Suction catheter guided insertion of the ProSeal™ laryngeal mask airway is superior to the digital technique

[L'insertion du masque laryngé ProSeal™, guidée par une sonde d'aspiration, est supérieure à la technique digitale]

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Purpose: We tested the hypothesis that digital insertion of the ProSeal™ laryngeal mask airway (ProSeal™ LMA) is more successful when using a suction catheter (SC) as a guide.

Methods: Two hundred and forty-three patients (ASA physical status I–III; aged 18–84 yr) were randomly allocated for the digital or SC-guided technique. The digital technique was performed according to the manufacturer's instructions. The SC technique involved priming the drain tube with the SC so that it protruded by 15 cm, blindly inserting the SC into the pharynx to a depth of 15 cm, followed by the digital technique. Failed insertion was defined by any of the following criteria: 1) failed passage into the pharynx; 2) malposition; and 3) ineffective ventilation. Any airway trauma, and visible or occult blood was noted. Sore throat, dysphonia and dysphagia were assessed 16 to 24 hr postoperatively.

Results: Fewer insertion attempts were required with the SC-guided technique ($P = 0.02$), but first attempt and overall success were similar. The time taken to provide an effective airway was shorter for the SC-guided technique (36 ± 24 sec *vs* 44 ± 28 sec, $P = 0.02$). A lateral approach was required less frequently with the SC-guided technique (0% *vs* 4%, $P = 0.0004$). There were no adverse events. Mouth trauma was more frequent with the digital technique ($P = 0.04$), but overall trauma was similar. There were no differences in the frequency of visible or occult blood. There were no differences in postoperative airway morbidity.

Conclusions: The SC-guided technique is more frequently successful than the digital technique and is associated with less mouth trauma during insertion of the ProSeal™ LMA. We suggest that the SC technique may be a useful alternative when the digital technique fails.

***Objectif** : Tester l'hypothèse voulant que l'insertion digitale du masque laryngé ProSeal™ (ML ProSeal™) soit mieux réussie avec une sonde d'aspiration (SA) comme guide.*

***Méthode** : L'insertion digitale ou guidée par une SA ont été aléatoirement appliquées chez 243 patients d'état physique ASA I-III, de 18 à 84 ans. La technique digitale a été réalisée selon les instructions du fabricant. La technique SA comprenait l'amorçage du drain avec la SA pour qu'il sorte de 15 cm, l'insertion à l'aveugle de la SA dans le pharynx jusqu'à une profondeur de 15 cm, puis la technique digitale. L'échec de l'insertion était défini par n'importe lequel de ces critères : 1) passage manqué dans le pharynx ; 2) malposition et 3) ventilation inefficace. Tout trauma aux voies aériennes et la présence de sang visible ou occulte étaient notés. Le mal de gorge, la dysphonie et la dysphagie ont été évalués de 16 à 24 h après l'opération.*

***Résultats** : La technique guidée par SA a requis moins d'essai (P= 0,02), mais la réussite du premier essai et le succès global étaient similaires. Avec la technique guidée par SA, le temps nécessaire au contrôle des voies aériennes a été plus court (36 ± 24 s vs 44 ± 28 s, P = 0,02) et une approche latérale a été moins souvent nécessaire (0 % vs 4 %, P = 0,0004). Il n'y a pas eu d'événements indésirables. Les lésions buccales ont été plus fréquentes avec la technique digitale (P = 0,04), mais globalement, les traumas ont été similaires. Il n'y a pas eu de différence pour la fréquence de sang visible ou occulte ni pour la morbidité postopératoire des voies aériennes.*

***Conclusion** : La technique guidée par SA est plus souvent réussie que la technique digitale et est associée à moins de lésion buccale pendant l'insertion du MI ProSeal™. La technique SA peut donc remplacer la technique digitale en cas d'échec.*

