Original Article

A novel technique for insertion of ProSeal™ laryngeal mask airway: Comparison of the stylet tool with the introducer tool in a prospective, randomised study

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ABSTRACT

Background and Aims: The ProSeal™ laryngeal mask airway (PLMA) has a soft cuff which tends to fold on itself during insertion, resulting in reduced first-attempt success rate. We compared the standard introducer technique of PLMA insertion with a novel method to prevent folding of the cuff using a Rüsch™ Stylet **Methods:** This randomised superiority trial included 120 American Society of Anesthesiologists I–II patients between 18 and 80 years, undergoing elective surgeries under general anaesthesia using a PLMA for airway management. The PLMA was inserted using the standard introducer tool in sixty patients (Group IT), while in sixty other patients, a Rüsch™ Stylet was inserted through the drain tube up to its tip. (Group ST). The primary outcome was first-attempt success rate. Secondary outcomes included overall insertion success, number of attempts, total time to successful insertion, presence of air leaks, haemodynamic response to insertion and quality of fit assessed using Brimacombe's fibre-optic scoring. Continuous variables were compared using independent *t*-test or Mann–Whitney U-test and categorical variables were analysed using Chi-square test or Fisher's exact test. **Results:** First-attempt success rate of insertion was higher in Group ST compared to Group IT (95% vs. 82%, $P = 0.04$). Favourable grade of placement was better in Group ST (86.7% vs. 52.5%, $P < 0.001$). Overall insertion success rates and haemodynamic responses were comparable between the groups. **Conclusions:** PLMA insertion using the stylet tool has a higher first-attempt insertion success and superior placement compared to insertion using the conventional introducer tool.

Key words: Airway, introducer, laryngeal mask, ProSeal™ laryngeal mask airway, stylet

INTRODUCTION

The ProSeal™ laryngeal mask airway (PLMA) is a supraglottic airway device with a modified cuff that provides improved quality of seal, and a drainage tube to evacuate gastric content and decompress the stomach, thereby reducing the risk of aspiration.[1-3] The manufacturers recommend insertion using digital manipulation or use of a curved metal introducer. However, the first-attempt success rate with these techniques may be as low as 61%[4] but usually varies between 81% and 90%.

Failure of insertion may occur because of impaction at the back of the mouth of the large soft cuff of the PLMA, which tends to fold on itself during insertion,

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resulting in malposition. Folding of the cuff has been reported in 10%–11% of PLMA insertion attempts using the introducer tool.[5,6] Alternative techniques to overcome this limitation include insertion of a gastric tube, suction catheter, gum elastic bougie, flexi-slip stylet, optical stylet, and flexible bronchoscope, into the drainage tube. Most of these techniques involve blind insertion of the PLMA with the guiding tool protruding beyond the drain tube, increasing the risk of oropharyngeal and oesophageal trauma.[7] Gum elastic bougie-guided insertion of PLMA aided by laryngoscopy[8] may pose a potential risk for oesophageal trauma by the bougie and an increased haemodynamic stimulation from laryngoscopy.[4] The flexible bronchoscope is expensive and cumbersome for use during routine PLMA insertions.

In contrast to the previous methods, we used a Rüsch™ Stylet inserted into the drain tube up to tip of the cuff and preshaped the PLMA. This technique provides stability to its soft distal portion, thus preventing the tip from folding on itself without increasing the risk of trauma. We conducted a randomised controlled trial comparing PLMA insertion using this technique with that using the standard introducer tool. The primary outcome was first-attempt success rate of PLMA insertion. Secondary outcome measures were a number of insertion attempts, total time to successful insertion, haemodynamic response to insertion and quality of fit assessed using Brimacombe's fibre-optic scoring system.[9]

METHODS

The study was approved by the Institutional Ethics Committee of a tertiary university teaching hospital. Written informed consent was obtained from all participants. Adult patients (American Society of Anesthesiologists physical status I–II, aged between 18 and 80 years and having a Mallampati score of I or II with mouth opening more than 2.5 cm) scheduled for breast, urological or gynaecological surgeries under general anaesthesia using a PLMA for airway management were included in the study. Exclusion criteria included patients with anticipated difficult airway, emergency surgeries, inadequate fasting, body mass index >35 kg/m^2, coagulopathy and pre-existing sore throat.

