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Insertion of the ProSeal™ laryngeal mask using a suction catheter as an insertion guide: a comparison with digital insertion

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Summary : The aim of the present study was to evaluate the ease of insertion of the ProSeal™ laryngeal mask airway (PLMA) using a suction catheter (SC) as an alternative to the conventional manufacturer-recommended digital technique of insertion.
Methods: Two hundred ASA I or II patients in the age group of 18-60 years, males and females, and scheduled to undergo a surgical procedure requiring general anesthesia, were randomly divided into 2 groups. In Group I (n = 100), the insertion of PLMA was performed using a digital technique as recommended by the manufacturer, and in Group II (n = 100), the insertion of PLMA was performed using an SC as an insertion guide.
Results : In group I, PLMA insertion was successful at first attempt in 91 patients (91%), at second attempt in 5 (5%), and at third attempt in 2 (2%), while 2 patients (2%) had failed insertion and were intubated to maintain airway during surgery. In Group II, PLMA insertion was successful at first attempt in 98 (98%) patients and at second attempt in 2 (2%). Fewer insertion attempts were required with the SC-guided technique, but the overall success was similar. The time taken to provide an effective airway was longer for the SC-guided technique (31.97 ± 2.38 seconds vs 24.84 ± 4.34 seconds, $p < 0.05$). Lateral approach was used in 6 (6%) patients of Group I and no patients of Group II ($p < 0.05$). There was no statistically significant between- group difference in the incidence of adverse events related to PLMA placement.
Conclusion: To conclude, in spite of longer time for the placement of PLMA, the use of an SC as an insertion guide provides slightly better results than the digitally-guided technique.

Key words : Proseal LMA ; suction catheter ; digital technique.

Introduction

The ProSeal™ laryngeal mask airway (PLMA) is a supraglottic device, which has a modified cuff to improve the seal, a drain tube to prevent aspiration and gastric insufflation, facilitate the passage of the gastric tube, and provide information about possible malposition (1, 2).
The manufacturer recommends a digital and introducer tool technique for the insertion of the PLMA but, with both these techniques, it remains more difficult than the insertion of a classic laryngeal mask airway (CLMA). The main reasons for failure to insert when using the digital technique are impaction within the back of the mouth, and glottic inlet in 6% of adults when using a non-guided technique (3). To overcome this problem, an introducer tool has been proposed, but this has not lead to a significantly higher success rate as compared to the digital technique (4). Various other instruments, which have been used as a guide to facilitate insertion, include an aspiration catheter (5), fibreoptic scope (6), and a gum elastic bougie (GEB) (7, 8, 9) with varying results.
The use of a suction catheter (SC) to guide the insertion has been suggested to be associated with more success than the digital technique. This SC technique is soft, less traumatic, easily available, and low in cost. It does not require laryngoscopy thus causing less reflex stimulation (10).
A search in the available literature revealed few studies on the ease of insertion of PLMA using a SC as a guide (10-12). Hence, the present study was conducted with the primary aim of comparing the ease of insertion of PLMA using a suction catheter as a guide to a digitally-guided insertion.

Material and methods

After Institutional Review Board approval and patient's written informed consent, two hundred patients of either sex, age between 18 and 60 years, having an ASA physical status I or II, and scheduled for an elective surgery under general anesthesia were enrolled in the study. Exclusion criteria were

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patients with known or predicted difficult airways, limited mouth opening (interdental distance < 2.5 cm), body mass index > 35 kg m^{-2} or patients at risk of aspiration, respiratory tract pathology, and gastroesophageal reflux disease. All patients underwent detailed preoperative evaluation the day prior to surgery and relevant preoperative investigations were performed. They were kept fasting for 6 hours prior to the scheduled time of surgery and premedicated with alprazolam 0.25 mg the night before and in the morning 2 hours before surgery.

