



A Prospective Randomised Clinical Trial for the Comparison of Two Techniques for the Insertion of Proseal Laryngeal Mask Airway in Adults-Index Finger Insertion Technique versus 90° Rotation Technique

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Objective: The 90° rotation technique for inserting the Proseal laryngeal mask airway (PLMA) is reported to be better than the standard index finger insertion technique to improve the insertion success rate. The objective of this study was to evaluate and compare the ease of insertion through the 90° rotation and standard insertion techniques in terms of number of attempts, duration of insertion and occurrence of complications.

Methods: One hundred and twenty adult patients were allocated to either a standard technique group or rotation technique group with 60 patients in each. In the rotation technique group, the entire cuff of the PLMA was placed in the patient's mouth in a midline approach without finger insertion, rotated 90° counter-clockwise around the patient's tongue, advanced and rotated back until resistance was felt.

Results: The success rate of the rotation technique group at the first insertion attempt was greater than that of the standard index finger insertion technique (98% vs. 78%; $p=0.001$), and less time for insertion was required (11.88 ± 3.62 s vs. 25.98 ± 10.92 s; $p<0.0001$). The incidence of post-operative sore throat was lower (15% vs. 38.34%; $p=0.0067$), and blood staining on the PLMA was less (11.7% vs. 45%; $p<0.0001$). The increase in the mean arterial pressure was more in the standard technique group.

Conclusion: The 90° rotation technique has a higher success rate at first insertion attempt for inserting the ProSeal LMA than the index finger insertion technique with less time for insertion and fewer side effects.

Keywords: LMA insertion techniques, 90° rotation technique, airway management, laryngeal masks, ProSeal LMA

Introduction

Dr. Archie Brain modified the classic laryngeal mask airway (cLMA) in 2001 and thus devised the Proseal laryngeal mask airway (PLMA) (1). This double lumen, double cuff PLMA has some clear advantages over its predecessor (1, 2). Placing the LMA in the correct position requires skill. Standard Brain's cLMA insertion technique (the classic technique) is more manipulative as it requires finger insertion and guidance (3). Various cLMA insertion techniques have been tested with regard to ease of insertion in all age groups (4, 5). These techniques have been used for the insertion of PLMA. They include digital insertion, which is the classic technique; introducer-guided insertion, which allows the PLMA to be inserted like the intubating LMA; and gum elastic bougie (GEB)-guided insertion (6-8).

The manufacturer provides a silicone-coated, malleable metal introducer with the PLMA. GEB-guided insertion requires a laryngoscope and intentional insertion into the oesophagus. It is therefore unlikely to be the first technique of choice. The insertion time of the PLMA is longer than that of the cLMA. PLMA insertion is more difficult than the classic technique because it has a softer bowl and its edge is more curved (9). A 180° rotation technique involving insertion of the mask back-to-front like a Guedel airway has been used. However, this technique results in some residual rotation in the coronal plane in adults and does not improve ease of insertion in children (3, 5, 10, 11).

A 90° rotation technique has been described, and it is more successful than the standard technique and is associated with less airway morbidity (12). It does not involve the use of additional introducer aids. The reported first attempt success rate is 67%–90% with the standard cLMA insertion technique (13, 14), whereas it is 86% in adults and 99% in children with

the rotation insertion technique (3, 15). With regard to the success rate and ease of cLMA insertion, the 90° rotation insertion technique has not been widely studied in adult populations (16, 17).

The objective of this study was to evaluate and compare the ease of PLMA insertion through the 90° rotation technique with that of the index finger insertion technique (henceforth referred to as the standard technique) in terms of number of attempts, insertion time, airway morbidity, gastric insufflation and leaks around the cuff and haemodynamic changes.

Methods

This prospective randomised clinical study was conducted at a tertiary care hospital on patients undergoing short, elective surgical procedures requiring general anaesthesia. A total of 120 adult surgical candidates of each sex, aged 18–60 years, with ASA I or II and Mallampati I or II, were randomly divided into two groups of 60 each (with computer-generated random numbers). These candidates were undergoing short elective surgery that required general anaesthesia and did not require tracheal intubation. The two groups were designated as Group S (n=60, standard index finger insertion technique) and Group R (n=60, rotation insertion technique).

Patients with significant acute or chronic lung disease, pathology of the neck or upper respiratory tract, potentially difficult intubation, increased risk of aspiration (hiatus hernia, gastro-oesophageal reflux or full stomach), pregnant women and BMI of >30 were excluded.

