Comparison of First Attempt Success Rate between Two Insertion Techniques of Proseal Laryngeal Mask Airway

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Abstract

Background: The Pro Seal laryngeal mask airway (ProSeal LMA) is a relatively new laryngeal mask device designed to improve ventilator characteristics and offer protection against aspiration and gastric insufflation. But there were occasional problems like failed insertion and inadequate ventilation, in placing Pro Seal LMA using the classical digital technique. To overcome these problems, newer placement technique like introducer tool placement and Gum elastic bougie aided placement were advised.

Aim: To compare the first attempt success rate between bougie guided insertion versus introducer guided insertion of Pro Seal LMA.

Methodology: This prospective comparative study was conducted in the Dept. of Anesthesiology, Govt. Medical College, Thiruvananthapuram, a tertiary care centre. A total of 100 patients, requiring general anaesthesia with supraglottic airway device, of age between 20-60 years with ASA I and II were enrolled in the study. The enrolled patients were divided randomly into two groups-Group 1 and Group 2.

Group 1 - ProSeal LMA insertion by bougie guided technique.
Group 2 - ProSeal LMA insertion of introducer technique.

Data were collected about ease of insertion, number of attempts and time taken to provide an effective airway, efficacy of seal, ease of gastric tube placement, haemodynamic responses and blood staining. Data also collected about postoperative airway morbidity.

Results: The first attempt success rate was high in bougie guided insertion of Pro Seal LMA (98% vs 86%). The effective airway time is longer in patients with bougie guided insertion compared to introducer guided insertion.

Conclusion: The bougie guided insertion of Pro Seal LMA has a higher first attempt success rate than the introducer technique.

Keywords: airway, ProSeal LMA, technique.

Introduction

The Pro Seal LMA was introduced by Dr. Archie Brain in 2000[1]. Pro Seal LMA has a gastric drainage tube, placed lateral to the main airway tube. The gastric drainage tube forms a channel for regurgitated gastric contents and prevents gastric insufflation and pulmonary aspiration.

When the device is used for controlled ventilation, the ProSeal LMA provides a high eroropharyngeal leak pressure than the Classic LMA [2]. However, the Pro Seal LMA is reported to be more difficult to insert than the Classic LMA, as its larger and the softer cuff is prone to folding. The manufacturer recommends that the Pro Seal...
LMA be inserted using either manipulation with the fingers or a curved metal introducer. Nonetheless, first attempt success rates of Pro Seal LMA insertion range from 81% to 87%, which is lower than the Classic LMA(2, 3, 4). To overcome these problems, newer techniques to facilitate insertion of the Pro Seal LMA, including priming the drain tube with a guiding instrument such as a suction catheter (6), a gastric tube (7), a gum elastic Bougie (8), a Flexi-Slip stylet (9), and even a fiber optic bronchoscope (10-11) were devised. In the following prospective randomized study, we have tested the hypothesis that bougie-guided laryngoscope aided insertion of the Pro Seal LMA is more frequently successful than using the curved metal introducer. Other advantages of guided technique for the airway rescue are that

1. Oral pathology can be identified as laryngoscope is used
2. Gastric tube insertion is as the drain tube and esophagus are prealigned.

### Materials and Method

This study was conducted in the Dept. of anaesthesiology, Govt, Medical College, Thiruvananthapuram for a period of six months. One hundred patients of ASA I–II, undergoing a surgery in the supine position requiring general anaesthesia with supraglottic airway device, of age between 20-60 years were selected for this study based on the inclusion and exclusion criteria.

Exclusion criteria included an anticipated difficult airway, morbid obesity, duration of surgery more than 3 hours, mouth opening < 4 cm, inadequate fasting, pregnant woman and pre-existing sore throat or hoarseness. Sample size was calculated using the formula

\[ n = \frac{2(Z_{a/2} + Z_{1-\beta})^2}{d^2} \]

Significant level .05 power 80%, \( P_1 = 100\% \) \( P_2 = 84\% \) \( P = 92 \)

\[ n = \frac{2(1.96 + .842)^2 x 92 x 8}{16^2} = 45 \text{ rounded as 50} \]

N=50 each group,

The selected patients were evaluated preoperatively and written informed consent was obtained from each patient. Patient data was recorded in the proforma. Details regarding age, sex, weight, airway assessment and ASA class were recorded. Basal heart rate, systolic and diastolic blood pressure were noted. Enrolled patients were allotted randomly to one of the two groups.

Group 1 – Pro Seal LMA insertion by bougie guided laryngoscope aided technique.

Group 2 – Pro Seal LMA insertion of introducer technique.

Normal fasting guidelines were followed. On arrival in operation theatre an intravenous infusion of normal saline was started. The standard monitoring with continuous electrocardiography, noninvasive blood pressure, pulse oximetry and capnography were used for both groups. Patients were premedicated with intravenous inj. Glycopyrrolate 0.2 mg inj. Midazolam 1 mg, fentanyl 2 micro gm/kg before induction of anaesthesia. Each patient was anesthetized in the supine position with the head resting on a 10-cm high pillow. The size of the Pro Seal LMA was selected according to the patient’s weight: size 3 for those ≤50 kg, size 4 for those >50 kg. The cuff was fully deflated and the back surface lubricated. Propofol 2 mg/kg were administered as induction agents, and vecuronium 0.1 mg/kg given to facilitate Pro Seal LMA insertion.

