

Comparison of three insertion techniques of ProSeal laryngeal mask airway: A randomized clinical trial

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Abstract

Background and Aims: We aimed to compare three techniques for insertion of ProSeal laryngeal mask airway (PLMA).

Material and Methods: Two hundred ten patients (American Society of Anaesthesiologists I-II, aged 18-60 years) undergoing general anesthesia using the PLMA as an airway management device were randomly allocated to digital (D), rotational (R), or pharyngoscopic (P) techniques. In the D group ($n = 70$), the PLMA insertion was performed by using digital manipulation. In the R group ($n = 70$), the PLMA was inserted into the mouth, rotated anticlockwise through 90° and advanced into the hypopharynx. In the P group ($n = 70$), the PLMA was inserted after gentle pharyngoscopy using laryngoscope. Success rate at the first attempt, insertion time, airway manipulations required, and postoperative complications were noted.

Results: Insertion at first attempt was more successful with P technique than the R and D groups (100% vs. 98.5% vs. 81.4% respectively, $P < 0.01$). Insertion time was shortest for the P group which was statistically significant compared to the group D ($P < 0.001$), but comparable with the R group. None of the patients required manipulation in the P group compared to the group R ($P = 0.04$) and D ($P < 0.001$). Blood staining (group P = 2.8% vs. group R = 2.8% vs. group D = 22%, $P < 0.0001$) and sore throat (group P = 0% vs. group R = 6.9% vs. group D = 16.7%, both: $P < 0.005$) were lower with the pharyngoscopic technique.

Conclusion: We conclude that the pharyngoscopic technique for PLMA insertion is more successful with lower incidence of complications (mucosal bleeding and sore throat).

Key words: Insertion technique; ProSeal laryngeal mask airway, success rate

Introduction

ProSeal laryngeal mask airway (PLMA) has a wedge-shaped dorsal cuff to improve the seal and a drainage tube lateral to the airway tube. The drainage tube provides a channel for gastric tube placement which prevents gastric insufflation and pulmonary aspiration.^[1-4] This second tube can also determine the correct positioning of the mask compared to classic laryngeal mask airway (cLMA).^[4] The PLMA has a higher oropharyngeal and esophageal leak pressure than the cLMA.^[4-8]

PLMA insertion is generally performed blindly. It is more difficult to insert at first attempt than the cLMA, with success rates at first attempt varying between 82% and 100%.^[7,8] The PLMA, when placed using the digital technique or introducer tool, does pose problems during placement, because of impaction at the back of the mouth, folding over of the cuff, and failure of the distal cuff to reach its correct position in the hypopharynx, leading to inadequate ventilation.

Many new techniques have been described to overcome these problems such as use of a gastric tube,^[9,10] suction catheter,^[11] gum elastic bougie (GEB),^[12] fiberscope,^[13] with higher

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success rates and better placement of the PLMA. Gastric tube or suction catheter may not be sufficiently stiff to guide the PLMA around the back of the mouth. Disadvantages of GEB technique are airway stimulation, pharyngeal trauma, and requirement of an assistant.^[14] These techniques can be used as a backup when the digital technique fails. Hwang *et al.*^[15] recently described insertion of PLMA with 90° rotational technique with an overall success rate of 100% as compared to standard digital technique.

Most of the techniques of ProSeal insertion are performed blindly. We propose that pharyngoscopy using a laryngoscope might improve insertion conditions by widening the pharynx and facilitate advancing the PLMA against the posterior pharyngeal wall. We hypothesized that the success rate of insertion of the PLMA under pharyngoscopy would be more successful compared to 90° rotational technique or the conventional digital method.

Material and Methods

After obtaining Institute Ethics Committee clearance, this prospective, randomized clinical study was undertaken in our institute. 210 patients scheduled to undergo short surgical procedures with general anesthesia using a PLMA were recruited for the study. Adults of either sex in the age group of 18-60 years, belonging to American Society of Anaesthesiologists physical status I-II were included. Patients with anticipated difficult airway (mouth opening <2.5 cm), those at risk of aspiration (nonfasted, gastroesophageal reflux disease, pregnancy) or with recent sore throat were excluded. An informed consent was taken from the included patients. Randomization was determined using random number generator, and then the techniques were concealed in opaque sealed envelopes until before induction.

All patients were kept nil per oral from 10 pm on the previous night and were premedicated with pantoprazole 40 mg orally on the night before surgery and pantoprazole 40 mg and 8 mg ondansetron 2 h before surgery. On arrival in the operation theater, baseline hemodynamic parameters including heart rate (HR), blood pressure (BP), and room air saturation were noted. An intravenous line was secured with an 18 G IV cannula. Patients were preoxygenated preoperatively. Anesthesia was induced with midazolam 0.05 mg/kg, fentanyl 2 mcg/kg, propofol 2 mg/kg and atracurium 0.5 mg/kg. Depending on the patient's weight, PLMA size 3 or 4 was inserted with the patient in sniffing position, by one of three techniques. Anesthesiologists who had experience in PLMA insertion for 2 years were the investigators in this study. HR and mean BP were recorded 1 min before and 1, 5, 10 min after insertion.

