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Research Article

Comparison of ProSeal laryngeal mask airway placement techniques using digital, introducer tool and gum elastic bougie in anaesthetized paralyzed patients

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ABSTRACT

Background: Conventionally laryngeal mask airway (LMA) is placed in the oral cavity using fingers without the need for laryngoscope. ProSeal laryngeal mask airway (PLMA) placement is relatively difficult owing to its bulky design and sometimes require alternative techniques. We compared three techniques (digital, introducer-tool, gum-elastic bougie) for its placement.
Methods: One hundred fifty patients of ASA class I & II of either sex, undergoing surgery under general anaesthesia were randomly allocated to one of the three groups. Standard anaesthesia protocol comprising of glycopyrrolate, thiopentone, vecuronium and halothane in oxygen plus nitrous oxide was used. Insertion attempts, success rate and time taken were noted after confirmation of proper placement. Efficacy of airway seal, oropharyngeal leak pressure (OLP) , ease of gastric tube insertion, trauma to oropharyngeal structures, postoperative airway morbidity were noted. Haemodynamic monitoring was done throughout the procedure.
Results: First attempt success rate as well as overall success rate was high in gum elastic bougie group. Although in this group insertion time was slightly longer. Airway seal was also better in this group as shown by high OLP. Airway trauma was comparable in all the three groups.
Conclusions: Gum elastic bougie guided PLMA insertion is a good alternative if traditional methods of its placement fail.

Keywords: General anaesthesia, Airway management, PLMA, Insertion techniques

INTRODUCTION

Since its introduction into clinical practice in 1988, the LMA has gained wide spread popularity and has become one of the essential component of airway management.[1] However there are certain limitations in its use. The LMA does not provide effective seal against pulmonary aspiration of gastric contents. Its low pressure seal is inadequate for positive pressure ventilation especially when lung compliance is low.[2,3] To overcome these problems, the ProSeal laryngeal mask airway (PLMA) was developed by AIJ Brain in 2000. It incorporates a modified cuff to improve the seal and a drain tube to prevent aspiration and gastric insufflations.[4] Its insertion is relatively difficult owing to its bulky design and nonrigid nature.[5] The commonly recommended techniques for its insertion are the digital technique using index finger and the technique using introducer tool.[6] An alternative method using gum elastic bougie has been described to have a higher success rate.[7] We compared the efficacy of these three techniques for PLMA insertion in our population.

METHODS

The approval from the hospital's ethics committee and written informed consent from the patients was obtained. We studied 150 patients of ASA class I and II, between 18-70 years of age of either sex, scheduled to undergo elective surgery under general anaesthesia. Patients with a known or predicted difficult airway, mouth opening less than 2.5 cm, BMI >35 kg/m^2 and history of regurgitation were excluded from the study. Routine investigations were carried out. Patients were kept fasted for 6 hours and premedicated with tablet alprazolam 0.25 mg and tablet ranitidine 150 mg orally at bed time and 2 hrs preoperatively. On arrival in operating room routine monitors like heart rate (HR), electrocardiogram (ECG), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), and end tidal CO_2 ($EtCO_2$) were attached. Patients were randomly allocated to one of the three groups using coded envelope. PLMA was inserted as groups given below:
Group D (n=50) - digital technique
Group I (n=50) – introducer tool technique
Group G (n=50) – using gum elastic bougie (GEB)

Standard anaesthesia protocol comprising of glycopyrrolate (0.2 mg), midazolam (0.03 mg/kg), thiopentone (4-6 mg/kg), and vecuronium (0.1 mg/kg) was used. Anaesthesia was maintained with halothane (0.5%) in 67% nitrous oxide and oxygen. After ventilating the patient for 120 seconds well lubricated PLMA of appropriate size (size 3 in females and size 4 in males) was introduced using one of the three techniques as per group assigned. The resident in anaesthesiology having performed more than 25 PLMA insertions independently with each technique carried out the PLMA insertion under the supervision of consultant anesthesia with more than 20years of experience in the field. Patients head was positioned in sniffing position. In group D & I PLMA insertion was done as per manufacturer's instruction manual. In group G, a well lubricated 15FG GEB was passed through the drain tube of PLMA and the distal straight end of GEB was placed 5-10 cm into the oesophagus using gentle laryngoscopy while the curved end projected from the PLMA and the assistant held the PLMA. The laryngoscope was removed and PLMA inserted digitally using GEB as a guide. GEB was then removed while retaining the PLMA in position.

