Original Article

Comparison of insertion characteristics of LMA ProSeal from the front and head-end of the patient: A randomized pilot study

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Abstract

Background and Aims: LMA ProSeal (PLMA) is a commonly used airway maintenance device in elective procedures and is routinely inserted from the head-end of the patient. It is also used in pre-hospital emergencies where it may not always be possible to access the head-end. This study aims to compare the insertion characteristics of PLMA when inserted while standing, either at the head-end or from the front.

Material and Methods: After institutional ethics committee approval, 60 consenting patients of either sex, between 18 and 60 years, ASA class I/II, and scheduled to undergo elective surgeries were randomly allocated to either group H (head-end insertion) or group F (front-end insertion). Patients with anticipated difficult airway, chronic respiratory disease, obesity, and who were pregnant were excluded. Insertion time, ease of insertion, fiber optic view, ease of drain tube insertion, number of attempts and success rate were noted. Normally distributed quantitative variables were compared using *t*-test, and qualitative variables were compared using Chi-squared test. A $P < 0.05$ was considered significant.

Results: Insertion time in group H (23.76 ± 4.48 s) was lesser than in group F (30.53 ± 6.23s) ($P = 0.027$). Ease of insertion ($P = 0.052$), fiber optic view, ease of drain tube placement ($P = 1.000$), and number of attempts ($P = 1.000$) were comparable among the groups.

Conclusion: Although the insertion time from the front is longer than from the head-end, the other insertion characteristics of PLMA including ease of its insertion, placement and success rate of placement are similar when it is inserted from the front or from the head-end. It is an appropriate airway device for securing the airway when the head-end is inaccessible.

Keywords: Airway, emergency health service, fiber optic grading, insertion technique, introducer tool, ProSeal LMA

Introduction

Supraglottic airway devices (SADs) have transformed the face of airway management not only in the elective but also in emergency scenarios. LMA ProSeal (PLMA) is a widely used device during elective procedures as well. There are three described techniques for its insertion: digital technique, introducer tool (IT) technique, and gum elastic bougie–guided technique. It can be inserted from either the head-end or from the front of the patient.[1] However, we could not locate any study comparing the insertion characteristics and correct placement of PLMA using IT with different operator positions. The primary outcome of the study was to compare the insertion time of PLMA when inserted from the head-end or from the front. The secondary outcomes were ease of insertion, fiber optic view, ease of drain tube insertion, number of attempts for successful placement, success rate of insertion in the first attempt, maneuvers, hemodynamic responses, and complications.

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Material and Methods

The study was conducted at a tertiary care teaching institute between November 2018 and April 2020 after obtaining clearance from the Institutional Ethical Committee-Human Research (letter no. IEC-HR/2018/36/11R dated 26-10-2018). The procedures adopted were in accordance with the Declaration of Helsinki, 2000. The study was registered with the clinical trial registry (Trial registration number: CTRI/2018/11/016281). A written, informed consent was obtained before enrolling the patients.

This prospective, randomized study was conducted on 60 American Society of Anesthesiologists (ASA) physical status I/II patients of either sex, aged between 18 and 60 years with Mallampati class I or II airway and body mass index (BMI) of <30 kg/m^2 who were scheduled to undergo an elective surgical procedure under general anesthesia requiring PLMA insertion. Patients with a mouth opening of <3 cm, chronic obstructive pulmonary disease, asthma, gastroesophageal reflux, oropharyngeal mass, features of raised intracranial pressure, and who were pregnant were excluded.

As per a computer-generated random number table, patients were assigned to one of two groups: group H (anesthesiologist position on the head-end of the patient, $n = 30$) or group F (anesthesiologist position in front of the patient on the right side, $n = 30$). Allocation concealment was done using sequentially numbered and sealed opaque envelopes. The patient was blinded to the group allocation, but the observer noting the insertion characteristics was not blinded to the group allocation.

