Gum Elastic Bougie-guided Insertion of the ProSealTM Laryngeal Mask Airway Is Superior to the Digital and Introducer Tool Techniques

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Background: The authors compare three techniques for insertion of the $ProSeal^{\text{TM}}$ laryngeal mask airway.

Methods: Two hundred forty healthy patients aged 18-80 yr were randomly allocated for ProSealTM larvngeal mask airway insertion using the digital, introducer tool (IT), or gum elastic bougie (GEB)-guided techniques. The digital and IT techniques were performed according to the manufacturer's instructions. The GEB-guided technique involved priming the drain tube with the GEB, placing the GEB in the esophagus under direct vision, and inserting the ProSealTM larvngeal mask airway using the digital technique with the GEB as a guide. Failed insertion was defined by any of the following criteria: (1) failed pharyngeal placement; (2) malposition (air leaks, negative tap test results, or failed gastric tube insertion if pharyngeal placement was successful); and (3) ineffective ventilation (maximum expired tidal volume < 8 ml/kg or end-tidal carbon dioxide > 45 mmHg if correctly positioned). Any visible or occult blood was noted. Sore throat, dysphonia, and dysphagia were assessed 18-24 h postoperatively.

Results: Insertion was more frequently successful with the GEB-guided technique at the first attempt (GEB, 100%; digital, 88%; IT, 84%; both P < 0.001), but success after three attempts was similar (GEB, 100%; digital, 99%; IT, 98%). The time taken to successful placement was similar among groups at the first attempt but was shorter for the GEB-technique after three attempts (GEB, 25 \pm 14 s; digital, 33 \pm 19 s; IT, 37 \pm 25 s; both: P < 0.003). There were no differences in the frequency of visible blood, but occult blood occurred less frequently with the GEB-guided technique (GEB, 12%; digital, 29%; IT, 31%; both: P < 0.02) but was similar among techniques if insertion was successful at the first attempt. There were no differences in postoperative airway morbidity.

Conclusion: The GEB-guided insertion technique is more frequently successful than the digital or IT techniques. The authors suggest that the GEB-guided technique may be a useful backup technique for when the digital and IT techniques fail.

THE *ProSeal*TM laryngeal mask airway (PLMA; Laryngeal Mask Company North America, San Diego, CA) is a new laryngeal mask device with a modified cuff to improve the seal and a drain tube to prevent aspiration and gastric insufflation. The manufacturer recommends inserting

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the PLMA using digital manipulation, like the LMA-ClassicTM, or with an introducer tool (IT), like the Intubat*ing*TM LMA (Laryngeal Mask Company North America).² The mean (range) frequency of insertion success at the first attempt for these techniques is $84\% (81-100)^{3-9}$ and 95% (90-100), 3,10,11 respectively, with the main causes of insertion difficulty being impaction at the back of the mouth and failure of the distal cuff to reach the hypopharynx.^{3,5,7,12} Howarth et al.¹³ recently described an insertion technique that overcomes these difficulties by using a gum elastic bougie (GEB) placed in the esophagus to guide the PLMA around the back of the mouth and into its correct position in the hypopharynx (figs. 1 and 2). In a preliminary descriptive study, Howarth et al. 14 subsequently reported no failed uses from 100 consecutive insertions. In the current study, we test the hypothesis that GEB-guided insertion is more frequently successful than the digital and IT techniques.

Materials and Methods

Two hundred forty patients (American Society of Anesthesiologists physical status class I or II; age, 18 - 80 yr) undergoing minor peripheral surgery while 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 GEB-guided techniques. Approval from the Cairns Base Hospital ethics committee and written informed consent were obtained. Patients were excluded if they were aged younger than 18 yr, had a known or predicted difficult airway, had a mouth opening less than 2.5 cm, had a body mass index greater than 35 kg/m², or were at risk of aspiration.

Anesthesia was given with the patient in the supine position and with the patient's head on a standard pillow of 7 cm in height. A standard anesthesia protocol was followed, and routine monitoring was applied. Fentanyl, 1 μ g/kg, and midazolam, 0.05 mg/kg, were administered. Patients were preoxygenated for 3 min. Anesthesia was induced with 1.5–3 mg/kg propofol given over 30 s, and the PLMA (size 4 for women, size 5 for men) was inserted when there was no response to jaw thrust. Additional boluses of 0.5 mg/kg propofol were given as required until an adequate level of anesthesia was achieved for placement. Anesthesia was maintained with 2–4% sevoflurane in oxygen and air. Facemask ventilation was performed until conditions were suitable for insertion.