After cuff inflation, the PLMA was connected to the anaesthesia breathing system. The correct placement was judged by ability to ventilate the patient without substantial leak at an airway pressure ≤20 cm H_2O, auscultation of breath sounds and observation of $EtCO_2$ trace. The presence or absence of oropharyngeal air leak, gastric air leak were checked. Drain tube air leak were detected by placing the bolus of clear lubricant over the proximal end of the drain tube.

A well lubricated 60 cm 14FG gastric tube was inserted through drain tube and correct placement was assessed by suction of fluid or detection of injected air by epigastric stethoscopy during apnoea. Placement was labeled as easy, difficult or not possible. Oropharyngeal leak pressure (OLP) was measured by switching off the ventilator and by closing the expiratory valve of the anesthesia breathing system at a fixed gas flow of 3 lt/min and noting the airway pressure(maximum allowed 40 cm H_2O) at which equilibrium is reached.

Two attempts were allowed before one technique was considered as a failure and one attempt with the other technique was made. In case of failed digital technique, first the introducer tool technique was tried and if this too failed then the GEB technique was tried. In case of failed introducer tool technique, first the digital technique was tried and if it failed then the GEB technique was tried, while in case of failed GEB technique, first the digital technique and then the introducer tool technique was tried. In case of total failure, alternative method to secure the airway was used.

The ease of insertion, number of attempts and time taken to place PLMA (picking up the PLMA until confirmation of successful placement), incidence of airway trauma (blood-stained bougie or PLMA) was noted. A failed attempt was defined as removal of the device and reinsertion. Haemodynamic monitoring was carried out continuously and recorded at regular intervals.

Intraoperative analgesia was given in the form of injection pethidine 0.5 mg/kg intravenously and maintenance of anaesthesia was done using halothane (0.5%) in oxygen and nitrous oxide. At the conclusion of surgery neuromuscular blockade was reversed. Postoperative morbidity like sore throat, dysphagia and dysphonia if occurred were noted.

We projected a difference of 20% for first attempt success rate between the groups to be significant, a sample size of 50 patients per group will generate power of>85% and type-I error <0.05.

Statistics

The analysis of variance (ANOVA) test was used to compare the groups for parametric data (age, weight, height, OLP, insertion time) while categorical data (gender, ASA-status, airway trauma and morbidity) was compared using Chi square test or Fisher exact test (whichever applicable). The haemodynamic changes over the time were analysed using repeated measures ANOVA test. The statistical analysis was carried out using SPSS software version 16 (Chicago, IL, USA). The p-value <0.05 was taken as significant.

RESULTS

There were no differences in demographic data among three groups (p>0.05) as shown in Table - 1. PLMA placement in group G was successful in 100% patients at

first attempt. The first attempt success rates were higher in group G than group D (p=0.023) and was similar to group I (p=0.213). There was no statistical difference between group D and group I (p=0.241). In group D alternate technique was required in 5 patients; in one IT technique was successful while in 4 GEB technique was required. In group I digital technique was successful as an alternate technique after failure of IT technique.

Table 1: Demographic profile of the patients. Age, weight, height expressed as mean±SD and range; gender and ASA class as number and percentage.

	Group-D (n=50)	Group-I (n=50)	Group-G (n=50)
Age (In yrs)	36.34±13.24 (18-70)	37.26±14.08 (18-66)	39.12±13.05 (18-65)
Weight (In kg)	57.84±10.49 (40-80)	59.62±9.28 (40-76)	57.02±9.14 (38-79)
Height (In cm)	160.4±7.63 (150-178)	161.34±7.96 (150-180)	159.10±6.34 (150-172)
Sex (Male:Female)	21:29 (42%/58%)	24:26 (48%/52%)	18:32 (36%/64%)
ASA-Class (I:II)	45:5 (90%/10%)	46:4 (92%/8%)	46:4 (92%/4%)

The mean time taken in group G was longer(p<0.05) than in group D and group I. Mean oropharyngeal leak pressure was significantly higher in group I and group G as compared to group D (p<0.003 and <0.001 respectively) as shown in table - 2.

Table 2: Insertion attempts, overall success rate, time taken for insertion, and oropharyngeal leak pressure (OLP).