After preoperative checkup, patients were wheeled into the operating room. Routine monitoring including non-invasive oscillometric blood pressure, electrocardiography, and pulse oximeter were attached. An 18-G intravenous cannula was inserted and intravenous (IV) inj. ringer's lactate was started. Anesthesia was induced with morphine 0.1 mg/kg IV and propofol 2–3 mg/kg IV till there was a loss of response to verbal commands. Vecuronium bromide 0.1 mg/kg IV was given after ensuring adequate bag and mask ventilation. An appropriately sized PLMA as per the manufacturer's recommendation was chosen. After checking the cuff for leaks, the tip was lubricated with a water-soluble lubricant and it was mounted on the IT. During insertion, the head of the patient was kept in the sniffing position and the PLMA was held in the dominant hand of the anaesthesiologist performing the insertion. Maneuvers, if required, was done with the non-dominant hand. The IT was removed carefully and the cuff was inflated with recommended volume of air. An anesthesia breathing circuit was attached and ventilation was started. Correct placement of PLMA was confirmed by auscultation of the chest and appearance of square wave capnography on the monitor. A lubricated gastric tube of appropriate size was passed through the drain tube. If more than three attempts were required, an endotracheal tube (ETT) of appropriate size was inserted.

Oxygen saturation, blood pressure (BP), and heart rate (HR) were monitored throughout the procedure. Anesthesia was maintained with 60% nitrous oxide, 40% oxygen and isoflurane, and intermittent top-ups of vecuronium bromide. Minute ventilation was adjusted to maintain an $EtCO_2$ between 35 and 40 mmHg. Neuromuscular blockade was reversed after completion of surgery with neostigmine 0.05–0.08 mg/kg IV and glycopyrrolate 0.008–0.01 mg/kg IV. The PLMA was removed once the patient was awake and spontaneous respiration had been achieved. The device was inspected for any bloodstain. Postoperative sore throat was recorded in the postoperative care unit up to 2 h before shifting the patient to ward.

Insertion time (time from opening of mouth till appearance of first capnography wave form), ease of PLMA insertion[2] (grade 1: no resistance; grade 2: mild resistance; grade 3: moderate resistance; grade 4: unable to pass device), fiber optic view of the glottis and esophagus,[3] ease of drain tube placement[2] (grade 1: easy; grade 2: difficult; grade 3: unable to pass), number of attempts and success rate of placement in the first attempt, maneuvers (jaw thrust, assistant help, lateral rotation of device, etc.), hemodynamic responses (at the time of insertion, 1 min, 5 min, 10 min post insertion, at the time of removal, 5 min post removal) and complications (trauma or sore throat) were noted.

On extensive search of literature, we could not find any direct study comparing time to insertion of PLMA when inserted from the head-end or the front of the patient. So, a sample size could not be determined. Hence this study was carried out as a pilot study with 30 cases in each group as a convenience sample.

The results were reported as mean ± SD or frequency (percentage). Quantitative parameters were compared using unpaired *t*-test or Mann–Whitney *U* test as appropriate. Qualitative data was compared using Chi-squared test or Fisher's exact test. All statistical calculations were done using the Statistical Package for the Social Sciences (SPSS) version 20.0. A P value of <0.05 was considered significant.

Results

Sixty-seven patients were assessed for eligibility and 60

were randomized [Figure 1]. In one of the patients in group H, the device could not be inserted in three attempts and an ETT was inserted for airway maintenance. Thus, 59 patients were analyzed, with 29 in group H and 30 in group F.

The two groups were similar with respect to the demographic profile [Table 1].

The mean insertion time was lesser in group H (23.76 ± 4.48 s) compared to group F (30.53 ± 6.23 s) ($P = 0.027$). The ease of insertion of PLMA was grade 1 in 29/29 patients (100%) in group H compared to 25/30 (83.3%) in group F. In 5/30 patients (16.7%) in group F, the ease of device insertion was grade 2. No patient in either group had grade 3 or 4 ease of device insertion. The overall ease of device insertion was comparable between the two groups ($P = 0.052$).

