Clinical Investigation

Validation of the unassisted, gum-elastic bougie-guided, laryngeal mask airway-ProSeal™ placement technique in anaesthetized patients

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ABSTRACT

Aims: The laryngeal mask airway-ProSeal™ can be inserted digitally, by introducer tool, or by railroading it over a bougie placed first in the patient's oesophagus, which is highly successful, but as originally described, requires an assistant. An unassisted bougie-guided placement technique has also been described, but no data on its effectiveness have been reported. **Methods:** We reviewed data collected during a randomized, controlled trial comparing the air-Q® Intubating Laryngeal Airway and LMA-Proseal™, in which all LMA-Proseal™ devices were inserted using the unassisted (one-operator), bougie-guided placement technique. **Results:** Forty-eight devices were placed. All devices were placed successfully. Successful placement was achieved in 47 (98%) patients on first attempt and in one (2%) patient on the third attempt. Mean (SD) time required for insertion establishing ventilation was 28 (11) s. Mean (SD) airway seal pressure was 30 (6) cmH_2O. Gross blood was found on four (8%) devices upon removal, but no oropharyngeal injuries were noted on oral exam in the recovery unit prior to discharge. The most common complaints in recovery and 24 h post-operatively were sore throat [discharge: mild = 18/48 (38%); 24 h: mild = 9/38 (19%), moderate = 1/38 (3%)] and pain on swallowing [discharge: mild = 7/48 (15%); 24 h: mild = 2/38 (6%)]. **Conclusions:** Our data confirm that in experienced hands, bougie-guided placement of the LMA-Proseal™ without the aid of an assistant can be accomplished quickly and successfully without affecting the expected clinical performance of the device.

Key words: Bougie, insertion, LMA, Proseal

INTRODUCTION

The LMA-ProSeal™ (pLMA, LMA North America, San Diego, CA, USA) was the first supraglottic airway device (SAD) to incorporate an oesophageal vent port. The manufacturer recommends digital insertion or use of their insertion tool.[1] However, first-attempt insertion success can be as low as 70% for both techniques.[2] Insertion failure with these techniques most often results from pLMA impaction in the pharynx inhibiting device passage into the hypopharynx.[3-6] Alternatively, the tip may fold over or pass directly into the glottic inlet. In attempts to avoid these complications, the vent port has been exploited by placing a gum–elastic bougie (GEB) intentionally into the oesophagus and then railroading the pLMA over it.[7] In the initial report of this technique, the pLMA was placed successfully in 100 consecutive patients without failure.[8] More contemporary reports described similar first-attempt insertion success rates of 97–100%.[2,9-11] Further, better alignment of the drain tube to the oesophagus and airway tube to the vocal cords has been reported with this technique.[12] However, despite the reported advantages, a practical limitation of the technique is its two-operator requirement. In response, a single-operator technique, where the pLMA is preloaded on the GEB, held as a unit, and placed without the aid of an assistant, has been suggested,[13] but its clinical success has not been reported. Thus, our aim was to report on a series of

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patients in whom the pLMA was placed using the unassisted (single-operator), GEB-guided technique with specific attention to insertion success, insertion time, mask bowl-to-glottic opening relation and oropharyngolaryngeal complaints.

METHODS

We reviewed data collected during a prospective, randomized trial comparing the air-Q® Intubating Laryngeal Airway (Mercury Medical, Clearwater, FL, USA) and the pLMA[14] in which all pLMAs were inserted using the unassisted, GEB-guided placement technique. The trial (ClinicalTrials.gov Identifier: NCT01328405) was approved by the University of Wisconsin Health Sciences Minimal Risk Institutional Review Board and all subjects were enrolled after providing written informed consent. Patients were eligible if they were ≥18 years old and scheduled for elective, outpatient surgery in which general anaesthesia with SAD placement was planned. Exclusion criteria included symptomatic gastrooesophageal reflux disease, prior esophagectomy, hiatal hernia, emesis within 24 h of surgery and known oropharyngeal pathology, making a proper SAD fit unlikely. Anaesthesia was induced intravenously with fentanyl (0–2 mcg/kg) and propofol (2–3 mg/kg), and maintained with 2–3% sevoflurane in 50% oxygen. Neuromuscular blocking drugs were not used as part of the anaesthetic induction. All pLMAs were placed using the unassisted, GEB-guided placement technique.[13] Specifically, the cuff of each pLMA was first fully deflated and flattened. A lubricated, Portex 15 Fr, 60 cm coude-tipped bougie (Smiths Medical, Dublin, OH, USA) was placed straight-end first into the proximal end of the vent port until approximately 20 cm extended past the distal edge of the device [Figure 1]. A size 3 Macintosh laryngoscope was placed into the patient's mouth to displace the tongue and hypopharyngeal tissues anteriorly without attempting to directly view the epiglottis or vocal cords. With the pLMA and bougie held as a unit in the right hand, the bougie extending from the vent port was inserted into the oesophagus under visualization. The laryngoscope was then removed and the pLMA was railroaded over the bougie into position until a firm stop was noted. The bougie was then removed and the cuff was inflated to a pressure of 60 cmH_2O using a hand-held manometer. Ventilation was assessed by chest rise and the presence of an appropriate end-tidal carbon dioxide gas tracing on the multi-gas analyser monitor. Subsequently, airway seal pressure

