Original Article

Usefulness of bougie-preloaded proseal laryngeal mask airway versus digital insertion technique in correct placement of the device

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Abstract

Background and Aims: Digital technique of proseal laryngeal mask airway (PLMA) insertion carries high chance of failed first attempt successful placement. We aimed to compare the number of attempts taken for correct placement of bougie-preloaded PLMA versus traditional digital insertion technique. Ease of insertion, time taken, hemodynamic responses during insertion, and evidence of trauma were also assessed.

Material and Methods: This prospective, randomized, open-label study was performed in 60 patients. All patients were administered general anesthesia according to a standardized protocol.After induction of general anesthesia in group P, proseal insertion was performed following the traditional digital technique. In group B, bougie-preloaded PLMA was used. A soft gum elastic bougie was passed through the gastric channel of PLMA, with 15cm protruding distally through the gastric port. Attempts at successful insertion and ease of insertion were noted.

Results: Time taken for successful insertion was significantly shorter in group B compared to group P (15.3 ± 4.5 vs. 57 ± 12.02 s, respectively). The first attempt success in group B was 90% versus 60% in group P. The number of moderate to hard insertion was significantly lesser in group B (10 vs. 40, respectively). Blood stain on device was seen in 3.3% in group B compared to 30% in group P. MAP at insertion and at 1, 3, and 5 min was significantly higher in group P. Heart rates were comparable.

Conclusion: Bougie-preloaded proseal insertion has significantly higher first attempt insertion success rates and is significantly faster and less traumatic with blunted blood pressure response compared to traditional digital insertion technique.

Keywords: General Anesthesia, gum elastic bougie, laryngeal mask airway, proseal

Introduction

Proseal laryngeal mask airway (PLMA) is a second-generation laryngeal mask airway (LMA) with high laryngeal cuff sealing pressure and has a gastric port which helps to decrease gastric insufflation and the risk of aspiration.[1] Placement of PLMA is conventionally done by the digital technique, but has a higher risk of failed first attempt successful placement as compared to classic LMA.[2] We hypothesized that gum elastic bougie (GEB) - preloaded PLMA placement technique might ensure faster securing of airway at the first attempt, with lesser airway trauma and lesser requirement of laryngoscopy or external airway manipulation for optimal placement. It could also be a hemodynamically stable technique with blunted stress response as laryngoscopy was avoided.

The primary objective of our study was to compare the number of attempts taken for correct placement of bougie-preloaded PLMA versus traditional digital insertion technique.

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The secondary objectives comprised assessment of ease of insertion, time taken for it, hemodynamic responses during the procedure, and evidence of trauma as evidenced by blood-stained secretions or blood on device while removing at the end of the surgery following both techniques of insertion.

Material and Methods

This prospective, randomized, open-label study was performed after obtaining the institutional ethical committee clearance (IEC-AIMS-2020-ANES-031, dated 09-03-2020) and informed patient consent. It was registered in the clinical trial registry India (CTRI/2020/04/024576). In our study, we included patients of American Society of Anesthesiologists Physical Status (ASA PS) 1–3 in the 18–60 years age group, undergoing short surgical procedures like breast and upper limb surgeries. We excluded patients with obesity, hiatus hernia, pregnancy, full stomach, longstanding diabetes, restricted mouth opening, and those posted for emergency surgeries.

We conducted a pilot study in 20 patients where airways of equal number of patients were secured either with bougie-preloaded PLMA or following conventional digital technique. The first attempt success rate of correct device placement was 100% in the bougie-preloaded group compared to 70% in the digital technique group. Using the formula

$$n = (Z_{\alpha/2} + Z_{\beta})^2 * (p_1 (1 - p_1) + p_2 (1 - p_2))/(p_1 - p_2)^2,$$

where $Z^{\alpha}_{/2}$ is the critical value of the normal distribution at $\alpha/2$ and Z^{β} is the critical value of the normal distribution at β with 95% confidence interval and 90% power, the sample size was calculated to be 25 in each group. However, we were able to include 60 patients in our study.

