Suction Catheter-Guided Technique of ProSeal™ Laryngeal Mask Airway Insertion has a Lower Incidence of Trauma and Sore Throat Compared With a Standard Introducer Tool: A Randomized Controlled Trial

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ProSeal laryngeal mask airway (PLMA) insertion is often difficult. Suction catheter-guided PLMA insertion was compared with the standard introducer tool-assisted technique. One hundred sixty female patients undergoing laparoscopic gynecologic procedures under general anesthesia were randomized into two groups—the suction catheter group (Group SC) and the introducer tool group (Group IT). First-attempt success rate, insertion time, manipulation required, incidence of trauma, and incidence and severity of throat discomfort were compared. PLMA was inserted successfully in the first attempt in 72 of 80 patients in Group SC and in 67 of 80 patients in Group IT ($P = .241$). Time for successful insertion was $17.31 \pm 6.50$ seconds in Group SC and $22.65 \pm 7.17$ seconds in Group IT ($P = .001$). Manipulation to get a proper fit was required in 9 of 80 patients in Group SC compared with 19 of 80 patients in Group IT ($P = .037$). Minor airway trauma was noted in 11% of patients in Group SC and 28% of patients in Group IT ($P = .001$). The incidence and severity of sore throat was significantly lower with the suction catheter than with the introducer tool. Suction catheter-guided PLMA insertion requires less time, fewer manipulations, and results in lower incidence and severity of sore throat than with the introducer tool. Both techniques have a similar first-attempt success rate.

Keywords: Introducer tool, laryngeal mask airway, ProSeal LMA, suction catheter

The ProSealTM laryngeal mask airway (PLMA) is a second-generation supraglottic device. Its additional features include a gastric drain tube that allows gastric decompression, and a dorsal cuff that improves the pharyngeal seal. The standard insertion techniques recommended by the manufacturer include using a curved metal introducer tool or by digital manipulation. However, even with the use of the introducer tool, the large, pliable cuff of the PLMA tends to fold on itself during insertion.$^1$ This often results in the need for multiple insertion attempts and may sometimes lead to airway trauma.

Several alternative techniques have been described to aid successful PLMA insertion and include the use of a gum elastic bougie,$^2$ intubation stylet,$^3$ and suction catheter.$^4$ The suction catheter is an attractive option because it is inexpensive, disposable, and readily available. However, there has been no direct comparison of PLMA insertion techniques using the suction catheter against the standard introducer tool technique.

We hypothesized that the insertion of the PLMA using a suction catheter is more efficient and less traumatic than the introducer tool technique.
METHODS
This trial was registered in the Clinical Trial Registry of India (CTRI/2020/05/025008). After receiving institutional ethics committee approval and written informed consent, female patients aged between 18 and 65 years, with American Society of Anesthesiologists physical status I and II, scheduled for elective laparoscopic gynecologic procedures under general anesthesia were enrolled into the study. Patients having a predicted difficult airway on physical assessment, a mouth opening smaller than 2.5 cm, history of recent sore throat, aspiration risk, or any contraindication to the use of supraglottic airway devices were excluded. Patients were randomly allocated into two groups based on the insertion technique (i.e., introducer tool-assisted [Group IT] or suction catheter-guided [Group SC]) using a sealed, opaque envelope technique.

Standard fasting guidelines were followed. After positioning the head of the patient on a standard size pillow, anesthesia was induced with intravenous fentanyl 2 mcg/kg and propofol 2 mg/kg total body weight. Patients were mask ventilated with positive pressure ventilation using 100% oxygen following a loss of consciousness. Twenty seconds after propofol injection, patients were assessed for the readiness of PLMA insertion (loss of jaw tone and lack of motor response to firm trapezius squeeze). If readiness for PLMA insertion was not achieved, 0.5 mg/kg of propofol was repeated, and the patient was reassessed after 20 seconds. After acceptable conditions were achieved, a PLMA of appropriate size based on body weight was inserted after coating the dorsal aspect of the fully deflated and flattened PLMA cuff with a water-based lubricant, using one of the two techniques described below:

1) Group IT: Insertion was performed per the manufacturer’s instructions—the PLMA was loaded onto the introducer tool and was inserted with continuous pressing along the palatopharyngeal curve until definite resistance was felt, after which the introducer tool was detached and removed. A suction catheter was then inserted at full length through the gastric drain port.