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THE ProSeal™ laryngeal mask airway (ProSeal™ LMA; Intavent Orthofix, Maidenhead, UK) is a relatively new LMA device with a modified cuff to improve the seal and a drain tube to help prevent aspiration and gastric insufflation, facilitate passage of a gastric tube, and provide information about malposition.[1] The manufacturer recommends inserting the ProSeal™ LMA using digital manipulation or with an introducer tool, but both these techniques have lower success rates than the classic LMA.[2] Four new techniques have recently been described to facilitate insertion; all involve priming the drain tube with a guide that is directed into the proximal esophagus. Our group described the use of a suction catheter (SC);[3] Drolet and Girard[4] the use of a gastric tube; Brimacombe *et al.*[5] the use of a fibreoptic scope; and Howarth *et al.*[6] the use of a gum elastic bougie. However, only the gum elastic bougie technique has been the subject of a randomized control trial. In this study, we test the hypothesis that the success rate of the ProSeal™ LMA insertion is increased when using an SC as a guide.

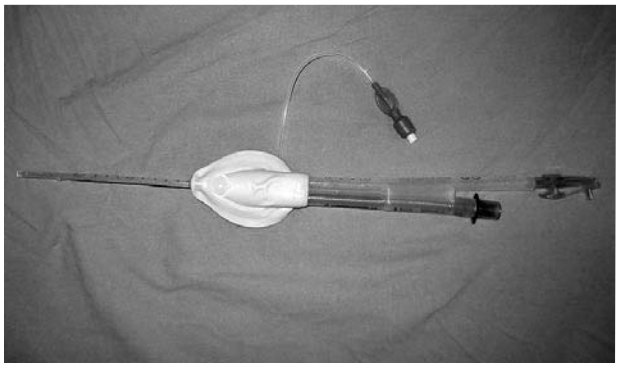

FIGURE The ProSeal™ laryngeal mask airway drain tube primed with the suction catheter.

Methods

Ethical Committee approval and written informed consent were obtained. Two hundred and forty-three patients (ASA physical status I–III, aged 18–84 yr) undergoing ambulatory surgery in the supine position were randomly allocated (according to whether the last digit of the hospital number was odd or even) into two groups for ProSeal™ LMA insertion using the digital (even) or SC-guided (odd) techniques. Patients were excluded if they were < 18 yr, < 50 kg, had a known or predicted difficult airway, mouth opening < 2.5 cm, a body mass index > 35 $kg \cdot m^2$, or were at risk of aspiration.

Patients were premedicated with midazolam 0.02 $mg \cdot kg^{-1}$ *iv* 15 min before induction. A standard anesthesia protocol was followed and routine monitoring was applied. Anesthesia was in the supine position with the patient's head on a standard pillow, 7 cm in height. Following preoxygenation for three minutes, anesthesia was induced with a propofol infusion set to a target concentration of 7 $\mu g \cdot mL^{-1}$ and remifentanil 0.4 $\mu g \cdot kg^{-1}$ *iv*. The ProSeal™ LMA was inserted when there was loss of corneal reflex, apnea and no response to jaw thrust.[7] Additional boluses of propofol 0.5 $mg \cdot kg^{-1}$ *iv* were given as required until an adequate level of anesthesia was achieved for the ProSeal™ LMA placement. The manufacturer's weight-based recommendations were used for size selection.[8] Neuromuscular blocking drugs were not administered. Anesthesia was maintained with a propofol infusion set to a target concentration of 2 to 3 $\mu g \cdot mL^{-1}$ and an infusion of remifentanil at 0.05 to 0.2 $\mu g \cdot kg^{-1} \cdot min^{-1}$. Face mask ventilation was performed until conditions were suitable for insertion. Patients underwent volume controlled ventilation using O_2 33% and air with the tidal volume set at 10 $mL \cdot kg^{-1}$ and the rate adjusted to maintain the end-tidal CO_2 between 35 to 45 mmHg.

