Original Article

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Anaesthesia Section

Comparison of Digital and Bougie-aided Technique for Proseal Laryngeal Mask Airway Insertion in Mastoid Surgery: A Randomised Clinical Study

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ABSTRACT

Introduction: While placing the Proseal-laryngeal Mask Airway (PLMA) using the digital technique, there may be failed insertion or inadequate ventilation. Therefore, a placement technique using the Gum Elastic Bougie (GEB)-aided placement was employed.

Aim: To compare the clinical efficacy of Proseal Laryngeal Mask Airway (PLMA) insertion by two different techniques viz. Digital and Gum elastic bougie-aided, in mastoid surgery in adult patients done under General Anaesthesia.

Materials and Methods: In this randomised clinical study conducted at the Department of Anaesthesiology, R.G. Kar Medical College, Kolkata, West Bengal, India from November 2016 to December 2022. A total of 88 patients of American Society of Anaesthesiologists (ASA) class I and II of either sex undergoing mastoid surgery using the PLMA as an airway management device were allocated to Digital (Group D) and gum elastic Bougie (Group B) techniques. Parameters studied included the percentage of successful insertion of PLMA on the first attempt, number of attempts required and time taken for successful insertion of PLMA and postoperative complications if any. The t-test was used to compare the groups regarding PLMA insertion time, while categorical data such as airway trauma was compared using Chi-square test or Fischer's-exact test (whichever applicable).

Results: In the present study 88 patients were included, with 44 patients in each of the two groups. The difference in Mallampati scoring of both groups was statistically insignificant. In the present study 68.18% patients in Gum elastic bougie group and 70.45% patients in Digital group were of ASA Grade I, showing no statistical significance between these two groups regarding ASA status. In Group B (GEB), PLMA was successfully inserted in 95.45% of cases on the first attempt, and in group D (digital) the corresponding figure was 77.27% and 22.72% of cases required a 2nd attempt, this difference was statistically significant (p-value<0.001). The difference of PLMA insertion mean time was statistically significant between the two groups (24.33±3.209 seconds in gum elastic bougie group whereas in digital group it was 13.42±3.228 seconds) (p-value <0.001).

Conclusion: The GEB-aided Proseal-LMA insertion is more successful in the first attempt than in the digital technique. Although GEB-aided insertions of PLMA took longer, they helped achieve higher oropharyngeal leak pressure. With peak airway pressures less than 20 cm of H_2O there was no audible leak from the drain tube and there were fewer failed insertions.

Keywords: Anaesthesia, Gum elastic bougie-aided placement, Intubation

INTRODUCTION

Failure to intubate can cause mortality and account for 30% of overall anaesthetic brain damage and death [1]. In 1983, Dr. Archie Brain described a new device called the Laryngeal Mask Airways (LMA). It has many advantages, like no chance of trauma to vocal cords and avoidance of laryngoscopy therefore minimal pressure responses. However, regurgitation of gastric contents into respiratory tract is always a potential complication. Poor placement of the LMA has been associated with gastric fluid aspiration, neuropraxias, and sore throat [2]. As airway pressure increases during PPV, gas leaks occur into the oropharynx and, more significantly, into the oesophagus [3].

Malposition increases the risk of leaks and overpressure (>25 cm of H2O) and may lift the LMA tip from its correct position in the hypopharynx, elevating the distal cuff from the larynx and exposing the oesophageal inlet. If the leak is large or prolonged, it may lead to gastric distension, impairing respiratory function and increasing the risk of regurgitation [4]. The seal efficacy of LMA depends on the fit between the groove that surrounds the glottis and the oval shaped cuff of the LMA [5]. Seal achieved by LMAs provides less protection against pulmonary aspiration than a properly inserted cuffed tracheal tube does [6]. Archie Brain invented the PLMA in 2001 [7]. This double-lumen, double-cuff LMA separates the respiratory and Gastrointestinal (GI) tracts thus providing a safe escape channel for any regurgitated material. The double cuff of the PLMA gives a better seal around the glottis, so it is superior for positive pressure ventilation [7,8].