The patients were randomly divided into two equal groups of 30 each based on computer-generated random sequence of numbers. Sequentially numbered opaque, sealed envelopes were used to conceal the allocation. All patients were kept nil per oral 6 h for solids and 2 h for clear fluids and were premedicated with oral alprazolam 0.25mg on the night before the surgery, metoclopramide 10 mg and pantoprazole 40 mg on the night before the surgery and 2 h before start of surgery. All patients were administered general anesthesia according to a standardized protocol. On patient's arrival in the operation theater, standard preinduction monitors like electrocardiogram, pulse oximeter, and noninvasive blood pressure monitor were attached. Patients were preoxygenated for 3 min. Anesthesia was induced with midazolam 0.05 mg/kg, fentanyl 2 μg/kg, and propofol 2–2.5mg/kg. Once the lower jaw was relaxed and the patients were apneic, PLMA insertion was attempted with head in extension in both the groups.

In group P, proseal insertion was performed following the traditional digital technique. In group B, bougie-preloaded PLMA was used. A soft GEB was passed through the gastric channel of the PLMA after placing a dollop of lubricating gel. The bougie was placed in such a way that 15 cm of it was protruding distally through the gastric port[Figure 1a]. The PLMA was then inserted into the oral cavity, making the protruding tip of bougie pass blindly into the esophagus [Figure 1b]. During this time, an assistant had held the proximal end of the bougie firmly to prevent it from getting retracted back into the gastric channel of PLMA. After the protruding part of the bougie had passed distally without resistance, the PLMA was pushed down over the bougie till it was properly seated. Once the PLMA was placed, the bougie was taken out from the gastric channel, breathing circuit was connected, and bag ventilation was initiated.

The time taken for successful device placement was documented as the time taken from introduction of proseal into the oral cavity and appearance of square wave end-tidal carbon dioxide ($EtCO_2$) waveforms. The ease of insertion of PLMA was graded as easy, moderate, hard, and impossible and documented in both groups by the anesthesiologist who placed the PLMA. In the absence of confirmatory signs of PLMA placement, PLMA was taken out and reintroduced. The number of attempts taken was documented and a maximum of three attempts were allowed.Those patients were intubated and excluded from the study.

Following successful placement of PLMA, a flexible fiberoptic bronchoscope (FOB) was passed through the PLMA and the

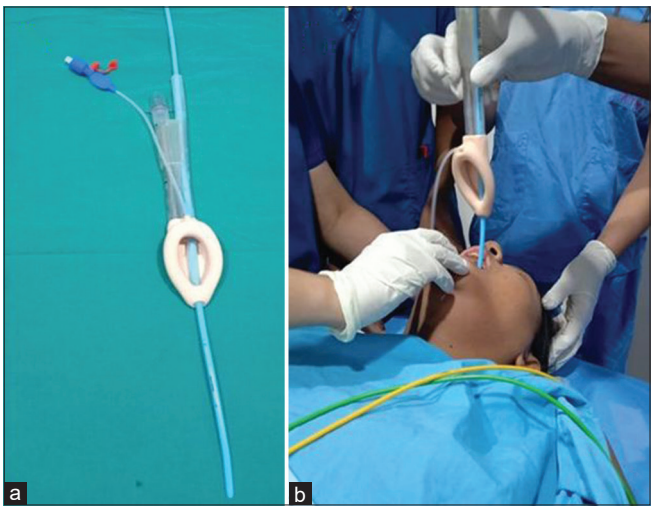

Figure 1: (a) Gum elastic bougie-preloaded PLMA, (b) insertion of GEB-preloaded PLMA. PLMA = proseal laryngeal mask airway

fiberoptic view of the structures distal to PLMA was assessed and scored as described in Table 1.[3] The hemodynamic variables like heart rate, mean arterial pressure, and oxygen saturation were documented at baseline, after induction, and immediately after PLMA insertion, 1, 3, and 5 min after PLMA placement. Any incidence of desaturation to <95% was documented. To determine whether PLMA insertion was traumatic, presence of blood stain on device at extubation was noted in both groups. All cases were done by a single anesthetist who was well experienced and skilled in PLMA insertion.