The digital technique was performed according to the manufacturer's instructions[8] and involved the use of the index finger to press the ProSeal™ LMA into, and advance it around, the palatopharyngeal curve. The SC-guided technique involved the following steps: 1) priming the drain tube with a well-lubricated (KY™, Johnson and Johnson, Maidenhead, UK) water-based gel 18-FG SC (Vygon Corporation, Norristown, PA, USA) so that it protruded 15 cm beyond the distal aperture of the drain tube (Figure); 2) opening the mouth and blindly inserting the SC into the pharynx to a depth of 15 cm at the incisors – slight changes in the trajectory of the SC were permitted, but if persistent tactile resistance was encountered, the SC was placed using a laryngoscope; and 3) digital insertion as above. All insertions were in the sniffing position with the cuff fully deflated and using a midline approach. If tactile resistance was felt at the back of the mouth, a lateral approach was used.[9] The lateral approach is identical to the midline approach except that the cuff is not placed symmetrically across the hard palate, but rather placed across it at an angle of approximately 45° with the proximal end pressed against one side and the distal end pressed against the other. The cuff is advanced into the oropharynx with its lateral distal side as the leading edge, and then straightened out once in the laryngopharynx. Once the ProSeal™ LMA 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.[8] The presence/absence of oropharyngeal air leaks (detected by listening over the mouth),[10] gastric air leaks (detected by listening with a stethoscope over the epigastrium),[11] drain tube air leaks (detected by placing a lubricant over the proximal end of the drain tube), or an end-tidal CO_2 > 45 mmHg was recorded.

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,[11] failed SC insertion if pharyngeal placement successful);[12] and 3) ineffective ventilation (no end-tidal CO_2 trace, or maximum expired tidal volume < 8 mL·kg^{-1}, or end-tidal CO_2 > 45 mmHg if correctly positioned). The time between picking up the prepared ProSeal™ LMA (cuff deflated, lubricated, SC attached) and successful placement was recorded. The etiology of failed insertion was documented. If insertion failed after three attempts, an alternative airway management strategy was used. Once insertion was successful, the intracuff pressure was set at 60 cm H_2O using a digital manometer (Mallinckrodt Medical, Athlone, Ireland) and the oropharyngeal leak pressure was determined using the manometric stability technique.[10]

Any episodes of hypoxia (SpO_2 < 90%) or other adverse events were documented. All cases were conducted by four experienced users (> 1,000 uses each technique). Any visible or occult blood staining on the ProSeal™ LMA or SC was noted at removal. Occult blood was detected by washing each item of equipment in 100 mL water for two minutes and testing it with a dipstick for hemoglobin, as described by Parker and Day.[13] The teeth, mouth, lips and tongue were inspected for evidence of trauma.

Patients underwent a structured telephone interview 16 to 24 hr after surgery. Patients were asked about sore throat (constant pain, independent of swallowing), dysphonia (difficulty/pain on speaking) and dysphagia (difficulty/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 the perioperative data, and blinded trained observers collected the data the following day.

Statistics

Sample size was based upon a projected difference of 10% between the groups for first attempt success rate, a type I error of 0.05 and a power of 0.915, and was based on studies reporting first attempt success rates.[6,14–23] The distribution of data was determined using Kolmogorov-Smirnov analysis.[24] Data were compared using a paired t test for parametric data and Chi-squared test for non-parametric data. Data are presented as mean ± standard deviation unless otherwise stated. Significance was taken as $P < 0.05$. Statistical analysis was performed using SPSS v. 12.0 program (SPSS Inc, Chicago, IL, USA) running on a personal computer.

TABLE I Demographic data and total induction dose of propofol for the suction catheter and digital techniques

	SC technique (n = 135)	*Digital technique (n = 108)*
Age (yr)	48 ± 15 (18–75)	49 ± 18 (18–84)
Weight (kg)	70 ± 14 (45–120)	73 ± 13 (44–110)
Height (cm)	167 ± 9 (144–193)	165 ± 9 (145–192)
Male: female (*n*)	51:84	49:59
ASA I/II/III (*n*)	60/68/7	48/54/6
Anesthesia time (min)	53 ± 22 (30–142)	53 ± 20 (25–126)
Propofol (mg)	182 ± 58	188 ± 63

SC = suction catheter; ASA = American Society of Anesthesiologists. Data are mean ± standard deviation (range) or numbers.