Failure to insert and inadequate ventilation can occur while placing PLMA using the classical digital technique. Newer placement techniques have been introduced, each claiming to be better than the other. Using a GEB-aided PLMA insertion has been found to be more successful in inserting the PLMA on the first attempt, also time taken for successful placement is shorter [9]. The GEB-guided technique is usually successful as it reduces PLMA impaction at the back of the mouth, prevents folding over of the distal cuff and also guides the distal cuff directly into the hypopharynx [10]. Any displacement of the cuff that occurs while removing the GEB can be corrected by pushing the PLMA back into position. However, the GEB-guided technique may potentially cause stimulation and pharyngo-oesophageal trauma as the GEB is stiff and it is not designed for oesophageal placement, which might lead to a higher incidence of dysphagia postoperatively [11].

There may be haemodynamic changes and pharyngoesophageal trauma leading to postoperative complications. Mastoid surgeries under general anaesthesia can be performed by inserting a PLMA, which has a gastric drain tube and superior airway seal characteristics [12]. In the present study digital technique and gum elastic bougie guided technique of PLMA insertion was compared in patients undergoing mastoid surgery under GA with regard to the percentage of successful insertion of PLMA on the first attempt, number of attempts required and the time taken for successful insertion of PLMA, haemodynamic changes, and postoperative consequences.

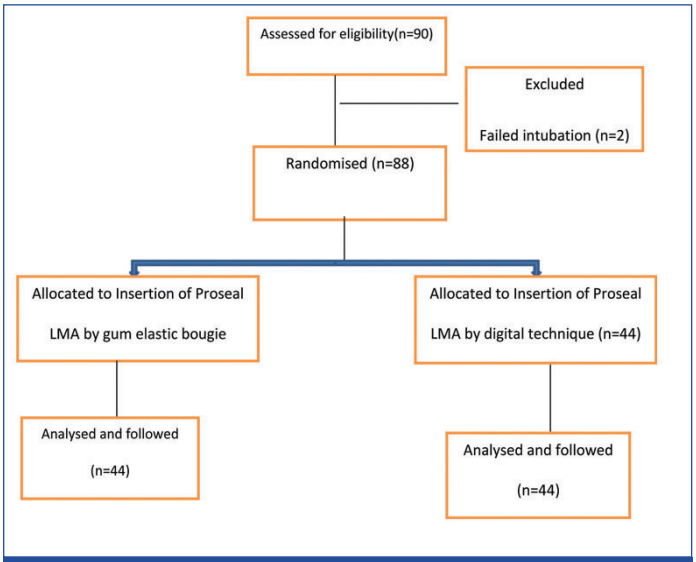
MATERIALS AND METHODS

A randomised clinical study was conducted at Department of Anaesthesiology, R.G. Kar Medical College, Kolkata, West Bengal, India from November 2016 to December 2022 after obtaining Institutional Ethical committee (ECR/322/Inst/WB/2015) clearance and patients' written informed consent.

Sample size calculation: Sample size was calculated with 80% power and 95% confidence interval (CI). Sample size was 88 so 44 patients were taken in each group.

Inclusion criteria: Patients of ASA class I and II, Mallampatti score I and II 18-50 years of age, either sex and those scheduled to undergo elective mastoid surgery under general anaesthesia.

Exclusion criteria: Patients with difficult airway, mouth opening less than 4 cm, Body Mass Index (BMI)>35 kg/m^2 and any history of regurgitation and severe systemic disease. There were no dropouts as all 88 patients (44 in each group) were included. Patients who refused were excluded at the first stage. Routine investigations were carried out. Willing patients fulfilling the inclusion criteria were included in the sample through systematic random sampling. Every 3rd patient was included, and the 1st patient was selected with the help of a random number. The Consolidated Standards of Reporting Trials (CONSORT) diagram is provided [Table/Fig-1].