We conducted a randomised superiority trial with two parallel groups using 1:1 allocation with sixty patients in each group. Using a centralised computer-generated table of random numbers placed in sealed envelopes, patients were assigned randomly to one of the two groups before insertion of PLMA. The standard introducer tool was used to guide PLMA insertion in sixty patients (Group IT), and the Rüsch™ stylet was used to guide PLMA insertion in sixty other patients (Group ST) by the same anaesthesiologist, who was experienced and well versed with PLMA insertion. The patients were unaware of the insertion technique.

Patients were not pre-medicated. In the operating room (OR), the heart rate (HR), blood pressure (BP) and arterial oxygen saturation (SpO_2) were monitored. The size of the PLMA was selected using the manufacturer's weight-based formula (size 3 for weight <50 kg, size 4 for weight 50–70 kg and size 5 for weight >70 kg).[10] The PLMA cuff was deflated using the device provided by the manufacturer, and the dorsal surface of the cuff was lubricated using a water-based lubricant. Patients were pre-oxygenated using 100% oxygen for 3 min in supine position with head placed over 7 cm high pillow to achieve sniffing position. Patient was administered 2 μg/kg of fentanyl intravenously. Anaesthesia was induced using intravenous propofol of 2.5–4 mg/kg. The PLMA was inserted when there was no response to jaw thrust[11] using the midline approach, with either the introducer tool or stylet, depending on the group allocated.

In Group IT, after opening the mouth, the PLMA was inserted (after attaching the metal introducer) using the dominant hand and then advanced around the palate pharyngeal curve using a single-handed technique until a resistance was felt.[12] The metal introducer was then removed. In Group ST, the stylet was lubricated with water-based lubricant, passed down the drainage tube up to the tip of the PLMA, and then bent at the tube end to prevent migration beyond the end of the drain tube. The PLMA was preshaped with the help of the stylet to get a shape similar to that achieved when the metal introducer is used [Figure 1]. Insertion technique was the same as that in Group IT. After placement of PLMA, the stylet was removed. Any visible trauma during insertion or blood staining on the stylet/introducer was noted.

Insertion time was noted as the time from opening of mouth to completion of PLMA insertion i.e., removal of introducer/stylet. Total time to successful insertion was the sum of insertion time of each insertion attempt. The cuff was inflated with air up to the inflation volume recommended. The anaesthesiologist

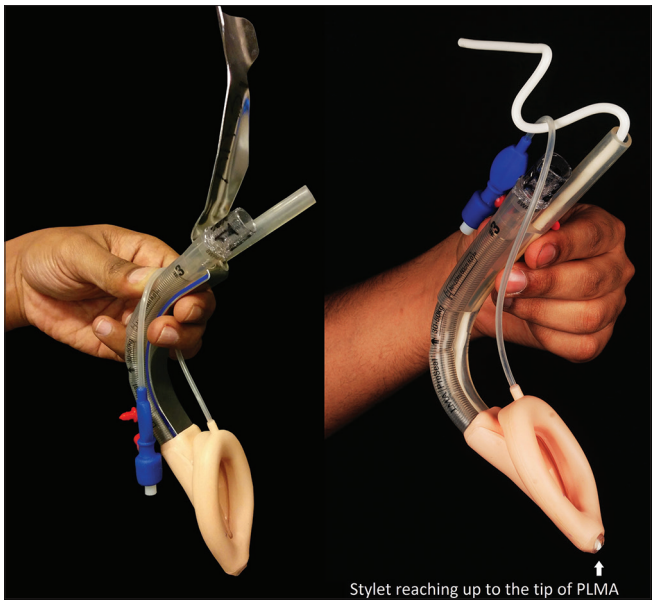

Figure 1: A ProSeal laryngeal mask airway with introducer tool B ProSeal laryngeal mask airway with Rüsch™ Stylet tool

who inserted the PLMA did not participate in further patient management. Time to insertion and number of attempts were recorded by an independent anaesthesiologist present in the OR. All other assessments and parameters recorded after insertion of the PLMA, and data analysis was done by another independent investigator who was unaware and blinded to the insertion tools used.

