BIS value (50-45). Manual ventilation was used if necessary. No stimuli were applied during the five minute period post induction. The study ended when the patient was considered to have reached an adequate depth of anaesthesia and was well settled after insertion of LMA ProSeal. Induction time and insertion time were assessed and recorded. Systolic blood pressure, heart rate and SpO₂ were measured every minute for the first five minutes after induction.

All the data were collected and analysed using SPSS statistical package. Data are expressed as mean values (SD). Statistical analysis was performed by using one way ANOVA, Paired T test, 2-sample test and Kruskal Wallis for non-parametric data. A probability value of <0.05 was considered significant.

Results

The study was conducted in 120 ASA grade 1 & 2 patients, scheduled for elective surgical procedures requiring general anaesthesia.

Table 1: Comparison of induction time and insertion time among the four groups

Variables	Groups (n=30)				p value
	Group P (Propofol)	Group PF (Propofol+Fentanyl)	Group S (Sevoflurane)	Group SF (Sevoflurane+Fentanyl)	
Induction time (sec)	35.30 (3.725)	34.53 (3.235)	45.87** (4.273)	46.87* (2.330)	<0.001
Insertion time (sec)	31.13 (4.369)	29.17 (4.434)	36.20** (3.978)	34.00* (4.194)	<0.001

Results are expressed as mean (SD).

p - value

** Highly Significant

Significant

Table 2: Comparison of ease of LMA ProSeal insertion among the four groups

Ease of LMA ProSeal insertion	Groups (n=30)				p value
	Group P (Propofol)	Group PF (Propofol+ Fentanyl)	Group S (Sevoflurane)	Group SF (Sevoflurane+ Fentanyl)	
Easy (3)	24 (80%)	28 (93.3%)	24 (80%)	29 (96.7%)	0.097
Difficult (2)	6 (20%)	2 (6.7%)	6 (20%)	1 (3.3%)	
Impossible (1)	0	0	0	0	