[Table/Fig-1]: A CONSORT flow diagram.

Group B (44)-Insertion of PLMA by GEB;

Group D (44)-Insertion of PLMA by digital technique.

Study Procedure

Patients included were kept NPM after midnight and tab. Lorazepam 1 mg was given night before surgery. On arrival to the Operation Theatre (OT) aspiration prophylaxis was given with inj. Ranitidine 50 mg i.v. and inj. Metoclopramide 10 mg i.m. and premedicated with inj.Glycopyrrolate 0.2 mg i.m. In OT after placing the standard minimum monitoring devices {Electrocardiography (ECG), Non Invasive Blood Pressure (NIBP), Pulse Oximetry (SpO_2)} and preoxygenation for 5 min. all patients were given inj Midazolam 2 mg i.v., inj. Fentanyl 2 mcg/kg i.v., inj. Lignocaine(preservative free) 1.5 mg/kg i.v.in the supine position and with the patient's head on a standard pillow of 4 inches in height. Anaesthesia was induced with 2 mg/kg Inj. Propofol i.v. Neuromuscular blockade was achieved with Vecuronium Bromide 0.1 mg/kg i.v. Three minutes were allowed for full relaxation of the jaw before placing the device.

PLMA was selected according to body weight, and all devices were inserted after cuff deflation and lubrication of the distal end. In Group D, the digital technique the index finger was used to press the PLMA into and advance it around the palatopharyngeal curve. In group B, the gum elastic bougie was introduced with its straight end first, leaving the 5 cm bent portion protruding from the proximal end for the assistant to grip and the maximum length protruding from the distal end so that the person introducing the PLMA can manipulate. The GEB-guided technique involved the following steps [13].

1. Under laryngoscope guidance distal portion of the GEB was placed 5-10 cm. into the esophagus, and the assistant held the PLMA and the proximal portion of the GEB.
2. The laryngoscope was removed once the GEB was introduced.
3. The PLMA was inserted using the digital insertion technique while the assistant stabilized the proximal end of the GEB so it did not penetrate further into the esophagus.
4. Once the PLMA was in position The GEB was removed.

After the PLMA was inserted into the pharynx, the cuff was inflated with recommended inflation volume of air and effective ventilation was established. The LMA was then fixed. Patients were ventilated with a tidal volume of 6 mL/kg, respiratory rate of 12 breaths/min. and an Inspiratory Expiratory ratio (I:E ratio) of 1:2. Oropharyngeal air leaks (detected by listening over the mouth), gastric air leaks (detected by listening with a stethoscope over the epigastrium); drain tube air leaks (detected by placing lubricant over the proximal end of the drain tube), or an end tidal carbon dioxide greater than 45 mmHg was noted. In two patients there was air leak, one oropharyngeal air leak and one drain tube air leak. Both patients were excluded from the study as it could not be corrected even after three attempts. Anaesthesia was maintained with isoflurane 0.6% in oxygen and nitrous oxide, and neuromuscular blockade was maintained with intermittent inj. of Vecuronium Bromide. Data were collected regarding monitoring from time to time. After the procedure neuromuscular blockade was reversed with inj. Glycopyrrolate 0.01 mg/kg i.v. and inj. Neostigmine 0.05 mg/kg i.v. and the PLMA was removed. After 18-24 hrs patients were interviewed for post operative complications.

Percentage of successful insertion of PLMA in 1st attempt, number of attempts required for successful insertion was noted. Successful insertion of the device was confirmed by manual ventilation, square wave capnography, no audible leak detected from the drain tube with peak airway pressures less than 20 cm of H_2O. If there was a leak below 20 cm of H_2O it was taken as significant and suggested a malposition.

The Gel displacement test, was done by placing a water-soluble gel (0.5-1 mL) at the proximal end of the drain tube so that it forms a column of about 2-3 cm. A typical position is one that moves only slightly up and down or barely at all. If gel ejection occurs along with mild PPV, it suggests a leak from the drain tube and an inadequate seal between the device and the hypopharynx. A positive test indicates an airway leak [14].