The posterior and lateral aspects of the deflated mask were coated with a water-based lubricant. In the digital technique (Group D) the PLMA was inserted using the index finger and advanced along the palatopharyngeal curve into the hypopharynx until definite resistance was felt. In the rotational technique (Group R) it was held with the cuff facing right laterally, inserted until the entire cuff was inside the mouth, and then rotated anti-clockwise through 90° and advanced into the hypopharynx until definite resistance was felt. In the pharyngoscopic technique (Group P) it was held like a pen and inserted into the pharynx after pharyngoscopy (pushing the tongue to the left side of the mouth) using a laryngoscope. The following airway maneuvers (chin lift and jaw thrust) by investigators were allowed for PLMA insertion.

Once the PLMA was inserted into the hypopharynx, the cuff was inflated with an appropriate volume of air. An effective airway was judged by a square wave on capnography and no audible oropharyngeal air leak with peak airway pressures of 12-14 cm H₂O. The requirement for manipulation (chin lift, jaw thrust) while inserting the PLMA was recorded. Insertion time was the time between picking up the PLMA and successful placement. The PLMA was repositioned if there was failed passage of PLMA into the pharynx, audible air leak, failed gastric tube insertion or ineffective ventilation (expired tidal volume <8 ml/kg and end-tidal carbon dioxide >45 mmHg). The number of insertion attempts was recorded. If placement failed after three attempts, insertion was recorded as a failure and the technique of insertion was changed. At the end of surgery, PLMA was removed after recovery criteria were met. An anesthetist blind to the method of insertion recorded the presence or absence of visible blood on PLMA. Patients were asked for sore throat 1 h postoperatively.

Episodes of broncho/laryngospasm and desaturation were not recorded as the PLMA insertion was done under adequate depth of anaesthesia after neuromuscular blockade and change of technique was immediate whenever the placement of PLMA failed.

Statistics

Sample size was determined on the basis of a previously published study^[15] in which the success rate for the first attempt at the insertion of PLMA using standard method was 85%. Accepting 15% incremental improvement in success rate, we calculated minimum sample size of 63 patients in each group, assuming type 1 error (two-tailed test) to be 5% and power of 0.8. Therefore, 70 patients per group were enrolled to compensate for possible dropouts.

The primary outcome was the success rate of insertion at the first attempt. Secondary outcomes were insertion

time, the number of airway manipulations and postoperative complications. Mann-Whitney U-test was used to compare the age, weight, time for insertion, MAP and HR. The number of insertion attempts (success rates), manipulations, and the occurrence of complications like blood staining on PLMA and sore throat were compared using Chi-square analysis and Fisher exact test. $P < 0.05$ was considered significant. The statistical analysis was conducted using Statistical Package for Social Sciences (SPSS version 18, IBM Corp., USA 2010).

Results

The demographic data was comparable among groups [Table 1]. Insertion was more frequently successful with the pharyngoscopic technique at the first attempt than the 90° rotational or digital techniques (100% vs. 98.5% vs. 81.4% respectively, $P < 0.005$). There were no failures of pharyngoscopic technique. 90° rotational technique failed in one patient after a single attempt. The digital technique failed in 13 patients after single attempt, six patients after the second attempt and three patients after three attempts. The overall success rate of the digital technique was 95.7% [Table 2].

Insertion time was shortest for the pharyngoscopic group. This was statistically significant compared to the digital group ($P < 0.001$), but comparable with the rotational technique [Table 2]. None of the patients required manipulation in pharyngoscopic technique compared to rotational ($P = 0.04$) and digital technique ($P < 0.001$) [Table 2].

There was no significant change in hemodynamics (HR and mean BP) among the three groups. The incidence of blood staining (Group P and Group R = 2.8% vs. Group D = 22%, $P < 0.001$) was lower with both pharyngoscopic and the rotational technique as compared to the digital technique [Table 3]. None of the patients in pharyngoscopic group had sore throat postoperatively (Group P = 0% vs. Group R = 7.1% vs. Group D = 16.7%, both: $P < 0.05$) [Table 3].

Discussion

PLMA insertion is generally performed blindly and is more difficult to insert at first attempt than the cLMA.^[4,6,8] The success rate of first attempt insertion using standard digital technique is almost 79-96%.^[6,8] An unfortunate consequence of this technique is that the anesthesiologist's fingers may scrape against the patient's lower teeth. Many alternative techniques such as rotational, fully or partially inflated cuff, change of head position, GEB-guided, lateral, use of introducer technique have been described to improve the success rate of PLMA insertion.^[9-12] We

used pharyngoscopy technique using laryngoscope which improves the insertion conditions by widening the pharynx. Laryngoscopic technique has been previously described for insertion of the cLMA.^[16]

We found that the first attempt success rate was higher with pharyngoscopic technique. The first attempt success rate for the digital technique was similar to that in previous studies.^[6,8]

The number of insertion attempts was more for the digital group. Causes for failed insertion were impaction at the posterior part of the pharynx and folding over of the distal cuff.^[6] The ability to insert the PLMA after previous failure to insert with digital technique in three cases shows better insertion with pharyngoscopic technique.

