Guided Insertion of the ProSeal Laryngeal Mask Airway Is Superior to Conventional Tracheal Intubation by First-Month Anesthesia Residents After Brief Manikin-Only Training

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Abstract

In the following pilot study, we compared conventional laryngoscope-guided tracheal intubation (tracheal intubation) and laryngoscope-guided, gum elastic bougie-guided ProSeal laryngeal mask airway insertion (guided ProSeal) for airway management by first-month anesthesia residents after brief manikin-only training. Five first-month residents with no practical experience of airway management were observed performing these techniques in 200 ASA I–II anesthetized, paralyzed adults. Each resident managed 40 patients, 20 in each group, in random order. The number of insertion attempts, effective airway time, ventilatory capability during pressure-controlled ventilation set at 15 cm H_2O, airway trauma, and skill acquisition were studied. Data were collected by unblinded observers. Insertion was more frequently successful (100% versus 65%) and effective airway time was shorter (41 ± 24 s versus 89 ± 62 s) in the guided ProSeal group (both $P < 0.0001$). Expired tidal volume was larger (730 ± 170 mL versus 560 ± 140 mL) and end-tidal CO_2 lower (33 ± 4 mm Hg versus 37 ± 5 mm Hg) in the guided ProSeal group during pressure controlled ventilation (both $P < 0.0001$). Blood staining was more frequent on the laryngoscope (24% versus 2%; $P < 0.0001$) in the tracheal intubation group. There was evidence for skill acquisition in both groups. We conclude that laryngoscope-guided, gum elastic bougie-guided insertion of the ProSeal laryngeal mask airway is superior to conventional laryngoscope-guided tracheal intubation for airway management in terms of insertion success, expired tidal volume, and airway trauma by first-month anesthesia residents after brief manikin-only training. The guided ProSeal technique has potential for cardiopulmonary resuscitation by novices when conventional intubation fails.

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The Classic Laryngeal Mask AirwayTM (LMA; Laryngeal Mask Company, Henley-on-Thames, UK) is recommended for use by inexperienced personnel during cardiopulmonary resuscitation (1). Advantages over conventional laryngoscope-guided tracheal intubation (tracheal intubation) are more rapid insertion and increased success rate (2–4), but the LMA does not prevent aspiration or gastric insufflation, and ventilatory capability is limited by the low-pressure seal with the pharynx. The ProSeal laryngeal mask airway (PLMA; Laryngeal Mask Company) is a variation of the LMA that is more suitable for cardiopulmonary resuscitation, as it has a modified cuff to improve the seal and a drain tube to provide a channel for regurgitated fluid, prevention of gastric insufflation, and insertion of a gastric tube (5). Coulson et al. (6) showed that digital insertion of the PLMA and LMA by inexperienced personnel after manikin-only training was equally successful in anesthetized adults, with success rates of approximately 90% after 2 min. Howarth et al. (7) described a new insertion technique for the PLMA with a success rate approaching 100% by experienced personnel. The technique involves placing a gum elastic bougie or tracheal tube guide in the esophagus under laryngoscope guidance and railroading the PLMA into position along its drain tube (guided ProSeal). In the following pilot study, we compared the guided ProSeal technique with conventional tracheal intubation for airway management by first-month anesthesia residents after brief manikin-only training.

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Five first-month residents with no practical airway management experience (no anesthesia, intensive care, or emergency medicine residencies; never inserted a tracheal tube or laryngeal mask airway) participated in the study. Airway management training involved i) a 2-h didactic lecture, ii) a demonstration of

the tracheal intubation and guided ProSeal techniques using a standard advanced life support manikin (Laerdal International A/S, Kopenhagen, Denmark), and iii) 5 supervised insertions using the advanced life support manikin.

Two-hundred consecutive patients (ASA physical status I–II, aged 18–65 yr) undergoing routine general, gynecological, or peripheral musculoskeletal surgery in the supine position were studied. Ethical committee approval and written, informed consent were obtained. Patients were excluded from the trial if they had a known or predicted difficult airway, oropharyngeal pathology, mouth opening <3.0 cm, a body mass index >30 kgm−2, or were at increased risk of aspiration. Patients were randomly allocated into two equal-sized groups: in one group airway management was with the tracheal intubation technique and in the other with the guided ProSeal technique. Each trainee performed airway management on 40 patients, 20 with each technique. Randomization was by computer-generated numbers and allocation by opening a sealed opaque envelope immediately before the procedure.

