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ORIGINAL ARTICLE

Oral gastric tube-guided insertion of the ProSeal™ laryngeal mask is an easy and noninvasive method for less experienced users

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Abstract
Purpose The ProSeal™ laryngeal mask airway (PLMA) can be more difficult to insert than the classic laryngeal mask, especially in patients who have a thin palate with a steep oropharyngeal curve. Here, an oral gastric (OG) tube-guided technique is considered as a method that makes it easier to successfully insert a PLMA.
Methods Sixty patients who were scheduled to undergo general anesthesia without neuromuscular blocking were randomly allocated into two groups: 30 patients with PLMA inserted by the standard digital technique, and 30 with the PLMA inserted by an OG tube-guided technique. Most PLMA insertions were performed by less experienced users. The success rate at the first attempt, the time taken to insert the PLMA, the difficulty of the procedure, and the incidence of oropharyngeal trauma and postoperative sore throat were compared between the two groups.
Results PLMA insertion was successfully achieved at the first attempt using the OG tube-guided technique in all 30 patients. The OG tube-guided insertion required fewer attempts ($P = 0.04$) and led to a less difficult insertion procedure ($P = 0.02$) than the standard digital insertion. Effective ventilation during anesthesia was achieved in all patients, with a lower mean cuff pressure in the OG tube-guided technique group ($P = 0.02$). The frequency of blood sticking to the PLMA tube ($P < 0.001$) and the incidence of postoperative sore throat ($P = 0.003$) were lower in the OG tube-guided group than the standard digital technique group.
Conclusions OG tube-guided PLMA insertion is easier for less experienced users, trainees, and experts as well as less invasive for patients than the standard digital insertion.

Keywords PLMA · Gastric tube · For trainees · Airway management · Complication

Introduction

The ProSeal™ laryngeal mask airway (PLMA; Intavent Orthofix, Maidenhead, UK) is a laryngeal mask that has a modified cuff to improve the seal as well as a drain tube to help prevent pulmonary aspiration and gastric insufflation [1–5]. A gastric tube can be inserted through the PLMA drain tube, thereby excluding possible malposition of the airway [1, 3, 6]. However, the PLMA can be more difficult to insert than the classic laryngeal mask airway. Reported success rates of PLMA insertion at the first attempt are 82–100% [3, 4, 7–10]. The following two factors are likely to lead to unsuccessful PLMA insertion. A PLMA is a relatively large object to insert, and the drain hole tip of the PLMA may get caught on the uvula.

Several techniques have been stated to improve the success rate of PLMA insertion, including one where a drain tube is primed with an assisting device that guides the LMA into the proximal esophagus. García-Aguado et al. [11, 12] used a suction catheter as the assisting device, Brimacombe and Keller [13] used a fiberoptic scope, and Howath et al. [14] used a gum elastic bougie. The techniques that use the suction catheter and the gum elastic bougie were studied in a randomized control trial [12, 14].

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In the present study, we investigated a new technique for inserting a PLMA, which uses an oral gastric (OG) tube as a guide via the drain tube of the mask. We evaluated this technique in patients undergoing gynecological or breast or urological surgery under general anesthesia. To test our hypothesis that this OG tube-guided insertion would be a useful technique, we evaluated the technical difficulty involved in its use, its validity for airway management, and the incidence of oropharyngeal trauma resulting from its use, and compared the results with those obtained when employing the standard digital technique in the 60 randomly allocated patients.

Materials and methods

All of the experimental protocols in the present study were approved by the internal review committee of the Osaka Medical Center for Cancer and Cardiovascular Diseases. This was a prospective, randomized comparison of an OG tube-guided PLMA insertion technique with the standard digital technique. Written informed consent was obtained from the patients, who were blinded to the PLMA insertion methods used. During April 2009 to July 2009, 837 consecutive patients received a general anesthetic for surgery in our institute, 85 (10.2%) of whom were provided with a PLMA. Among these, 60 patients (age range 18–85 years; American Society of Anesthesiologists physical status I–III; 27 patients undergoing conization for uterine cervical cancer, 22 mastectomy for breast cancer, 6 endoscopic transurethral resection for urinary bladder cancer, 3 open biopsy for sarcoma in the limbs, 1 myomectomy for uterine myoma, and 1 resuture of the abdominal wall) were randomly allocated into two groups: 30 patients with a PLMA inserted by the standard digital technique, and an equal number of patients with a PLMA inserted by the OG tube-guided technique. Patients were excluded if they were <18 years, had a body mass index >30 kg/m^2, a height of <150 cm, or were at risk of pulmonary aspiration. Mask size #4 was inserted into female patients and #5 into males, respectively. In 55 of the 60 cases (91.6%), PLMA insertion was performed by anesthesiologists who had <3 years of experience or had used the standard technique <100 times (so-called "trainees"), while the remaining 5 insertions were performed by experts.

