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**ABSTRACT**

Background: ProSeal Laryngeal mask airway (ProSeal™ LMA) is an advanced supraglottic airway device which has an additional port for gastric succioning. We conducted a Comparative study of two techniques of insertion of ProSeal™ LMA in children. Digital technique of insertion compared with Bougie Guided Technique of insertion.

Method: Eighty children (ASA 1–II, aged 1–16 yr) were randomly allocated for ProSeal™ LMA insertion using the digital or bougie-guided technique. The digital technique was performed according to the manufacturer's instructions. The bougie-guided technique involved priming the drain tube with a bougie, placing the bougie in the oesophagus under direct vision and railroading the ProSeal™ LMA into position. Data were collected about the ease of insertion (number of attempts and time taken to provide an effective airway), ease of gastric tube placement, haemodynamic responses, blood staining and post operative airway morbidity.

Results: In bougie guided technique, there were changes in heart rate (12 vs 5, \( P<0.0001 \)), changes in blood pressure was more (11 mg Hg vs 6 mm Hg, \( P=0.0001 \)) and effective airway time was longer (48 vs 32 s, \( P=0.0001 \)). There were no differences between groups regarding success rate of insertion, ease of gastric tube placement, bloodstaining, and postoperative airway morbidity.

Conclusion: To conclude, the digital technique of ProSeal™ LMA insertion has similar characteristics compared with the bougie guided insertion in children, but the digital technique has more stable hemodynamics compared with the bougie guided technique. The effective airway time is more in bougie guided technique compared with digital technique. The success rate of LMA insertion, success rate of gastric tube placement, incidence of trauma and postoperative airway morbidity are similar in both digital technique group and bougie guided group.

**INTRODUCTION**

The ProSeal laryngeal mask airway (ProSeal LMA)\(^1\)\(^,\)\(^2\) is an advanced supraglottic airway device with a drain tube to prevent aspiration and gastric insufflation. The paediatric ProSeal LMA (PLMA) lacks the dorsal cuff.\(^4\) The PLMA available sizes are 1, 1.5, 2 and 2.5.

In the following prospective randomized study, we have done a comparative study of Digital technique with bougie guided technique of insertion of ProSeal™ LMA in children. The parameters like success rate of insertion, hemodynamic parameters like heart rate and blood pressure, effective airway time, ease of gastric tube placement, blood staining and postoperative airway morbidity were compared.

**MATERIALS AND METHODS**

After obtaining approval from hospital ethics committee and written informed consent from patients, the study was conducted at the Government Villupuram Medical College Hospital. 80 children belonging to physical status of ASA Grades I and II scheduled for minor procedures duration < 30 min were included for study. Children who had difficult airway, abnormal airway anatomy, head and neck surgeries, who were at risk of aspiration were excluded from the study. Patients were fasted for at least 6 h for solids and 4 h for liquids.

Premedication was with i.v. Glycopyrrolate 0.004 mg/kg, and i.v. Ondansetron 0.1 mg/kg 5 min prior to induction of anaesthesia. A standard anaesthesia protocol was followed and routine intraoperative monitoring applied, including pulse oximeter, noninvasive blood pressure monitor, Etco2 monitor and precordial stethoscope. Preoxygenation with 100 % O2 done for 5 min. Patients underwent intravenous induction with propofol 3 mg/kg. Following induction, mask ventilation was performed until conditions suitable for ProSeal™ LMA insertion [apnoea and lack of response to jaw thrust] were obtained. The sizes 2 and 2.5 were used in children weighing 10-20 kg and 20-30 kg respectively. Maintenance of anaesthesia was with oxygen, nitrous oxide and 1% sevoflurane. Muscle relaxation was maintained with intermittent doses of inj. atracurium 0.1 mg/kg. At the end of the procedure i.v. glycopyrrolate 0.004 mg/kg followed by i.v. neostigmine 0.05 mg/kg for adequate reversal of residual neuromuscular blockade was given. After adequate oral succioning ProSeal™ LMA was removed. Standard postoperative monitoring and care was given. Post operative analgesia was given with paracetamol rectal suppositories 20 mg/kg 6 hourly for 24 hrs.

