Gum Elastic Bougie-Guided Insertion of the ProSeal Laryngeal Mask Airway Is Superior to the Digital and Introducer Tool Techniques in Patients with Simulated Difficult Laryngoscopy Using a Rigid Neck Collar

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BACKGROUND: We compared three techniques for insertion of the laryngeal mask airway ProSeal™ (PLMA) in patients with simulated difficult laryngoscopy using a rigid neck collar.

METHODS: Ninety-nine anesthetized healthy female patients aged 19–68 yr were randomly allocated for PLMA insertion using the digital, introducer tool (IT) or guided techniques. Difficult laryngoscopy was simulated using a rigid neck collar. The laryngoscopic view was graded before PLMA insertion. The digital and IT techniques were performed according to the manufacturer's instructions. The guided technique involved priming the drain tube with an Eschmann tracheal tube introducer, placing the introducer in the esophagus under direct vision and railroading the PLMA into position. Failed insertion was defined by any of the following criteria: 1) failed pharyngeal placement, 2) malposition, and 3) ineffective ventilation.

RESULTS: The median laryngoscopic view was 3 and the mean interincisor distance was 3.3 cm. Insertion was more frequently successful with the guided technique at the first attempt (guided 100%, digital 64%, IT 61%; $P < 0.0001$), but success after three attempts was similar (guided 100%, digital 94%, IT 91%). The time taken for successful placement was similar among groups at the first attempt, but was shorter for the guided technique after three attempts (guided 31 ± 8 s, digital 49 ± 28 s, IT 54 ± 37 s; $P < 0.02$).

CONCLUSION: The guided insertion technique is more frequently successful than the digital or IT techniques in patients with simulated difficult laryngoscopy using a rigid neck collar.

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The laryngeal mask airway ProSeal™ (PLMA) is a relatively new laryngeal mask airway (LMA) device with a large wedge-shaped double-cuff to improve the seal and a drain tube to prevent aspiration and gastric insufflation.[1] The manufacturer recommends inserting the PLMA using digital manipulation, like the LMA Classic™, or with an introducer tool (IT), like the LMA Fastrach™[2]; however, the first attempt success rate with these techniques averages about 90% because of impaction at the back of the mouth, folding over of the cuff, and failure of the distal cuff to reach its correct position in the hypopharynx.[3–7] In 2002, Howarth et al.[8] reported a 100% (100/100) first attempt success rate for a new technique which involved placing an Eschmann tracheal tube introducer (or "gum elastic bougie" [GEB]) in the esophagus and railroading the PLMA into position along its drain tube. Subsequent studies showed that this technique was superior to digital manipulation or the IT[7] and that it was the best backup technique if either recommended technique failed.[9] LMA devices have an established role in difficult laryngoscopy[10] and the PLMA is particularly suited for airway rescue as it can protect the airway and facilitate high airway pressure ventilation.[11] In the following study, we tested the hypothesis that guided insertion is more frequently successful than the digital and IT techniques in patients with simulated difficult laryngoscopy using a rigid neck collar.

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METHODS

Ninety-nine female patients (ASA physical status grade 1–2, aged 19–68 yr) undergoing elective gynecological surgery in the supine position were randomly allocated (by opening a sealed opaque envelope) into three equal-sized groups for PLMA insertion using the digital, IT, or guided techniques. Ethical committee approval and written informed consent were obtained. Patients were excluded if they were <19 yr, had a known or predicted difficult airway, a body mass index >35 kg/m^2, or were at risk of aspiration. All cases were conducted by three anesthesiologists with 3–5 yr training (>75 uses each technique). Each anesthesiologist conducted 11 insertions with each technique.

All patients were premedicated with midazolam 0.05–0.1 mg/kg orally 1 h preoperatively. Anesthesia was in the supine position with the patient's head in the neutral position on the operating table. A standard anesthesia protocol was followed and routine monitoring applied. Patients were administered oxygen for 3 min. Induction of anesthesia was with fentanyl 2–4 μg/kg and propofol 2.5–3.0 mg/kg given over 30 s. Neuromuscular blockade was with rocuronium 0.4 mg/kg. Maintenance of anesthesia was with remifentanil 0.25–0.5 $\mu g \cdot kg^{-1} \cdot min^{-1}$ and propofol 75–125 $\mu g \cdot kg^{-1} \cdot min^{-1}$ in O_2 33% and air. Patients were ventilated via a facemask for 3 min and then a stiff neck (Stifneck® Select Collar™, Laerdal Medical Corp., Wappingers Falls, NY), which has been used by other groups to simulate the difficult airway,[12,13] was applied according to the manufacturer's instructions.[14] Direct laryngoscopy was performed by one of the authors (C.K.) using a Macintosh blade size 3 to grade the laryngoscopic view (Cormack and Lehane). No laryngeal manipulation was done during grading. Afterwards the PLMA (all size 4) was inserted.

