Clinical Investigation

Comparative evaluation of gum-elastic bougie and introducer tool as aids in positioning of ProSeal laryngeal mask airway in patients with simulated restricted neck mobility

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ABSTRACT

Background: The ProSeal laryngeal mask airway (PLMA) is a unique laryngeal mask with a modified cuff to improve seal and a channel to facilitate gastric tube placement. This is a better device in difficult airway situations compared to classic laryngeal mask airway. This prompted us to study the ease of insertion and positioning of PLMA in patients with simulated restricted neck mobility while using gum elastic bougie (GEB) group or introducer tool (group IT) to aid insertion. **Methods:** Sixty ASA I or II patients, aged between 18 years and 60 years, undergoing minor non-head and neck surgeries in the supine position were studied. A rigid neck collar was used to simulate restricted neck mobility in all patients. After anaesthetising the patients with a standard protocol, the PLMA was inserted using either of the technique using the tongue depressor to open the mouth. The ease of insertion, positioning, haemodynamic responses to insertion and other complications related to the procedure were noted. **Results:** Regarding demographic variables, both groups were similar. The mean time taken for insertion of PLMA in group GEB was 67.80 s as compared to 46.79 s in group IT ($P<0.05$). Patients of group GEB had better positioning assessed by an intubating fiberscope with less end tidal carbon-di-oxide ($ETCO_2$) values. Systolic and diastolic blood pressures were similar. The incidence of sore throat, dysphagia, and dysphonia were higher in IT group in the 12 h, but similar in 24 h. **Conclusion:** Guided insertion technique with GEB took a longer time, but had a better positioning and lower $ETCO_2$ values when compared to IT technique.

Key words: Difficult airway, gum elastic bougie, ProSeal laryngeal mask, simulation

INTRODUCTION

The ProSeal laryngeal mask airway (PLMA) introduced in the year 2000 is a unique supraglottic airway device with a large wedge shaped double cuff to improve the seal. The advance in design with a drain tube improved its ability to protect a patient from aspiration of regurgitated gastric contents.[1] It also improves airway seal and facilitates controlled ventilation and useful even in cases of failed intubation.[2,3] The manufacturer recommends insertion of PLMA by two techniques namely digital and introducer tool (IT). The digital technique needed full mouth opening and good extension of the neck. IT technique was feasible with minimal mouth opening and was associated with high success rate than digital technique. Studies have reported that the respective frequency of successful first attempt insertion with digital was 84% and IT was 95%.[2] The main reported causes of failed insertion are: Impaction at the back of mouth, failure to guide the tip into the hypopharynx and the cuff folding over.[4] Howath *et al*.[5] used an aided insertion technique with the gum elastic bougie (GEB) that overcame most of these problems. The advantage of bougie guided

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insertion is that it prevents the cuff folding over which reduces the risk of aspiration and gastric insufflation in patients at risk. The introduction of PLMA using GEB raised the first time insertion success rate and correct positioning to 100% without any evidence of airway complications in normal patients.[4] However, a potential disadvantage of the GEB-guided technique is that an assistant is needed to stabilize the PLMA at the proximal end while the intubator feeds 5-10 cm of GEB in the esophagus. Many of these airway devices were thought to be useful in patients with decreased neck movements. Hence, the present study was designed to compare IT with GEB as aid for insertion of PLMA in patients with simulated restricted neck mobility in terms of ease of insertion, positioning and complications.

METHODS

Sixty ASA I and II patients, aged between 18 years and 60 years undergoing minor non-head and neck surgeries in the supine position were selected for the study. The study was approved by the hospital ethics committee. After analysing the earlier studies and the expected results, a sample size of 60 was decided with an alpha power of 0.8. A thorough pre-anaesthetic evaluation and airway assessment was done in all patients. Patients with body mass index more than 30 kg/m^2, mouth opening less than 2.5 cm, and increased risk of aspiration were excluded from the study. All patients were explained about the study with special reference to simulation of difficult intubation using a rigid neck collar for the purpose of this research study only and an informed written consent was obtained. The pre-anaesthetic instructions included fasting for at least 8 h for solids and pre-medicating them with tablet ranitidine 150 mg, tablet metoclopramide 10 mg and tablet diazepam 10 mg.orally, the previous night and on the morning of the procedure.