Approval was obtained from the departmental research committee and institutional ethics board, and written informed consent was obtained from each patient. All patients received a tablet of diazepam (5 mg) orally the night before the surgery for anxiolysis. In the operation theatre, an intravenous line was established with a 20G cannula. Standard anaesthesia monitors included non-invasive blood pressure, pulse oximeter, electrocardiogram and end-tidal carbon dioxide monitor. Baseline blood pressure, heart rate (HR) and peripheral O₂ saturation were recorded. The anaesthesia protocol was standardised. Patients of both groups were intravenously administered metoclopramide (10 mg) and ranitidine (50 mg) 15 min before surgery. Three sprays of 10% lignocaine were applied to the posterior oro-pharynx. Midazolam (0.02 mg kg⁻¹) and fentanyl (1 mcg kg⁻¹) were intravenously administered. Following pre-oxygenation for 2 min, anaesthesia was induced with propofol titrated to the loss of verbal contact with the patient, loss of eyelash reflex and relaxation of the jaw. If coughing, gagging or body movement occurred during insertion of the device, propofol (1 mg kg⁻¹) was added to achieve an adequate level of anaesthesia. For safety concerns, before the insertion of the devices after loss of verbal contact, we checked that hand-ventilation with a face mask was possible. Once the patient became apnoeic and an adequate depth of anaesthesia was achieved based on clinical judgement (i.e.

jaw relaxation), the deflated PLMA size 3 in females and size 4 in males was inserted. Before insertion of the PLMA, the cuff was partially inflated (i.e. filled with half the recommended air, 10 mL in size 3 and 15 mL in size 4). In the standard technique (Group S), the PLMA was placed using Brain's insertion technique. The patient's head was positioned with the head extended at the atlanto-axial joint and flexed at the neck with the non-dominant hand. The PLMA was held like a pen, and the index finger was placed at the junction of the PLMA tube and cuff. The index finger was used to press the PLMA against the hard palate and posterior pharyngeal wall until definite resistance was felt at the base of the hypopharynx. The PLMA was then held with the non-dominant hand, and the index finger was removed.

In the rotation technique (Group R), the entire cuff of the PLMA was placed in the patient's mouth in a midline approach without finger insertion, rotated 90° counter-clockwise around the patient's tongue, advanced and then rotated back until resistance was felt.

Following PLMA insertion in both techniques, the PLMA was inflated with 20 mL of air in size 3 and 30 mL in size 4 to obtain proper seal. Successful placement was checked by chest expansion, reservoir bag movement and appearance of capnographic tracing. The end point of each insertion was when there was bilateral chest movement, a square wave on a capnograph and an SpO₂ of >95%. The surgeon was requested not to clean, drape or position the patient until 5 min after the placement of the supraglottic device to avoid any stimuli likely to interfere with the findings. Anaesthesia was maintained with sevoflurane and oxygen plus nitrous oxide. Patients were intraoperatively monitored for HR, non-invasive blood pressure and SpO₂. At the completion of the surgery, the PLMA was removed in a deep plane of anaesthesia.

Study parameters

Attempts of insertion - Number of attempts taken to insert the PLMA

Insertion time (s) (18): This is the time interval between holding the airway device up and confirmation of the correct placement by bilateral air entry on chest auscultation.

The end point of each insertion was when there was bilateral chest movement, a square wave on a capnograph and an SpO₂ of >95% (18).

Oropharyngeal leak (grade) (16): This signifies malposition of the device. It is detected by giving 20 cm H₂O pressure and is divided into grade 1 (no leak), grade 2 (palpable leak), grade 3 (audible leak with appropriate ventilation), grade 4 (audible leak with inappropriate ventilation), grade 5 (complete obstruction with no ventilation).

Haemodynamic changes: Such as HR, systolic blood pressure, diastolic blood pressure, mean arterial pressure (MAP)

and SpO₂ at the time points before insertion, immediately after insertion and 2 and 5 min after insertion were measured.

Complications: Variables studied were incidence values of the intraoperative gastric insufflation, blood staining of the device at removal and post-operative sore throat.

Statistical analysis

Sample size: A previous study reported 17% higher success rate with the 90 degree rotation technique (19). Expecting a minimum difference of 17% in the success rate we chose a sample size of 60 patients per group. This will give a power of 80% to the study considering type 1 error of 0.05 (two-tailed).