The fiber optic view of the glottis obtained through the airway tube and that of the esophagus obtained through the drain tube were comparable in both the groups [Table 2].

The ease of insertion of drain tube was grade 1 (easy) in 29/29 patients (100%) in group H and in 29/30 (96.7%) in group F. In 1/30 patients (3.3%) in group F, the ease of drain tube insertion was grade 2 (difficult). This difference was statistically similar among the groups ($P = 1.000$).

In group H, PLMA was inserted in the first attempt in 28/29 patients (96.5%), whereas two attempts were required for successful PLMA placement in 1/29 patients (4.5%). In group F, PLMA was inserted in the first attempt in 28/30 patients (93.3%) and two attempts were required in 2/30 patients (6.7%). However, this difference was not significant ($P = 1.000$).

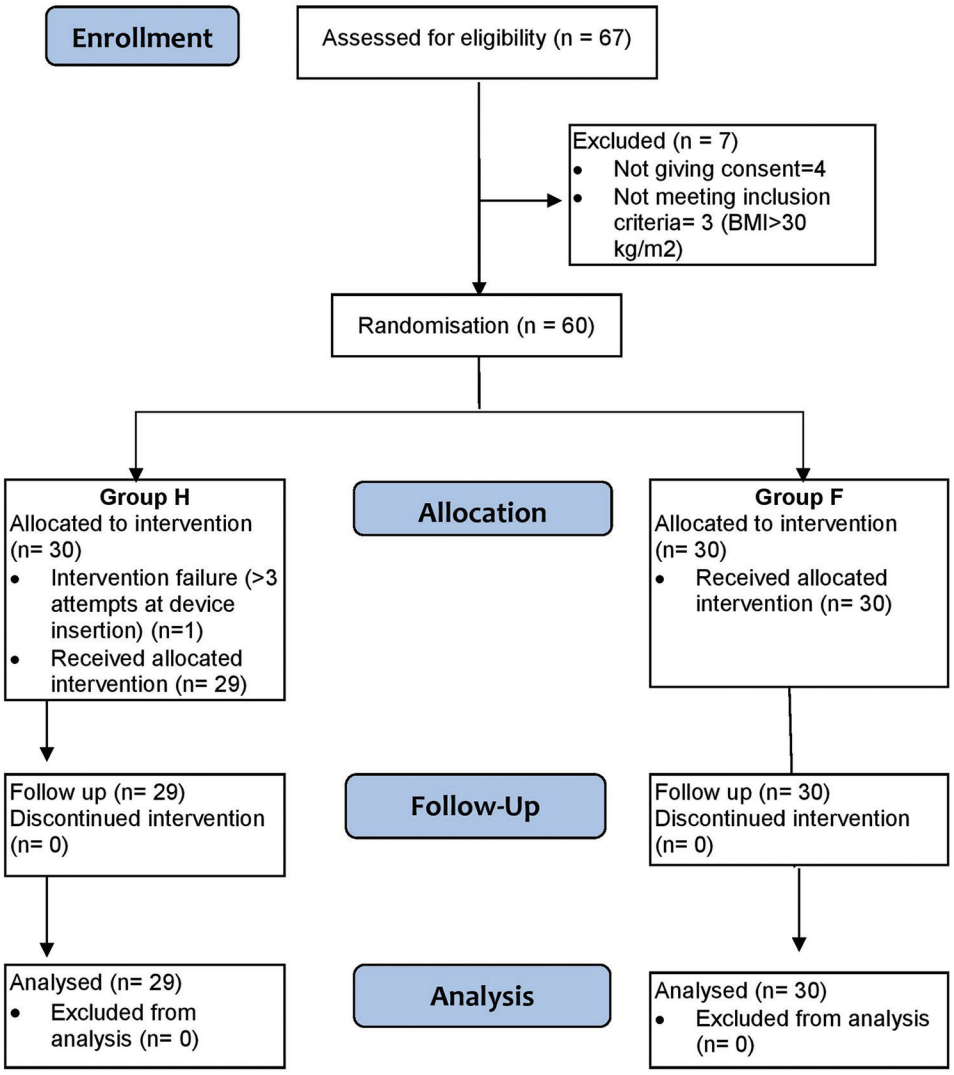

Figure 1: CONSORT flow diagram

The PLMA insertion did not require any maneuvers in 28/29 patients (96.5%) in group H compared to 25/30 patients (83.3%) in group F ($P = 0.228$). In 1/29 patients (4.5%) of group H, jaw thrust was required. In group F, 1/30 patients (3.3%) required head tilt maneuver, 3/30 (10%) required jaw thrust, and another 1/30 patients (3.3%) required both jaw thrust and assistant help for successful placement of PLMA.

The mean HR, systolic BP at baseline, device insertion 1, 5, and 10 min after insertion, at removal, and 5 min post removal are shown in Tables 3 and 4, respectively. There was no significant difference between the two groups with respect to the HR ($P = 0.314$) and systolic BP ($P = 0.827$) at the above-mentioned time points. The diastolic BP at the corresponding time points was also comparable among the groups ($P = 0.791$).

Blood staining of the PLMA post removal was noted in two patients each in group H and group F. None of the patients in group H and group F complained of sore throat after 2 h postoperatively.

Discussion

In this study, we compared the insertion characteristics of the PLMA when inserted with the operator standing either at the head-end or in front of the patient. The key findings from this study were that insertion of PLMA took considerably lesser time with the operator standing on the head-end compared to standing in front of the patient. The ease of device insertion, fibrotic view obtained from the airway tube as well as the drain tube, ease of drain tube insertion, number of attempts for successful device insertion, maneuvers required for successful placement, hemodynamic changes during insertion, and complications were comparable. Assistant help to maintain jaw thrust and head stabilization was required only in one patient.