Total number of children studied was 80, they were divided into two groups Group D digital technique 40 and Group B bougie guided technique 40. The digital insertion technique of insertion involved the use of the index finger to press the ProSeal™ LMA into and advance it around, then palatopharyngeal curve\(^ 3\). For the bougie-guided technique, the drain tube of the ProSeal™ LMA was primed with a lubricated bougie 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 for the anaesthesiologist to manipulate. The bougie guided technique involved the following steps:

1) With the aid of a laryngoscope, the distal portion of the bougie was placed 5 cm in to the oesophagus while the assistant held the ProSeal™ LMA and proximal portion
2) laryngoscope was removed and The ProSeal™ LMA was inserted using the digital technique while the assistant stabilized the proximal end of the bougie so it did not penetrate further into the oesophagus
3) The bougie was removed while the ProSeal™ LMA was held in position\(^ 4\).

All techniques were performed in the sniffing position with the cuff fully deflated and using a midline or slight lateral approach. Once the ProSeal™ LMA was inserted into the pharynx the cuff fully was inflated with air until effective ventilation was established or the maximum recommended inflation volume (size 2-10 ml, size 2.5 14 ml). A well lubricated 60 cm long gastric tube (10 F for size 2, 12 F for size 2.5) was inserted through the drain tube if there was no air leak up to the drain tube. Correct gastric tube placement was assessed by suction of fluid or detection of injected air by epigastric stethoscope.\(^ 3\) Three attempts of ProSeal™ LMA insertion were allowed before insertion was considered a failure. Failed insertion was defined by any of the following criteria (i) oropharyngeal impaction (failed passage into the pharynx); (ii) laryngeal impaction (airway obstruction, mid–portion of the bougie); (iii) mechanical airway obstruction (airway obstruction, mid–portion of the bougie); (iv) reflex airway obstruction (airway obstruction, mid–portion of the bougie); (v) folding over of the bougie; (vi) inadequate seal (clear airway, mid–portion of bile block between teeth, low airway pressure oropharyngeal air leaks).

One person was assigned for doing procedure, second person was...
assigned for anesthesia monitoring and the third person was assigned for observing the parameters. The time between picking up the laryngoscope or prepared ProSeal™ LMA (cuff deflated, lubricated, guide attached) and successful placement was recorded. The effective airway time was noted for all cases. The etiology of failed insertion was documented if insertion failed after three attempts a single attempt of alternative technique was perenmitted. In all cases endotracheal intubation was to be used as rescue technique of securing the airway. Heart rate and MAP were recorded one minute before and after insertion. Any episodes of hypoxia or other adverse events were documented.

Ability to pass a gastric tube through the gastric port was noted and the number of attempts were recorded. Any visible blood staining on the guide, laryngoscope, or proeseal LMA was noted at removal. The mouth, lips and tongue were inspected for evidence of trauma. Patients and parents underwent a structured investigation 8-24 hrs after surgery. Patients, parents were asked about sore throat, dysphonia and dysphagia are recorded.

RESULTS and DISCUSSION
The collected data are tabulated and compared. Data are given as mean (SD) or absolute numbers. NS, not significant

<table>
<thead>
<tr>
<th>Technique</th>
<th>Digital (40)</th>
<th>Bougie-guided(40)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effective airway time(s)</td>
<td>31.83(7.07;24-55)</td>
<td>48.88( 6.75;34-60)</td>
<td>P&lt;0.0001</td>
</tr>
<tr>
<td>Attempts :1/2/3(n)</td>
<td>59/1/0</td>
<td>40/0/0</td>
<td>NS</td>
</tr>
<tr>
<td>Gastric tube insertion attempts :1/2/3(n)</td>
<td>36/4</td>
<td>36/4</td>
<td>NS</td>
</tr>
</tbody>
</table>

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<tr>
<th>Haemodynamic variables</th>
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<tbody>
<tr>
<td>MAP pre-insertion (mmHg)</td>
<td>76.08 (4.25)</td>
<td>75 (5.17)</td>
<td>NS</td>
</tr>
<tr>
<td>MAP post insertion (mmHg)</td>
<td>82.65 (5.44)</td>
<td>86.23 (5.5)</td>
<td>Significant</td>
</tr>
<tr>
<td>HR pre insertion (beats / min)</td>
<td>100 (9.1)</td>
<td>97.8 (7.9)</td>
<td>NS</td>
</tr>
<tr>
<td>HR post –insertion (beats/min)</td>
<td>104.9 (9.2)</td>
<td>109.9 (7.1)</td>
<td>significant</td>
</tr>
<tr>
<td>Blood staining ProSeal™ LMA</td>
<td>1/39</td>
<td>4/36</td>
<td>NS</td>
</tr>
<tr>
<td>Gastric tube</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
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<tr>
<th>Airway morbidity</th>
<th></th>
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<tbody>
<tr>
<td>Dysphonia</td>
<td>0/0/0</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>2/0/0</td>
</tr>
<tr>
<td>Sore throat</td>
<td>1/0/0</td>
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</tbody>
</table>