The digital and IT insertion techniques were per-

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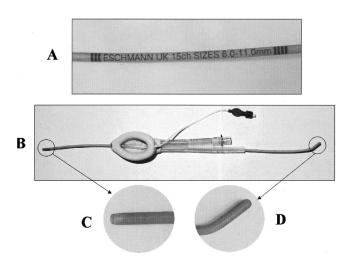


Fig. 1. The gum elastic bougie. (A) View of the middle portion with depth markers and specifications. (B) The $ProSeal^{TM}$ laryngeal mask airway with the gum elastic bougie mounted inside the drain tube. The straight end is distal (C), and the bent end is proximal (D).

formed 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 GEB-guided technique, the drain tube of the PLMA was primed with a lubricated GEB 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 GEB-guided technique involved the following steps: (1) under gentle laryngoscope guidance, the distal portion of the GEB was placed 5-10 cm into the esophagus while the assistant held the PLMA and the 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 GEB so it did not penetrate further into the esophagus; and (4) the GEB was removed while the PLMA was held in position.¹⁴ All techniques were performed with the patient in the "sniffing position" with the cuff fully deflated and using a midline approach. A slight lateral approach was used if tactile resistance was felt at the back of the mouth. When the PLMA was inserted into the pharynx, the cuff was inflated with air until effective ventilation was established or the maximum recommended inflation volume was reached. Fixation was according to the manufacturer's instructions.²

Patients were ventilated at an inspired tidal volume of 12 ml/kg, a respiratory rate of 12 breaths /min, and an inspiratory:expiratory ratio of 1:2. The presence or absence of oropharyngeal air leaks (detected by listening over the mouth¹⁶), gastric air leaks (detected by listening with a stethoscope over the epigastrium¹⁷), drain tube

air leaks (detected by placing lubricant over the proximal end of the drain tube), or an end-tidal carbon dioxide greater than 45 mmHg was noted. A suprasternal notch tap test was performed, and the outcome was noted. A well-lubricated, 60-cm-long, 14-French 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, negative tap test results, and failed gastric tube insertion if pharyngeal placement was successful); and (3) ineffective ventilation (maximum expired tidal volume < 8 ml/kg or end-tidal carbon dioxide > 45 mmHg if correctly positioned). The time between picking up the laryngoscope or prepared PLMA (cuff deflated, lubricated, IT and GEB attached) and successful placement was recorded. The etiology of failed insertion was documented. If insertion failed after three

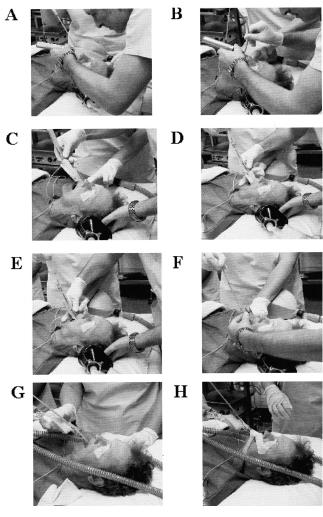


Fig. 2. (A-H) Photo sequence for gum elastic bougie-guided insertion of the $ProSeal^{TM}$ laryngeal mask airway.

Table 1. Demographic Data and Total Dose of Propofol

	Digital	Introducer Tool	Gum Elastic Bougie	
Age, yr	44 ± 10 (20–72)	45 ± 16 (18–75)	41 ± 13 (18–78)	
Height, cm	166 ± 11 (155–203)	169 ± 17 (149–198)	166 ± 12 (154–199)	
Weight, kg	64 ± 14 (45–122)	67 ± 14 (43–110)	$66 \pm 18 (42-99)$	
M:F	36:44	37:43	39:41	
Propofol, mg	189 ± 35	194 ± 40	192 ± 33	

Data are mean ± SD (range) or numbers.

attempts, a single attempt was permitted with each of the alternative techniques in random order (by opening a sealed opaque envelope). When insertion was successful, the intracuff pressure was set at 60 cm $\rm H_2O$ using a digital manometer (Mallinckrodt Medical, Athlone, Ireland), and the oropharyngeal leak pressure was determined. ¹⁶

Any episodes of hypoxia (oxygen saturation measured by pulse oximetry $[\mathrm{Spo_2}] < 90\%$) or other adverse events were documented. All cases were conducted by a single experienced user (> 1,000 uses of each technique). Any visible or occult blood staining on the GEB, laryngo-scope, IT, or PLMA was noted at removal. Occult blood was detected by washing each item of equipment in 100 ml water for 2 min and testing it with a dipstick for hemoglobin, as described by Parker and Day. ¹⁹ The mouth, lips, and tongue were inspected for evidence of trauma.

Patients underwent a structured interview 18-24 h after surgery. Patients were asked about sore throat (constant pain, independent of swallowing), dysphonia (difficulty or pain on speaking), and dysphagia (difficulty or pain on swallowing). Symptoms were graded by the patient as mild, moderate, or severe. Patients were unaware of the insertion technique used. Unblinded trained observers collected data during anesthesia, and a blinded trained observer collected the data the next day.