The intracuff pressure was measured using a cuff pressure monitor and kept below 60 cm H_2O. The HR, BP and arterial SpO_2 were recorded during insertion of the PLMA and every minute for the next 10 min and thereafter at every 5 min. After connecting the airway tube to the breathing system, the patient's lungs were ventilated using a tidal volume of 8 mL/kg, a respiratory rate of 12/min and an inspiratory: expiratory ratio of 1:2. End-tidal carbon dioxide ($ETCO_2$) was noted every minute for 10 min and thereafter at every 5 min. Effective ventilation was defined as expired tidal volume of at least 8 mL/kg and end-tidal CO_2 <45 mmHg when correctly positioned.[6]

The presence of oropharyngeal air leaks[13] (detected by listening over the mouth), gastric air leaks[14] (detected by listening with a stethoscope over the epigastrium) and drain tube air leaks[6] (detected by placing lubricant through the proximal end of the drain tube and watching it getting expelled by the rising air) was noted. A well-lubricated 60 cm long, 12-Fr gastric tube was inserted through the drain tube if there was no air leak through it. Correct gastric tube placement was assessed by suction of gastric fluid or by listening for air sounds over epigastrium with a stethoscope, soon after injecting air into the gastric tube. After successful PLMA insertion, the oropharyngeal leak pressure was determined.

Three attempts were allowed before PLMA insertion was considered a failure and the patient was intubated thereafter. Failed PLMA insertion was defined by any of the three criteria: (1) failed passage into the pharynx; (2) malposition (air leaks despite cuff inflation or failed gastric tube insertion if pharyngeal placement was successful) and (3) ineffective ventilation.[6] The quality of the fit of the PLMA in the glottis was assessed after successful insertion, using a flexible bronchoscope (3.7 diameter bronchoscope of Karl Storz, Germany) passed through the airway tube (following a brief disconnection of PLMA from the circuit) and positioned at the laryngeal aperture of the PLMA. A flexible bronchoscope was passed down the airway tube and the placement of the PLMA was scored using Brimacombe's fibre-optic scoring system (only vocal cords visible - 4, vocal cords plus posterior epiglottis visible - 3, vocal cords plus anterior epiglottis visible - 2, vocal cords not seen, but function adequate - 1, vocal cords not seen and failure to function - 0).[9] Brimacombe scores of 4 or 3 were considered favourable and 2, 1 or 0 were considered unfavourable placement. If the bronchoscopic view showed the oesophageal opening, the PLMA was reinserted and it was considered as an unfavourable view.

Any episodes of hypoxia (SpO_2 <90%) or other adverse events during the study were documented. Anaesthesia was maintained using 2%–3% isoflurane in 50% oxygen and air and intermittent intravenous fentanyl. Intravenous rocuronium was administered for surgical relaxation, if required. $ETCO_2$ concentration was maintained within the range of 35–40 mmHg. At the end of the surgical procedure, the PLMA was removed when the patient's airway reflexes had fully returned. Presence of blood stains if any on the PLMA after removal was noted. Post-operative sore throat, dysphagia or any airway complications if present was recorded on the day of surgery and on the following day. Symptoms if present were graded by the patient as mild, moderate or severe.

The sample size was calculated assuming that the first-attempt success rate would increase from 80% in Group IT to 97% in Group ST. In each group, 54 patients would be required for the study to have

80% power with an alpha error of 5%. To account for a few dropouts, we took sixty cases in both arms. Continuous variables were compared using independent *t*-test or Mann–Whitney U-test as per the distribution of the data. Categorical variables were analysed using Chi-square test or Fisher's exact test (for binary variable). The statistical analysis was performed using SPSS software version 20 for Windows (IBM, Armonk, NY). A $P < 0.05$ was considered statistically significant.

RESULTS

One hundred and thirty-seven patients were screened from September 2013 to November 2013. Seventeen patients were excluded during screening. One hundred and twenty patients were randomised, sixty patients to Group IT and sixty patients to Group ST [Figure 2]. Forty-six patients underwent breast surgery, 11 urological surgery and 63 underwent gynaecological surgery. The mean duration of surgery was 52 ± 43.1 min in Group IT and 61 ± 67.7 min in Group ST ($P = 0.25$). All 120 patients were included in the final analysis. There were no differences in the demographic data between the two groups [Table 1].