The categorical variables were compared using Pearson Chi-square test or Fisher's exact test, and the continuous variables using independent sample *t*-test. Statistical analyses were conducted using Statistical Package for the Social Sciences (SPSS) Version 20.0 for Windows (IBM Corporation, Armonk, NY, USA).

Results

Data of 60 patients were analyzed [Figure 2]. The demographic variables and distribution of ASA PS were comparable in both groups. The time taken to secure the airway was significantly shorter in group B compared to group P (15.3 ± 4.5 vs. 57 ± 12.02 s, $P < 0.001$). The number of attempts needed for correct device placement was significantly lesser in group B. The first attempt success in group B was 90%versus 60%in group P. The number of moderate to hard insertion of PLMA was also significantly lesser in group B (10% in group B versus 40% in group P). Fibreoptic view grades 1 and 2 were attained in all patients in group B compared to 33.3% in group P. FOB of grades 3 and 4 was not observed in group B, whereas it was seen in 66.7% of patients in group P. Blood stain on the device was seen in only one patient (3.3%) in group B compared to 30% of the patients in group P [Table 2]. MAP (mean arterial pressure) at intubation and 1, 3, and 5 min after PLMA insertion was significantly higher in group P. Heart rate was comparable in both the groups [Table 3]. There was no incidence of desaturation to <95% in any patient in both the groups.

Table 1: Fiberoptic assessment of anatomical position of proseal against the glottis

Grades	AP rima distance
Grade 1	75%-100%
Grade 2	50%-75%
Grade 3	25%-50%
Grade 4	0-25%
Grade 5	No vocal cords, only epiglottis visible
Grade 6	No epiglottis or epiglottis visible

AP rima=anterior–posterior rima glottidis

Table 2: Comparison of time taken, ease and number of attempts at insertion, FOB grades, and incidence of blood staining

Variables	Group B (*n*=30) *n* (%) Mean±SD	Group P (*n*=30) *n* (%) Mean±SD	*P*
Insertion			0.015
Easy	27 (90.0)	18 (60.0)	
Moderate to hard	3 (10.0)	12 (40.0)	
No. of attempts			0.104
One	27 (90.0)	21 (70.0)	
Two or more	3 (10.0)	9 (30.0)	
Saturation <95%			0.237
No	30 (100.0)	27 (90.0)	
Yes	-	3 (10.0)	
FOB grade			<0.001
1-2	30 (100.0)	10 (33.3)	
3-4	-	20 (66.7)	
Blood stain			0.012
No	29 (96.7)	21 (70.0)	
Yes	1 (3.3)	9 (30.0)	
Time taken for insertion in seconds	9.3±1.5	57.0±45.02	<0.001

FOB=fiberoptic bronchoscope

Table 3: Comparison of heart rate and mean arterial pressures

Time	Heart rate Mean±SD		*P*
	Group B	Group P	
Baseline	91.0±14.6	93.2±14.9	0.572
At induction	90.4±15.7	85.8±12.6	0.209
At insertion	90.4±16.9	88.3±11.1	0.565
1 min	91.1±17.3	86.5±12.0	0.244
3 min	91.1±16.1	89.6±12.9	0.679
5 min	90.1±13.7	87.7±12.7	0.491
Mean arterial pressure			
Baseline	75.2±11.8	80.6±11.8	0.081
At induction	76.2±9.9	77.8±9.9	0.542
At insertion	77.1±10.6	80.6±9.6	0.190
1 min	82.0±11.2	92.6±14.2	0.002
3 min	76.4±9.6	84.2±14.0	0.015
5 min	73.7±10.6	83.3±11.9	0.002

SD=standard deviation

Discussion

PLMA is considered superior to classic LMA as it is a second-generation device that was designed to provide higher sealing pressures which will help to provide positive pressure ventilation without much leak. It also decreases the risk of aspiration with the help of a separate gastric drainage port to avoid gastric insufflation.[1] However, the success rate of correct placement of PLMA in the first attempt using the digital insertion technique is considered less compared to Classic Laryngeal Mask Airway (CLMA).[2] This could be due to the larger cuff seal, impaction at the back of the