TABLE II Insertion success, insertion time, etiology of failed insertion and oropharyngeal leak pressure for the suction catheter and digital techniques

n	*SC technique 135*	*Digital technique 108*	*P value*
Insertion success (*n*)			
- First attempt	131 (97)	96 (89)	
- Second attempt	4 (3)	8 (7)	0.02
- Third attempt	0 (0)	2 (2)	
- Overall	135 (100)	106 (98)	0.039
Lateral approach required (*n*)	1 (1)	13 (12)	0.0004
Insertion time (sec) *	36 ± 24	44 ± 28	0.02
Etiology of failure (*n*)			
- Failed passage into pharynx	2 (2)	2 (2)	NS
- Malposition†	1 (1)	8 (7)	NS
- Failed ventilation‡	1 (1)	1 (1)	NS
Oropharyngeal leak pressure	36 ± 4	35 ± 5	NS

SC = suction catheter; NS = not significant. Data are mean ± standard deviation or numbers (%). *Data from the two failed insertions not included; †Drain tube air leaks and failed gastric tube insertion if pharyngeal placement successful; ‡Maximum expired tidal volume < 8 mL·kg^{-1} or end-tidal CO_2 > 45 mmHg if correctly positioned.

Results

Demographic data and the mean induction dose of propofol were similar in the two groups (Table I). The type/frequency/duration of surgical procedures

TABLE III Incidence of airway trauma, and visible and occult blood on the ProSeal™ LMA and airway instruments

	SC technique (n = 135)	*Digital technique (n = 108)*
Trauma (*n*)		
- teeth	0 (0)	0 (0)
- mouth	0 (0)	4 (4)*
- lips	4 (3)	5 (5)
- tongue	3 (2)	1 (1)
Overall	7 (5)	10 (10)
Visible blood (*n*)		
- ProSeal™ LMA	11 (8)	9 (8)
- SC	0 (0)	
Overall	11 (8)	9 (8)
Occult blood (n)		
- ProSeal™ LMA	25 (18)†	26 (24)
- SC	4 (3)	
- Both	1 (1)	
Overall	25 (18)†	26 (24)‡

SC = suction catheter; LMA = laryngeal mask airway; Data are number of patients (%). *$P = 0.04$; † 22/131 (16) when insertion successful at first attempt; ‡ 16/96 (16) when insertion successful at first attempt.

TABLE IV Incidence of airway morbidity at 16 to 24 hr postoperatively

	SC technique (n = 135)		*Digital technique (n = 108)*	
Airway morbidity	Mi/mod/sev	Total	Mi/mod/sev	Total
- Sore throat	13/1/1	15 (11)	5/1/1	7 (7)
- Dysphagia	11/5/0	16 (12)	4/3/1	8 (9)
- Dysphonia	8/1/0	9 (7)	2/1/0	3 (3)

SC = suction catheter; Mi = mild; mod = moderate; sev = severe. Data are numbers (%).

were similar in the two groups. Insertion success rates, insertion time, etiology of failed insertion, and oropharyngeal leak pressure data are presented in Table II. No patient required laryngoscope guided placement of the SC. Fewer insertion attempts were required with the SC-guided technique ($P = 0.02$), but first attempt and overall success were similar. The time required to establish an effective airway was shorter for the SC-guided technique ($P = 0.02$). A lateral approach was required less frequently with the SC-guided technique ($P = 0.0004$). Mean oropharyngeal leak pressures were similar in the two groups, and there were no adverse events. Airway trauma data are summarized in Table III. Mouth trauma was more frequent with the digital technique ($P = 0.04$). There were no differences with respect to the frequency of visible or occult blood, or postoperative airway morbidity (Table IV). There were no differences in performance among anesthesiologists.