The first-attempt success rate of insertion and the total time to successful insertion was significantly better in Group ST compared to Group IT, 95% versus 82% and 11.13 ± 6.8 and 14.4 ± 10.5 s, respectively. Fibre-optic view assessment could only be performed in only 119 patients, as one patient had needed to be intubated in Group IT. Favourable Brimacombe grading was significantly better in Group ST. The insertion success rate, insertion time, reasons for attempt failure, oropharyngeal leak pressure, quality of fit assessed by Brimacombe's fibre-optic grading and adverse events are given in Table 2. The haemodynamic responses to PLMA

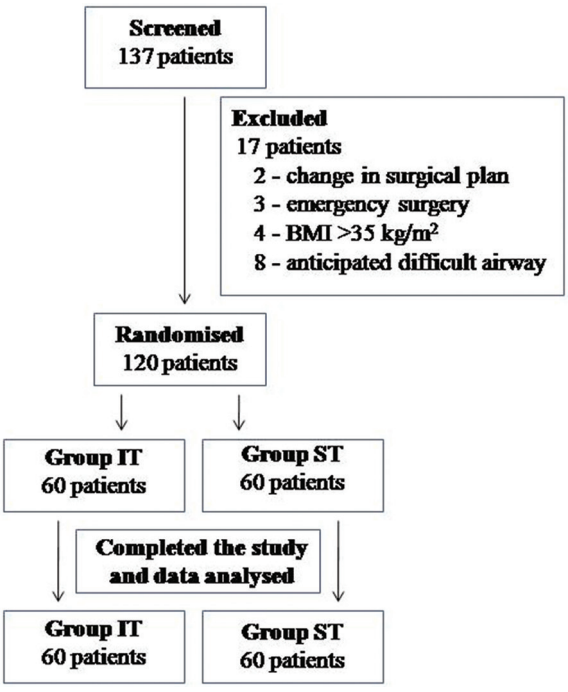

Figure 2: Study consort diagram. BMI = Body mass index, Group IT = Stylet group, Group ST = Introducer tool group

Table 1: Demographic data of the patients

Demographic Data	Group IT (*n*=60)	Group ST (*n*=60)
Age (years)	49.7±10.67	47.9±11.1
Height (cm)	146.7±7.2	147.1±8.7
Weight (kg)	55.9±9.2	56.9±8.7
BMI (kg/m^2)	26.6±3.7	27.1±3.6
Sex (male/female)	5/55	5/55
ASA physical status (I/II)	38/22	40/20
MPC score (I/II)	34/26	33/27

Values expressed as mean±SD (range) or n. BMI – Body mass index; ASA – American Society of Anesthesiologists; MPC – Mallampati classification; SD – Standard deviation

Table 2: ProSeal™ laryngeal mask airway insertion results

PLMA Insertion Results	Group IT (*n*=60)	Group ST (*n*=60)	*P*
Insertion success			
First attempt	49 (82)	57 (95)	0.04*
Second attempt	7 (12)	3 (5)	
Third attempt	3 (5)	0	
Overall	59 (98.3)	60 (100)	
Insertion time (seconds)			
First attempt success	10.7±6.5	10.1±4.9	0.62
Total of all attempts	14.4±10.5	11.13±6.8	0.04*
Reason for attempt failure			
Failed pharyngeal placement	4	0	0.12
Malposition			
Leak$^+$	11	3	0.02
Failed gastric tube insertion	4	0	0.06
Failed ventilation^{++}	1	0	1.00
Oropharyngeal leak pressure (cm H_2O)	31±6.1	30±5.2	
Brimacombe score**			
4	14	41	<0.001*
3	17	11	
2	24	7	
1	4	1	
0	0	0	
Favourable view (Grade 4 and 3)	31 (52.5)	52 (86.7)	<0.001*
Unfavourable view (Grade 2, 1 and 0)	28 (47.4)	8 (13.3)	
Visible blood on PLMA	2 (3)	2 (3)	1.00
Visible blood on introducer device	1 (1.6)	0	1.00
Adverse events	3 (5)	2 (3)	1.00
Sore throat	6 (10)	5 (8.3)	1.00

Values expressed as mean±SD or *n* (%). *P<0.05, Group IT versus Group ST, **Data from the one failed insertion in Group IT not included, $^+$Oropharyngeal, gastric or drain tube air leaks, $^{++}$Maximum expired tidal volume <8 mL/kg or end-tidal carbon dioxide >45 mmHg. PLMA – ProSeal™ laryngeal mask airway; SD – Standard deviation

