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Comparison of First Attempt Success Rate between Two Insertion Techniques of Proseal Laryngeal Mask Airway

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Abstract
Background: *The Pro Seal laryngeal mask airway (ProSeal LMA) is a relatively new laryngeal mask device designed to improve ventilator characteristics and offer protection against aspiration and gastric insufflation. But there were occasional problems like failed insertion and inadequate ventilation, in placing Pro Seal LMA using the classical digital technique. To overcome these problems, newer placement technique like introducer tool placement and Gum elastic bougie aided placement were advised.*
Aim: *To compare the first attempt success rate between bougie guided insertion versus introducer guided insertion of Pro Seal LMA.*
Methodology: *This prospective comparative study was conducted in the Dept. of Anesthesiology, Govt. Medical College , Thiruvananthapuram, a tertiary care centre . A total of 100 patients, requiring general anaesthesia with supraglottic airway device, of age between 20-60 years with ASA I and II were enrolled in the study. The enrolled patients were divided randomly into two groups-Group 1and Group 2.*
Group 1 -ProSeal LMA insertion by bougie guided technique.
Group 2 -ProSeal LMA insertion of introducer technique.
Data were collected about ease of insertion, number of attempts and time taken to provide an effective airway, efficacy of seal, ease of gastric tube placement, haemodynamic responses and blood staining. Data also collected about postoperative airway morbidity.
Results: *The first attempt success rate was high in bougie guided insertion of Pro Seal LMA (98% vs86%). The effective airway time is longer in patients with bougie guided insertion compared to introducer guided insertion*
Conclusion: *The bougie guided insertion of Pro Seal LMA has a higher first attempt success rate than the introducer technique.*
Keywords: *airway, ProSeal LMA, technique.*

Introduction

The Pro Seal LMA was introduced by Dr. Archie Brain in 2000[1]. Pro Seal LMA has a gastric drainage tube, placed lateral to the main airway tube. The gastric drainage tube forms a channel for regurgitated gastric contents and prevents gastric insufflation and pulmonary aspiration. When the device is used for controlled ventilation, the ProS eal LMA provides a high eroropha-ryngeal leak pressure than the Classic LMA [2]. However, the Pro Seal LMA is reported to be more difficult to insert than the Classic LMA, as its larger and the softer cuff is prone to folding. The manufacturer recommends that the Pro Seal

LMA be inserted using either manipulation with the fingers or a curved metal introducer. Nonetheless, first attempt success rates of Pro Seal LMA insertion range from 81% to 87%, which is lower than the Classic LMA[3, 4, 5]. To overcome these problems , newer techniques to facilitate insertion of the Pro Seal LMA, including priming the drain tube with a guiding instrument such as a suction catheter [6], a gastric tube [7], a gum elastic Bougie[8], a Flexi-Slip stylet [9] and even a fiber optic bronchoscope [10, 11] were devised . In the following prospective randomized study, we have tested the hypothesis that bougie-guided laryngoscope aided insertion of the Pro Seal LMA is more frequently successful than using the curved metal introducer. Other advantages of guided technique for the airway rescue are that

1. Oral pathologycan be identified as laryngoscope is used
2. Gastric tube insertion is as the drain tube andesophagus are prealigned.

Materials and Method

This study was conducted in the Dept.of anaesthesiology, Govt, Medical College, Thiruvananthapuram for a period of six months. One hundred patients of ASA I–II, undergoing a surgery in the supine position requiring general anaesthesia with supraglottic airway device ,of age between 20-60 years were selected for this study based on the inclusion and exclusion criteria.

Exclusion criteria included an anticipated difficult airway, morbid obesity, duration of surgery more than 3 hours, mouth opening < 4 cm, inadequate fasting,pregnant woman and pre-existing sore throat or hoarseness. Sample size was calculated using the formula

$$n = \frac{2(Z_{a/2} + Z_{1\text{-beta}})^2}{d^2}$$

Significant level .05 power 80%, P_1= 100% P_2 =84% P= 92

$$n = \frac{2(1.96+.842)^2 \times 92 \times 8}{16^2} = 45$$ rounded as 50 each group

N=50 each group,

The selected patients were evaluated preoperatively and written informed consent was obtained from each patient. Patient data was recorded in the proforma. Details regarding age, sex, weight, airway assessment and ASA class were recorded. Basal heart rate, systolic and diastolic blood pressure were noted .Enrolled patients were allotted randomly to one of the two groups.