Discussion

We found that insertion of the ProSeal™ LMA was more successful using the SC-guided technique. Our success rate for the digital technique was similar to previous studies.[14,20] The two main causes of failed insertion with the digital technique are impaction with the back of the mouth and glottic inlet.[14,17,19,25] The SC-guided technique is more frequently successful because it directs the distal cuff around the oropharyngeal inlet and toward the esophagus; however, impaction can still occur, albeit rarely, as the SC can enter the glottic inlet and the SC may be insufficiently rigid to guide the distal cuff around the oropharynx, where the oropharyngeal axis is < 90°. Insertion can also occasionally fail due to the tongue buckling up at the back of the mouth. One solution to all these problems is to place the SC under direct vision using a laryngoscope, as recommended for the gum elastic bougie-guided technique.[15] We used the largest size SC that would fit down the drain tube to increase stiffness. Another useful method for increasing stiffness that we did not evaluate is to cool the SC in a fridge. Magill forceps may occasionally be required to feed the SC into the esophagus. Other potential advantages of the SC-guided technique are (i) the distal cuff is less likely to fold over as the drain tube is stiffer; (ii) the SC is already in the esophagus providing some protection against regurgitation; and (iii) the SC can be used as a guide to reinsertion if the ProSeal™ LMA is displaced.

There are three other guides which have been used to facilitate insertion of the ProSeal™ LMA. Brimacombe *et al.* showed that the laryngoscope-guided, gum elastic bougie-guided technique was superior to the digital technique[15] and superior to the introducer tool technique if the digital technique failed.[26] The advantages over the SC are that the gum elastic bougie is sufficiently rigid to eliminate impaction at the back of the mouth, and can be more easily directed into the esophagus. The disadvantage is that laryngoscope-guidance is required as the bougie is too stiff to be placed blindly. Drolet and Girard[4] described the use of a blindly placed gastric tube: the advantage over the SC is that there is no need to insert a gastric tube; and the disadvantage is that it is usually softer, making impaction and misplacement more likely. Brimacombe *et al.*[5] described the use of a fibreoptic scope: the advantage over the SC is that it can easily be directed around the oropharynx and into the esophagus; disadvantages are increased costs and a potential increase in the time required to secure the airway. Perhaps the ideal aid for placement is a guide combining the best features of the SC and gum elastic

bougie. Such a guide would have its distal portion like the SC, and the proximal portion resembling the gum elastic bougie.

We found that mouth trauma was more frequent with the digital technique. This is probably related to the increased difficulty with insertion. In principle, it might be related to increased use of the lateral approach, but we consider this unlikely as less resistance is encountered with the lateral approach. There was a trend for increased frequency of airway morbidity with the SC technique (sore throat 11 *vs* 7%; dysphagia 12 *vs* 9%; dysphonia 7 *vs* 3%). A much larger study will be required to confirm or refute this trend. We also found that occult blood was detected on the SC in four of 135 patients. This is higher than reported by Brimacombe *et al.*[15] for the laryngoscope-guided, gum elastic bougie guided technique where no occult blood was detected on the gum elastic bougie in a cohort of 80 patients. We speculate that microscopic mucosal tears occur when the SC rubs against the posterior pharyngeal wall. Perhaps the frequency of occult blood would be reduced if the SC were placed under direct vision.

A limitation of our study is that all insertions were performed by experienced users and our results may not necessarily apply to less experienced personnel. However, we consider that the digital technique probably requires more skill than the SC technique. A further limitation is that the groups were of unequal size. This was due to the technique of randomizing the patients according the whether the hospital number ended in an odd or even digit. This form of randomization is not ideal and may have led to differences between group characteristics. Finally, intraoperative data were collected by unblinded observers – a possible source of bias.

We conclude that the SC technique is more frequently successful than the digital technique and is associated with less mouth trauma during insertion of the ProSeal™ LMA.

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