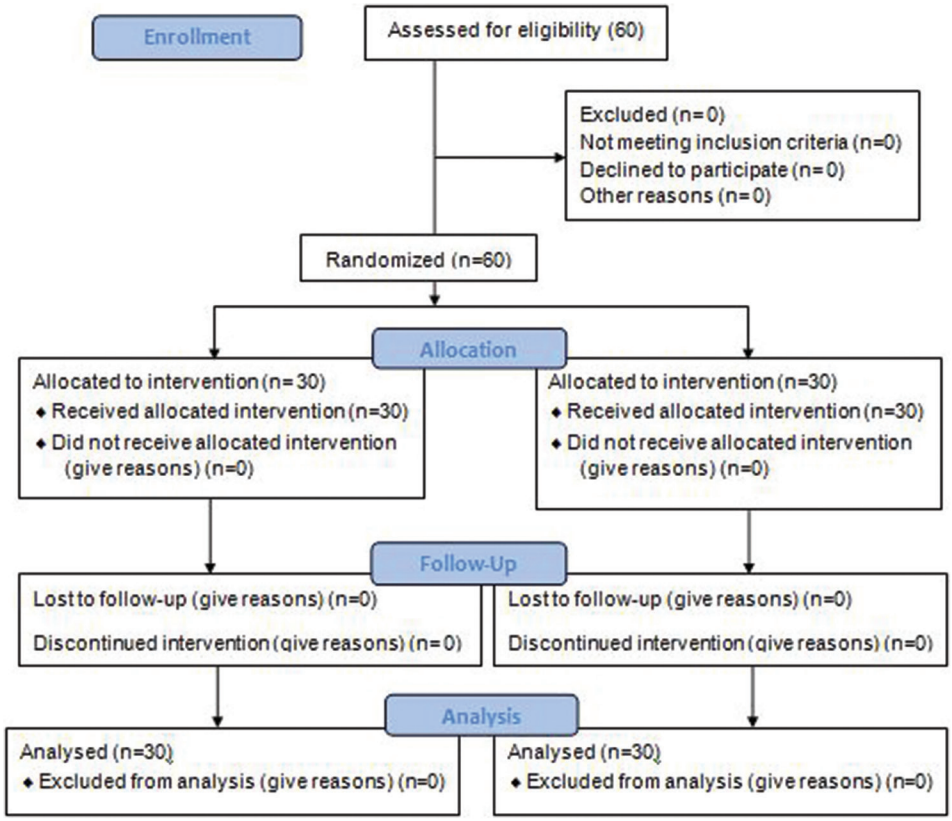

Figure 2: CONSORT flow diagram

mouth, cuff folding over, and failure of the distal cuff to reach its correct position in the hypopharynx, leading to inadequate ventilation.[2] In order to avoid these problems of digital insertion technique, several newer techniques of PLMA insertion have been devised, such as 90° intraoral rotational technique,[4] laryngoscopy and FOB-assisted placement,[5] placement with the assistance of suction catheter,[6] gastric tube,[7]and GEB with laryngoscopy assistance.[8] It is documented that among these techniques, the success rate of PLMA placement with GEB is higher.[9]

GEB can be used for PLMA insertion in two ways. One method is the laryngoscopy-assisted GEB insertion followed by railroading of PLMA technique, which requires two handlers.[8] The other method is the unassisted technique where PLMA is preloaded with GEB, the straight end of the GEB is then inserted into the esophagus, and the PLMA is inserted along with GEB as a single unit. This technique does not require laryngoscopy and can be performed by a single handler.

The ideal technique for PLMA insertion should be the one that ensures faster and higher success rate of optimal placement in the first attempt, with less airway manipulation and trauma. It should also result in minimal hemodynamic stress response during insertion with minimal postoperative complications like sore throat, dysphagia, and dysarthria. Considering all these requirements, it is suggested that the technique followed in our study, such as bougie-preloaded PLMA insertion without laryngoscopic assistance, is a superior technique.

