Comparison of bougie-guided insertion technique of proseal laryngeal mask airway with digital technique in adults undergoing general surgery

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DOI: https://doi.org/10.33545/26643766.2019.v2.i2b.41

Abstract
Among the techniques used for Proseal LMA placement, we compared digital technique with bougie guided technique in terms of effective airway time, number of attempts required, hemodynamic response and complications. This prospective randomised comparative study included 60 ASA I/II patients who were divided in two groups as group A (digital technique) and group B (bougie guided insertion). The effective airway time was 35.17+/–15.54 seconds in group A vs 46.40+/–9.23 seconds in group B, p value <0.01. The first attempt successful placement was more in group B (93.3%) vs Group A (70 %). The hemodynamic response was comparable in both groups, except post induction 1 min value. The effective airway time was less in group A and first attempt successful insertion rate was more in group B. The complications were less with bougie guided technique.

Keywords: proseal lma, digital technique, bougie guided insertion technique

1. Introduction
The laryngeal mask airway (LMA) is a landmark airway device invented by Sir Archie Brain [1, 2, 3] in 2000. The Proseal laryngeal mask airway (PLMA) [4, 5] is specialized LMA with modified cuff to improve seal around the glottis and the drain tube to enhance scope and safety of the device during ventilation. It comes with a silicone coated malleable metal introducer (the distal end of which fits into the locating strap and the proximal end fits into the airway tube) to facilitate placement of LMA. Folding of the cuff is seen in 10-11% of the cases using the introducer tool [6]. PLMA insertion using the standard techniques can lead to folding of the cuff, impaction at the back of mouth, distal cuff not able to reach hypopharynx and thus resulting in inadequate ventilation [7]. The techniques available for placement are (i) introducer method (ii) digital method and (iii) guided method. Some modifications like thumb placement, lateral approach, introducer tool placement, gum elastic bougie guided placement were introduced for proper placement of the device. Sheila N [6] used Rusch Stylet in the drain tube. Kadirehally B [7] compared the digital technique with PLMA insertion using 90 degrees anticlockwise rotation and using gentle pharyngoscopy and concluded that pharyngoscopy technique is more successful with less complications.

This study was conducted to compare the classical digital placement technique of PLMA with bougie guided placement technique in terms of effective airway time, number of attempts required, hemodynamic response and complication rates.

1.1 Aims and Objectives
To compare bougie guided insertion technique of PLMA with digital insertion technique in adults undergoing general surgery using PLMA as an airway device

Primary Objective
- Effective airway time (time required from picking up the laryngoscope/ Proseal LMA to confirmation of adequate ventilation)

Secondary Objective
- Number of attempts required for successful placement of PLMA
- Hemodynamic response to insertion of PLMA
- Early complications like airway trauma, blood staining on PLMA / Laryngoscope / Bougie and gastric distension
- Delayed complication like sore throat, dysphonia and dysphagia.
2. Materials and Methods
This prospective randomized comparative study was done in a tertiary care hospital. The sample size was calculated as 60 in each group taking significance level (alpha α error) as 5% and power of the study (1−β) as 80%.

The patients were recruited in two groups
Group A (digital technique) and Group B (Bougie guided) using computer allocated random sequence.

Patients 18 to 60 years of age, either sex, ASA I and II posted for general surgery using PLMA as an airway device were included in the study. Patients who refused to consent for the study, those with increased risk of aspiration and those with anticipated difficult airway were excluded from the study.

After Institutional Ethics Committee approval, the patients who fulfilled inclusion and exclusion criteria and who gave valid informed consent were recruited in the study.

After securing intra venous access and attaching standard monitors, anesthesia induction was done.

Patients were pre-mediated with Inj. Ondensetron 0.1 mg IV & Inj. Ramitidine 50 mg IV. Patients received Inj. Midazolam 0.03 mg / kg IV and Inj. Fentanyl 2 mcg/kg IV and were induced with Inj. Propofol (2 mg/kg) and Vecuronium (0.1 mg/kg). Three minutes later sniffing position was given and Proseal LMA was inserted by digital/bougie-guided technique as per the study group.