A standard anesthesia protocol was followed and routine monitoring was applied. The head/neck was on a standard pillow 7 cm in height. Induction of anesthesia was with fentanyl 2 μg/kg and propofol 2.5–3.0 mg/kg. Maintenance of anesthesia was with sevoflurane 2% in O2 33% and air. Neuromuscular blockade was with rocuronium 0.6 mg/kg. Patients were ventilated via a facemask for 3–5 min until the train-of-four ratio was 0%. The equipment for airway management was placed by the patient's head along with an appropriate-sized syringe. A 7.0 mm inner diameter tracheal tube or size 4 ProSeal LMA was used for females, and a size 8.0 mm inner diameter tracheal tube or a size 5 ProSeal LMA was used for males. When the patient was stable (Spo2 >95%, end-tidal CO2 <45 mm Hg, heart rate >40 bpm, mean arterial blood pressure >55 mm Hg), the trainee was instructed to proceed with airway management. The tracheal intubation technique involved i) obtaining the best possible view of the vocal cords with a Macintosh laryngoscope blade, and ii) inserting the tracheal tube through the vocal cords into the trachea. The guided ProSeal involved i) obtaining the best possible view of the hypopharynx with a Macintosh laryngoscope blade, ii) inserting a gum elastic bougie with its straight end first through the hypopharynx into the proximal 5 cm of the esophagus, and iii) railroading the ProSeal LMA along its drain tube into the pharynx. Once inserted, the cuff was inflated with

air, the proximal tube was connected to the anesthesia breathing system, manual ventilation commenced, and the gum elastic bougie was removed.

The trainee was given a maximum of two attempts to obtain an effective airway. A failed attempt was defined as removal of the device from the mouth. An effective airway was defined as 2 consecutive breaths with an expired tidal volume ≥6 mL/kg. Insertion was considered to have failed if an effective airway was not obtained after two attempts. Timing started when the trainee touched the airway management equipment. If insertion failed, the reason for failure was categorized as either failure to insert the device into the larynx or pharynx or failure to achieve effective ventilation once in the larynx or pharynx. If insertion failed, the data were excluded from the analysis of effective airway time and ventilation. All devices were fixed by taping the tube in the midline over the chin.

The anesthesiologist took control of the airway if: i) an effective airway was obtained, ii) there were two failed attempts, or iii) the Spo2 decreased to less than 90%. The only assistance received during insertion was gentle mouth opening by a trained anesthesiology technician. In the guided ProSeal group, the trainee was asked to insert a lubricated 60 cm long 14F gastric tube through the drain tube if there was no air leak up the drain tube during ventilation. Correct gastric tube placement was assessed by suction of fluid or detection of injected air during epigastric auscultation. The residual gastric volume was documented. The intracuff pressure was set and held constant at 30 cm H2O for the tracheal tube and 60 cm H2O for the ProSeal LMA using a digital manometer (Mallinckrodt Medical, Athlone, Ireland). Patients underwent pressure controlled ventilated at peak airway pressure set at 15 cm H2O, positive end-expiratory pressure set at 5 cm H2O, a respiratory rate of 12 breaths/min, an inspiratory flow rate of 50 L/min, and a fresh gas flow of 3 L/min. The expired tidal volume and end-tidal CO2 were documented after 5 min by averaging three consecutive readings. In the guided ProSeal group, oropharyngeal leak pressure was measured and documented. Any blood staining on the laryngoscope, gum elastic bougie, tracheal tube, or ProSeal LMA was documented at the end of the procedure.

Data were collected by unblinded observers. The distribution of data was determined using Kolmogorov-Smirnov analysis (8). To generate confidence intervals, consecutive sums were calculated

and divided by the number of performed procedures. Statistical analysis was with paired Student's t-test, {chi}2 test and Fisher's exact test. Significance was taken as $P < 0.05$.

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There were no important differences in the baseline characteristics of patients in the two groups (Table 1). Insertion was more often successful (100% versus 65%) and effective airway time was shorter in the guided ProSeal group for the first 10 uses, the second 10 uses, and overall (all $P < 0.0001$) (Tables 2 and 3). All failures in the tracheal intubation group ($n = 61$) and guided ProSeal group ($n = 6$) were the result of inadequate views of the vocal cords and hypopharynx, respectively. Expired tidal volume was larger and end-tidal CO2 lower in the guided ProSeal group (both $P < 0.0001$). Blood staining was more frequent on the laryngoscope ($P < 0.0001$) and airway device ($P = 0.02$) in the tracheal intubation group and was detected on the gum elastic bougie in 2 patients in the guided ProSeal group. In the guided ProSeal group, oropharyngeal leak pressure was 32 ± 6 cm H2O, gastric tube insertion was always successful at the first attempt, and the residual gastric volume was 4.4 ± 9 (0-155) mL. There was evidence for skill acquisition: when comparing the performance during the first and second 10 uses, effective airway time was shorter in both groups ($P < 0.001$) and fewer insertion attempts were required in the tracheal intubation group ($P < 0.0001$). There were no episodes of hypoxia or other adverse events.