Patients were randomized into two groups of thirty each by a closed envelope technique to have either IT (group IT) or GEB (group GEB) as aids for insertion of PLMA. Difficult airway was simulated by using a rigid neck collar. The collar was of the same size, but adjustable to suit individual needs and restriction of neck movements was achieved in all cases [Figure 1].

All patients were monitored with electrocardiogram, pulse oximetry and non-invasive blood pressure monitor. Main stream end tidal carbon-di-oxide ($ETCO_2$) (Capnostat CO_2 sensor, Novametrix Medical Systems, USA) was attached to the breathing system. Induction of anaesthesia was done with Thiopentone sodium 5 mg/kg and morphine 0.1 mg/kg. Neuromuscular blockade was achieved with vecuronium 0.1 mg/kg. Patients were ventilated using an appropriate sized face mask with 1% Halothane in 66% nitrous oxide and 33% oxygen using circle system with CO_2 absorber. The PLMA was inserted 3 min after injection of vecuronium. A stopwatch was used to keep track the timing. In Group IT, the IT was used to aid insertion and positioning of PLMA. With the head in a neutral position the mouth was opened by pushing the jaw caudally and the PLMA was positioned into the pharynx using a single handed rotational technique advancing it around the palatopharyngeal curve as per the recommendations of the manufacturer. Then, the IT was removed and cuff inflated with maximum recommended volume of air (20 ml for size 3 and 30 ml for size 4 PLMA). If the introduction of the PLMA was not possible or unsatisfactory the rigid collar was removed and PLMA was inserted again using the same insertion protocol. If the insertion still failed, patient was intubated with cuffed oral endotracheal tube using Macintosh laryngoscope. In Group GEB, a lubricated GEB was inserted into drain tube of PLMA, leaving the 5 cm of its bent portion protruding from the proximal end. With the head in a neutral position, a tongue depressor was used to facilitate mouth opening and the distal portion of the GEB was introduced in the midline and placed 5-10 cm into the oesophagus while an assistant was holding the PLMA and stabilizing the bougie. PLMA was guided into position over the tongue depressor by the anaesthesiologist while the assistant held the proximal end of the GEB so that it did not penetrate further into the oesophagus. The bougie and tongue depressor were then removed

Figure 1: Simulated difficult airway

leaving the PLMA in position. The cuff was inflated with maximum recommended volume of air. If the introduction of the PLMA was not possible or unsatisfactory the rigid collar was removed and PLMA was inserted again using the same insertion protocol. If the insertion still failed, patient was intubated under direct laryngoscopy with Macintosh laryngoscope using cuffed oral endotracheal tube.

After positioning the PLMA, the circle breathing system was connected and patients were ventilated. The effective airway was judged by capnograph trace and auscultation of bilateral breath sounds. PLMA position was assessed by passing the intubating fibrescope (IFS) through the airway lumen of the PLMA to view the glottis from the distal end of the lumen and graded as follows:

Grade 1: Only vocal cords seen
Grade 2: Vocal cords + posterior surface of epiglottis visible
Grade 3: Vocal cords + anterior surface of epiglottis visible
Grade 4: Vocal cords not seen but oesophagus visible.

Time taken for insertion in group IT was defined as the time from starting of introduction of PLMA into the mouth to confirmation with square wave pattern of capnograph. In GEB group, it was defined as the time from the introduction of tongue depressor into the mouth to confirmation with square wave pattern of capnograph. The ease of insertion of PLMA was decided by assessing time taken for PLMA insertion, number of attempts and grading by IFS for correct positioning of PLMA. The haemodynamic and respiratory parameters namely heart rate, systolic blood pressures (SBP) and diastolic blood pressures (DBP), oxygen saturation, respiratory rate and $ETCO_2$ were recorded at pre-induction, post-induction, post- laryngeal mask airway (LMA) placement, 1, 3, 5, 10, 15 and 20 min. Any visible blood staining on the GEB, tongue depressor, PLMA and/or IT were noted at removal. Patients were interviewed at 12 h and 24 h after surgery for sore throat, dysphagia and dysphonea. Symptoms were graded as mild, moderate or severe. All data collected were entered into the proforma at the time of collection and then into an excel spreadsheet. The data were analysed using the SPSS (Version 17) software. The parametric data were analysed with Student *t*-test and the non-parametric data were analysed with Chi-square test.