The use of aids—like the IT or the gum elastic bougie—is known to improve the success rate of placement and the position of PLMA with respect to the glottis.[4] We used the IT technique for PLMA insertion both from the head end as well as from the front. Many studies have evaluated the time taken for insertion of the PLMA. The end points for the measurements vary from one study to another. However, most of the studies have found that it takes somewhere between 15 to 30 s for securing the airway and attaining effective ventilation with PLMA.[5–7] Similar timings were observed in our study as well. Since the anesthesiologists are more familiar with the insertion of airway maintenance devices from the head-end, it comes as a very conventional position to them, and hence it took lesser time for insertion from this position. Insertion of the device from the front took longer time as it was a relatively new and unconventional position. With more practice, the PLMA insertion time from the front may also reduce. The ease of device insertion was comparable from the head-end or the foot-end.

In 57/59 patients (96.6%) included in the study, the bowl of the PLMA aligned well with the glottic opening as the vocal cords and epiglottis were visualized when the fiber optic bronchoscope was introduced from the airway tube. The epiglottis did not cover the opening of the trachea, thus ensuring proper ventilation. However, in 2/30 patients (6.7%) of the front-end group, the vocal cords

Table 1: Demographic profile

	Group H (n=29)	Group F (n=30)	P
Age (years)*	37.37±10.16	38.33±12.26	0.239
Height (cm)*	158.10±5.61	156.17±4.90	0.710
Weight (kg)*	59.77±8.85	58.70±7.54	0.587
BMI (kg/m^2)*	23.86±2.94	24.06±2.87	0.690
Gender (M:F)†	4:25	5:25	
Size of PLMA (3:4:5)†	5:23:1	3:27:0	

**Values are expressed as mean±SD; †Values are expressed as ratio; P<0.05 is significant*

Table 2: Fiber optic view from the airway and drain tube

Grading	Description	Group H (n=29)	Group F (n=30)	P
Laryngeal Field				
1	Vocal cords not seen and device functions inadequately	0	0	0.219
2	Vocal cords not seen but device functions adequately	0	2	
3	Vocal cords and anterior epiglottis	24	20	
4	Vocal cords and posterior epiglottis	5	8	
5	Only vocal cords visible	0	0	
Esophagus				
1	Sealed orifice of esophagus	1	1	0.682
2	Crescent-shaped opening of esophagus	5	8	
3	Full opening of esophagus	23	21	