The study design was prospective, randomized, and controlled. On arrival in the operation room, monitors were applied and baseline parameters like heart rate (HR), electrocardiogram (ECG), non-invasive blood pressure(NIBP) and arterial oxygen saturation(SpO_2) [S/5 Datex Ohmeda, USA] were recorded. An intravenous line was secured with an 18 G cannula and all patients received normal saline infusion. Using a computer-generated random number table, patients were randomly allocated to one of the following two groups :

Group I (n = 100): Insertion of PLMA using a digital technique.

Group II (n = 100): Insertion of PLMA using a suction catheter.

After preoxygenation for 3 minutes, general anesthesia was induced with fentanyl 2 μg.Kg-1, glycopyrrolate 0.1 mg, propofol 2-3 mg.Kg-1 followed by vecuronium 0.1 mg.Kg-1 intravenously. The patient's lungs were manually ventilated using a face mask, with 1% inspired isoflurane and 50% nitrous oxide in oxygen for three minutes. Once the jaw of the patient was relaxed, the eyelash reflex absent, and the patient apneic, a well lubricated, appropriately sized PLMA was inserted with cuff deflated. In group I, the digital technique was performed according to the manufacturer's instructions and involved the use of the index finger to press the ProSeal™ LMA into, and advance it around the palatopharyngeal curve. In group II, the SC-guided technique involved the following steps:

Priming the drain tube with a SC, well-lubricated with water-based gel so that it protrudes 15 cm beyond the distal aperture of the drain tube, opening the mouth and blindly inserting the SC into the pharynx to a depth of 15 cm at the incisors, followed by the insertion of a well lubricated PLMA along the palatopharyngeal curve. A size 4 (in males) and 3 (in females) was used.

After insertion of the PLMA, the cuff was inflated with an appropriate volume of air as recommended by Brain (30 & 40 ml for size # 4 & 5, respectively). Successful placement was judged by the ability to ventilate without leak at an airway pressure of ≤ 20 cm of H20 and a satisfactory capnography tracing during gentle manually assisted ventilation. Various tests for the adequate placement of the PLMA were also performed which included: gel and soap test, suprasternal notch tap test, "Brimacombe bounce" and gastric tube insertion (4). Once an effective airway was obtained, the oropharyngeal leak pressure (OLP) was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 l/min, noting the airway pressure (maximum allowed = 40 cm H^2O) at which equilibrium was reached. All insertions were done in the sniffing position and using a midline approach. If resistance was encountered, a lateral approach was used (1).

A maximum number of three attempts were allowed. In case of failure to achieve adequate placement with three attempts, an alternative method of securing the airway using direct laryngoscopy was employed. All PLMA placements were performed by the same anesthesiologist. After insertion, anesthesia was maintained with isoflurane 0.5 to 1% and 66% N_2O in oxygen using closed circuit with controlled ventilation (Aestiva 5, Datex Ohmeda) to maintain an end tidal CO_2 between 30 and 35 mmHg.

The ease of insertion of PLMA was judged by the number of attempts and time taken to place PLMA (recorded from picking up the prepared PLMA with cuff deflated, lubricated, and SC attached until confirmation of successful placement). The use of a lateral approach, oropharyngeal leak pressure, any adverse events during the procedure and incidence of airway trauma (blood-stained PLMA) was noted. Hemodynamic monitoring was carried out continuously and recorded at regular intervals. Postoperative sore throat, cough and hoarseness of voice were noted. Any episodes of hypoxia (SpO_2 < 90%) or other adverse events were documented.

The statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 15.0 for Windows). All quantitative variables were estimated using measures of central location (mean, median) and measures of dispersion (standard deviation and standard error). The normality of data distribution was checked by measures of skewness and Kolmogorov Smirnov tests of normality. For normally distributed data, means were compared using student's t-test between groups. For skewed data, the Mann -Whitney U test

was applied. For time related comparison, paired t-test or Wilcoxon signed rank test was applied. Qualitative or categorical variables were described as frequencies and proportions. Proportions were compared using Chi square or Fisher's exact test, whichever was applicable. All statistical tests were two-sided and performed at an α level of 0.05, and a p value < 0.05 was considered statistically significant.