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Table 1. Demographic Characteristics

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Table 2. Number of Insertion Attempts and Ventilation and Blood Staining Data

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Table 3. Skill Acquisition Data

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Airway management was more successful with the guided ProSeal technique. This is because transoral passage of instrumentation into the hypopharynx is easier than into the glottic inlet. There are four reasons why: first, the hypopharynx is a posterior structure and is easier to locate; second, it is wider providing a bigger target; third, it is funnel- rather than tubular-shaped so that imprecisely positioned instrumentation will be redirected to the target; and, fourth, it is better aligned with the oropharyngeal axis, making instrumentation less likely to get snagged. Insertion was similarly successful to the guided ProSeal technique as performed by experienced anesthesiologists (7,9,10) but more successful than the digital technique as performed by postanesthesia care unit nurses (90%) (6). It was also more successful than classic LMA insertion as performed by paramedics (94%) (3) and medical trainees (95%) (2). Our success rates for tracheal intubation were similar to previous studies by non-anesthesiologists (2,3).

Airway trauma was less frequent with the guided ProSeal technique. This is not surprising, as more force is required to see

the glottic inlet than the hypopharynx. Perhaps the pharyngeal/esophageal mucosa is stronger than the laryngeal/tracheal mucosa, as it has evolved to accommodate solid bodies and not just the passage of gas. There is considerable evidence that tracheal intubation is more traumatic than conventional LMA insertion (11). A potential danger of the guided ProSeal technique is injury to the esophagus. Avoiding force during passage of the gum elastic bougie into the esophagus should reduce the risk of esophageal trauma. The gum elastic bougie 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. Nonetheless, we have used the guided ProSeal technique as the primary technique on more than 6000 occasions without any evidence of minor or major esophageal injury, including an absence of occult blood on the gum elastic bougie in 580/580 tested. The distal portion of the esophageal tracheal Combitube, which is a large blunt object, is blindly placed in the esophagus and the frequency of airway trauma for out-of-hospital cardiac arrest is approximately 1:200 (12). The frequency of airway trauma for passage of a small blunt object placed under direct vision should be considerably less.

Gastric tube insertion was always successful with the guided ProSeal technique. This is because the drain tube and esophagus are pre-aligned by the gum elastic bougie. The ProSeal LMA provided better ventilation than the tracheal tube for a given peak airway pressure. This supports the findings of Voyagis et al. (13,14) who found that tidal volumes were larger for the classic LMA than the tracheal tube for a given peak inspiratory pressure. In principle, this could be related to reduced resistance to gas flow along the device, or within the lungs, or both; however, it is likely to be related to reduced pulmonary airway resistance, as the internal diameter of the PLMA airway tube is similar to the tracheal tube and the glottis, which normally contributes up to 25% of total airway resistance (15), is not bypassed. There is evidence that pulmonary airway resistance is lower for the classic LMA than the tracheal tube (16,17).

We found good evidence for skill acquisition for the tracheal intubation technique (improvement in success rates and shorter effective airway time) but only moderate evidence for the guided ProSeal technique (shorter effective airway time only). At first glance this suggests skill acquisition is easier with the tracheal intubation technique; however, the lack of improvement in

success rates with the guided ProSeal technique reflects the very high early success rate.

Our study has four limitations. First, we did not include groups in which the ProSeal LMA was inserted digitally or with the introducer tool or in which the tracheal tube was inserted using a gum elastic bougie; however, the gum elastic bougie-guided technique is superior to the digital and introducer tool techniques (9). It is not known whether a gum elastic bougie increases the success rate for tracheal intubation in patients with normal airways. Second, data were collected unblinded, a possible source of bias. Third, we were unable to perform a pre-study power analysis for the primary variables because of a lack of data and, strictly speaking, we conducted a pilot study; however, the P values for all the primary variables were very low, suggesting that, if anything, our study was over-powered rather than under-powered. Fourth, we did not measure cardiovascular responses or airway morbidity; however, it is likely that the hemodynamic response and airway morbidity will be greater for the tracheal intubation technique based on the increased frequency of airway trauma.

There is evidence from clinical studies that the correctly positioned PLMA isolates the gastrointestinal tract from the respiratory tract, and evidence from a cadaver study that the efficacy of seal with the esophagus is 50–80 cm H2O (18). In addition, there have been 10 reports of airway protection from gastric contents with the PLMA: 3 using prototype PLMAs (19–21) (3 cases) and 7 using the commercial PLMAs (22–28) (11 cases). Most of these involve protection from passive regurgitation (with probably low esophageal pressures), but protection from active vomiting (with probably high esophageal pressures) has also been reported (28). However, aspiration can occur if the PLMA is malpositioned (29). An advantage of the guided technique over the digital or introducer tool techniques is that malposition of the distal cuff is rare. A further advantage is that the tests of malposition, such as the suprasternal notch tap test (30) and bubble test (31), are unnecessary. The guided ProSeal technique is contraindicated if there is suspected or known trauma to the esophagus.

We conclude that laryngoscope-guided, gum elastic bougie-guided insertion of the PLMA is superior to conventional laryngoscope-guided tracheal intubation for airway management in terms of insertion success, expired tidal volume, and airway

trauma by first-month anesthesia residents after brief manikin-only training. The guided ProSeal technique has potential for cardiopulmonary resuscitation by novices when conventional intubation fails. Field studies are warranted.

Footnotes

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