The sample size was based on a projected difference of 10% between the groups for first attempt success rate, a type I error of 0.05, and a power of 0.9 and was based on studies reporting first attempt success rates. $^{3-11,14}$ If the randomized device failed, all variables (other than oropharyngeal leak pressure) were assigned to the initial randomized device (intention to treat). The distribution of data were determined using Kolmogorov-Smirnov analysis. 20 Statistical analysis was with paired t test and chi-square test. Data are mean \pm SD unless otherwise stated. P < 0.05 was considered significant.

Results

There were no differences in demographic data or doses of anesthetic agents among groups (table 1). Insertion was more frequently successful with the GEB-guided technique at the first attempt than the digital or IT techniques (both: P < 0.001), but overall successes were similar (table 2). The time taken to successful

placement was similar among groups at the first attempt but was shorter for the GEB-technique after three attempts (both: P < 0.003). A lateral approach was required less frequently with the GEB-guided technique (both: P < 0.00001). There were no failed uses of the GEB-guided technique. The digital technique failed in one patient; a single attempt with the IT technique also failed, and a single attempt with the GEB-guided technique was successful. The IT technique failed in two patients; a single attempt with the digital technique was successful in one, and a single attempt with the GEBguided technique was successful in the other. The etiology and frequency of failed insertion were similar for the digital and IT techniques (table 2). There were no episodes of hypoxia or other adverse events. No patient had mouth or tongue trauma, but two patients had minor cuts on the lips (table 3). There were no differences in the frequency of visible blood among groups, but occult blood occurred less frequently with the GEB-guided technique than with the digital or IT techniques (both: P < 0.02). Occult blood was similar among techniques if insertion was successful at the first attempt. There was no visible or occult blood on the GEB or IT. There was

Table 2. Insertion Success, Insertion Time, Etiology of Failed Insertion, and Oropharyngeal Leak Pressure among Techniques

	Digital	Introducer Tool	Gum Elastic Bougie
n	80	80	80
Insertion success			
First attempt	70 (87)	67 (84)	80 (100)
Second attempt	7 (9)	8 (10)	0 (0)
Third attempt	2 (3)	3 (4)	0 (0)
Overall	79 (99)	78 (98)	80 (100)
Lateral approach required	35 (44)	28 (35)	0 (0)
Insertion time, s			
First attempt	27 ± 12	28 ± 14	25 ± 14
Overall*	33 ± 19	37 ± 25	25 ± 14
Etiology of failure			
Failed passage into pharynx	8 (10)	11 (14)	0 (0)
Malposition†	6 (8)	9 (11)	0 (0)
Failed ventilation‡	1 (1)	0 (0)	0 (0)
Oropharyngeal leak pressure	31 ± 8	30 ± 9	31 ± 8

Data are mean \pm SD or numbers (%).

^{*} Data from the three failed insertions not included. † Drain tube air leaks, a negative tap test, and failed gastric tube insertion if pharyneal placement successful. ‡ Maximum expired tidal volume less than 8 ml/kg or end-tidal carbon dioxide greater than 45 mmHg if correctly positioned.

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Table 3. Incidence of Airway Trauma and Visible and Occult Blood on the *ProSeal*™ Laryngeal Mask Airway and Airway Instruments

	Digital	Introducer Tool	Gum Elastic Bougie
n	80	80	80
Trauma			
Mouth	0 (0)	0 (0)	0 (0)
Lips	0 (0)	1 (1)	1 (1)
Tongue	0 (0)	0 (0)	0 (0)
Overall	0 ` ′	1 `´	1 `´
Visible blood			
PLMA	3 (4)	4 (5)	2 (3)
Introducer tool	. ,	0 (0)	` ,
Gum elastic bougie		. ,	0 (0)
Laryngoscope			0 (0)
Overall	3	4	2 `
Occult blood			
PLMA	23 (29)*	25 (31)	10 (12)
Introducer tool	` ,	0 (0)	. ,
Gum elastic bougie		` ,	0 (0)
Laryngoscope			8 (10)
Overall	23 (29)*	25 (31)†	10 (12)‡

Data are number of patients (%).

no visible blood on the laryngoscope, but occult blood was detected on eight occasions. There were no differences in postoperative airway morbidity among groups (table 4).

Discussion

We found that insertion was more frequently successful at the first attempt and that the time taken to successful placement was shorter using the GEB-guided technique. The principle cause of failed and/or delayed insertion with the digital and IT techniques are impaction of the PLMA at the back of the mouth, which results in failed passage into the pharynx, or folding over of the distal cuff, or the distal cuff being directed into the glottic inlet rather than the hypopharynx. The GEB-guided technique is more frequently 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 the hypopharynx. The reduced need for a lateral approach

with the GEB-guided technique shows how it avoids resistance at the back of the mouth.