The basis of this technique is that an elongated object when inserted blindly into the oral cavity usually goes into the esophagus. If the tip of the GEB inserted through the gastric port passes to the esophagus, the alignment of gastric port toward the esophagus will be accurate when PLMA is railroaded over the GEB. This avoids distal cuff impaction along the posterior pharyngeal curve and ensures correct placement of the distal cuff anterior to the esophagus. This optimal position can be confirmed with better fiberoptic view of structures at glottis inlet, adequate ventilation (6–8ml/kg) with higher sealing pressures, chest expansion on positive pressure ventilation, and appearance of regular square wave capnography. Though there is a possibility of GEB going to trachea, we have not come across such a situation during the conduct of our study.

There are several studies suggesting that laryngoscopy-assisted, bougie-guided PLMA insertion technique provides nearly 100% success rate on first attempt insertion compared to

digital insertion technique.[10-13] Our study was also consistent with these studies, as we were also able to achieve 90% first attempt insertion success rate compared to 60% with the digital technique. However, the major difference from most of the previous studies was that we avoided laryngoscopy.

The time taken for insertion of PLMA by laryngoscopy-assisted, GEB-guided PLMA insertion was more compared to digital insertion.[14,15] However, we found that it took significantly lesser time for insertion with bougie-preloaded technique (15.3 ± 4.5 vs. 57 ± 12s), suggesting it to be a faster technique. Since the time taken to securing the airway was faster, there were no episodes of hypoxia during PLMA insertion by this technique. Difficulty in proper placement and requirement of higher number of attempts might have resulted in prolonged insertion time in group P. Regarding the optimal placement of PLMA as confirmed by FOB scores of grade 1–2, our study is in accordance with previous studies where GEB-guided PLMA was found to provide better optimal fiberoptic grades.[16,17]

While comparing the hemodynamic variables during device insertion, it was found that MAP was significantly lesser in GEB-preloaded PLMA insertion technique compared to digital technique. All the previous studies showed that the hemodynamic variables were comparable between both groups.[10,13] It is expected that in GEB-preloaded PLMA insertion, the stress response will be lesser as laryngoscopy and airway manipulations are avoided. However, the heart rate was comparable in both groups.

It was previously documented that the incidence of trauma manifested by blood staining on the PLMA by both techniques was comparable.[8,11] However, in our study, there was significantly lesser trauma compared to the digital technique (3.3% vs. 33.3%, respectively). This is contrary to other studies which suggested that blindly inserting bougie might lead to esophageal mucosal trauma and, in some cases, could cause perforation of the pharyngeal walls. These complications could be avoided to a great extent by the use of a soft GEB, by properly lubricating the bougie, and by slow, gentle advancement of the straight end of bougie, taking care to stop when resistance is encountered.

The major imitation of the study was that it was not double-blinded one as masking the techniques of insertion of the device was not possible. Though the outcome measurements were recorded by an anesthesia technician unaware of the study protocol, likelihood of a certain degree of bias cannot be ruled out.We did not assess the postoperative complications like occurrence of sore throat, dysarthria, or dysphagia.The sealing leak pressures were also not measured. Adequate depth of anesthesia for PLMA insertion was assessed only clinically. Bispectral index monitoring, which would have yielded more reliable information on anesthetic depth, was not used due to its limited availability.

As the same anesthetist performed all PLMA insertions, bias based on varying skills of different handlers was removed. However, this could have partly contributed to the longer insertion time observed in our study compared to other trials. Though bougie-preloaded PLMA insertion is an already described technique, the purpose of our study was to reinforce its usefulness in quick and less-traumatic airway securing in the first attempt while using PLMA.

Conclusion

Bougie-preloaded proseal insertion has significantly higher first attempt insertion success rates and is significantly faster and less traumatic with blunted blood pressure response compared to traditional digital insertion technique.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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