More than three attempts for insertion was considered a failure. Criteria for defining failed insertion included:

1. Wrong placement – done into the pharynx.
2. Malposition (air leaks, negative tap test results, failed gastric tube insertion though successful pharyngeal placement of PLMA).
3. Ineffective ventilation (end tidal carbon dioxide > 45 mmHg albeit correctly positioned) [15].

The time taken for successful insertion of PLMA was recorded from picking up the prepared PLMA (cuff deflated, lubricated, gum elastic bougie attached) to successful placement of the PLMA. If insertion failed after three attempts, the patient was then intubated.

Any episode of hypoxia (SpO2< 90%) or any other adverse events were documented. Visible or occult blood staining on the gum elastic bougie, laryngoscope or the PLMA was noted at the time of removal of the device. Evidence of trauma in the mouth, lips and tongue were inspected for.

After the operative procedure, 18-24 hours later, all patients underwent a structured interview where they were asked about the presence of sore throat, dysphagia. Patients graded symptoms as mild, moderate or severe without being aware of the insertion technique. Unblinded observers collected intraoperative data, whereas postoperative data was collected by sister in charge of the ward who was a blinded observer.

The primary outcomes were the percentage of successful insertion of P-LMA on the first attempt, number of attempts required and time taken for successful insertion of P-LMA. The secondary outcomes were haemodynamic changes and postoperative consequences.

STATISTICAL ANALYSIS

The t-test was used to compare the groups for age, weight, height and PLMA insertion time. Gender, ASA-status, airway trauma and dysphagia was compared using Chi-square test or Fisher exact test as applicable. The statistical analysis was carried out using Statistical Package for the Social Sciences (SPSS) software version 16.0 (Chicago, IL, USA).

RESULTS

A total of 88 patients were included in the present study, each Group having 44 patients. Patients of the study groups were comparable with respect to demographic data [Table/Fig-2].

Variables	Group B (Mean±SD)	Group D (Mean±SD)	p-value
Age (in years)	36.16±4.83	37.25±7.27	0.16
Height (in cm)	156.31±5.214	155.72±3.77	0.19
Weight (kg)	54.02±4.12	53.1±4.19	0.068
Gender	F-30 (68.18%)	F-28 (63.63%)	
Distribution (M/F) n (%)	M-14 (31.82%)	M-16 (36.36%)	

[Table/Fig-2]: Age, gender height and weight distribution for all the patients.
p>0.05* statistically insignificant; F-Female M-Male

Mallampati scoring and ASA physical status in both groups were statistically insignificant. In the postoperative period, patients were interviewed for postoperative complications, specifically the presence of sore throat and dysphagia 18-24 hours after the operative procedure. No statistically significant results were found for the occurrence of moderate sore throat in Group B and Group D [Table/Fig-3].

Variables	Group B	Group D	p-value
Mallampati score (I/II)	28/16	30/14	0.65
ASA I/II	30/14	31/13	0.81
Sore throat Mild/moderate/none	22/2/20	20/0/24	0.67
Dysphagia Mild/moderate/none	20/3/21	7/0/37	0.002

[Table/Fig-3]: ASA and Mallampati scores as well as sore throat and dysphagia monitoring results.

Number of attempts required and time taken for each insertion of PLMA was noted in both groups. In group B PLMA was inserted successfully in most of the cases in first attempt whereas in group D the rate of successful insertion in first attempt was less requiring a 2nd attempt, this statistically significant. The mean time taken for PLMA insertion was longer in Group B, whereas in Group D, it took significantly less time [Table/Fig-4].