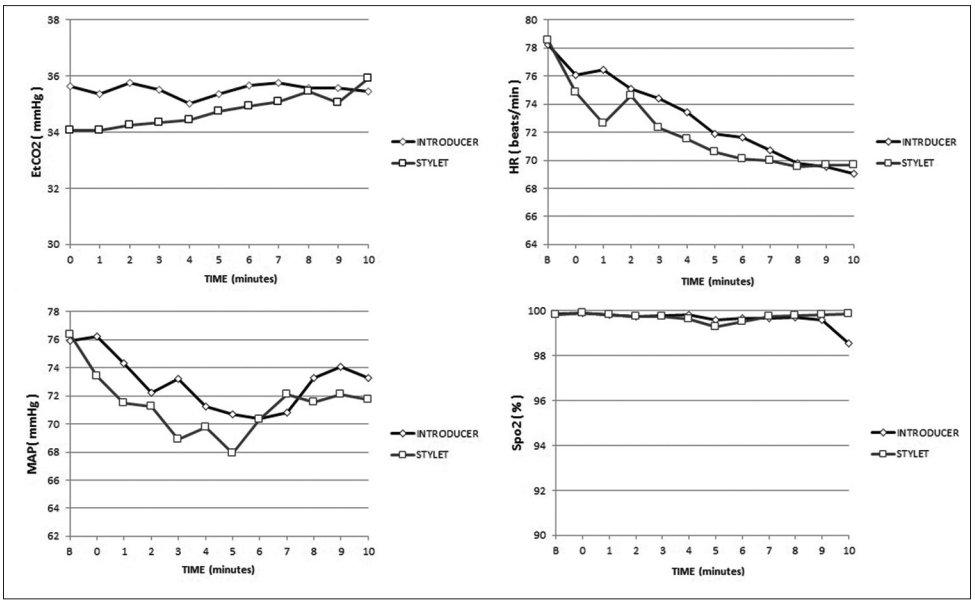

Figure 3: Line diagram showing the end-tidal carbon dioxide, heart rate, mean arterial pressure and oxygen saturation up to 10 min after ProSeal™ laryngeal mask airway insertion. B = Baseline value, 0 = immediately after ProSeal™ laryngeal mask airway insertion. $p > 0.05$ between Group IT and Group ST at all time points

insertion were comparable between the groups. There was no significant difference in SpO_2 or $ETCO_2$ between the groups [Figure 3]. Malpositioning of the PLMA was the most common reason for attempt failure. In Group IT, there were four failed insertions due to failed pharyngeal placement, and in four cases, the gastric tube could not be inserted through the drain tube. This did not occur in any of the patients in Group ST. There were 11 air leaks in Group IT (five drain tube, three gastric and three oropharyngeal air leaks) which was significantly higher than in Group ST (three drain tube air leaks).

Five patients (4%) had adverse events overall, three patients (5%) in Group IT and 2 (3.3%) in Group ST. In Group IT, one patient had three failed attempts at PLMA insertion requiring intubation. One patient had laryngospasm during bronchoscopy. In one patient during the bronchoscopic view assessment, the oesophageal opening was seen. Thus, as per study protocol, the PLMA was reinserted. In Group ST, two patients had laryngospasm during bronchoscopy. In the three cases with laryngospasm during bronchoscopy, the patient desaturated transiently up to a SpO_2 of 80%, they were given 100% oxygen, the depth of anaesthesia was increased using intravenous propofol and the spasm was relieved.

DISCUSSION

The preshaped PLMA insertion using the stylet tool inserted up to the end of the drain tube had a higher first attempt insertion success rate than using the conventional introducer tool (95% vs. 82%, respectively, $P = 0.04$) and fewer attempts for successful insertion in our study. The quality of placement as assessed by bronchoscopic evaluation was significantly better using this novel technique. Previous studies have reported the first-attempt insertion success rate of PLMA using the introducer tool to be between 81% and 90%,[2,5,6,15-21] similar to that observed in our study.

Several studies[5,18,22,23] reported the main causes of failed PLMA placement were either folding of the tip of the cuff over itself or impaction of the PLMA at the back of the mouth. In Group IT, there were failed insertions due to failed pharyngeal placement and the gastric tube not being successfully inserted through the drain tube (not seen in Group ST), showing that the tip of the PLMA was folded on itself. This resulted in malposition and leaks and to complete ventilation failure one patient in this group. Our technique involved insertion of the stylet up to the tip of the drain tube, so the PLMA cuff cannot fold on itself. The stylet shapes and stiffens the cuff of the PLMA, which may have prevented failed pharyngeal placement and malpositioning.

