Original Research Article

Indian Journal of Anesthesia and Analgesia
January – February 2020; 7(1) (Part -II): 414-419
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7120.56

Comparative Study of Three Techniques of Proseal Laryngeal Mask Airway (PLMA) Insertion In Patients Undergoing Elective Surgeries

S Navaneetha Krishnan[1], M Prem Kumar[2]

[1]Associate Professor, Department of Anesthesiology, Saveetha Medical College Hospital, Thandalam, Kanchipuram Chennai, Tamil Nadu 602105, India. [2]Associate Professor, Department of Anesthesiology, Saveetha Medical College Hospital, Thandalam, Kanchipuram Chennai, Tamil Nadu 602105, India.

Abstract

Background: The LMA has revolutionized airway management and its use are now standard practice in General Anesthesia. The rationale behind the study was to compare three techniques of Proseal Laryngeal Mask Airway (PLMA) insertion. *Objectives:* To assess the superiority of placement with three techniques of Proseal Laryngeal Mask Airway insertion with respect to 1. Number of attempts to successful placement 2. Insertion time 3. Oropharyngeal leak pressure 4. Fiber Optic Bronchoscopy (FOB) Grading. *Materials and Methods:* A randomized prospective comparative study was done for a period of 1 year. The study was carried out at Saveetha Medical College and Hospital. The study was conducted on 90 adult patients of either sex, in the age of 18–65years, belonging to ASA I and II with Modified Mallampati Score I & II posted for elective surgeries. Systemic sampling was used. All patients were kept on fasting for 8 hrs. SPSS version 20 was used for analysis. One-way ANOVA and Chi-square test was used for analysis. p - value of < 0.05 is considered statistically significant. *Results:* There was no significant difference between the three groups in terms of age, weight, ASA, MMS. The insertion time for Group-G was 22.5 ± 5.0 sec and Group-IT was 14.2 ± 3.3 sec which were significantly higher than Group D (11.37 ± 2.7 sec). GEB guided PLMA insertion was successful in 30/30 (100%) and IT guided insertion was also successful in 30/30 (100%) in the first attempt. Oropharyngeal leak pressure in Group IT (26 ± 3.3) and Group G (27.8 ± 2.3) was significantly higher when compared to Group D. *Conclusion:* We conclude that GEB-guided insertion and Introducer technique is comparable to digital technique in successful placement of PLMA. However, GEB and IT technique provides better airway seal compared to digital technique.

Keywords: Proseal LMA; General anesthesia, Oropharyngeal leak pressure; Fiber-optic grading; Gum elastic bougie.

How to cite this article:

S Navaneetha Krishnan, M Prem Kumar. Comparative Study of Three Techniques of Proseal Laryngeal Mask Airway (PLMA) Insertion In Patients Undergoing Elective Surgeries. Indian J Anesth Analg. 2020;7(1 Part -II):414-419.

Introduction

The LMA has revolutionized airway management and its use are now standard practice in General Anesthesia.[1,2] Since, the introduction of LMA in 1988, it has challenged the supposition that tracheal intubation is the only acceptable way to maintain clear airway and provide positive

Corresponding Author: M Prem Kumar, Associate Professor, Department of Anesthesiology, Saveetha Medical College Hospital, Thandalam, Kanchipuram Chennai, Tamil Nadu 602105, India.

E-mail: vanisu1990@gmail.com

Received on 09.12.2019, **Accepted on** 16.01.2020

pressure ventilation. Widespread use of LMA was restricted due to its risk of gastric distension, pulmonary aspiration of gastric contents and fear of inadequate ventilation.[3] PLMA insertion with digital technique/IT was successful in 87% and 84% patients in first attempt, while 10% of insertions required second attempt in most of the studies.[4–6] The principle cause of failed and/or delayed insertion with the digital and IT techniques were impaction of the PLMA at the back of the mouth, which resulted in failed passage into the pharynx, or folding over of the distal cuff, or the distal cuff being directed into the glottis inlet rather than the hypopharynx.[6] To overcome these problems of digital technique, Insertion techniques like IT and Gum Elastic Bougie (GEB) aided placement were introduced. These newer techniques have better placement.[7] GEB-guided PLMA insertion was successful in 100% patients in first attempt. Insertion was more frequently successful with the GEB-guided technique at the first attempt than the digital or IT techniques. The GEB-guided technique is more frequently successful because it reduces impaction at the back of the mouth, prevents folding over of the distal cuff, and guides the distal cuff directly into the hypopharynx.[6,7] The Purpose of this study was to evaluate if GEB and IT technique would offer better placement than Digital technique.