The digital and IT insertion techniques were performed according to the manufacturer's instructions.[2] The digital technique involved the use of the index finger to press the PLMA into, and advance it around, the palatopharyngeal curve. The IT technique involved attaching the IT, using a single-handed rotational technique to press the PLMA into, and advance it around, the palatopharyngeal curve, and removing the IT. For the guided technique, the drain tube of the PLMA was primed with a lubricated Eschmann tracheal tube introducer with its straight end first, leaving the 5-cm bent portion protruding from the proximal end (for the assistant to grip), and the maximum length protruding from the distal end (for the anesthesiologist to manipulate). The guided technique involved the following steps: 1) under gentle laryngoscope guidance, the distal portion of the guide was placed 5–10 cm into the esophagus while the assistant held the PLMA and proximal portion; 2) the laryngoscope was removed; 3) the PLMA was inserted using the digital insertion technique while the assistant stabilized the proximal end of the guide so it did not penetrate further into the esophagus; and 4) the guide was removed while the PLMA was held in position.[8] All techniques were performed with the cuff fully deflated and using a midline approach. Once the PLMA was inserted into the pharynx, the cuff was inflated with air until effective ventilation was established or the maximum recommended inflation volume reached. Fixation was according to the manufacturer's instructions.[2]

Patients' lungs were ventilated at an inspired tidal volume of 10 mL/kg, a respiratory rate of 12/min and an inspiratory:expiratory ratio of 1:2. The presence/absence of oropharyngeal air leaks (detected by listening over the mouth[15]), gastric air leaks (detected by listening with a stethoscope over the epigastrium[16]), drain tube air leaks (detected by placing lubricant over the proximal end of the drain tube), or an end-tidal CO_2 >45 mm Hg was noted. A well-lubricated 60-cm long, 14-Fr gastric tube was inserted through the drain if there was no air leak up the drain tube. Correct gastric tube placement was assessed by suction of fluid or detection of injected air by epigastric stethoscopy.

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 or failed gastric tube insertion if pharyngeal placement successful); and 3) ineffective ventilation (maximum expired tidal volume <8 mL/kg or end-tidal CO_2 >45 mm Hg if correctly positioned). The time between picking up the laryngoscope or prepared PLMA (cuff deflated, lubricated, IT and guide attached) and successful placement was recorded. The etiology of failed insertion was documented. If insertion failed after three attempts, a single attempt was permitted with the guided technique. Once insertion was successful, the intracuff pressure was set at 60 cm H_2O using a digital manometer (Mallinckrodt Medical, Athlone, Ireland).

Cardiorespiratory data were collected every minute before and after PLMA insertion. Any episodes of bradycardia (<40/min), tachycardia >100/min, or systolic hypotension (<80 mm Hg) were documented, as were any episodes of hypoxia (Spo_2 < 90%) or other adverse events. Visible blood staining on the guide, laryngoscope, IT, or PLMA was noted at removal.

Data about failed passage into the pharynx, insertion time, and the etiology of failure were collected by an unblinded observer. Data about malposition, effective ventilation, hypoxic episodes, and blood staining were collected by an observer blinded to the insertion technique. Sample size was based on a projected difference of 25% among the groups for first attempt success rate, a Type I error of 0.05 and a power of 0.8, and was based on studies [3–5,8,17–23] reporting first attempt success rates. If the randomized device failed, all variables were assigned to the initial randomized device (intention-to-treat). The distribution of data was determined using Kolmogorov-Smirnov analysis.[24]

Table 1. Insertion Success, Insertion Time, Etiology of Failed Insertion and Visible Blood Among Techniques. Data are Mean ± SD or Numbers (%)

	Digital	Introducer tool	Guide
N	33	33	33
Insertion success (*n*)			
First attempt	21 (64)	20 (61)	33 (100)
Second attempt	8 (24)	5 (15)	0 (0)
Third attempt	2 (6)	5 (15)	0 (0)
Overall	31 (94)	30 (91)	33 (100)
Insertion time (S)			
First attempt	35 ± 10	35 ± 7	31 ± 8
Overall[a]	49 ± 28	54 ± 37	31 ± 8
Etiology of failure (*n*)			
Failed passage into pharynx	12 (36)	13 (39)	0 (0)
Malposition[b]	8 (27)	13 (33)	0 (0)
Failed ventilation[c]	2 (6)	1 (3)	0 (0)
Visible blood (*n*)			
ProSeal LMA	2 (6)	2 (6)	1 (3)
Introducer tool		1 (3)	
Guide			0 (0)
Laryngoscope			0 (0)
Overall	2	3	1

[a] Data from the five failed insertions not included.