We found that the time taken to successful placement was shortest in the pharyngoscopic technique. This time difference may not be significant for the routine cases, but it is important in emergency situations where securing the airway is of prime importance. Insertion time was shorter for both pharyngoscopic and rotational technique compared to the digital one. Previously Hwang *et al.*^[15] found no difference to insertion time between rotational and digital technique.

PLMA is more difficult to insert than cLMA due to the large dorsal cuff and the rigid end.^[17] PLMA is difficult to place in the mouth, leaves less room for the index finger and requires manipulations like jaw thrust and chin lift. We found none of the patients required manipulations for PLMA insertion in the pharyngoscopic technique group, compared to the other two techniques.

A popular method of PLMA insertion using GEB with a laryngoscope has been shown to improve the ease and overall success of PLMA insertion in adults compared to digital and introducer techniques.^[14,18] However, this method needs an assistant^[19] and causes trauma to mouth and esophagus.^[20] The advantage of the pharyngoscopic technique is that it doesn't require assistance and does not cause trauma. Complications like blood staining and sore throat were less frequent with the pharyngoscopic technique.

Table 1: Patient characteristics

Variables	Group D (n = 70)	Group R (n = 70)	Group P (n = 70)
Age (years)	39.2±15.1	38.5±12.4	39±14.7
Weight (kg)	57±11.4	56.1±12.9	56.7±10.9
Male:female (n)	36:34	30:40	32:38
ASA I:ASA II (n)	55:15	58:12	52:18

Values are mean ± standard deviation. ASA = American Society of Anaesthesiologists physical status

Table 2: Insertion results

Parameter	Group D (n = 70)	Group R (n = 70)	Group P (n = 70)	P (Group R vs. P)
Attempts				
1 st /2 nd /3 rd / >3	57/7/3/3	69/1/0/0	70/0/0/0	
Overall	67 (95.7)	70 (100)	70 (100)	
Success rate at 1 st attempt				
P		0.007*	$<0.001^*$	0.319
Manipulations present (yes/no)	32/38	8/62	0/70	
P		$<0.001^*$	$<0.001^*$	0.004*
Insertion time (seconds)	22 \pm 5	18 \pm 4	17 \pm 4	
P		$<0.001^*$	$<0.001^*$	0.502

*P < 0.05 = Statistically significant

Table 3: Incidence of visible blood on the ProSeal laryngeal mask airway and sore throat

Parameter	Group D	Group R	Group P	P (Group R vs. P)
Blood staining present (yes/no)	16/54	2/68	2/68	
P		$<0.001^*$	$<0.001^*$	0.989
Sore throat present (yes/no)	12/58	5/65	0/70	
P		0.07	$<0.001^*$	0.024

*P < 0.05 = Statistically significant

This may be due to the lack of impaction at the mouth and the need for fewer insertion attempts. Pharyngoscopy keeps the mouth wide open and prevents the tongue being pushed back into the air passage resulting in easy insertion.

Evans *et al.* demonstrated that PLMA causes a minimal hemodynamic response to the insertion.^[21] In our study, there was no significant change in HR and mean BP among all the groups. This finding is in concurrence with other studies.^[14,15] The disadvantage of the pharyngoscopic technique may be the potential for laryngoscopic reflexes. But there was no significant difference in hemodynamic response in our study, probably because technically pharyngoscopy was done instead of full laryngoscopy hence lower amount of force was required.

Size 5 PLMA was not used in patients of all the groups weighing more than 80 kg as some patient's passive mouth opening was not sufficient to accommodate a mask of that size. Tan *et al.* have showed that the size 5 PLMA in Asian population resulted in increased mucosal injury and that size 3 and 4 resulted in an effective glottic seal.^[22]

Our study has a number of limitations. First, intraoperative data was collected by unblinded observers. However, postoperative data was collected by blinded observers. Second, fiberoptic grading of PLMA placement was not done. Third,

cuff seal pressure was not measured. The leak pressure was assessed at only 12 cm H₂O, and ventilation was maintained thereafter. The most common airway sealing pressure test involves listening over the mouth and noting the airway pressure at which the gas escapes. Keller *et al.*^[5] concluded that for clinical purposes, the manometry stability test may be the appropriate test for comparing the airway seal pressures. Fourth, this study was done in paralyzed patients so there was minimal resistance in the oropharynx for pharyngoscopy during PLMA insertion, and only mild airway trauma was encountered. This may not be the case in spontaneously breathing patients.

Conclusion

Pharyngoscopic technique has a higher first attempt success with few airway manipulations. We conclude that pharyngoscopic technique for PLMA insertion is overall more successful than the digital technique and a decreased incidence of complications in terms of sore throat and mucosal bleeding without increasing the hemodynamic response.

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Conflicts of interest

There are no conflicts of interest.

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