Materials and Methods

This study was a randomized, prospective, comparative study. After obtaining institutional Ethical committee clearance and patient's written informed consent, the study was carried out at Saveetha Medical College and Hospital. The study was conducted on 90 adult patients of either sex, in the age of 18–65 years, belonging to ASA I and II with Modified Mallampati Score I & II posted for elective surgeries. The study was conducted from July 2015–July 2016 (12 months).

Inclusion criteria:

Includes age group of 18–65yrs who were Posted for elective surgeries, belonging to ASA I and II with Modified Mallampati Score I/II. Patients willing to participate and giving informed consent were included.

Exclusion criteria:

Age group below 18 and above 65 were excluded Patients posted for Emergency surgery Belonging to ASA III, IV, V Patients with increased risk of aspiration (e.g.: Hiatus hernia, Gastro Esophageal Reflux Disease, obesity, pregnancy, etc.). Patients with anticipated difficult airway (e.g.: inter incisor distance < 2 cm, Modified Mallampatti Score III and IV).

Patients were randomly allocated into Three Groups by computer based randomization:

1. Group D - PLMA insertion by Digital technique-30 patients;
2. Group IT - PLMA insertion by Introducer tool technique-30 patients;
3. Group G - PLMA insertion by Gum Elastic Bougie guided technique-30 patients.

All patients were kept on fasting for 8 hrs. They were given aspiration prophylaxis with Tab. Ranitidine 150 mg Per Oral and Tab. Metoclopromide 10 mg PO at 6 am on the Day of surgery. Patients were premedicated with Inj. Glycopyrolate 0.2 mg IV one hour before surgery. After the placement of standard minimum monitoring ECG, Pulse oximetry, NIBP, Capnography, the patient was kept in Sniffing position. All the patients were premedicated with Inj. Fentanyl 2 mcg/kg and Preoxygenated for 3 min with 100 percent oxygen. Anesthesia was induced with Inj. Propofol 2–3 mg/kg IV given over 30 sec and maintained with 1–2% Isoflurane in oxygen and N_2O (50% : 50%) with facemask ventilation & PLMA was inserted when there was adequate jaw relaxation. In patients weighing between 30 and 50 kg size 3 PLMA (TELEFLEX TM, United States) was used and in patients weighing between 50 and 70 kg size 4 PLMA was used. An experienced anesthetist who was well-trained in using PLMA, performed the PLMA insertion.

Group-A: (*Digital Technique*) Digital insertion technique was performed according to manufacturer's instruction. The Digital technique involved the use of the index finger to press the PLMA into and advance it around the Palatopharyngeal curve.

Group-B: (*Gum Elastic Bougie guided insertion*) – The drain tube of the PLMA was primed with lubricated 60 cm long, (16F) Gum elastic bougie with its straight end first, leaving the 5 cm bent portion protruding from the proximal end (for the assistant to grip), and the maximum length protruding from the distal end (for anesthetist to manipulate) was 30 cm.

Group-C: (*Introducer tool Technique*) – The IT technique involved attaching the Introducer tool using a single-handed rotational Technique to press

the PLMA into oropharynx and advance it around the palatopharyngeal curve and removing the IT.