Most of the techniques studied to facilitate PLMA insertion prevent the PLMA cuff from folding as the guiding tool protrudes beyond the drain tube. Of them, the gastric tube and suction catheter are soft and

may fail to guide the PLMA around the oropharyngeal inlet.[15,24] In contrast, the gum elastic bougie being stiff guides the cuff directly into pharynx without folding.[25] Brimacombe recommends insertion of the gum elastic bougie into the proximal oesophagus under laryngoscopic vision.[6,8] Although this technique has 100% first-attempt insertion success rate, even with laryngoscopy, there is a potential to cause pharyngoesophageal trauma[4,19] since the bougie is stiff and not designed for oesophageal placement. In addition, there is a haemodynamic response to laryngoscopy. Hence, this technique is recommended as a backup when introducer techniques fail.[8] In our technique, the stylet tip remains within the drainage tube, avoiding airway trauma during blind insertion, and thus does not requiring laryngoscopy.

Chen *et al*.[22] used an optical stylet i.e. the Foley Airway Stylet Tool beyond the tip of the drain tube and compared it with the introducer tool for PLMA insertion. There was no difference in the insertion success rates between the two techniques; however, the time taken for insertion and the incidence of sore throat was more with the use of the optical stylet. They used muscle relaxant during PLMA insertion in the study; thus there was minimal resistance at the time of insertion and only mild airway trauma reported. Hence, this technique may not be safe to use in spontaneously breathing patients and does not appear to have any advantages over the traditional introducer for routine PLMA insertion. The PLMA-guided over flexible bronchoscope can provide higher insertion success rates and proper PLMA placement; however, it is expensive and cumbersome for routine insertions.

Chen *et al*.[5] studied a technique using a stylet in the drain tube. However, they inserted the stylet 2 cm short of the distal end of the drainage tube within the cuff. They had a higher success rate at first-attempt PLMA insertion and the shorter insertion time compared to using the introducer tool, similar to our study. Although they did not have any incidence of the PLMA tip folding on itself in their study, the authors admit that this is possible with their technique. They used clinical assessment to evaluate the PLMA placement, while we used additional assessment using a flexible bronchoscope. This study was not blinded, leaving a potential for bias and haemodynamic response during the PLMA insertion was not compared in their study.

In our study, the total insertion time for all attempts was significantly higher in Group IT due to increased number of attempts for successful insertion. There was no significant difference in the incidence of adverse events between the groups. We found no significant difference in the incidence of blood on PLMA insertion tool after removal between the groups. Post-operative sore throat was also similar between the groups and lower than reported in other studies.[5,6,22] This may be due to the shorter duration of surgery in both groups compared to these studies.

A major strength of our study is that we used bronchoscopic assessment of the glottis in addition to clinical assessment to evaluate the quality of fit of the PLMA in both techniques. Despite successful function of the PLMA, anatomical placement of the PLMA was unfavourable in 47% patients in the IT Group, compared to only 13% in the ST Group. This shows that clinical assessment alone is inadequate to assess the quality of fit of the PLMA. Hence, bronchoscopic assessment is necessary to scientifically confirm the superiority of any insertion techniques with respect to proper placement of the PLMA. Another strength of our study is that all assessments and parameters after insertion of the PLMA were recorded by an independent investigator blinded to the insertion technique. Admittedly, the person inserting the PLMA could not be blinded to the type of device used for introducing the PLMA.

One of the dangers of cuff folding over is that it would increase the risk of gastric insufflation, regurgitation and pulmonary aspiration. Clinically however, ventilation would be unhindered, as higher airway pressures would still be achieved.[19, 26] Since ventilation is unaffected, this may often go unrecognised in clinical practice and is potentially dangerous. Hence, passing the stylet up to the tip of the drain tube definitively prevents the PLMA tip from folding over itself unlike in the introducer technique where there is a potential for this to happen. In addition, since the stylet is within the drain tube and not protruding beyond the tip of the PLMA, there is no increased risk of airway trauma. The stylet stiffens and shapes not only the tube but also the PLMA cuff, facilitating easy passage into the pharynx without the need for any muscle relaxants or any increased haemodynamic response in comparison to other described techniques. These properties make this novel technique an ideal method for PLMA insertion today. A limitation of this study is that since we excluded patients with an anticipated difficult airway, thus our results may not apply to patients with a difficult airway.

CONCLUSIONS

ProSeal™ LMA insertion using the stylet tool inserted up to the end of the drain tube has a higher first-attempt insertion success rate and superior quality of fit in comparison to insertion using the conventional introducer tool. This is a simple, safe and effective technique that can be routinely used for ProSeal™ LMA insertion.

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Conflicts of interest
There are no conflicts of interest.

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