No. of attempts required for PLMA insertion	Group B	Group D	Total	p-value
1st attempt	42/95.45%	34/77.27%	76	0.013
2nd attempt	2/4.54%	10/22.72%	12	
Time taken for PLMA insertion (in sec.) (Mean±Std. Deviation)	24.33±3.209	13.42± 3.228		<.00001

[Table/Fig-4]: Number of attempts required for PLMA insertion.
p<0.0.5 significant, p<0.001**highly significant

Haemodynamic monitoring was conducted to detect changes in pulse, systolic, diastolic and mean Blood Pressure (BP), oxygen saturation, End-Tidal Carbon Dioxide ($ETCO_2$), and ECG [Table/Fig-5-7]. There was an increase in pulse, systolic, diastolic, and mean blood pressure after one and five minutes of PLMA insertion, with more pronounced changes in Group B patients than in group D, this was statistically significant. After this time period until the end of the surgery, no further statistically significant haemodynamic changes were noted. In Group B, sinus tachycardia was observed in 81.48% and 34.56% of cases at one minute and five minutes after PLMA insertion, respectively, whereas in Group D, it was seen in 19.75% and 11.11% of cases at one minute and five minutes after PLMA insertion, respectively, which was statistically significant. No further statistically significant changes in oxygen saturation (SpO_2) and $EtCO_2$ concentration were observed throughout the surgery duration. Similarly, no further statistically significant ECG changes were noted after the mentioned time period until the end of the surgery. In Group B patients, PLMA insertion after direct laryngoscopy with the placement of GEB took more time during airway manipulation compared to Group D, where PLMA insertion with the help of a finger took less time, leading to more sympathetic stimulation and subsequent haemodynamic alterations in Group B, which were statistically significant.

Pulse	Group B	Group D	p-value
PAC	74.78	76.27	0.10
Preop	80.32	84.51	0.09
During insertion	108.94	95.10	<0.00001
5 min after insertion	95.88	88.56	<0.00001
15 min after insertion	84.41	79.69	0.12
At extubation	81.26	79.77	0.20

[Table/Fig-5]: Pulse monitoring results.
p<0.001**highly significant p>0.05* statistically insignificant; PAC-Preanaesthetic check-up

Pulse	Group B	Group D	p-value
PAC	72.99	71.65	0.072
Preop	78.77	77.05	0.18
During insertion	95.05	84.02	<0.00001
5 min after insertion	90.02	81.37	<0.00001
15 min after insertion	80.85	80.04	0.31
At extubation	77.99	77.49	0.27

[Table/Fig-6]: Diastolic blood pressure monitoring results.
p<0.001**highly significant; p<0.05* statistically significant

Pulse	Group B	Group D	p-value
PAC	124.36	126.46	0.06
Preop	131.74	133.01	0.34
During insertion	154.10	141.75	<0.00001
5 min after insertion	146.14	137.91	<0.00001
15 min after insertion	131.81	132.04	0.42
At extubation	131.23	130.07	0.11

[Table/Fig-7]: Systolic blood pressure monitoring results.
p<0.001**highly significant; P<0.05* statistically significant

DISCUSSION

The LMA Proseal is a reusable supraglottic device designed to allow higher glottic seal pressures and permits gastric drainage, separating the respiratory tract from the alimentary tract. This characteristic enables better ventilation and protects against aspiration. Proper insertion of this device is of utmost importance to prevent malpositioning and achieve optimum glottic seal pressure to provide PPV [16]. The PLMA is slightly bulkier than the classic LMA, posing difficulties in its placement. Various techniques have been described in the literature to overcome these challenges [9,10,17].

In the digital technique, the larger cuff of PLMA poses difficulty in placement, as it leaves less space for the index finger and is also more probable to get folded. GEB assisted PLMA insertion facilitates circumnavigation of oropharyngeal inlet and with less chances of getting impacted at the back of the mouth and cuff folding [18,19].