Success rate of insertion
The first attempt success rate was comparable for the digital technique with the bougie guided technique of insertion of ProSeal™ LMA. Obtaining an effective airway took a longer time with the bougie guided technique. Our study findings regarding the success and easy of insertion was similar to a cohort evaluation of the PLMA in 100 children 1 in which they concluded that even without prior experience and using unconventional insertion, pediatric PLMAs (including size 1.5) can be easily inserted and provide an effective airway. Effective Airway Time is defined by the time between picking up the laryngoscope or prepared ProSeal™ LMA [cuff deflated,lubricated, guide attached] and successful placement and effective ventilation. The effective airway time was 32 seconds with digital technique compared with 48 seconds in bougie guided technique. The additional 16s is clinically and statistically significant. In our study the effective airway time was prolonged in bougie guided group 12’s more than that occurred in previous study done by Brimacombe J in 2004.

Incidence Of Trauma
Any visible blood staining on the guide, laryngoscope or ProSeal™ LMA was noted at removal. The mouth, lips and tongue were inspected for evidence of trauma. There was of 4 cases of trauma inbougie guided technique. Our study findings regarding the success and easy of insertion was similar to a cohort evaluation of the PLMA in 100 children 1 in which they concluded that even without prior experience and using unconventional insertion, pediatric PLMAs (including size 1.5) can be easily inserted and provide an effective airway. Effective Airway Time is defined by the time between picking up the laryngoscope or prepared ProSeal™ LMA [cuff deflated,lubricated, guide attached] and successful placement and effective ventilation. The effective airway time was 32 seconds with digital technique compared with 48 seconds in bougie guided technique. The additional 16s is clinically and statistically significant. In our study the effective airway time was prolonged in bougie guided group 12’s more than that occurred in previous study done by Brimacombe J in 2004.

Gastric Tube Placement
A well lubricated 60 cm long gastric tube [10 F for size 2, 12 F for size 2.5] was inserted through the drain tube if there was no air leak up to the drain tube. The success rate of 90 % for gastric tube insertion is same in both digital guided technique group and bougie guided technique group. The main cause of failure is high coefficient of friction between silicone in gastric tube and plastic tube [gastric tube]. This finding was similar to the previous study.2

Haemodynamic Changes
Heart rate and MAP were recorded one minute before and after insertion in both groups. Regarding the hemodynamic changes there was a 12% change in post insertion heart rate bougie guided technique compared to 5% change in digital technique group was clinically and statistically significant. Regarding the MAP there was a 15% change in post insertion MAP in bougie guided technique compared to 8% change in digital technique which shows significant hemodynamic responses in bougie guided technique. The increase in establishment of effective airway time can explain the increased hemodynamic responses in bougie guided technique.

Postoperative Airway Morbidity
Patients/parents were asked about sore throat [constant pain/ independent of swallowing, dysphonia [difficulty/pain during speaking] and dysphagia [difficulty/pain on swallowing] and recorded. Regarding the postoperative airway morbidity there was 1 case of airway morbidity in digital group compared with 4 cases in bougie guided group which is clinically and statistically significant. This finding was similar to the previous study.3 The major advantage of digital technique is the lesser hemodynamic responses when compared to bougie guided technique. The disadvantage of bougie guided technique is the increased haemodynamic responses when compared to digital technique and the statistically significant delay of 16 seconds delay in effective airway time. Avoiding force during insertion of laryngoscope and passage of the bougie reduces the risk of trauma but increases the effective airway time. Adequate lubrication of Ryles tube increases the success rate of gastric tube placement. Adverse Respiratory Events: No patients in any of the groups had any adverse respiratory event like episodes of hypoxia [sp02< 90%] or laryngospasm.

Conclusion
We conclude that the digital technique of ProSeal™ LMA insertion has equal success rate compared with the bougie guided insertion in children. The effective airway time is longer in case of bougie guided insertion. The digital technique of bougieguided insertion has more stable hemodynamics compared with the bougieguided insertion. The incidence of trauma, gastric tube placement and post operative airway morbidity are similar in both digital technique of insertion and bougie guided ProSeal™ LMA insertion in children.

References
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