2) Group SC: The gastric drain tube of the PLMA was lubricated with a water-based gel; an 18-gauge suction catheter was inserted into the gastric drain tube so that its tip is protruded 10 cm beyond the distal aperture; the mouth was opened and the tip of the suction catheter was guided into the oropharynx along the midline; the PLMA was gently pushed into the throat, holding the stem, until definite resistance was felt. The suction catheter was then pushed in at full length through the gastric drain tube.

The cuff was inflated with the recommended volume of air using a 50 mL syringe after PLMA insertion. Insertion of the PLMA was considered successful if the following two conditions were satisfied:

1) smooth insertion of a suction catheter up to its full length through the gastric drain tube;
2) visible chest rise on bag ventilation with adjustable pressure-limiting valve set at 20 cm H2O, without an audible leak.

Figure 1 demonstrates the two techniques of PLMA insertion that are compared in this study. PLMA insertion for the purpose of this study was performed by qualified anesthesiologists who have completed at least three years of specialist training in anesthesiology. Trainees were not involved in the insertion process. If there was any difficulty with inserting the PLMA into the oropharynx, an assistant standing near the patient's head and facing the anesthetist helped facilitate insertion by opening the patient's mouth and applying a jaw-thrust maneuver—termed “airway manipulation.” In the event that the patient moved during insertion or the PLMA insertion was not successful, 0.5 mg/kg propofol was repeated and re-insertion was attempted after 20 seconds. The cause of failed insertion was documented. The time from picking the PLMA in hand for each insertion attempt to the detection of a square-wave EtCO2 waveform was noted as the time for successful PLMA insertion. The number of attempts required for successful insertion was also noted. If more than one attempt was required, only the time for the successful PLMA insertion attempt was considered. If the second attempt at PLMA insertion failed, or if the patient started desaturating at any point because of PLMA insertion difficulty (fall in Spo2 by more than 5% from baseline), further insertion attempts were discontinued, and appropriate alternative airway management procedures initiated. The event was termed “PLMA insertion failure.” All patients received intravenous (IV) dexamethasone 0.1 mg/kg at the onset of surgery and ondansetron 4 mg IV at the conclusion of surgery.

At the end of the surgery, the PLMA was removed and any signs of airway trauma (visible bleeding in the oral cavity, blood stain on the PLMA cuff or during oral suction) were noted. After 2 hours following the conclusion of the surgery, patients were asked about symptoms of throat discomfort—sore throat (throat pain or irritation), dysphonia (difficulty or pain on speaking), and dysphagia (difficulty or pain on swallowing). Patients were asked to subjectively grade each of the symptoms using a simple 3-point Likert scale as 0—none; 1—mild (occasional); 2—moderate (constant but bearable); or 3—severe (unbearable). A blinded observer collected the postoperative data.

• Outcomes. The primary outcome was the difference in the first-attempt success rate of PLMA insertion. The secondary outcomes included time for successful insertion, number of attempts required, manipulation required, incidence of visible airway trauma, and incidence and severity of postprocedural throat discomfort.

• Sample Size. The sample size was calculated using
a two-tailed chi-square test model based on published data. Considering an 82% first-attempt success rate of the standard introducer tool-assisted insertion technique, an expected 17% improvement in success rate (i.e., 99% success) with the suction catheter technique, type I error of 0.05 and power of 90%, 74 patients were required per group. With an added safety margin to compensate for possible dropouts, 80 patients were recruited in each arm of the study.

• **Statistical Methods.** The statistical analysis was done using Microsoft Excel and IBM SPSS software. Data were summed up as mean ± standard deviation (SD), median with interquartile range or percentage as appropriate. Quantitative continuous parameters were compared using unpaired t-test. Likert scale data were compared using the Mann-Whitney U test. Qualitative parameters were compared using the chi-square test. A P value of < .05 was considered significant.