Group 1: Whom the bougie-guided technique used, the drain tube of the Pro Seal LMA was primed with a lubricated 16 f gum elastic bougie with its straight end protruding 30 cm beyond the drain tube and the bent portion protruding from the proximal end. Under laryngoscopic guidance, the distal portion of the bougie was placed 5-10 cm into the oesophagus. The laryngoscope was removed and the ProSeal LMA was inserted using the digital insertion technique with bougie as guide and the bougie was removed while the Pro Seal LMA was held in position.

Group 2: In this group, the Pro Seal LMA was inserted using the metal introducer according to the manufacturer’s instructions: the patient’s
mouth was opened and the lubricated Pro Seal LMA was inserted into the patient’s mouth using
the introducer; the Pro Seal LMA was advanced using a one-handed technique until resistance was
encountered; and the introducer was removed, leaving the Pro Seal in position.

Once the Pro Seal LMA was inserted into the pharynx, the cuff was inflated with air until
effective ventilation was established or the maximum recommended inflation volume was
reached. Ventilation was judged to be optimal if the following four test passed-Bilateral adequate
chest movement, Stable oxygenation not less than 95%, Square wave capnography and normal range
dish pressure and SpO2 before and after insertion and complications like laryngospasm, coughing, were
recorded at the end of operation after attaining adequate recovery from anaesthesia. The Proseal
LMA was removed .and the device as checked for any evidence of trauma by looking for blood
staining on the device. Postoperative sore throat, dysphagia and dysphonia were recorded in the
postoperative care unit. Data were analyzed using computer software, statistical package for social
science version 10.

**Observation and Results**

Of the 100 patients studied, the statistical analysis showed that the two groups – Pro Seal LMA
insertion by bougie guided technique and insertion by introducer technique were comparable in
terms of patient characteristics such as age, gender, weight, comorbid conditions and ASA
status.

**Table 1: Comparison of Mallampatti class based on groups**

<table>
<thead>
<tr>
<th>MPC</th>
<th>Group 1</th>
<th>Group 2</th>
<th>( \chi^2 )</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Count</td>
<td>Percent</td>
<td>Count</td>
<td>Percent</td>
</tr>
<tr>
<td>I</td>
<td>22</td>
<td>44.0</td>
<td>5</td>
<td>10.0</td>
</tr>
<tr>
<td>II</td>
<td>22</td>
<td>44.0</td>
<td>35</td>
<td>70.0</td>
</tr>
<tr>
<td>III</td>
<td>6</td>
<td>12.0</td>
<td>10</td>
<td>20.0</td>
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</tbody>
</table>

The distribution of patients according to Mallampatti classification was different. Most
patients of the introducer guided group belonged to MPC II. This difference is significant
statistically using Mannwhitney U test. No MPC IV patients were taken up for this study.

Two groups were comparable based on the thyromental distance and there is no significant
difference measured by Fisher Exact test. Mouth opening among the two groups were comparable
and there is no significance statistically as measured by Fisher Exact test. Based on the
weight and the physical characteristics the size of the device was selected. Pro seal LMA size 4 was
used in 56% of patients with bougie guided insertion and in70% patient’s introducer guided
insertion.
The first attempt success rate is high in bougie guided insertion of Proseal LMA (98 vs 86%). The difference between both the groups regarding first attempt success rate was significant statistically \( p< .05 \). No patients more than two attempts for successful placement.

The effective airway time was longer in patient with bougie guided insertion of Proseal LMA compare to introducer guided insertion (35+/- 5.9 vs 23.4 +/- 8.8). The difference between two groups was significant statistically.

Heart rate, mean arterial pressure and mean \( \text{SpO}_2 \) were comparable in both groups over the three phases and not significant statistically.
it was found that the difference was not statistically significant. Dysphagia was seen in 20% patient in bougie guided insertion where as it was not seen introducer guided insertion. Using Fisher Exact test it was found that it was statistically significant.

Discussion
There were no significant difference between groups with respect to the demographic data. Of the 100 patients studied the percentage of patients in each age group was comparable. The percentage of patients of gender in each group was comparable even though the sex ratio favours male sex. Using Fisher Exact test it was found that the difference was not statistically significant.

Airway assessment data
In our study the distribution of patients according to mallampatti classification was different. 70% of the introducer guided group below to MPC II. This difference is statistically significant. But this is contrary to previous studies[12], which showed that ease of insertion of LMA does not correlate with Mallampatti class. Macroy and Moriari[13] showed that LMA positioning was related to Mallampatti class. But the sample size was low as in our study. Composite data from 2000 patients suggest that LMA insertion is not affected by Mallampatti class in the hands of experienced LMA users [14].