In the present study, Group B (GEB) PLMA was successfully inserted in 95.45% of cases on the first attempt, while in group D the rate of successful insertion in first attempt was 77.27%, requiring a second attempt in 22.23% of cases which was statistically significant (p-value 0.001). In a study by Kuppuswamy A and Azhar N bougie-guided insertion of PLMA was compared with the digital technique in adult patients undergoing elective minor surgeries [9]. In their study GEB-guided PLMA insertion was successful in 96.7% patients on the first attempt, only one patient required second attempt. In digital technique in 86.7% of patients, with 10% requiring a second attempt, though statistical analysis did not reveal a significant difference. Another study by Brimacombe J et al., compared the GEB-guided insertion technique of PLMA with either digital or with an introducer tool techniques, finding GEB-guided insertion to be superior to the digital and introducer tool techniques, similar to the present study [10].

In the present study, the mean time taken for PLMA insertion was 24.33±3.209 seconds in Group B (GEB), while in Group D (digital), it was 13.42±3.228 seconds, which was statistically significant (p-value < 0.001). A study conducted by Kuppuswamy A and Azhar N that effective time for GEB-guided insertion of PLMA was longer than that of digital technique, this was statistically significant and it is consistent with the present study [9]. However, Brimacombe J et al., in their study found GEB-guided technique took less time than digital or introducer tool technique [10]. The extra time required for laryngoscopy and bougie placement increased the effective airway time in gum elastic bougie technique.

The most common cause of failed insertion on first attempt in both groups was the malposition of the PLMA, as detected by the Gel displacement test and negative suprasternal notch tap test (also known as “Brimacombe bounce”) [15,16]. Malposition was higher with digital technique which was identical to the study by Kuppuswamy A and Azhar N However, in other studies, glottic impaction and unsuccessful passage into the pharynx were found to be the most frequent causes of malposition [9,10].

Monitoring was conducted to detect changes in pulse, systolic BP, diastolic BP and Mean Blood Pressure (MAP), oxygen saturation, $EtCO_2$ and ECG. There was an increase in pulse, systolic, diastolic, and mean blood pressure after one and five minutes of PLMA insertion, more pronounced in Group B (GEB) patients than in Group D (digital), which was statistically significant. However, no further statistically significant haemodynamic changes were noted until the end of the surgery. There were no statistically significant changes in SpO_2 and $EtCO_2$.

In Group B, sinus tachycardia was observed in 81.48% and 34.56% of cases one minute and five minutes after PLMA insertion, respectively, whereas in Group D, it was seen in 19.75% and 11.11% of cases at one minute and five minutes after PLMA insertion, respectively, which is statistically significant. No further statistically significant tachycardia was noted. In the study by Kuppuswamy A and Azhar N sore throat was frequently found in digital technique but was was not statistically significant [9].

In Group B, PLMA was inserted after direct laryngoscopy with the placement of GEB taking more time during airway manipulation, leading to more sympathetic stimulation and subsequent haemodynamic alterations. In the postoperative period, after 18-24 hours, patients were interviewed for the presence of sore throat and dysphagia.

No statistically significant results were found for the occurrence of moderate sore throat in Group B and Group D, with an incidence of sore throat at 4.54% in Group B and 0% in Group D. Although, in the study conducted by Kuppuswamy A and Azhar N sore throat was more frequent with the digital technique, it was not statistically significant [9].

In Group B, moderate dysphagia was found in 4.54% of patients, while in Group D, it was found in 0% of patients, which was statistically significant (p-value < 0.01). Similarly, in other studies, dysphagia was found to be more frequent with GEB-aided PLMA insertion techniques [9,10].

The higher incidence of dysphagia in GEB-guided PLMA insertion can be attributed to the placement of GEB in oesophagus [20-22].

Limitation(s)

The PLMA placement grading was not confirmed by Fibre optic. Observers who collected data intraoperative were not blinded, but postoperative data was collected by blinded observers

CONCLUSION(S)

The authors concluded that with the help of GEB PLMA is inserted more successfully in the first attempt compared to digital technique, but time taken for PLMA insertion is more when inserted with the help of a gum elastic bougie. At 1 and 5 minutes after PLMA insertion with the help of a GEB, there are more significant haemodynamic changes compared to PLMA insertion using the digital technique. Dysphagia is more common when PLMA is inserted with the help of GEB.

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