	Group-D(n=50)	Group-I(n=50)	Group-G(n=50)
Attempts taken (1/2/failed)	43/2/5	47/2/1	50/0/0
Success rate	90%	98%	100%
Insertion time (in secs)	20.42± 8.70	20.60± 4.82	24.62± 5.46
OLP(in cmH_2O)	33.0± 3.31	34.84± 2.61	35.54± 2.08
Gastric tube insertion (easy/difficult/ failed)	44/2/0	50/0/0	50/0/0

Haemodynamic responses in three groups were comparable in terms of changes in heart rate, systolic and diastolic blood pressure at various time intervals (Figure - 1, 2 and 3). Oropharyngeal injury was more in group I than in group D and G, however it was not statistically significant. Post-operative airway morbidity was less in group G than other groups (p<0.05) as shown in Table - 3.

Table 3: Airway trauma and post-operative (24 hrs after surgery) airway morbidity.

	Group-D(n=45)	Group-II(n=49)	Group-III(n=50)
Blood stained PLMA	11	7	10
Trauma(lip/teeth /gums)	0/0/0	3/4/3	0/0/0
Sore-throat	11	10	6
Dysphagia	7	3	0
Dysphonia	0	0	0

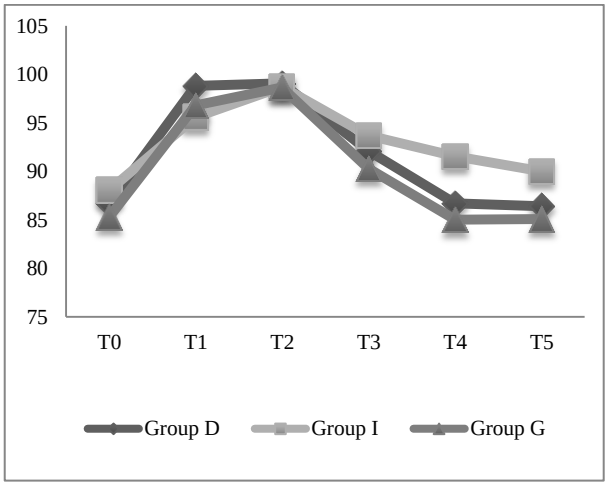

Figure 1: Variation in heart rate in three groups at various time intervals.
(T0=Baseline, T1=After induction, T2=1min after PLMA placement, T3=3mins after PLMA placement, T4=5mins after PLMA placement, T5=10mins after PLMA placement).

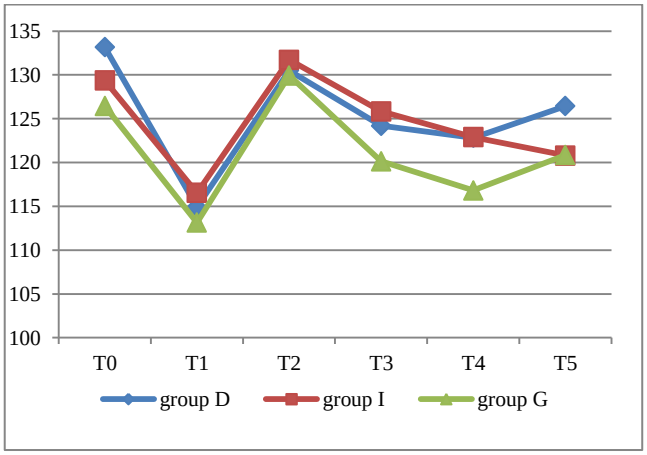

Figure 2: Variations in systolic blood pressure in three groups at various time intervals.
(T0=Baseline, T1=After induction, T2=1min after PLMA placement, T3=3mins after PLMA placement, T4=5mins after PLMA placement, T5=10mins after PLMA placement).

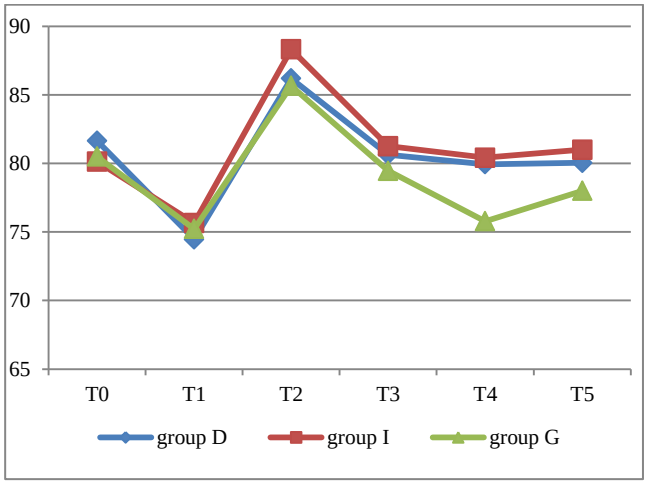

Figure 3: Variations in diastolic blood pressure in three groups at various time intervals.
(T0=Baseline, T1=After induction, T2=1min after PLMA placement, T3=3mins after PLMA placement, T4=5mins after PLMA placement, T5=10mins after PLMA placement).