Study data were analysed using the Student’s t test for independent parametric data, general linear model for repeated measure parametric data, chi-squared test or Fisher’s exact test for non-parametric data. Statistical software used were Statistical Package for the Social Sciences (SPSS Inc.; Chicago, IL, USA) 14.0 version, GraphPad InStat 3.06 and Microsoft Office Excel 2007.

Results

The total number of patients was 120 and 60 patients were assigned to each group. None of the patients dropped out of the study. Both groups were comparable with regard to demographic data, i.e. age, sex, body mass index (BMI), Mallampati grade and duration of surgery (Table 1).

Group R exhibited 98% success at the first insertion attempt and group S exhibited 78% with a significant statistical difference between the two groups (p=0.001). The insertion time was significantly less with the rotational technique compared with the standard technique (11.88 vs. 25.98 s; p<0.0001). The incidence of oropharyngeal leak was similar in the two groups (p=0.716). The two groups showed no significant difference in the incidence of gastric insufflations (p=0.789). We observed a higher percentage of blood staining of the PLMA with the standard technique than with the rotation technique (45% vs. 11.7%, p<0.0001). Fewer patients in the rotational technique group had post-operative sore throat compared with those in the standard technique (15% vs. 38.34%, p=0.0067) (Table 2).

There was no significant difference in HR between the two groups at different intervals. However, MAP showed a significant increase with the standard technique after insertion and at 2 min after insertion compared with the rotation technique (p=000) (Figure 1).

Discussion

This study demonstrates that the 90° rotation technique is superior and has advantages over the standard technique with respect to insertion attempts, insertion time, blood staining of the PLMA and sore throat. It is associated with less hae-

	Group S	Group R	P
Age (years) Mean±SD	28.88±10.05	28.75±9.16	0.94
Gender			
Male	10 (17%)	9 (15%)	1
Female	50 (83%)	51 (85%)	1
Duration of surgery			
Mean (min)±SD	22.3±5.9	23.6±6.4	0.12
SD: standard deviation			

	Group S	Group R	P
Insertion attempts			
1	47 (78%)	59 (98%)	<0.001
>1	13 (22%)	1 (2%)	
Insertion time in seconds (mean±SD)	25.98±10.92	11.88±3.62	<0.001
Oropharyngeal leak			
Grade I	48 (80%)	51 (85%)	0.716
Grade II	7 (11.67%)	6 (10%)	
Grade III	5 (8.33%)	3 (5%)	
Gastric Insufflation			
Yes	9 (15%)	7 (11.67%)	0.789
No	51 (85%)	53 (88.33)	
Blood staining of PLMA			
Yes	27 (45%)	7 (11.7%)	<0.001
No	33 (55%)	53 (88.3%)	
Sore throat			
Yes	23 (38.34%)	9 (15%)	0.007
No	37 (61.66%)	51 (85%)	
PLMA: Proseal laryngeal mask airway			

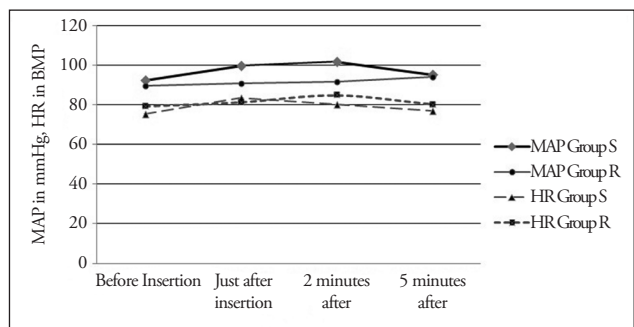


Figure 1. Haemodynamic changes
MAP: mean arterial pressure; HR: heart rate; BMP: beats per minute

modynamic disturbances at insertion. All techniques except the standard technique involve the use of various additional aids for insertion. In the classical technique, which is a digital technique, excessive force may be required to correctly position the PLMA. Here, there is more probability of multiple insertion attempts, prolonged insertion time, trauma to airway and failure of PLMA insertion.

Brodrik et al. (20) has mentioned the reason for placement difficulty, and LMA insertion failure is due to the downfolding of the epiglottis and backward rotation of LMA in 10% of his study population with the recommended standard Brain's insertion technique. Very few studies have been conducted regarding rotation insertion as an alternative method for insertion in the adult population (16, 17, 20).