**RESULTS**

Figure 2 shows the flow of participants in the trial. Both groups were similar with regard to demographic and anthropometric characteristics (Table 1). Table 2 shows the qualitative parameters. The PLMA was inserted successfully in the first attempt in 72 out of 80 patients (90%) in Group SC and 67 out of 80 patients (84%) in Group IT (P = .241). The time required for a successful insertion was 17.31 ± 6.50 seconds in Group SC and 22.65 ± 7.17 seconds in Group IT (P < .001). Airway manipulation to obtain a proper fit was more frequently required in Group IT (19/80) than in Group SC (9/80; P = .037). Oral bleed or blood staining was present in nine patients in Group SC and 22 patients in Group IT (P = .001). Symptoms of throat discomfort were more frequent with the introducer tool (19/80) than with the suction catheter (8/80; P = .020). Figure 3 shows the response of individual patients on the 3-point Likert scale assessing the severity of throat soreness. The overall severity of throat soreness was significantly lower with the suction catheter (mean score ± SD = 0.30 ± 0.10) compared with the introducer tool (mean score ± SD = 0.77 ± 0.59; P < .001). There was no difference in the overall severity of dysphagia or dysphonia.

**DISCUSSION**

The PLMA is a suitable alternative to the endotracheal tube for laparoscopic surgeries under general anesthesia. It offers greater pharyngeal seal pressure in comparison with the LMA ClassicTM (cLMA). However, PLMA insertion is reported to be more difficult and has a lower success rate than the cLMA. This study compared the insertion of the PLMA using a suction catheter-guided technique with the standard introducer technique. A first-attempt success rate of 84% was achieved using the introducer tool. This is consistent with the findings of previous studies which have reported first-attempt success for introducer tool-assisted PLMA placement of approximately 82%. The first-attempt success rate achieved using the suction catheter technique was 90%. Although this difference did not reach statistical significance, the trial may have been underpowered as the observed success rate using a suction catheter was less than the expected success rate used for sample size estimation. The 90% first-attempt
success rate achieved using the suction catheter technique is comparable with the 91% success rate described for cLMA by Brimacombe and associates.\(^6\)

High first-attempt success rates have been reported for other modified PLMA insertion techniques. Brimacombe and colleagues reported a 100% success rate with the use of a gum elastic bougie. The technique requires direct laryngoscopy for guiding the tip of the bougie into the esophagus.\(^2\) Myatra and associates achieved a 95% success by preforming the pharyngeal curvature using a Rusch intubation stylet through the gastric drain port.\(^3\) In comparison with the current study, García-Aguado and colleagues reported a higher success rate of 97% with the use of a suction catheter.\(^4\) This may be attributed to their use of direct laryngoscopy for directing the suction catheter in the event that resistance was encountered.

In the current study, the process of inserting the PLMA was approximately 5 seconds faster with the suction catheter compared with the introducer tool. This difference in insertion time, albeit small, may be vital in situations where quick airway securement is essential. Assistance in airway manipulation was less often needed with the suction catheter than with the introducer tool. By preventing the buckling of the PLMA cuff during insertion, the suction catheter may help to quickly guide the PLMA tip into proper position, without the frequent need for manipulation, thus reducing the insertion time. The suction catheter method may be easier in such situations because a trained assistant may not always be present during the process of PLMA insertion. The additional step of detaching the introducer tool after PLMA placement may also contribute toward the longer insertion time in Group IT.

The presence of blood upon removal of a supraglottic airway indicates trauma during device insertion. In our study, 28% patients in the introducer tool group had evidence of oral trauma, which is in line with the findings of previous studies that have reported approximately 22–36% incidence of minor airway trauma using the standard technique of PLMA insertion.\(^8,9\) The incidence

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**Figure 2.** CONSORT Diagram Showing Flow of Participants in the Trial
of airway trauma observed with the suction catheter was much lower, at 11%.