The two study groups were comparable based on the thyromental distance (56% of the patients of bougie guided group and 70% of the introducer guided had thyromental distance >6.5 cm ; rest 45% in bougie guided had thyromental distance <= 6.5 cm ). The result is not statistically significant. Mouth opening among the two groups were comparable. [70% patients had mouth opening >6cm and 30% had mouth opening between 4-6 cm ;(P>0.05.). The result is insignificant. Based on weight and physical characteristics the size of the Pro Seal LMA was selected. Pro Seal LMA size 4 was used in 56% of patients with bougie guided insertion while in 70% patients with introducer guided insertion uses Pro Seal LMA size 4. this bears no particular effect on the outcome and is therefore statistically insignificant.(P>0.05). Kihara et al[15] found that size selection for the ProSeal LMA was equally effective using the manufacturer’s weight based formula, in terms of ease of insertion.

First attempt success rate
In our study we found that the first attempt success rate was high in bougie guided insertion of PLMA (98% vs 86%). The difference between both groups regarding first attempt success rate is statistically significant (P<0.05). The overall success rate is equal in both groups. No patient required more than two attempts for successful placement. These findings in our study is similarly reflected in the reports by Anitha Nileshwar et al[16] who compared bougie guided insertion and introducer tool technique. The success rate for insertion of Pro Seal LMA at first attempt was higher in gum elastic bougie guided group (96%vs 80%) , although overall success was similar in both groups. Martinez Pons et al [17] also discovered the ease of placement of PLMA with a gastric tube inserted. They found that easier insertion of PLMA if the drain tube is primed with an 18 G gastric tube prior to Pro Seal LMA insertion .they also found that the first attempt success rate improves from 91%-100%. Anand Kuppuswamyetal[18] compared digital technique and bougie guided insertion of ProSeal LMA and found that 96.7% patients in first attempt and Pro Seal LMA with digital technique was successful in 86.7%. These were comparable to other studies[19, 20,21].

Effective Airway Time
In our study we found that the Effective airway time is longer in patients bougie guided insertion and introducer guided insertion. The difference between the two groups was statistically significant. Similar findings were observed in various studies[13,16,18,21].

In our study we found that the effective airway time was longer in patients with bougie guided insertion compared to introducer guided insertion (35+/−5.9 seconds vs 23.4+/−8.8seconds). The
difference between two group was statistically significant. Similar to our study various other studies also found that the mean airway insertion time was longer with bougie guided insertion than with the introducer tool guided insertion of Pro Seal LMA.\textsuperscript{[16,18,19]}

**Haemodynamic parameters**

Both insertion technique of Pro Seal LMA are comparable with respect to the haemodynamic parameters. The mean pulse rate and mean arterial pressure shows no significant change in two insertion technique. Other studies also showed no statistical difference in haemodynamic response to ProSeal LMA insertion by digital, bougie guided insertion or introducer guided insertion.\textsuperscript{[18,19,22-24]}

**Complications**

In our study we found that the overall complications in both groups were comparable and statistically insignificant. Comparing individual complications, blood staining on the device and sore throat are although common in introducer guided group it is not statistically significant. Coughing was more in bougie guided group. Using Fishers exact test it was found that the difference is not statistically significant. Dysphagia was seen in 20% of patients bougie guided insertion. It is not associated with introducer guided insertion. Using Fishers exact test it was found that the difference is statistically significant.

Anand Kuppusamy\textsuperscript{[18]} in a study comparing bougie guided insertion of Pro Seal LMA vs digital insertion found that the incidence of blood staining of Pro Seal LMA was same in both groups. Sore throat occurred in 10% patients in digital technique, while it was not noted in GEB technique. But the difference was not statistically significant. Teoh C Y et al.\textsuperscript{[25]} compared introducer tool and bougie guided insertion in children and found that the frequency of airway related problems were similar in both groups.

In our study there was no episode of hypoxia noted in the intra operative period. The mean SpO2 was comparable and was statistically insignificant.

The first attempt success rate was higher with Gum Elastic Bougie technique than introducer Tool technique. Several studies conducted on adult and paediatric patients confirm this finding.\textsuperscript{[10,19,23]} The higher first attempt success rate with GEB technique is due to the fact that it reduces the impaction at the back of the mouth, prevents folding over of distal cuff and guides the distal cuff directly in to its correct position in the hypopharynx when Pro Seal LMA is primed with Gum Elastic Bougie. The effective airway time was longer with Gum Elastic Bougie-guided insertion than introducer tool technique in our study. This is in concurrence with the studies conducted in adult and paediatric patients.\textsuperscript{[23]} Effective airway time was Longer with GEB-guided technique because of increased time needed for laryngoscopy and Gum Elastic Bougie placement.

**Conclusion**

Our study of two insertion techniques of Pro Seal LMA, bougie guided vs introducer guided during general anaesthesia showed that the bougie guided insertion was associated with significantly higher first attempt success rate and was much easier to insert with fewer manipulations. Though bougie-guided insertions of Pro Seal LMA took longer time, it had less number of failed insertions. Gum Elastic Bougie guided, laryngoscope aided insertion of Pro Seal LMA is an excellent alternative to other insertion techniques in adults.

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