All of the patients were routinely monitored during general anesthesia. Following preoxygenation for 3 min, anesthesia was induced with a bolus infusion of propofol 1.5–2 mg/kg and fentanyl 0.05–0.1 mg. Neuromuscular blocking drugs were not administered. Additional boluses of intravenous propofol 0.5 mg/kg were given as required to achieve an adequate level of anesthesia during PLMA placement. The PLMA mask was inserted into the patients only after the anesthesiologists had confirmed loss of consciousness based on the patient's responses to verbal commands, loss of corneal reflex, and apnea. All of the patients were in the sniffing position with a relatively extended head during insertion of the PLMA with the cuff fully deflated. We defined the process of PLMA insertion as beginning at mouth opening and ending with the start of ventilation. The duration of PLMA insertion was measured.

The digital insertion technique was performed according to the manufacturer's instructions, using the index finger to press the PLMA mask into the mouth and advance it around the palatopharyngeal curve. The OG tube-guided technique involved the following steps: (1) priming the drain tube of the PLMA, which was well lubricated with water-based gel (KY^{TM}, Johnson and Johnson, Pinewood, UK), for a 16 Fr orogastric tube^{TM} (OG; Salem Sump Tube soft type, type 216-S, Nippon Sherwood Medical Industries Co., Ltd. in Tyco Healthcare Japan Group, Tokyo, Japan) such that it protruded 5–10 cm beyond the distal tip of the drain tube (Fig. 1), (2) by opening the mouse and pushing the handle of PLMA while inserting the OG tube tip into the oropharynx blindly. In cases where the anesthesiologists encountered resistance during insertion, they were instructed to pull the PLMA up and retry the insertion. Once the PLMA was inserted into and placed in the pharynx, the cuff was inflated with 15 mL air, which was added if necessary. Cuff pressure was measured with a hand cuff pressure meter (Mallinckrodt Medical Inc., Los Angeles, CA, USA). The presence or absence of oropharyngeal air leaks was detected by listening over the mouth; gastric air leaks by listening with a stethoscope over the epigastrium; and drain tube air leaks by placing a lubricant over the proximal end of the drain tube, respectively. Then a 16 Fr orogastric tube^{TM} was passed into the stomach. The PLMA mask was fixed according to the manufacturer's

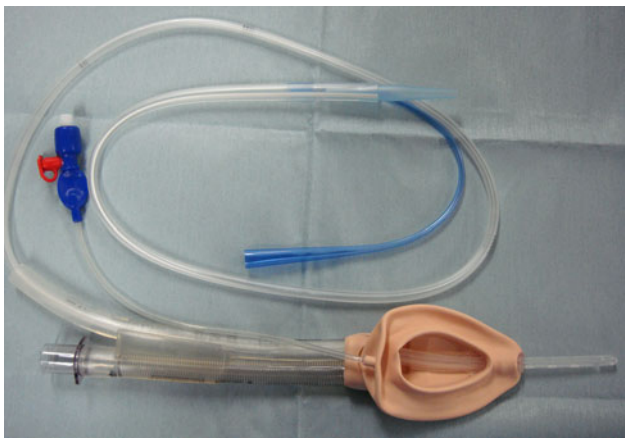

Fig. 1 ProSeal^{TM} laryngeal mask airway with a 16 Fr nasogastric tube^{TM} in the drain tube (and protruding 5–10 cm beyond its distal aperture)

instructions. When the patient could be mechanically ventilated to achieve an end tidal CO_2 of <45 mmHg, the placement was considered to be successful and noted. The number of successful attempts and failures, the need for assistance, for instance with a laryngoscope, and the reasons for unsuccessful cases were recorded. The anesthesiologists who attempted the PLMA insertions were queried about the difficulty of the procedure.

Three attempts were allowed before insertion was considered a failure. Failed insertion was defined by any of the following criteria: (1) failed passage into the pharynx, (2) malposition (air leaks, failed OG insertion if pharyngeal placement was successful), and (3) ineffective ventilation (no end-tidal CO_2 trace or a maximum expired tidal volume of <8 mL/kg, or an end-tidal CO_2 of >45 mmHg if correctly positioned). If there were any episodes of ineffective ventilation during anesthesia or any other adverse events, an alternative airway management strategy was used. The anesthesiologist and the nurse (blinded to the insertion method) evaluated the presence or absence of blood sticking to the mask after extubation by viewing. The teeth, mouth, lips, and tongue were carefully inspected for evidence of oropharyngeal trauma. The patients, who were unaware of the insertion technique used, were interviewed about postoperative throat symptoms in a ward on the same night as the operation or during the following morning, and the symptoms were graded as asymptomatic, uncomfortable, or painful. Trained observers collected the perioperative data on the following day.