Group 1 –Pro Seal LMA insertion by bougie guided laryngoscope aided technique.

Group 2 –Pro Seal LMA insertion of introducer technique.

Normal fasting guidelines were followed. On arrival in operation theatre an intravenous infusion of normal saline was started. The standard monitoring with continuous electrocardiography, noninvasive blood pressure, pulse oximetryand capnography were used for both groups. Patients were premedicated with intravenous inj. Glycopyrrolate 0.2mg inj. Midazolam 1 mg, fentanyl 2micro gm /kg before induction of anaesthesia. Each patient was anesthetized in the supine position with the head resting on a 10-cm high pillow. The size of the Pro Seal LMA was selected according to the patient's weight: size 3 for those ≤50 kg, size 4 for those >50 kg). The cuff was fully deflated and the back surface lubricated. Propofol 2 mg/kg were administered as induction agents, and vecuronium0.1 mg/kg given to facilitate Pro Seal LMA insertion.

Group 1: Whom the bougie-guided technique used, the drain tube of the Pro Seal LMA was primed with a lubricated 16 f gum elastic bougie with its straight end protruding 30cm beyond the drain tube and the bent portion protruding from the proximal end. Under laryngoscopic guidance, the distal portion of the bougie was placed 5-10 cm into the oesophagus. The laryngoscope was removed and the ProSeal LMA was inserted using the digital insertion technique with bougie as guide and the bougie was removed while the Pro Seal LMA was held in position.

Group 2 :In this group, the Pro Seal LMA was inserted using the metal introducer according to the manufacturer's instructions: the patient's

mouth was opened and the lubricated Pro Seal LMA was inserted into the patient's mouth using the introducer; the Pro Seal LMA was advanced using a one-handed technique until resistance was encountered; and the introducer was removed, leaving the Pro Seal in position.

Once the Pro Seal LMA was inserted into the pharynx, the cuff was inflated with air until effective ventilation was established or the maximum recommended inflation volume was reached. Ventilation was judged to be optimal if the following four test passed-Bilateral adequate chest movement, Stable oxygenation not less than 95%, Square wave capnography and normal range end tidal CO_2 .

In both groups if it was not possible to ventilate the lungs the following airway maneuvers were allowed, chin lift, jaw thrust, head extension or flexion on the neck. After any maneuvers adequacy of ventilation was reassessed. If it was not possible to insert the device or ventilate through it, two more attempts of insertion were allowed. If placement had failed after three attempts, the case was abandoned and the patient was intubated with an endotracheal tube and this case was considered as a failed attempt .

After securing the device the patients were started on controlled ventilation and anaesthesia was continued with Oxygen, nitrous oxide and Isoflurane / sevoflurane.

First attempt success rate, number of insertion attempts and effective airway time were noted. The effective airway time in bougie guided insertion was the time between picking up the laryngoscope to the first successful breath by manual ventilation. The effective airway time in introducer guided technique was the time between picking up Proseal LMA mounted on introducer tool to the first successful breath by manual ventilation .Parameters like Heartrate, mean blood pressure and SpO_2before and after insertion and complications like laryngospasm, coughing, were recorded at the end of operation after attaining adequate recovery from anaesthesia. The Proseal LMA was removed .and the device as checked for any evidence of trauma by looking for blood staining on the device. Postoperative sore throat, dysphagia and dysphonia were recorded in the postoperative care unit. Data were analyzed using computer software, statistical package for social science version 10.

Observation and Results

Of the 100 patients studied, the statistical analysis showed that the two groups – Pro Seal LMA insertion by bougie guided technique and insertion by introducer technique were comparable in terms of patient characteristics such as age, gender, weight, comorbid conditions and ASA status.

Table 1: Comparison of Mallampatti class based on groups

MPC	Group 1		Group 2		$\chi 2$	p
	Count	Percent	Count	Percent		
I	22	44.0	5	10.0	14.67**	0.001
II	22	44.0	35	70.0		
III	6	12.0	10	20.0		

The distribution of patients according to Mallampatti classification was different. Most patients of the introducer guided group belonged to MPC II. This difference is significant statistically using Mannwhitney U test. No MPC IV patients were taken up for this study.