Primary Outcome Measures:

1. *Insertion time*: The Insertion time is defined as the time taken since taking PLMA/ Laryngoscope in hand till time taken to obtain effective airway as a spontaneous movement of the breathing system (shown by square wave capnography).
2. *No. of attempts*: (Number of attempts taken for a successful placement of PLMA)
3. *Oropharyngeal leak pressure*: (The oropharyngeal leak was determined by closing the Adjustable Pressure Limiting (APL) valve of the circle system at a fixed gas flow of 3 liters/min and recording the airway pressure at which equilibrium was reached (maximum allowed was 40 cm H_2O). Equilibrium was taken as the point at which an audible leak could be heard from the mouth. The Dragger anesthesia machine was used for recording airway pressure.)
4. *Grading of placement* (FOB Grading) After recording the above observations, a 5.5 mm fiber Optic Bronchoscope was passed through the LMA till its tip lies 1 cm proximal to the end and the view was assessed by a standard score devised by Brimacombe and Berry.

Sample Size Calculation:

Assuming the oropharyngeal leak pressure in previous studies, the sample size was estimated to be 20 in each group for a Type I error of 0.05 & power of 90 at 5% significance level. To make the study more precise, we took sample size of 30 in each group.

Statistical Analysis:

All data were collected, tabulated and expressed as Mean ± Standard deviation. The analysis of variance (One way ANOVA) test was used to compare the groups for parametric data (age, weight, OLP, insertion time) while the qualitative parameters such as ASA, ease of insertion, number of attempts were analyzed using the Pearson Chi-square test or Fisher exact test (whichever applicable). The statistical analysis was carried out using SPSS software version 20. The p - value < 0.05 was taken as significant.

Results

As per Table 1, The three groups were comparable with respect to the demographic characteristics. There was no significant difference between the three groups in terms of age, weight, ASA, MMS. ($p > 0.05$).

As per Table 2, the insertion time for Group-G was 22. 5 ± 5.0 sec and Group IT was 14. 2 ± 3. 3 sec which were significantly higher than Group D (11. 37 ± 2.7 sec). One-way Anova reveals p - value of 0. 001 which was significant. Hence, GEB guided and Introducer guided insertion of PLMA took longer time than digital technique for the successful placement.

Table 1: Demographic details of the patient

Parameters		Digital	Introducer	GEB	p - value
Age (yrs)		36.17	35.53	34.03	0.82
Weight (kg)		59.17	60.93	59.43	0.75
ASA	I	16	19	23	0.61
	II	14	11	7	
MMS	I	4	2	6	0.31
	II	26	28	24	

Table 2: Insertion time of PLMA with three techniques

Method	Insertion time	p - value
Digital	11. 37 ± 2.7	0.00
Introducer	14. 20 ± 3.3	
GEB	22. 57 ± 5.0	

Table 3: Comparison data of number of attempts between three groups in Insertion of PLMA

No. of Attempts	Group			Total (*n*)	*p* - value
	Digital	Introducer	Bougie		
1st Attempt	28 (93.3%)	30 (100%)	30 (100%)	88 (97.8%)	
2nd Attempt	2 (6.7%)	0	0	2 (2.2%)	
Total (*n*)	30	30	30		0.12

Table 4: Comparison of Oropharyngeal Leak Pressure between three groups

Method	Oropharyngeal leak pressure (cm of H_2O)	*p* - value
Digital	23 ± 2. 4	0.00
Introducer	26.5 ± 3.3	
GEB	27.8 ± 2.3	

Table 5: Comparison of Fiberoptic Grading between three groups

Grading of placement FOB		Group			Total	*p* - value
		Digital	Introducer	Bougie		
1	Count	3	3	1	7	0. 6
	% within Group	(10.0%)	(10.0%)	(3.3%)	(7.8%)	
2	Count	15	10	7	32	0. 4
	% within Group	(50. 0%)	(33.3%)	(23.3%)	(35.5%)	
3	Count	10	15	14	39	0. 4
	% within Group	(33.3%)	(50.0%)	(46.7%)	(43.3%)	
4	Count	2	2	8	12	0.04
	% within Group	(6.7%)	(6.7%)	(26.7%)	(13.3%)	
Total	Count	30	30	30	90	
	% within Group	(100%)	(100%)	(100%)	(100%)	
Clinically accepted		30	30	30		1. 00

According to Table 3, GEB guided PLMA insertion was successful in 30/30 (100%) and IT guided insertion was also successful in 30/30 (100%) in the first attempt. Insertion with digital technique was successful in 28/30 (93.3%) at the first attempt and it was placed successfully at the 2nd attempt by lateral technique in 2/30 (6.7%) patients. These data was not statistically significant ($p = 0. 12$).