Table I
Demographic data

	Group I (n=100)	Group II(n=100)
Age (yrs)	40.34 ± 12.75	40.30 ± 11.56
Weight (Kg)	64.68 ± 9.82	66.16 ± 9.43
Height (cm)	160.92 ± 7.53	160.52 ± 7.58
Body Mass Index Kgm^{-2}	24.9 ± 2.72	25.65 ± 3.06
Male/Female (n)	21/79	21/79
Duration of anaesthesia (min)	102 ± 50.75	103.25 ± 49.01

Results

Demographic data including type and duration of surgical procedures were comparable between groups (Table 1). Insertion success rates, number of attempts, insertion time, and oropharyngeal leak pressure data are presented in Table 2. No patient required laryngoscopic aid for the placement of SC. The total number of insertion attempts required for successful placement was significantly lower with the SC-guided technique (p = 0.005), but first attempt (p = 0.06) and overall success rates were similar (p = 0.497). Mean oropharyngeal leak pressures were also similar in the two groups (p = 0.054). The lateral approach was used in 6% of patients in Group I and none in Group II (p = 0.028). The time needed to establish an effective airway with the PLMA was significantly longer when using the SC-guided technique (p < 0.01) (Table 2). Adverse events are summarized in Table 3. There was no difference in the frequency of regurgitation, airway trauma (as evidenced by blood on the PLMA), or postoperative sore throat or hoarseness. There was no significant difference in hemodynamic and ventilatory parameters between the groups.

Discussion

The results of the present study reveal that a significantly lower number of insertion attempts are required with the SC-guided technique than with the conventional digital technique. Our results are in agreement with the results of García-Aguado et al., who also reported fewer insertion attempts with the SC-guided technique. However, first attempt and overall success rates are similar (10). Similar findings were reported by Lal et al., who proposed that the SC-guided insertion of the PLMA is an easy technique, with high first time and overall success rate of placement, short insertion time, and high oropharyngeal seal pressure. However, the authors did not compare it with any other technique (11). Another study suggested that the SC technique improves the success rate of PLMA insertion by untrained physicians, although the overall success

Table II
Insertion success, insertion time, etiology of malposition and oropharyngeal leak pressure for the digital and suction catheter guided techniques

	Group I (n=100)	Group II(n=100)	P value
Insertion success (n)			
First attempt	91	98	
Second attempt	5	2	
Third attempt	2	-	
Failed	2	-	
Overall number of attempts	113 (98)	102 (100)	p=0.005
Time Taken for PLMA insertion	24.84 ± 4.34 seconds	31.97 ± 2.38 seconds	p<0.05
Lateral approach required (n)	6	0	p<0.05
Oropharyngeal leak pressure	33.27(98) ± 3.12 cms of H_2O	32.47(100) ± 2.71 cms of H_2O	NS
Malposition (n)			NS
Inadequate placement	5	1	
Glottic insertion			
Tip folding	2	1	
	1	0	

NS Not significant

Table III
Adverse events

Parameters	Group I (n=100)	Group II (n=100)	p value
Bronchospasm	9	4	0.251
Visible blood on PLMA	12	10	0.652
Arterial desaturation <94 %	0	0	>0.05
Regurgitation of gastric content	0	2	0.497
Postoperative airway morbidity at 12 & 24 hrs Cough Sore throat Hoarseness	 3,0 3,2 1,0	 0,0 2,1 1,0	NS

Data are numbers

rate was lower (90.1 % vs 74.4%) as compared to the present study, probably because, in their study, the insertion was done by untrained physicians, while in the present study, by experienced anesthesiologists (12).