Postoperative sore throat (POST) is a minor yet often distressing complication of general anesthesia and may last for days. The incidence of POST with the standard techniques of PLMA insertion have been reported at approximately 25–33%. Alternative PLMA insertion techniques such as the use of a gum-elastic bougie, stylet, or the 90-degree rotational technique appear to have a lower incidence of POST at approximately 9–12%. Our study found that the incidence, as well as the severity, of POST was lower with the use of a suction catheter (10%) compared with the introducer tool (24%). It may therefore be inferred that techniques that prevent folding of the PLMA cuff during insertion lower the chances of airway trauma and POST by obviating manipulation and reducing the pressure exerted on the hard palate and posterior pharyngeal wall.

Our study had some limitations. We did not compare hemodynamic response during the process of PLMA insertion. Fiberoptic assessment of the quality of glottic alignment was not performed. Cuff pressure, which may contribute to POST, was not monitored after insertion. The study was limited to a narrow demographic profile—relatively young healthy adult females—therefore, extrapolation of the results to general population may not be accurate.

In conclusion, suction catheter–guided PLMA insertion has a comparable success rate, takes less time, and requires less frequent airway manipulation than introducer tool–assisted insertion. The incidence of airway trauma and POST is lower with the suction catheter compared with the introducer tool. The suction catheter is an inexpensive, readily available, and safe alternative for aiding PLMA insertion.

### REFERENCES


### Table 1. Demographic and Anthropometric Parameters (Data Expressed as mean ± SD or median [IQR])

<table>
<thead>
<tr>
<th>Serial no.</th>
<th>Parameter</th>
<th>Suction catheter</th>
<th>Introducer tool</th>
<th>*P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Age</td>
<td>28.36 ± 3.91</td>
<td>28.31 ± 4.29</td>
<td>0.9387*</td>
</tr>
<tr>
<td>2.</td>
<td>Weight</td>
<td>58.23 ± 10.00</td>
<td>58.14 ± 7.57</td>
<td>0.9503*</td>
</tr>
<tr>
<td>3.</td>
<td>Height (m)</td>
<td>1.60 ± 0.08</td>
<td>1.60 ± 0.07</td>
<td>0.9835*</td>
</tr>
<tr>
<td>4.</td>
<td>Body mass index (kg/m²)</td>
<td>22.68 ± 2.84</td>
<td>22.71 ± 2.35</td>
<td>0.9469*</td>
</tr>
<tr>
<td>5.</td>
<td>Modified Mallampati Grading</td>
<td>2 (1,2)</td>
<td>2 (1,2)</td>
<td>0.424*</td>
</tr>
</tbody>
</table>

### Table 2. Qualitative Parameters

<table>
<thead>
<tr>
<th>Serial no.</th>
<th>Parameter</th>
<th>Suction catheter [n = 80]</th>
<th>Introducer tool [n = 80]</th>
<th>*P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>First-attempt success</td>
<td>72 (90%)</td>
<td>67 (84%)</td>
<td>0.242</td>
</tr>
<tr>
<td>2.</td>
<td>Manipulation required</td>
<td>9 (11%)</td>
<td>19 (24%)</td>
<td>0.037</td>
</tr>
<tr>
<td>3.</td>
<td>Signs of trauma</td>
<td>9 (11%)</td>
<td>22 (28%)</td>
<td>0.001</td>
</tr>
<tr>
<td>4.</td>
<td>Symptoms of throat discomfort</td>
<td>8 (10%)</td>
<td>19 (24%)</td>
<td>0.020</td>
</tr>
</tbody>
</table>


**DISCLOSURES**

Name: Ajisha Aravindan, MD
Contribution: This author made significant contributions to the conception, design, and preparation of the manuscript to justify inclusion as an author.
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Name: Rajeshwari Subramaniam, MD
Contribution: This author made significant contributions to the supervision, design, and review of the manuscript to justify inclusion as an author.
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Ethical approval was given by the Institute Ethics Committee, AIIMS, New Delhi.

The trial was registered with Clinical trials registry India (CTRI), reference number CTRI/2020/05/025008.

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