Other potential advantages of this technique are that (1) routine use of the laryngoscope may help to maintain intubation skills, provide information about ease of intubation, and allow unexpected oropharyngeal pathology to be identified; (2) any displacement of the cuff occurring before GEB removal can be corrected by pushing the PLMA back into position; (3) gastric tube insertion should have a high success rate because the drain tube and esophagus are perfectly aligned; and (4) there is no need for tests to show that the distal cuff is correctly positioned and the drain tube is patent.

The potential disadvantages of the GEB-guided technique are the potential for stimulation and pharyngoesophageal trauma because the GEB is stiff and is not designed for esophageal placement (though it often enters the esophagus inadvertently during failed intubation).²¹ However, there were no episodes of airway protective reflex activation, and similar doses of propofol were required among the insertion techniques, suggesting that simulation is similar. This is probably because only slight force is needed to view the hypopharynx. Furthermore, occult blood was found less frequently with the GEB-guided technique, suggesting that it may in fact be less traumatic. This is probably related to the lack of impaction at the back of the mouth and the need for fewer insertion attempts. There was no occult blood on the GEB, suggesting that there was no esophageal injury. Iatrogenic esophageal trauma from passage of a tracheal or gastric tube is extremely rare and is usually associated with difficulty during placement²² and anatomic abnormalities such as an esophageal pouch. 23 Avoiding force during passage of the GEB into the esophagus should reduce the risk of esophageal trauma. However, until further data are available, perhaps the GEB-guided technique should be used as a backup when the digital or IT techniques fail. We have used the GEB-guided technique on more than 1,500 occasions, without any evidence of esophageal injury, including an absence of occult blood on the GEB in 287 of 287 tested. Perhaps a GEB could be specifically designed for PLMA insertion with an atraumatic distal portion to further reduce risk. Interestingly, the incidence of visible and occult blood on the PLMA (4% and 24%,

Table 4. Incidence of Airway Morbidity at 18–24 h Postoperatively

Airway Morbidity	Digital		Introducer Tool		Gum Elastic Bougie	
	Mild/Moderate/Severe	Total	Mild/Moderate/Severe	Total	Mild/Moderate/Severe	Total
Sore throat	8/4/0	12 (15)	10/3/1	14 (17)	7/1/1	9 (11)
Dysphagia	5/3/1	9 (11)	3/3/1	7 (9)	5/3/1	9 (11)
Dysphonia	2/3/0	5 (6)	4/2/1	7 (9)	2/2/1	5 (6)

Data are numbers (%).

^{* 16/70 (23)} when insertion successful at first attempt. † 18/67 (27) when insertion successful at first attempt. ‡ All patients with occult blood on the laryngoscope had occult blood on the *ProSeal*™ laryngeal mask airway (PLMA).

respectively) was lower than that reported by Parker and Day¹⁹ on the *LMA-Classic*TM (12% and 76% respectively). The incidence of occult blood on the laryngoscope (10%) was also lower than that reported by Parker and Day¹⁹ for intubation (78%). This may be related to the lower amount of force required to view the hypopharynx than the glottis. A further potential disadvantage of the GEB-guided technique is that an assistant may be required more frequently than for the digital and IT techniques, which may limit its use by single operators.

Drolet and Girard,²⁴ in 2001, and Brimacombe and Keller,²⁵ in 2002, described a similar guided technique for the PLMA using a gastric tube and a fiberoptic scope, rather than the GEB. An advantage of the gastric tube is that it is potentially less traumatic than the GEB; however, a gastric tube may not be sufficiently stiff to guide the PLMA around the back of the mouth. An advantage of the fiberoptic scope is that it obviates the need for laryngoscopy. It has been suggested that the GEB-guided technique may have a role in failed laryngoscope-guided tracheal intubation when the GEB has been accidentally placed in the esophagus because a PLMA can be easily railroaded along the misplaced GEB.²⁶

Our study has three limitations. First, all insertions were by a single experienced user, 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 GEB-guided technique. We speculate that anesthesiologists with laryngoscope skills but little experience with the PLMA will have a higher success rate with the GEB-guided technique. Second, we did not document hemodynamic changes, and it is possible that the hemodynamic stress response was higher for the GEB-guided technique. However, Howarth et al. 14 noted no increase in heart rate or blood pressure after GEB-guided insertion, and there is only anecdotal evidence that the hemodynamic stress response is clinically important. 27,28 Third, we did not include a fourth group in which the PLMA was inserted using laryngoscope guidance but without GEB guidance. In principle, laryngoscopy might have improved insertion conditions by widening the pharynx even after removal; however, we consider this unlikely.

We conclude that the GEB-guided insertion technique is more frequently successful than the digital or IT techniques. We suggest that the GEB-guided technique may be a useful backup technique for when the digital and IT techniques fail.

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