Group A - Digital technique
Proseal LMA was selected as per body weight chart. After well lubricating the cuff, the Proseal LMA was held like a pen as near as possible towards the mask end. Using the index finger, the PLMA was glided along the hard palate into the pharynx, gently pushed to ensure the mask is fully inserted and then inflated with recommended volume of air.

Group B - Bougie guided insertion
The Proseal LMA drain tube was primed with well lubricated 16F bougie with straight end protruding 30 cm beyond drain tube. Under laryngoscopic guidance, distal portion of GEB was placed 5 to 10 cm into the oesophagus. The laryngoscope was removed and PLMA was inserted using digital technique, while an assistant stabilized the proximal end of the bougie. The bougie was removed while PLMA was held in position. Inflated with recommended volume of air.

After placement of Proseal LMA, confirmation was done by auscultation of air entry on both sides of chest, EtCO2 graph on monitor and no audible air leak over oropharynx.

Three attempts were allowed before insertion to be considered as failure. In the event of a failed insertion of Proseal LMA after three attempts, patient was intubated with an endotracheal tube and surgery was allowed to proceed.

The effective airway time (time required from picking up the laryngoscope/Proseal LMA to confirmation of adequate ventilation) was recorded. When insertion was successful, cuff was inflated as per manufacturer’s guidelines. Pulse, blood pressure (mean arterial pressure) were recorded prior to insertion and at one, five, ten minutes intervals after insertion. Anaesthesia was maintained with oxygen, nitrous oxide and Isoflurane. At the end of procedure, patients were reversed with Inj. Neostigmine (0.05mg/kg) and Inj. Glycopyrrolate (0.08mg/kg). After complete reversal of neuromuscular blockade was achieved, Proseal LMA was removed once recovery criteria were met. Event complication like any visible blood staining on PLMA, laryngoscope and bougie were noted down. Mouth, lips, tongue were inspected for any evidence of trauma. Patients were interviewed 24 hours postoperatively regarding late onset complication like sore throat (constant throat pain even without swallowing), dysphonia (difficulty or pain on speaking), dysphagia (difficulty or pain on swallowing).

Statistical Analysis
The statistical analysis was done using unpaired t test. Man Whitney U test and Chi square test. A p value of <0.05 was considered as stastically significant. All statistical calculations were done using computer programs Microsoft Excel version 7 (Microsoft Corporation, NY, USA) and SPSS software version 21.0

3. Results
The demographic data was comparable in both the groups (Table 1).

In bougie guided group, successful placement was seen in single attempt in 93.3% patients compared to 70% in digital insertion group. Second and third attempts were required in 6.7% & 0% in bougie guided group as compared to 26.7% & 3.3% in digital group (Table 2).

Mean effective airway time for successful placement of PLMA was significantly more in bougie guided insertion group as compared to digital insertion group (46.4 vs 35.17 sec.; p<0.01) (Table 2).

Mean heart rate was comparable in both groups except 1min after post induction (p<0.05). Post Induction mean arterial pressure was significantly higher in bougie guided insertion group as compared to digital insertion group (p<0.05) while it was comparable in all other instances (p>0.05). (Table 3)

Mean oxygen saturation and mean end tidal CO2 concentration were comparable among both groups (p>0.05) (Table 3).

Incidence of blood staining on PLMA was more in digital insertion group (16.7%) as compared to bougie guided insertion group (3.3%). However the difference was statistically non-significant (p>0.19). Incidence of blood staining on laryngoscope was observed in 3 patients (10%) in bougie guided insertion group (Table 3).

Incidence of trauma to lip was observed in 4 patients (13.3%) in bougie guided insertion group as compared to none in digital insertion group (0%) while trauma to mouth was seen in 3 (10%) and 4 (13.3%) patients respectively. The difference was statistically non-significant with respect to incidence of trauma among both groups (p>0.05).