RESULTS

The demographic variables such as age, sex and body weight distribution were comparable between the two groups [Table 1]. The comparison of study parameters namely PLMA size, air leak, first attempt success rate, time taken for insertion and IFS grading is given in Table 2. Time taken for insertion of PLMA by GEB guided technique was significantly more ($P<0.0001$) when compared with IT technique. One case in GEB group PLMA could be placed after removal of neck collar. In IT group, even after removal of neck collar PLMA placement was not successful in two patients. These patients were intubated with an endotracheal tube using laryngoscope.

There were no significant changes in mean heart rate at different time intervals when compared between the two groups. Changes in SBP and DBP between both groups were similar. Patients in group GEB had better fibreoptic scores than the IT group. The $ETCO_2$ showed a significant difference between the groups at 3, 5, 10 and 20 min post-LMA insertion ($P<0.05$), the IT group having higher $ETCO_2$ compared to the GEB group [Figure 2].

Post-operative complications were assessed after 12 h and 24 h. 12 h after removal of PLMA, in GEB group, 11 (36.6%) had sore throat and dysphonia, whereas in IT group, it was 18 (60%). After 24 h, in GEB group, only one patient had dysphagia. In IT group, all patients were symptom free.

Table 1: Demographic variables

Group	Age in years mean±SD	Sex		Weight in kg mean±SD
		Male %	Female %	
GEB (*n*=30)	37.47±11.36	36.67	63.33	55.70±8.23
IT (*n*=30)	37.00±10.63	53.33	46.67	53.63±7.14

GEB – Gum elastic bougie; IT – Introducer tool

Table 2: Comparison of study parameters between GEB and IT groups

Parameters	GEB (*n*=30) (%)	IT (*n*=30) (%)
PLMA size		
3	13 (43.3)	11 (36.7)
4	17 (56.7)	19 (63.3)
Air leak	0	3 (10)
First attempt success rate	29 (96.6)	28 (93.33)
Insertion time in seconds	67.80±17.55	46.79±13.46
IFS grading		
1 and 2	24 (80)	18 (60)
3 and 4	6 (20)	12 (40)

GEB – Gum elastic bougie; PLMA – ProSeal laryngeal mask airway; IT – Introducer tool; IFS – Intubating fibrescope