Manufacturers recommend the digital insertion technique. However, the problem with this technique is that the large dorsal cuff is not easy to place in the mouth, leaving very little space for the index finger. This technique is more likely to cause folding of the tip, and impaction within the back of the mouth and glottic inlet. To overcome this problem, an introducer tool was released. The introducer enables insertion without placing a finger in the patient's mouth. No significant difference in the insertion success rate has been reported between the digital and the introducer technique (4, 13), although Brimacombe et al. found the insertion easier when using the introducer tool (14) Hence, to facilitate the insertion, various other rail road guides like gum elastic bougie(7, 8, 9), fibreoptic laryngoscope (6), or aspiration catheter (10-12) have been used. Those devices direct the tip into the proximal esophagus, and prevent the cuff folding over, which is the most dangerous malposition of the PLMA. However, the use of a gum elastic bougie and a fibreoptic laryngoscope entails additional cost. SC is cheap, and an easily available alternative. Moreover, the SC can be used as a guide for reinserting the device in case of displacement.

We found that the overall time taken for a successful placement of the PLMA was significantly longer when using the SC-guided technique, although the difference was not clinically relevant. In contrast, García-Aguado et al. reported shorter insertion time when using a SC-guided technique.10 The difference in our results could be attributed to the fact that they have taken account of the total time needed until the effective ventilation was achieved irrespective of the number of attempts. None of the patients in group II had folding of the tip of the PLMA as compared to two in group I. The difference in malposition between the two groups was not statistically significant. Our results are in agreement with Brimacombe et al., who reported that, with the digital technique, the incidence of tip folding is 3.4%. Similarly, García-Aguado et al. have reported an increased incidence of malposition of PLMA while using the digital technique as compared to SC (7% vs 1%), although the difference was not statistically significant (10).

In the present study, a lateral approach was more often used for a successful insertion of the PLMA in group I than in group II. Our results are in accordance with the study of García-Aguado et al. (digital technique 12%, SC-guided technique 1%) (10).

Oropharyngeal leak pressure in the two groups was not significantly different. The results of our study are in agreement with Evan et al, who concluded that mean oropharyngeal leak pressure in PLMA is 28 cm of H_2O (13). Similarly, García-Aguado et al. also reported no significant difference in oropharyngeal leak pressure between their two groups.10

Nine (9%) patients in group I and four (4%) patients in group II suffered from bronchospasm. The incidence of bronchospasm was higher in patients where a higher number of attempts was required, or when the insertion failed. Two patients of group I could not be ventilated effectively after three attempts, and were intubated, while none of the patients required intubation in group II. Although these incidences are not statistically different, this is clinically relevant, especially in emergency situations with a full stomach. Goldman et al. reported the incidence of bronchospasm to be 3 %, which is less than what we have observed in our study. The lower incidence could be attributed to the larger number of patients studied by Goldman, with a total of 2114.

The incidence of airway trauma and morbidity was higher in group I than in group II. This can be explained by the fact that the number of attempts and lateral approaches was higher in group I than in group II for successful placement. These results are not in agreement with the study done by García-Aguado et al. (10). They stated that the use of the SC-guided technique was associated with a higher

incidence of airway trauma and morbidity. They speculated that microscopic mucosal tear appears where SC rubs the posterior pharyngeal wall. However, we inserted primed PLMA after thorough lubrication of the SC tip. This is the reason why we had a lower incidence of morbidity with SC.

There are certain limitations to our study. First, the study is applicable to patients with a normal airway anatomy only. Whether the same outcome can be extrapolated to patients with anticipated difficult airway is subject to performance of similar large scale studies in those patients. Second, in our study, blinding was not possible for obvious reasons, and this can cause biased interpretations.

Conclusions

To conclude, the results of the present study show that, in spite of a longer time required for the placement of the PLMA, using SC as an insertion guide definitely provides good success rate for the placement of PLMA and thereby decreases the incidence of intraoperative adverse events, airway trauma and morbidity. Thus the SC can be used as a guide to facilitate the successful placement of the PLMA and might be superior to using a digital technique alone.

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