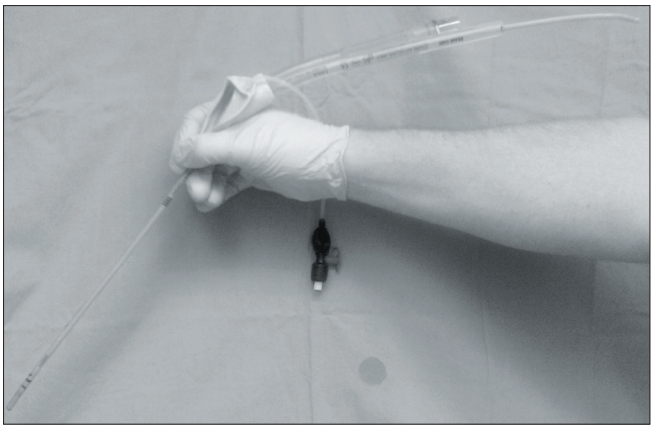

Figure 1: LMA-Proseal™ pre-loaded on gum–elastic bougie and gripped in the right hand for placement. The bougie tip extends approximately 20 cm out of the distal end of the gastric drainage channel

(ASP) was measured with the expiratory valve of the breathing circuit closed and the fresh gas flow set to 5 L/min. It was recorded as the pressure associated with an audible air leak from the oropharynx up to a maximum of 40 cmH_2O, at which the needle of the anaesthesia circuit manometer reached equilibrium. The mask bowl-to-glottic opening relationship was then assessed using a fibreoptic bronchoscope (FOB, Pentax FB-15V; Pentax Medical, Montvale, NJ, USA) placed to the airway tube termination and graded as follows: 1=full view of the vocal cords, 2=partial view of the cords including arytenoids, 3=epiglottis only or 4=other (SAD cuff, pharynx, other).[15]

All devices were inserted by one of the primary investigators, both equally experienced with the insertion technique. Insertion success was defined as device placement with observation of adequate ventilation within three attempts. An insertion attempt was marked if the device had to be removed from the patient's mouth and reinserted. Insertion time was measured from when the investigator began to insert the laryngoscope blade into the patient's mouth to confirmation of ventilation by end-tidal carbon dioxide tracing on the monitor. Before insertion, the devices were lubricated with water-soluble surgical gel. Use of viscous lidocaine and other topical anaesthetics was not allowed.

All devices were removed at the end of the case when the patient followed commands. Upon removal, the presence of visible blood or bile on the device was recorded and classified as none, mild, moderate or severe. An oropharyngeal exam was performed in the recovery unit to assess for injury. Patients were

administered a standardized questionnaire regarding oropharyngolaryngeal complaints before recovery unit discharge and 24 h post-operatively. Complaints were graded by the patients as none, mild, moderate or severe. All study data were recorded by one of the authors or a trained data collector.

RESULTS

Forty-eight pLMAs (1 size #3, 24 size #4 and 23 size #5) were placed in 25 male and 23 female American Society of Anesthesiology (ASA) physical status class I (n=22), II (n=23) and III (n=3) patients. Mean (SD) age, height, weight and body mass index were 39 (14) years, 175 (10) cm, 87 (23) kg and 28 (7) kg/m^2, respectively. Forty-seven (98%) pLMAs were successfully placed on first attempt. One (2%) pLMA required three attempts for successful placement. The mean (SD) insertion time and ASP were 28 (11) s and 30 (6) cmH_2O, respectively. The mean (SD) duration of use was 87 (52) min. Mild blood staining was evident on four (8%) devices upon removal, but no oropharyngeal injuries were noted on recovery unit exam. Bile staining was absent in all cases. In the recovery unit, 18 (38%) and seven (15%) patients complained of a mild sore throat and mild pain on swallowing, respectively. Ten patients (20%) could not be contacted for 24-h follow-up. Of the 38 reachable patients, nine (19%) complained of mild and one (3%) complained of moderate sore throat. Only two (6%) patients continued to have mild pain on swallowing 24 h post-operatively.

DISCUSSION

Our results demonstrate that the unassisted, GEB-guided, pLMA placement technique is highly successful on first attempt. Our first attempt and overall insertion success rates compare favourably with rates from several prior studies comparing assisted (two-operator), GEB-guided, pLMA placement with digital and tool insertion or digital insertion alone (98% vs. 97–100% and 100% vs. 100%, respectively).[2,9-11] Additionally, we observed the time required for placement that is consistent with mean times reported previously (28 s vs. 22–31 s).[2,9-11]

To the best of our knowledge, this is the first series of patients upon which the clinical performance of the unassisted, GEB-guided technique for pLMA placement has been highlighted. We believe this adaptation of the GEB-guided, pLMA placement technique is of clinical importance insofar as knowledgeable assistants inside the operating room may not be available in all locations or circumstances. Furthermore, when airway management occurs outside the operating room, the likelihood of expert assistance is even lower. Thus, it is reassuring to know that GEB-guided pLMA placement, which has previously been reported to be nearly universally successful on initial attempt with two-operators, does not need to be discarded from the airway manager's armamentarium in the absence of assistance.

We must advise some caution however. The patients reported in here were enrolled in a comparative trial of two SADs, where all devices were placed by two investigators, both of whom were experienced in the unassisted, GEB-guided placement technique and had been trained by the two physicians who first described it. Thus, a learning curve may be present, which is not reflected in our results, and the success rates we report may be higher than what others initially realize in their daily clinical practice. Particularly, it is possible that the novice operator may be deceived by advancement of the distal mask tip over the bougie when the bougie has not entered the oesophagus, but rather had become impacted while in the hypopharynx. In this case, the bougie may not be midline and the pLMA will be led around the back of the tongue, but not guided into the proper position as would occur if the bougie had been placed into the oesophagus. We also acknowledge that our study is limited by its lack of concurrent comparisons with the assisted, GEB-guided, digital insertion and introducer tool placement techniques. Nevertheless, the technique is easily learned and highly comparable in experienced hands.

CONCLUSION

In conclusion, our data confirm that in experienced hands, GEB-guided placement of the pLMA without the aid of an assistant can be accomplished quickly and successfully without impacting the expected clinical performance of the device.

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