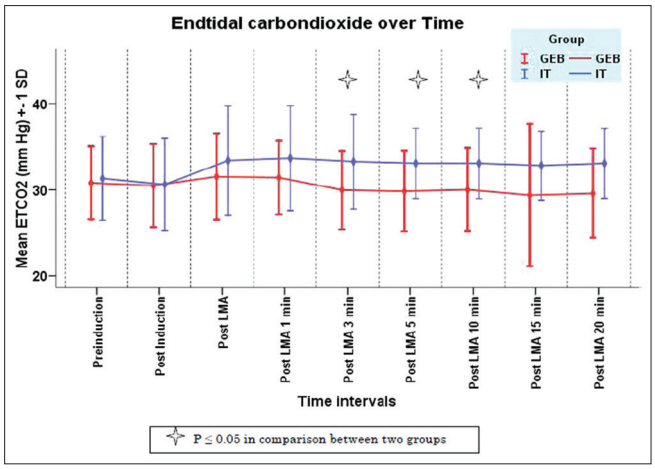

Figure 2: Endtidal carbondioxide at different time intervals

DISCUSSION

The rigid neck collar simulates difficult laryngoscopy. It does the same by (1) Reducing both head and neck movement, which is necessary to align the oropharyngeal axes (2) Reducing the mouth opening which is necessary to insert and manoeuvre the laryngoscope. Various studies have shown that application of such a collar decreases Lehane Cormack scoring of laryngoscopic vision.[6] The PLMA is a new airway device with a better seal for airway maintenance and prevention of aspiration. It has been successfully placed even in obese patients either in anaesthetic or critical care situations.[7-11] There are various described techniques of insertion of PLMA.[12] Guided insertion was more frequently successful than the digital and IT techniques in patients with simulated difficult airway with a rigid neck collar.[4,13,14] It was because it reduces impaction at the back of the mouth, prevents folding over of the distal cuff, and guides the distal cuff directly into its correct position in the hypopharynx.[5] In our study, we compared the ease of insertion, correct positioning, haemodynamic parameters and post-operative complications. We used tongue depressor instead of laryngoscope in the hope of causing less haemodynamic disturbance, but it was not achieved. We found overall first attempt success rate in patients of GEB group was slightly more than patients of IT group, but was not statistically significant, but earlier studies have found statistically significant increase in first attempt success rate with GEB.[6,15,16] In previous studies, the time taken for insertion with various techniques were similar but, in our study, it was longer in patients of GEB group than patients of IT group, the difference may be due to precisely defined different end points for satisfactory placement. While earlier studies timed for introduction of laryngoscope, the time started from picking up of the tongue depressor was taken as the initial time in our study. Eschertzhuber *et al*. compared three techniques for insertion of the PLMA in patients with simulated difficult laryngoscopy using a rigid neck collar.[6] and found that there was no difference in the haemodynamic response to insertion, which coincides with our findings. Nileshwar compared two techniques for insertion of PLMA (group GEB and group IT) assessed the glottis view by passing the fibreoptic scope through the airway lumen placed at the patient end of the PLMA.[15] They found group GEB had significantly better view (Grade 1) as compared to group IT. This conclusion goes along with our findings. Regarding the $ETCO_2$, difference was significant between the groups at 3, 5, 10 and 20 min post-LMA insertion ($P<0.05$), the IT group having higher $ETCO_2$ compared with the GEB group [Figure 2]. This higher in IT group may be due to mild obstruction to airflow caused by poor positioning of PLMA evidenced by IFS grading. No other study has looked at the $ETCO_2$ to assess the positioning of the PLMA. With regard to post-operative complications such as sore throat, dysphagia and dysphonea, IT group had more symptoms in the 12 h which became similar to Group GEB in 24 h. Nileshwar in a similar study, assessed the post-operative airway morbidity by interviewing the patient, within 1 h and 18-24 h after surgery, for sore throat, dysphagia and dysphonia[15] and their findings coincide with our results. Our study does not throw any new controversy. The basic new facts we want to establish are that a tongue depressor can be successfully used for this purpose and the confirmation of poor fibrescope findings with $ETCO_2$ readings.

CONCLUSION

We conclude that the guided insertion with a GEB technique using a tongue depressor is more frequently successful, taking longer insertion time, better IFS grading scores and $ETCO_2$ values than IT technique in patients with a simulated difficult airway using a rigid neck collar. The haemodynamic changes are similar. The post-operative complications like sore throat were more in IT group in the first 12 h, which became similar in 24 h.

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Announcement

CALENDAR OF EVENTS OF ISA - 2013

Certain important dates regarding awards of ISA are mentioned here for the members. All the applications should be sent by registered post (with Acknowledgement Due)

Date	Name of the Award/Post	Application has to be sent to
30th June 2013	Bhopal Award for Academic Excellence	Hony. Secretary, ISA
31st July 2013	KPR Young Anaesthesiologist Award State Chapter	Secretary, Kerala State
15th August 2013	Prof. A. P. Singhal Life Time Achievement Award	Hony. Secretary, ISA
31st October 2013	Dr (Mrs.) Rukmini Pandit Award - Publication format along with Conference Presentation Certificater	Hony. Secretary, ISA
31st October 2013	Y. G. Bhoj Raj Award - Best Review Article in IJA	Hony. Secretary, ISA
31st October 2013	Dr. Kop's Award	Chairman Scientific committee of ISACON with a copy to Hony Secretary ISA
27th November 2013	Dr. TN Jha Memorial & Dr. KP Chansoriya Travel grant	Hony. Secretary, ISA
27th November 2013	Late Dr. Venkata Rao Memorial Oration	Hony. Secretary, ISA
27th November 2013	Ish Narani Best Poster Award	Chairman Scientific Committee ISACON
28th November 2013	ISA GOLDCON QUIZ Competition	Chairman Scientific Committee ISACON
28th November 2013	Awards for 1. Best City Branch 2. Best State Branch 3. Best Metro Branch 4. Public Awarness Individual 5. Public Awarness City 6. Public Awarness State 7. Ether Day - City / State 8. Individual Drive 9. Highest Membership Drive	Hony. Secretary, ISA

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