Statistical analysis was performed using the JMP software package (SAS Institute, Inc., Cary, NC, USA) running on a personal computer. Data are presented as the number of patients or the mean ± standard deviation (Table 1), and were compared between groups using Fisher's exact test, the χ^2 test, the Mann–Whitney U test, or Student's t test, as appropriate. $P < 0.05$ was considered to be statistically significant.

Results

Demographic data for the patients were similar between the two groups (the standard digital technique vs. the OG tube-guided technique) with respect to age, gender, height, body weight, body mass index, and American Society of Anesthesiologists (ASA) physical status (Table 1). There was no difference between the groups regarding duration of the surgical procedure and total time of anesthesia. PLMA insertion by the OG tube-guided technique was successful at the first attempt in all 30 patients, a higher success rate than achieved when using the standard digital technique (100 vs. 73%, $P = 0.002$). The time required to place the PLMA mask and establish an effective airway was shorter in the OG tube-guided technique group than in the standard digital technique group ($P < 0.001$). While no patients in the OG tube-guided technique group required laryngoscopic guidance to place an OG tube or a PLMA, 3 cases in the standard digital technique group required such guidance. No patients required assistance to enforce mouth

Table 1 Comparison of data for the patients who had a PLMA inserted by the standard digital technique and those who had a PLMA inserted by the OG tube-guided technique

	PLMA insertion technique		*P*
	Standard digital ($n = 30$)	OG tube-guided ($n = 30$)	
Age (years)	47.8 ± 14.3[a]	48.1 ± 15.8[a]	0.94
Sex			
Male	3[b]	5[b]	0.45
Female	27[b]	25[b]	
Height (cm)	158.2 ± 5.8[a]	160.0 ± 7.1[a]	0.28
Body weight (kg)	53.7 ± 7.4[a]	57.5 ± 9.9[a]	0.10
Body mass index (kg/m^2)	21.3 ± 2.3[a]	22.3 ± 2.8[a]	0.12
ASA performance status			
I	19[b]	19[b]	0.49
II	11[b]	10[b]	
III	0	1[b]	
Duration of operation (min)	45 ± 30[a]	52 ± 25[a]	0.34
Duration of total anesthesia (min)	83 ± 35[a]	90 ± 32[a]	0.39
Duration of PLMA insertion procedure (s)	25.0 ± 16.0[a]	13.6 ± 5.1[a]	<0.001
Number of insertion attempts			
1	22[b]	30[b]	0.04
2	3[b]	0	
3	5[b]	0	
Difficulty of the PLMA insertion procedure			
Easy	9[b]	18[b]	0.02
Moderate	12[b]	10[b]	
Difficult	9[b]	2[b]	
Cuff pressure (mmHg)	34 ± 21[a]	25 ± 13[a]	0.02
Blood sticking to the PLMA mask after extubation			
Absent	19[b]	30[b]	<0.001
Present	11[b]	0	
Postoperative throat symptoms			
Asymptomatic	20[b]	29[b]	0.003
Uncomfortable	5[b]	1[b]	
Painful	5[b]	0	

PLMA ProSeal™ laryngeal mask airway, *OG* oral gastric, *ASA* American Society of Anesthesiologists

[a] Mean ± standard deviation

[b] Number of patients

opening during LMA insertion. Fewer insertion attempts were required with the OG tube-guided technique than the standard digital technique ($P = 0.04$). There were 13 failed attempts to insert in the standard digital technique group in all, but none in the OG-guided technique group. Among the 13 failures in the standard group, the PLMA did not advance into the pharynx in 6 cases, the PLMA was malpositioned in 4 cases, and adequate ventilation through the PLMA was not achieved in 3 cases. The anesthesiologists found the OG tube-guided technique to be easier to perform than the standard digital technique ($P = 0.02$). The mean cuff pressure was lower in the OG tube-guided technique group ($P = 0.02$), and there were no adverse events. Gross or minimal amounts of blood sticking to the PLMA tube were observed in 11 patients who underwent standard digital insertion, which was more frequent than observed in the OG tube-guided technique group ($P < 0.001$). The incidence of postoperative discomfort or pain in the throat was higher in the standard digital technique group than the OG tube-guided technique group ($P = 0.003$). Postoperative sore throat was managed conservatively; no patient needed additional treatment.