DISCUSSION

The Proseal LMA was designed to enable better ventilatory characteristics and prevent protection against aspiration.[4] Its placement however poses difficulties and to overcome them various techniques have been described and compared in the literature.[8,9] We compared the three commonly used techniques for PLMA insertion. The first attempt success rate with digital technique was 86% similar to previous studies which have described it to be 82.5-89%.[10-12] In group I where introducer tool was used the success rate was better than group D as reported earlier.[8,10] The pitfalls of digital technique is that the larger cuff is difficult to place in the mouth, leaves less space for the index finger and is more likely to fold over. But the insertion is easier with the introducer tool since it occupies less space than finger, directs the cuff around the oropharynx inlet and facilitates full depth of insertion.

The gum elastic bougie (GEB) is commonly used as a tracheal guide during difficult intubation. Howath was first to suggest its use for PLMA placement.[7,13] GEB assisted PLMA insertion facilitate circumnavigation of oropharyngeal inlet and there are minimal chances of impaction at the back of mouth and folding of cuff. It has been found to be more successful than digital and introducer tool technique. Our results are in concordance to previous studies.[8,9,14,15]

Gum-elastic bougie technique has been compared with conventional techniques in patients with simulated fixed cervical spine and it was noted that it is more successful than digital and introducer tool techniques.[16,17] We required two operators for this technique but Joffe et al showed that in experienced hands, GEB-guided placement of PLMA can be accomplished quickly and successfully without an aid of assistant.[18] Aguodo has described suction catheter guided technique for PLMA insertion.[19] Gastric tube and fibreoptic scope had also been used for PLMA placement.[20,21]

We noted a higher insertion time in group G which was though statistically significant but clinically non-significant (<5 seconds delay). The delay could be due to connecting the breathing circuit after removal of the gum elastic bougie. However Brimacombe in their study found slightly less time in GEB guided technique than digital and introducer tool technique.[8] OLP was better in GEB guided technique. It indicates that insertion of PLMA through this technique provides more effective seal than the digital technique similar to previous studies.[8,9]

Heart rate, systolic and diastolic blood pressure at 1,3 and 5 and 10 minutes after PLMA placement were recorded. Rise in all the three parameters occurred at 1 minute of PLMA placement and returned to basal value at 5 minutes. It was comparable in all the three groups. GEB guided technique might cause some rise as laryngoscopy is known to cause pressor response. However this did not occur because we used laryngoscope to just open the mouth without exerting any force. Moreover, oral and pharyngeal axes are more aligned than oral and laryngeal axes. Use of tongue depressor to aid GEB placement has also been reported in the literature.[17]

The potential disadvantage of GEB could be trauma since it is not meant for esophageal placement. Brimacombe et al suggested that GEB with atraumatic distal portion should be specifically designed for PLMA placement.[8] Contrary to this belief we found trauma to oropharyngeal structures more common in introducer tool technique. It is more likely due to the rigidness of the introducer. Postoperative airway morbidity was slightly more in group D probably due to the requirement of more force to insert the device into the hypopharynx with digital technique.

Our study had few limitations. First, the study was patially double-blinded as the intraoperative data was collected by unblinded observers but the postoperative data was collected by blinded observers. Secondly, we did not perform fibreoptic grading of the PLMA placement. Finally all insertions were carried out by experienced personnel to avoid learners curve. It is difficult to comment on success by novice.

CONCLUSION

We conclude that GEB guided PLMA insertion has higher success rate in comparison to other two techniques. It can be used as back-up technique for PLMA insertion after failure of digital or introducer-tool technique. Moreover it can be used as primary technique where there is failed intubation and PLMA is used as rescue device. Moreover the use of laryngoscope allows unexpected oropharyngeal pathology to be identified.

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