[b] Drain tube air leaks and failed gastric tube insertion if pharyngeal placement successful.

[c] Maximum expired tidal volume <8 mL/kg or end-tidal CO_2 >45 mm Hg if correctly positioned.

Statistical analysis was with paired *t*-test, one-way analysis of variance with *post hoc* Benferroni-Holm corrections for multiple comparisons and χ^2 test. Data are mean ± SD unless otherwise stated. Significance was taken as $P < 0.05$.

RESULTS

The mean (range) age, height, and weight were 41 (19–68) yr, 165 (147–180) cm, and 64 (43–105) kg, respectively. There were no differences in demographic data. There were no differences in Cormack and Lehane score (score 1, 2, 3, 4: $n = 0, 10, 74, 15$) or mean interincisor distance (3.3 ± 0.3 cm). Insertion was more frequently successful with the guided technique at the first attempt than the digital or IT techniques ($P < 0.0001$), but overall success was similar (Table 1). The time taken for successful placement was similar among groups at the first attempt, but was shorter for the guided technique after three attempts ($P < 0.02$). There were no failed uses of the guided technique.

The digital technique failed in two patients: a single attempt with the guided technique was successful in both cases. The IT technique failed in three patients: a single attempt with the guided technique was successful in all three cases. The etiology and frequency of failed insertion was similar for the digital and IT techniques (Table 1). There were no episodes of hypoxia. There were no differences in the frequency of visible blood among groups.

DISCUSSION

Guided insertion is more frequently successful than the digital and IT techniques in patients with simulated difficult laryngoscopy. The rigid neck collar simulates difficult laryngoscopy by reducing both head/neck movement (necessary to align the oropharyngeal axes) and mouth opening (necessary to insert and maneuver the laryngoscope). In our study, the application of the rigid neck collar resulted in a median laryngoscopic score of 3 and a mean mouth opening of 3.3 cm and was thus successful in simulating difficult laryngoscopy. An earlier study by our group found a similar result for patients with normal airways.[7] The guided technique is more successful because it reduces impaction at the back of the mouth, prevents folding over of the distal cuff, and guides the distal cuff directly into its correct position in the hypopharynx. Interestingly, we found that all failed insertions with the digital and IT techniques were subsequently successful with the guided technique. This supports the findings of another study by our group which showed that the guided technique is the best backup technique if either the digital or IT techniques fail.[9] Other advantages of the guided technique for airway rescue are that 1) oropharyngeal pathology can be identified as a laryngoscope is used; 2) gastric tube insertion is easy as the drain tube and esophagus are prealigned; and 3) the time-consuming tests for malposition are not required as malposition is rare.

Potential disadvantages over the manufacturer's recommended techniques are 1) stimulation from laryngoscopy and 2) esophageal trauma from the GEB. We found no differences in the hemodynamic response to insertion. This is not surprising as little force is required to view the hypopharynx. Esophageal trauma from passage of a gastric tube is extremely rare and is usually associated with anatomic abnormalities such as an esophageal pouch.[25] Avoiding force during passage of the guide into the esophagus should eliminate the risk of esophageal trauma. The GEB is not ideal for use with the PLMA, as the distal portion does not have an atraumatic tip. The development of an atraumatic esophageal guide is currently underway. We have used the guided technique as the primary technique on over 17,000 occasions without any evidence of minor or major esophageal injury, including an absence of occult blood on the GEB in 1096/1096 tested. We do not recommend blind placement of an Eschmann tracheal tube introducer, as there is a higher risk of trauma and misplacement.

Our study has four limitations. First, all insertions were by experienced users and our results may not necessarily apply to less experienced personnel. However, we consider that the digital and IT techniques probably require more skill than the guided technique. Second, we did not include a fourth group where the PLMA was inserted using laryngoscope

guidance, but without the guide. In principle, laryngoscopy might have improved insertion conditions by widening the pharynx even after removal; however, we consider this unlikely. Third, we used a rigid neck collar to simulate the difficult laryngoscopy scenario and our results may not apply to other difficult airway scenerios. Interestingly, Asai et al.[26] found that the ProSeal LMA was more successful than the LMA Classic™ with manual-in-line stabilization applied. Finally, intraoperative data were collected by unblinded observers, a possible source of bias.

We conclude that the guided insertion technique is more frequently successful than the digital or IT techniques in patients with a simulated difficult laryngoscopy using a rigid neck collar.

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