Discussion

In the present study, we found that PLMA insertion by the OG tube-guided technique is easier for anesthesiologists and less invasive for patients than insertion by the standard digital technique. Another digital method of PLMA placement has recently been described that rotates the airway by 90° during insertion to reduce resistance between the mask and the rear pharyngeal wall, thereby realizing a smooth insertion [15]. Although the technique was reported to show a higher success rate of insertion and a lower frequency of pharyngeal trauma than the standard digital method, it cannot be used when mouth opening is restricted (<2.5 cm) or when a large mass is present in the oral cavity [15]. The PLMA was successfully inserted by the OG tube-guided technique in all 30 patients, even when there was severely restricted mouth opening (1.5 cm in our experience) without using muscular relaxants. The OG tube-guided technique required less time to place the PLMA mask and less cuff pressure to maintain sufficient airway pressure during mechanical ventilation than the standard digital technique for such patients.

The success rate of PLMA insertion at the first attempt using the standard digital technique observed in our study appears to be relatively low (73%). This may be because most insertions were performed by less experienced users in this study. The predominance of females among our patients (86%) may also be a contributing factor, as Asian females were reported to occasionally have a thin and high-arched palate combined with a steep palatopharyngeal curve—an anatomical feature known to make PLMA insertion difficult [16]. In such cases, it is difficult to advance the tip of the PLMA towards the hypopharynx, thus resulting in malposition above the glottis. It is often necessary to insert fingers into the mouth in order to guide the tip of the PLMA tip and move the glottis aside. However, one must be cautious during this procedure because applying inappropriately large forces in the narrow oral space can not only cause oropharyngeal trauma but also bend the LMA cuff in the pharynx, thereby blocking effective ventilation [17]. The OG tube-guided technique is useful for preventing the application of unnecessary force in the oral space, because the OG tube efficiently leads the tip of the PLMA into the gullet entrance. That is why the OG tube-guided technique is less invasive than the standard digital insertion.

Three other guides that are used to facilitate the insertion of a PLMA have been described: these insertion techniques using a suction catheter, a gum elastic bougie, and a laryngoscope were all superior to the digital technique [11–14]. However, these techniques are recommended as backups for the digital technique [15]. An advantage of the OG tube-guided technique is that after successful PLMA placement, the drain tube is used to remove gastric contents during the operation. This means that this method needs no additional devices. To prevent rare but serious cases in which the OG tube is strangulated at the entrance to the glottis, meaning that it is unable to guide the mask to the gullet, we used a relatively large OG tube. A PLMA advances more smoothly when guided by a stiffer large-sized OG tube than a soft small-sized tube. We consider that the appropriate length of the OG tube beyond the aperture of the drain tube based on this study is 5–10 cm. Additionally, a Salem Sump soft-type OG tube is considered to be less invasive than other guides because the tip is originally round, and is assumed to insert blindly into the stomach (Fig. 1). To avoid mucosal injury in the oral cavity, we prefer to use a soft-type Salem Sump Tube over a standard type.

Mean cuff pressure in the OG group was lower than in the standard group. We think that a correctly positioned LMA tends to keep the cuff pressure low while ensuring no air leakage. Although we did not examine whether the cuff pressure affected the level of air leakage and the severity of postoperative discomfort/pain, we believe that the cuff pressure does indeed affect them.

A serious complication is associated with OG tube misplacement into the glottis. Thus, it is important to warn trainees of the risk of misplacement. Fortunately, OG tube misplacement is very rare, and we did not experience any during our study. An OG tube misplacement is easily recognized, as it is associated with a strong resistance

during insertion, or coughing by the nonparalyzed patient. The operator should not advance the OG tube with excessive force, as this can cause serious complications.

If the OG tube does not advance smoothly, it is easy to recognize tube malposition. In this case, the cause should be determined by observing the oropharynx using a fiberscope, after which the OG tube-guided insertion should be retried [12].

Our results support the idea that the OG tube-guided technique is useful for less experienced users or trainees as well as for expert anesthesiologists. We consider the OG tube-guided technique to be a very simple, easy, and noninvasive method. We emphasize that while it is simple, the OG tube-guided technique has great benefits. The OG tube can be used as not only a reliable guide but also a drainage route for gastric contents, bypassing the need for any other special or expensive equipment. Moreover, since this technique does not need a finger to be inserted into the oral cavity for PLMA insertion in most cases, it is also excellent from the viewpoint of minimizing the chance of perioperative infection.

In conclusion, the OG tube-guided PLMA placement technique is an easy, rapid, and safe technique for patients, and could be employed as the first-choice PLMA insertion technique.

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