As per Table 4, Oropharyngeal leak pressure in Group IT (26 ± 3. 3) and Group G (27.8 ± 2.3) was significantly higher when compared to Group D (23 ± 2.4). One Way Anova revealed *p* - value of 0.001 which was significant. Hence, better airway seal was achieved with GEB guided and IT guided technique when compared to Digital technique.

As per Table 5, in the grading of placement of FOB, significance level was seen only in Grade 4. ($p < 0.05$) which shows fiberoptic grading is comparable in all groups except in Grade 4 although it was clinically acceptable.

Discussion

The Proseal LMA provides an acceptable way to maintain a clear airway & positive pressure ventilation. It also reduces the risk of gastric insufflation, regurgitation and aspiration of gastric contents. Various insertion techniques have been developed by authors to overcome misplaced PLMA leading to ineffective ventilation. Previous studies with bougie guided technique have shown that the use of laryngoscope for Proseal Laryngeal Mask airway insertion helps to maintain intubation skills, improves placement and prevents folding of distal cuff. This technique also improves the success rate of gastric tube insertion compared with other techniques, hence indicating lesser incidence of cuff malpositioning. The disadvantages of this technique could be the hemodynamic response associated with the Laryngoscopy and airway trauma due to bougie insertion. However, studies have supported and denied the above findings. In our study, the first

attempt success rate for bougie guided technique (100%), Introducer Technique (100%), digital (93%) were similar in all the groups. The two failed cases by the digital technique was successfully placed by lateral technique in the second attempt. Our study was similar to a randomized control study done by Savita Saini[8] et al. where the 1st attempt success rate with bougie guided technique (100%) Introducer Tool 98%) and digital technique (90%). Maclean et al.[9] also had similar results with bougie guided technique (96%), Introducer

Technique (93%). J Brimacombe et al.[4] reported significant higher first attempt success rate with the GEB technique (100%) over other techniques [digital (88%), IT (84%)] and the success after 3rd attempt was similar in all the techniques. We noted a higher insertion time in bougie guided technique (22.57 ± 5.0 sec) than Introducer Technique (14.20 ± 3.3 sec) and Digital technique (11.37 ± 2.7 sec). This was comparable to savita et al.[8] (G 24 ± 5.4/ IT 20.6 ± 4.8/D 20 ± 8 sec). The longer insertion time noticed in bougie guided technique was due to laryngoscopic handling and removal of Bougie after insertion.

However, Brimacombe[4] and colleagues found lesser insertion time (G25 ± 14/IT 28 ± 14/D 27 ± 12) in GEB guided technique than digital and introducer tool technique. The authors noted that the difference in the study was due to the skill with which all anesthetists are conversant, was used in the GEB guided group and this might have contributed to the shorter time taken to insert the PLMA using GEB guidance[10] Oropharyngeal leak pressure indirectly indicates airway seal, higher the oropharyngeal leak pressure, better the airway seal. In our study, Oropharyngeal leak pressure was higher with bougie guided technique (27.8 ± 2.3) and Introducer technique (26.5 ± 3.3) than Digital technique (23 ± 2.4) which was comparable to Kuppusamy et al.[11] (D 23 ± 3.6/G 30 ± 4.7). However, few other studies[4,5,7,12] found higher Oropharyngeal Leak Pressure with bougie guided technique. Nileshwar et al.[12] and Maclean et al.[9] were other studies which showed similar results in fiberoptic grading. This explains the reason for the significant decrease in oropharyngeal leak pressure with Digital technique.

Conclusion

We conclude that GEB-guided insertion and Introducer technique is comparable with digital technique in successful placement of PLMA. GEB and IT technique provides better airway seal compared to digital technique. We suggest that GEB and IT technique can be used as a backup technique when digital technique fails.

Source of Funding: None.

Conflict of Interest: None declared.

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