Two groups were comparable based on the thyromental distance and there is no significant difference measured by Fisher Exact test .Mouth opening among the two groups were comparable and there is no significance statistically as measured by Fisher Exact test. Based on the weight and the physical characteristics the size of the device was selected. Pro seal LMA size 4 was used in 56% of patients with bougie guided insertion and in70% patient's introducer guided insertion.

Table 2 Comparison of first attempt success rate based on groups

Success Rate	Group 1		Group 2		$\chi 2$	p
	Count	Percent	Count	Percent		
First Attempt	49	98.0	43	86.0	4.89*	0.027
Second Attempt	1	2.0	7	14.0		

The first attempt success rate is high in bougie guided insertion of Proseal LMA (98 vs 86%). The difference between both the groups regarding first attempt success rate was significant statistically p< .0.05. No patients more than two attempt for successful placement.

Table 3 : Comparison of Effective Airway Time based on groups.

Group	Mean	SD	N	t	p
Group 1	35.0	5.9	50	7.71**	0.000
Group 2	23.4	8.8	50		

**:- Significant 0.01 level

The effective airway time was longer in patient with bougie guided insertion of Proseal LMA compare to introducer guided insertion (35+/-5.9 vs 23.4 +/- 8.8). The difference between two groups was significant statistically.

Table 4 : Comparison of Heart rate based on groups

		Mean	SD	N	t	P
Baseline	Group 1	77.2	6.6	50	1.85	0.067
	Group 2	74.6	7.6	50		
Induction	Group 1	91.2	7.5	50	1.94	0.055
	Group 2	88.3	7.3	50		
Insertion	Group 1	98.3	13.0	50	0.13	0.898
	Group 2	98.6	8.1	50		

Heart rate, mean arterial pressure and mean SpO_2 were comparable in both groups over the three phases and not significant statistically.

Table 4 : Comparison of mean arterial pressure based on groups

		Mean	SD	N	t	P
Baseline	Group 1	93.0	6.4	50	1.6	0.113
	Group 2	91.1	5.2	50		
Induction	Group 1	84.0	7.1	50	0.74	0.055
	Group 2	83.0	6.3	50		
Insertion	Group 1	97.7	9.5	50	0.27	0.791
	Group 2	97.2	8.5	50		

**:-Significant at 0.01 level

Table 5: Comparisonof Complications based on Group

Complications	Group 1		Group 2		p#
	Count	Percent	Count	Percent	
Blood staining on device	4	8.0	6	12.0	p>0.05
Sore throat	11	22.0	15	30.0	p>0.05
Dysphagia	10	20.0	0	0.0	p<0.001
Coughing	17	34.0	13	26.0	p>0.05

#: Fischer Exact group

Comparing the entire complications both groups are comparable and the result was statistically not significant. Blood staining and sore throat were more common in introducer guided group, though not significant statistically. Coughing was more in the bougie guided group. Using Fisher Exact test

it was found that the difference was not statistically significant. Dysphagia was seen in 20% patient in bougie guided insertion where as it was not seen introducer guided insertion. Using Fisher Exact test it was found that it was statistically significant.

Discussion

There were no significant difference between groups with respect to the demographic data. Of the 100patients studied the percentage of patients in each age group was comparable. The percentage of patients of gender in each group was comparable even though the sex ratio favours male sex. Using Fisher Exact test it was found that the difference was not statistically significant.

Airway assessment data

In our study the distribution of patients according to mallampatti classification was different. 70% of the introducer guided group below to MPC II. This difference is statistically significant. But this is contrary to previous studies[12], which showed that ease of insertion of LMA does not correleate with Mallampatti class. Macroy and Moriarit[13] showed that LMA positioning was releated to Mallampatti class . But the sample size was low as in our study. Composite data from 2000 patients suggest that LMA inseration is not affected by Mallampatti class in the hands of experienced LMA users [14].

The two study groups were comparable based on the thyromental distance (56% of the patients of bougie guided group and 70% of the introducer guided had thyromental distance>6.5 cm ; rest 45% in bougie guided had thyromental distance </= 6.5 cm). The result is not statistically significant. Mouth opening among the two groups were comparable. [70% patients had mouth opening >6cm and 30% had mouth opening between 4-6 cm ;(P>.0.05.). The result is insignif-icant. Based on weight and physical character-istics the size of the Pro Seal LMA was selected. Pro Seal LMA size 4 was used in 56% of patients with bougie guided insertion while in 70% patients with introducer guided insertion uses Pro Seal LMA size 4. this bears no particular effect on the the outcome and is therefore statistically insignificant.(P>0.05). Kihara et al[15] found that size selection for the ProSeal LMA was equally effective using the manufacturer' s weight based formula, in terms of ease of insertion.