The 90° rotation insertion technique is convenient because it does not require additional devices or use of fingers to aid insertion. The technique simply consists of insertion of the PLMA into the oral cavity, 90° rotation around the tongue and advancement (19). It may seem that rotating the large cuff inside the mouth may be difficult, but it is easy to insert PLMAs using the rotation insertion technique. For patients from the Indian subcontinent, a size 3 in females and size 4 in males were used (21).

In our study, the first attempt success rate of insertion was higher for the rotation technique group than for the standard technique group (98% vs. 78% with a mean difference of 20%; $p=0.001$). The study demonstrated that less time was required for PLMA insertion in the rotation group compared to the standard group (11.88 ± 3.62 s vs. 25.98 ± 10.92 s; 95% C.I – 11.157 to 17.043; $p<0.0001$). The technique is also beneficial in that it involves less morbidity in the form of a lower incidence of post-operative sore throat (15% vs. 38.34%; $p=0.0067$), blood staining of the PLMA (11.7% vs. 45%; $p<0.0001$) compared with the standard technique. The MAP increased significantly with the standard technique ($p<0.05$, during insertion 99.8 ± 12.34 mmHg vs. 90.77 ± 7.34 mmHg and at 2 minutes after insertion 101.78 ± 12.37 mmHg vs. 91.77 ± 7.34 mmHg).

Jeon et al. (19) reported a higher success rate at first insertion attempt for the rotation technique group than for the standard technique group (100% vs. 83%, respectively; $p=0.003$). In their study, less time was required for PLMA insertion in the rotation group compared to the standard group (11 ± 3 vs. 19 ± 16 s, $p=0.003$). The blood pressure change showed a group-insertion interaction effect ($p<0.001$). Although they claim that the blood pressure effect was statistically significant, the quantum of mean change was trivial and of no clinical relevance. Our study showed a greater difference in the time of insertion between the two groups, but the insertion time for PLMA was more or less comparable. They might have more experience in the use of the standard technique, which could explain the marginally less time for insertion with this technique. According to a study by Yun

et al. (22) in a total of 92 paediatric patients, the systolic, diastolic and mean blood pressure and HR increased significantly with the standard technique ($p<0.001$). Yun et al. (23), in a study involving a total of 126 paediatric patients aged 3 to 9 years, concluded that the incidence of sore throat was not significantly different (24% vs. 22%, $p=0.9$), which is in contrast to our study. Our incidence of sore throat was less with the rotation technique (15% vs. 38.34%, $p=0.0067$). We presume that age and prior oropharyngeal hygiene can be confounding factors.

However, our results agree with the findings of Kumar et al. (21) although the study was with cLMA, the technique used by them is the same as our technique, hence, it is of interest to study their findings. The incidence of trauma (blood stained LMA on removal) with the standard insertion technique was 28% compared to 6% with the rotation LMA insertion technique. They remarked that the insertion time was similar in the two techniques because the rotation cLMA insertion technique could be accomplished in less than 30 s 86% of the time compared to 78% with the standard cLMA insertion technique. They did find a difference between the two groups, but it was not statistically significant. Further, it can be argued that their definition of insertion time is different. They further claim that the frequency of the insertion attempts was similar in both the standard and rotation cLMA insertion techniques, which is in contrast to our study. However, their sample size was less robust than ours.

A 180° rotation technique similar to the technique of insertion of our age old oropharyngeal airway is also described. In a study conducted by Haghighi et al. (16), they compared two methods of cLMA insertion, "classic" versus "simplified" airway. Success in the first attempt in the latter group (86%) had no meaningful statistical difference compared with the classic group (80%, $p>0.05$). In the classic group, 32% of the cLMAs were blood stained compared to 16% in the simplified group ($p=0.06$).

The results are comparable to our study. It should be noted that their study was on a classic LMA and ours was on the PLMA. Our purpose in mentioning this study is because it involved a rotation technique, although a different kind. This 180° rotation technique involves greater rotation, and the device can be associated with higher torsion and more friction. It is our firm opinion that the 90° rotation technique is more advantageous, especially for the PLMA insertion.

Conclusion

From our study, we concluded that the success rate for the insertion of the PLMA at first attempt was greater and less time was required with the 90° rotation technique compared to the standard technique. The rotation technique has an additional advantage in the form of fewer hemodynamic changes and airway complications.

Ethics Committee Approval: Ethics committee approval was received for this study from the Institutional Ethics Committee of Krishna Institute of Medical Sciences Deemed University, (Decision dated 06.12.2012).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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