Incidence of sore throat was significantly associated with digital insertion (46.7% vs 6.7%; p<0.01) while more number of patients complained of dysphagia in bougie guided insertion group (6.7% vs 0%; p<0.01) (Table 3).

Table 1: Demographic data of the patient

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Group A (n=60)</th>
<th>Group B (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>44.63</td>
<td>42.97</td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>60.07</td>
<td>59.07</td>
</tr>
<tr>
<td>Sex(Male/Female)</td>
<td>15/15</td>
<td>19/11</td>
</tr>
<tr>
<td>ASA (I/II)</td>
<td>19/11</td>
<td>21/9</td>
</tr>
</tbody>
</table>
Table 2: Proseal LMA Insertion results

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>Total</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion Success</td>
<td></td>
<td></td>
<td></td>
<td>0.061</td>
</tr>
<tr>
<td>First attempt</td>
<td>21(70.0%)</td>
<td>28(93.3%)</td>
<td>49(81.7%)</td>
<td></td>
</tr>
<tr>
<td>Second attempt</td>
<td>8(26.7%)</td>
<td>2(6.7%)</td>
<td>10(16.7%)</td>
<td></td>
</tr>
<tr>
<td>Third attempt</td>
<td>1(3.3%)</td>
<td>0(0.0%)</td>
<td>1(1.7%)</td>
<td></td>
</tr>
<tr>
<td>Effective airway time</td>
<td>35.17 +/-15.54</td>
<td>46.40 +/-9.23</td>
<td>&lt;0.01</td>
<td></td>
</tr>
</tbody>
</table>

Complications

- Visible blood on PLMA (Yes/No): 5/25 | 1/29 | 6/54 (10.0%) | 0.19
- Visible blood on laryngoscope (Yes/No): 0/30 | 3/27 | 3/57 (5.0%) | NA

Trauma to

- Tongue: 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | NA
- Lip: 0 (0.0%) | 4 (6.7%) | 4 (6.7%) | 0.112
- Mouth: 4 (13.3%) | 3 (10.0%) | 7 (11.7%) | 1.0
- Gastric distension: 9 (30.0%) | 0 (0.0%) | 9 (11.7%) | <0.01
- Sore throat: 14 (46.7%) | 2 (6.7%) | 16 (26.7%) | <0.01
- Dysphonia / Dysphagia: 0 (0.0%) | 4 (6.7%) | 4 (6.7%) | 0.49

Table 3: Hemodynamic variables

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group</th>
<th>Pre Induction</th>
<th>Post induction (1 min)</th>
<th>Post induction (5 min)</th>
<th>Post induction (10 min)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Rate</td>
<td>A</td>
<td>73.80 +/-9.46</td>
<td>89.87 +/-8.85</td>
<td>82.87 +/-8.17</td>
<td>77.83 +/-9.17</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>72.77 +/-5.52</td>
<td>94.57 +/-8.75</td>
<td>85.70 +/-6.96</td>
<td>78.77 +/-5.06</td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td></td>
<td>0.607</td>
<td>&gt;0.01</td>
<td>0.132</td>
<td>0.823</td>
<td></td>
</tr>
<tr>
<td>Mean Arterial Pressure (MAP)</td>
<td>A</td>
<td>72.83 +/-6.36</td>
<td>91.40 +/-8.66</td>
<td>88.57 +/-8.11</td>
<td>86.53 +/-7.66</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>71.93 +/-5.90</td>
<td>100.03 +/-8.74</td>
<td>93.77 +/-8.24</td>
<td>89.13 +/-8.97</td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td></td>
<td>0.572</td>
<td>&gt;0.01</td>
<td>0.21</td>
<td>0.132</td>
<td></td>
</tr>
<tr>
<td>Spo2</td>
<td>A</td>
<td>99.30 +/-0.65</td>
<td>99.47 +/-0.51</td>
<td>99.67 +/-0.48</td>
<td>99.77 +/-0.43</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>99.23 +/-0.68</td>
<td>99.83 +/-0.38</td>
<td>99.93 +/-0.25</td>
<td>99.87 +/-0.35</td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td></td>
<td>0.599</td>
<td>&gt;0.01</td>
<td>0.234</td>
<td>0.325</td>
<td></td>
</tr>
<tr>
<td>EtCO2</td>
<td>A</td>
<td>31.60 +/-3.76</td>
<td>38.77 +/-2.81</td>
<td>38.00 +/-3.07</td>
<td>37.57 +/-2.79</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>31.60 +/-3.34</td>
<td>39.77 +/-3.10</td>
<td>37.83 +/-2.63</td>
<td>37.80 +/-2.54</td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td></td>
<td>1.0</td>
<td>0.196</td>
<td>0.822</td>
<td>0.736</td>
<td></td>
</tr>
</tbody>
</table>