Values are number of patients; P<0.05 is significant

Table 3: Comparison of heart rate changes among the study groups at various time intervals

Time Points (min)	Group H (*n*=29)	Group F (*n*=30)	*P*
Baseline	84.97±13.922	89.20±13.48	0.314
Insertion	77.21±11.86	80.90±12.85	
1 min	75.14±11.45	77.70±12.91	
5 min	74.45±10.00	78.63±12.37	
10 min	72.86±11.07	77.00±11.28	
Removal	82.86±12.10	81.93±14.92	
5 min post removal	84.52±10.28	84.10±11.65	

Values are expressed as mean±SD; P<0.05 is significant

Table 4: Comparison of systolic blood pressure changes among the study groups at various time intervals

Time Points (min)	Group H (*n*=29)	Group F (*n*=30)	*P*
Baseline	127.79±12.51	128.83±13.24	0.827
Insertion	103.45±9.95	100.40±7.94	
1 min	102.07±7.99	100.87±8.53	
5 min	106.97±11.16	109.60±13.36	
10 min	112.21±13.03	110.00±12.35	
Removal	125.41±11.38	128.70±11.03	
5 min post removal	126.83±9.89	129.20±12.38	

Values are expressed as mean±SD; P<0.05 is significant

could not be visualized but proper ventilation was possible. Previous studies have found similar results.[3,5] When the fiber optic bronchoscope was inserted through the drain tube, we could visualize the esophagus either as a sealed orifice, round opening, or as a crescent-shaped opening with comparable views in both the groups. The ease with which the drain tube can be passed is an indirect indicator of the alignment of the opening of the drain tube with the upper end of esophagus. Since the ease of passing drain tube was comparable among the two groups, it indicates that the placement of PLMA from front of the patient was anatomically as acceptable as from the head-end.

In our study, the success rate of insertion was 96.67% (29/30) from the head end and 100% from the front. The number of attempts and maneuvers required for successful placement was comparable between the two groups. Thus, neither the procedure of insertion nor the success rate and placement were difficult from the front of the patient. Head tilt and/or jaw thrust was required occasionally. These maneuvers have been described in previous literature as well.[6]

The strength of the study is that it is probably the first study that has tried to determine the insertion characteristics of PLMA with two different positions of the airway manager. Secondly, for confirmation of correct placement of the PLMA, the clinical indicators of adequacy like chest rise and square-wave capnography were supplemented with fiber optic grading to determine the relative position of the glottis with the airway tube and drain tube with the esophagus. However, there are several limitations: Firstly, this study was conducted on patients with normal airway in a normal operation theater setting where the head-end was otherwise accessible for manipulation and intervention. Thus, results cannot be extrapolated to patients with difficult airway or emergency out-of-hospital scenarios where where the head end manipulation is not possible. Secondly, PLMA insertion was performed by experienced anesthesiologists. Hence, results may not be applicable to less experienced persons or paramedics. The longer time taken for successful device insertion from the front of the patient may be due to the longer experience in insertion from the head-end. Furthermore, the airway device insertion was done under the effects of a muscle relaxant, so the results may not necessarily be the same when PLMA insertion is attempted without muscle relaxation. Thirdly, failed insertion was not included in the analysis which may have influenced the results to some extent.

Front-end PLMA insertion is an effective technique to secure the airway and provide ventilation. Thus, the PLMA is a good device to use when head-end of patients is not accessible. Further comparisons of front-end insertion technique in difficult airway scenarios and in emergency settings with operators having different levels of experience are recommended.

Conclusion

From the above study, we conclude that PLMA can be inserted successfully for securing airway from the front of the patient. Though the time taken for successful PLMA insertion was longer when the device was inserted from the front and it was clinically not significant, the placement is as successful and as easy as that from the head-end.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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