NS- Not Significant

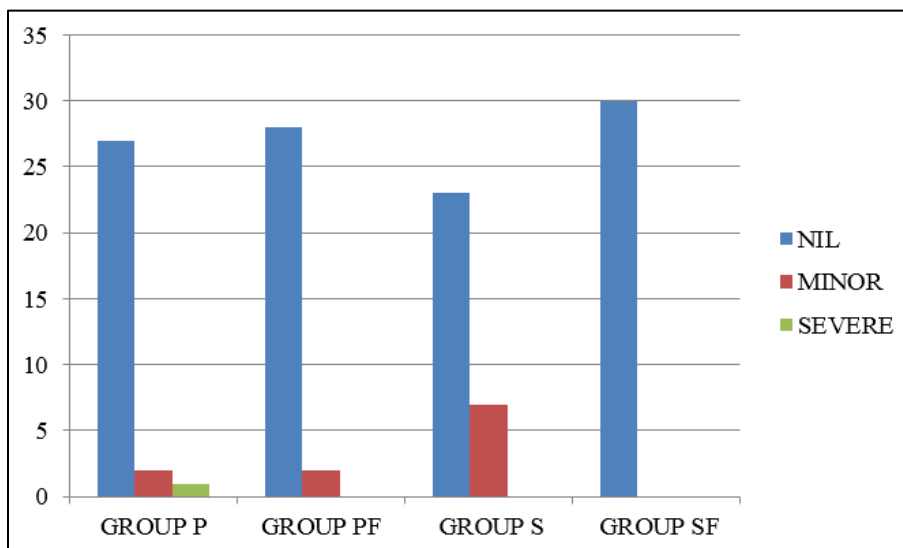


Fig. 1: Comparison of coughing among the four groups

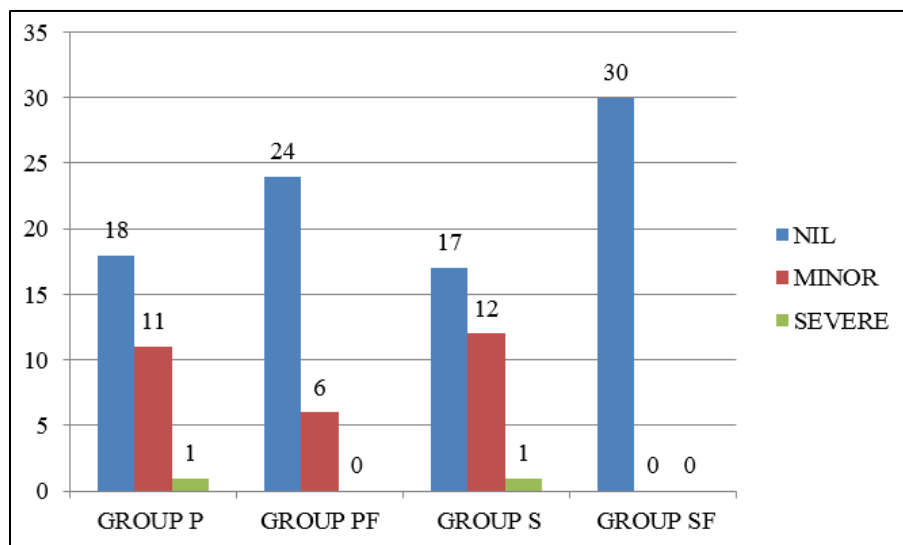


Fig. 2: Comparison of gagging among the four groups

Table 3: Comparison of patient movements among the four groups

Patient movements	Groups (n=30)				p value
	Group P (Propofol)	Group PF (Propofol+ Fentanyl)	Group S (Sevoflurane)	Group SF (Sevoflurane+ Fentanyl)	
3 (Nil)	9 (30%)	23 (76.7%)	18 (60%)	29 (96.7%)	<0.001**
2 (Moderate)	17 (56.7%)	7 (23.3%)	11 (36.7%)	1 (3.3%)	
1 (Vigorous)	4 (13.3%)	0	1 (3.3%)	0	

p - value

** Highly Significant

Significant

Discussion

The present study was conducted to evaluate the BIS guided conditions for LMA ProSeal insertion using Propofol (P), Propofol-Fentanyl (PF), Sevoflurane (S) and Sevoflurane-Fentanyl (SF) in adult ASA grade 1 and 2. The confounding factors were equally matched in all the four groups.

The induction time and insertion time was significantly decreased in patients in group P and PF and it takes less time for LMA ProSeal insertion as compared to groups S and SF because of prolonged jaw tightness in Sevoflurane group. J.E. Hall et al noted slower induction times with Sevoflurane compared with Propofol which was statistically significant though not clinically.⁴

When all the parameters were considered, Group PF provides best conditions for LMA ProSeal insertion. P. Sivalingam et al concluded in their randomized prospective study that a Sevoflurane –Alfentanil combination provided better conditions for LMA insertion as compared to Sevoflurane alone or a Propofol-Alfentanil combination.⁶

Group SF provides full jaw opening in 80% of patients, group PF provides full jaw opening in 76.7% of patients. In contrast, Dr. V. Priya et al concluded that Propofol is better than Sevoflurane for LMA insertion using the loss of eyelashes reflex as the end point of induction probably due to better jaw relaxation.⁷ Lian Kah TI et al inferred that prolonged jaw tightness after Sevoflurane induction may delay LMA insertion.⁸

M.P. Drage, J. Nunez et al (1996) conducted a randomized study in 60 patients of a ASA I and II aged 18-65 years scheduled for elective surgery, in whom use of the laryngeal mask was indicated. They concluded that conditions were significantly better when jaw thrust was used as clinical test compared with loss of verbal contact.⁹ A. Thwaites et al conducted a randomised, double-blind comparison of 8% Sevoflurane with Propofol as induction agent and concluded that apnea and coughing also occurred more in the Propofol group compared to Sevoflurane during transition from induction to maintenance.¹⁰