Fig 1: Line diagram showing study variables at various time points

~ 147 ~
4. Discussion

PLMA has been designed to enable better ventilation and reduce the risk of aspiration when it is properly placed. Some studies have been conducted earlier comparing various insertion techniques. We compared the bougie guided technique with digital technique with respect to effective airway time, hemodynamic response and the associated complications. It was found that the effective airway time was more in the bougie guided group, which could have been due to laryngoscopy done in that group, Saini S et al. Kuppuswamy et al. Lopez et al. noted similar findings. Comparable insertion time were noted by Brimacombe et al. Tanega et al. and Howarth et al. Successful placement of PLMA was achieved in 93.3% in bougie guided group as compared to 70% in digital group. When digital technique is used there is less space for index finger to maneuver because of large cuff of PLMA, whereas bougie guided insertion facilitate circumnavigation of oropharyngeal inlet and there are less chances of folding of PLMA. Howarth was the first one to suggest it's use for PLMA placement. We found similar results as earlier studies for success rate of insertion. Studies by Saini, Eschertzhuber et al. Tanega et al. Brimacombe et al. found bougie guided technique more successful than digital technique. The heart rate and blood pressure was higher in bougie guided group one min after induction which can be attributed to pressor response to laryngoscopy. Other parameters like O2 saturation and end tidal CO2 were comparable in both the group. Jung K et al. observed stress response for laryngoscopic guided insertion, however other authors didn't find much difference in hemodynamic parameters. In our study we found incidence of blood staining more in digital group however the difference was statistically non-significant. Earlier studies show similar results. The incidence of trauma to lip/mouth/tongue was more in bougie guided group whereas gastric detention was more in digital group. Lopez-Gil et al. found similar results. Brimacombe et al. suggested that special bougie with atraumatic distal end should be designed for PLMA placement. The incidence of sore throat was more in digital group whereas dysphagia was seen more in bougie guided group. Kuppuswamy et al. observed similar findings. Howarth et al. noted sore throat, dysphagia and dysarthria in 21%, 9% and 1% respectively in digital group. Evans et al. noted this in 23% of patients immediately after surgery and 16% of patient’s 24hours postoperatively.

5. Conclusion

We thus conclude that bougie guided PLMA insertion has higher first attempt success rate in comparison to digital technique and can be used as a backup technique after failure of digital technique. It can be used as a primary technique in cases of failed intubation. The main disadvantage of this technique is that it requires laryngoscopy and may cause esophageal trauma.

Limitations

Our study had few limitations. First, the study was partially double-blinded as the intraoperative data was collected by unblinded observers but the postoperative data was collected by blinded observers. Secondly, we did not confirm PLMA placement by fibreoptic bronchoscopy. Finally all insertions were carried out by experienced persons to avoid learners curve so it is difficult to comment on success by novice.

References

1. Brain AJI. Working Journal of Archie Brain Extract