First attempt success rate

In our study we found that the first attempt success rate was high in bougie guided insertion of PLMA (98% vs 86%). The difference between both groups regarding first attempt success rate is statistically significant (P<0.05). The overall success rate isequal in both groups. No patient required more than two attempts for successful placement. These findings in our study is similarly reflected in the reports by Anitha Nileshwar et al[16} who compared bougie guided insertion and introducer tool technique. The success rate for insertion of Pro Seal LMA at first attempt was higher in gum elastic bougie guided group (96%vs 80%) ., although overall success was similar in both groups. Martinez Pons et al [17] also discovered the ease of placement of PLMA with a gatric tube inserted. They found that easier insertion of PLMA if the drain tube is primed with an 18 G gastric tube prior to Pro Seal LMA insertion .they also found that the first attempt success rate improves from 91%-100%. Anand Kuppuswamyetal[18] compared digital technique and bougie guided insertion of ProSeal LMA and found that 96.7% patients in first attempt and Pro Seal LMA with digital technique was successful in 86.7% These were comparable to other studies[19, 20,21].

Effective Airway Time

In our study we found that the Effective airway time is longer in patients bougie guided insertion and introducer guided insertion. The difference between the two groups was statistically significant. Similar findings were observed in various studies [13,16,18,21}.

In our study we found that the effective airway time was longer in patients with bougie guided insertion compared to introducer guided insertion (35+/-5.9 seconds vs 23.4+/-8.8seconds). The

difference between two group was statistically significant Similar to our study various other studies [16,18,19,22,23] also found that the mean airway insertion time was longer with bougie guided insertion than with the introducer tool guided insertion of Pro Seal LMA [16,18 , 19]

Haemodynamic parameters

Both insertion technique of Pro Seal LMA are comparable with respect to the haemodynamic parameters. The mean pulse rate and mean arterial pressure shows no significant change in two insertion technique .Other studies also showed no statistical difference in haemodynamic response to ProSeal LMA insertion by digital, bougie guided insertion or introducer guided insertion.[18,19.22-,23,24].

Complications

In our study we found that the overall complications in both groups were comparable and statistically insignificant. Comparing individual complications, blood staining on the device and sore throat are although common in introducer guided group it is not statistically significant. Coughing was more in bougie guided group. Using Fishers exact test it was found that the difference is not statistically significant. Dysphagia was seen in 20% of patients bougie guided insertion. It is not associated with introducer guided insertion. Using Fishers exact test it was found that the difference is statistically significant.

Anand Kuppusamy[18] in a study comparing bougie guided insertion of Pro Seal LMA vs digital insertion found that the incidence of blood staining of Pro Seal LMA was same in both groups .sore throat occurred in 10% patients in digital technique, while it was not noted in GEB technique. But the difference was not statistically significant. Teoh C Y et al [25] compared introducer tool and bougie guided insertion in children and found that the frequency of airway releated problems were similar in both groups.

In our study there was no episode of hypoxia noted in the intra operative period. The mean SpO2 was comparable and was statistically insignificant.

The first attempt success rate was higher with Gum Elastic Bougie technique than introducer Tool technique. Several studies conducted on adult and paediatric patients confirm this finding.[10,19,23] The higher first attempt success rate with GEB technique is due to the fact That it reduces the impaction at the back of the mouth, prevents folding over of distal cuff and guides the distal cuff directly in to its correct position in the hypopharynx when Pro Seal LMA is primed with Gum Elastic Bougie. The effective airway time was longer with Gum Elastic Bougie-guided insertion than introducer tool technique in our study. This is in concurrence With the studies conducted in adult and paediatric patients[23]. Effective airway time was Longer with GEB-guided technique because of increased time needed for laryngoscopy and Gum Elastic Bougie placement.

Conclusion

Our study of two insertion techniques of Pro Seal LMA, bougie guided vs introducer guided during general anaesthesia showed that the bougie guided insertion was associated with significantly higher first attempt success rate and was much easier to insert with fewer manipulations. Though bougie-guided insertions of Pro Seal LMA took longer time, it had less number of failed insertions. Gum Elastic Bougie guided, laryngoscope aided insertion of Pro Seal LMA is an excellent alternative to other insertion techniques in adults

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