R. Walpole and M. Logan et al (1999) compared 4% and 8% sevoflurane in 50% N₂O with 50% O₂ in 60 unpremedicated elderly patient for day care surgeries. The study noted that LMA insertion was successfully achieved

in 8% sevoflurane group rapidly than the 4% sevoflurane group.¹¹

Coughing was not observed in any patient in group SF, 93.3% of patients in group PF, 90% of patients in group P and 76.7% of patients in group S. M E Molloy et al concluded that complications like coughing and head movements were practically similar in both Propofol and Sevoflurane groups.^{12,13} Ganatara S.B. et al concluded that haemodynamic stability was better with Sevoflurane-Flurane group but the Propofol-Fentanyl combination was more cost effective.¹⁴ Gruses E, Sungurtekin H (2004) sought to determine the propofol and hemodynamic effects as guided by BIS analysis during induction of anaesthesia. They have shown that propofol requirement by BIS during anaesthesia induction may decrease the dose and side effect and provide the satisfactory depth of anaesthesia.¹⁵

Easy LMA ProSeal insertion in first attempt was achieved in 96.7% of patients in group SF, 93.3% of Patients in group PF and 80% of patients in group S and group P. Difficult LMA ProSeal insertion required second attempt for insertion was seen in 20% of Patients in group P and group S, 6.7% of patients in group PF and 3.3% of Patients in group SF.¹⁶

No patient movements were observed in 96.7% of patients in group SF, 76.7% of patients in group PF, 60% of patients in group S and 30% of patients P. Moderate patient movements were observed in 56.7% patient in group P, 36.7% of patients in group S, 23.3% patients in group PF, 3.3% of patient in group SF, Vigorous patient movements were observed in 13.3% of patients in group P and 3.3% of patients in group S. Sahar M Siddik-Sayyid et al found that frequent incidence of movements and apnea were observed in Propofol group as compared to either Sevoflurane or Sevoflurane-Propofol group.¹⁷

P.S. Sebel, E. Long et al (1997) studied three hundred patients in seven centres prospectively for movement response rate to skin incision, with a standard anaesthetic technique in each of the centres. The movement response rate was significantly higher in control group at 43% with 13% in the BIS- guided group, but response rate were low at centers, which used larger doses of opioids. This study concludes that BIS can be used as monitor for anaesthetic gap with the hypnotics inhalation agent.¹⁸

Features like jaw opening, ease of LMA ProSeal insertion, larygospasm and airway obstruction did not reach statistical significance in our study may be due to lesser number of subjects in each group. The depth of anaesthesia between the four groups was maintained between BIS value of 50-45. However, a point to ponder is the difficulty of comparing the depth of anaesthesia between inhaled and IV anaesthetics. Exclusion of patients other than ASA grade I, II due to logistical issues may have affected the result. However more studies with larger samples are required before considering these observations as generalized.

Edith Fleischmann, Ozan Akia et al (1999) studied the onset time, recovery duration and drug cost with four different methods of inducing general anaesthesia. They noted post operative awakening was fastest in patients given Sevoflurane. The cost of induction was lowest with Sevo/Bag technique and thiopental. But nausea and vomiting was mostly seen in patients who had received Sevoflurane.¹⁹

To conclude, it is inferred from our study that the induction time was significantly decreased in patients in groups PF and P as compared to groups SF & S. It takes more time for LMA ProSeal insertion in patients in group SF and S as compared to groups P& PF. It reflects that group PF is better than group SF in having shorter induction time, insertion time and better haemodynamic stability but insertion conditions were better with group SF as compared to group PF though it was statistically insignificant. So group PF provides best conditions for LMA ProSeal insertion when all the parameters are compared with groups P, SF and S.

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