Original Research Article

Comparative study of various supraglottic devices with clinical and fiber optic assessment in elective laparoscopic procedures

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ABSTRACT

Background: Aim of present study was to compare the efficacy and safety of supraglottic devices (LMA supreme, LMA proseal and I-Gel) by clinical and fiberoptic evaluation in elective laparoscopic surgeries under general anaesthesia with controlled ventilation.

Methods: The design was a prospective, randomized study enrolling total 105 patients of either sex, (age 18-65 years), ASA grade I/II and mallampati score I and II, were randomly allocated to LS (LMAS), LP (PLMA), and IG (I-Gel) groups according to the supraglottic device applied. The three devices were compared as regards insertion parameters, adequacy of ventilation (oxygen saturation, endtidal carbon dioxide and air leak), fiberoptic vision and intra or postoperative complications.

Results: The overall ease of insertion of LMAS was found to be better than the other two devices. Adequacy of ventilation was comparable in all the study groups. Safety of these devices was found to be comparable but if OLP was considered as a marker of safety of the device, LMA proseal was a better option than the other two devices. There was no significant difference in the fiberoptic view of the laryngeal inlet between the three study groups but the number of patients with grade 4 view of laryngeal inlet fiberoptic was more in I gel than LMA proseal and LMA supreme.

Conclusions: It was concluded that the LMAS, PLMA and I-Gel are effective ventilatory devices during controlled ventilation, without major complications. But in clinical practice it is advisable to monitor peak airway pressure, OLP and laparoscopic view of gastric distension whenever these devices are used in laparoscopic surgeries.

Keywords: Gastric distension, Laparoscopic surgeries, LMAS, Oropharyngeal leak pressure, PLMA and I–Gel, Supraglottic devices

INTRODUCTION

Endotracheal intubations have served a golden role in airway management. But at the same time, it requires laryngoscopy which is not without the problems. Best way to avoid problems is to eliminate the instrumentation i.e. laryngoscopy itself. Supraglottic devices have proved to be boon in this regard in the present-day practice. Supraglottic airway devices (SGADs) have become increasingly popular and have replaced the routine use of endotracheal intubation for a large variety of procedures.1 Various models of SGADs are now marketed that are specifically designed to reduce the risk of aspiration. The most popular among this group has been the LMA ProSeal, LMA Supreme and I-Gel. The ProSeal is a reusable device made of silicone with an inbuilt gastric port, an inflatable posterior pharyngeal cuff for better airway seal and a rigid bite block. The Supreme,
introduced commercially in 2007, is a single-use SAD made of polyvinyl chloride with a gastric drain tube, large inflatable plastic cuff and preformed semi-rigid tube. The I-gel, also clinically introduced in 2007, is a single-use device comprising a soft gel-like cuff less mask, a narrow-bore gastric drain tube and an integral bite block. Numerous previous studies of these airway devices have demonstrated their easy, reliable insertion and low morbidity rate.\(^2\)\(^6\)

Oropharyngeal leak pressures (OLP) were commonly performed with the LMA in controlled ventilation as a marker of safety of the device and also performed to indicate the degree of airway protection, the feasibility for positive pressure ventilation and the likelihood for successful supraglottic airway placement.\(^1\) Thus the ventilation may be adequate inspite of the wide range of anatomical fit of these devices. The exact correlation between the clinical parameters and anatomical position can be assessed by Fibreoptic assessment of the positioning of the supraglottic airway devices. As a non-invasive tool, ultrasonography is found to be a better option for confirmation of the placement of device.\(^7\) In addition to the proper fit, any malposition or the view of the oesophageal inlet or gastric distension on laparoscopic view will decide the safety of these devices.

Hence present study was conducted with primary aim to compare the three devices from safety point of view and to correlate the clinical parameters of ventilation and exact positioning of the devices.

**METHODS**

This prospective, randomized controlled trial included total 105 patients belonging to ASA grade I and II of either sex with the age between 18-65 years and weight between 30 to 80 kilograms. Patients willing to give consent, Nil per oral patients and patients with only Mallampati score I and II were included in the study. Before starting the study ethical approval has been obtained from institutional ethical committee. A written informed consent was obtained from all the patients. Anesthesia with controlled ventilation in supine position. Prior to induction of anesthesia, spraying of pharynx with 4\% lignocaine was done. All patients received pre-medication with ondansetron 0.08mg/kg + midazolam 0.03mg/kg and fentanyl 1-1.5mcg/kg. After 5 minutes of preoxygenation, anesthesia was induced with propofol 2-2.5mg/kg intravenously or until the loss of eyelash reflex. Neuromuscular block was achieved with injection scoline 2mg/Kg. Ventilation by bag and mask was avoided unless and until patient required it. After the complete relaxation of the patient, selected supraglottic device was inserted using a single-handed rotational technique until resistance was met. Cuff of PLMA and LMA S was inflated to achieve 60cm of H\(_2\)O pressure which was measured by an aneroid manometer. Throughout the procedure cuff pressure was maintained at 60cm of H\(_2\)O pressure. The airway tube of the supraglottic device is attached to the closed circuit and an effective airway was confirmed by symmetrical chest movements on manual ventilation, auscultation of the bilateral lung fields, square waveform on capnography, absence of audible leak of gases through mouth or absence of audible leak of gases through oesophagus by epigastric stethoscope with peak airway pressure less than 15cm of H\(_2\)O and by absence of positive gel bubble test with peak airway pressure less than 15cm of H\(_2\)O.

Ease of insertion was assessed by the number of attempts taken to insert device, time taken for insertion of the device and by any head position or device manipulations required. A well lubricated nasogastric tube of size recommended by user manual was inserted through the nasopharynx for the insertion of the particular device. Size of the selected supraglottic device was determined as per user manual guidelines and was decided on the weight of the patients. For the Supreme and ProSeal groups, sizes 3 and 4 were used for weights of 30-50 kg and 50-70 kg respectively. For the I-Gel group, the recommendation was for sizes 3 and 4 to be used for weights of 30-50kg and 50-90kg respectively.

On operation table, baseline parameters like heart rate, systolic, diastolic and mean blood pressure, SPO2, ECG, respiratory rate were noted by using MP 50 Phillips multipara monitor. Head of the patient was kept in neutral position on a 7-inch round pillow in supine position. Prior to induction of anesthesia, spraying of pharynx with 4\% lignocaine was done. All patients received pre-medication with ondansetron 0.08mg/kg + midazolam 0.03mg/kg and fentanyl 1-1.5mcg/kg. After 5 minutes of preoxygenation, anesthesia was induced with propofol 2-2.5mg/kg intravenously or until the loss of eyelash reflex. Neuromuscular block was achieved with injection scoline 2mg/Kg. Ventilation by bag and mask was avoided unless and until patient required it. After the complete relaxation of the patient, selected supraglottic device was inserted using a single-handed rotational technique until resistance was met. Cuff of PLMA and LMA S was inflated to achieve 60cm of H\(_2\)O pressure which was measured by an aneroid manometer. Throughout the procedure cuff pressure was maintained at 60cm of H\(_2\)O pressure. The airway tube of the supraglottic device is attached to the closed circuit and an effective airway was confirmed by symmetrical chest movements on manual ventilation, auscultation of the bilateral lung fields, square waveform on capnography, absence of audible leak of gases through mouth or absence of audible leak of gases through oesophagus by epigastric stethoscope with peak airway pressure less than 15cm of H\(_2\)O and by absence of positive gel bubble test with peak airway pressure less than 15cm of H\(_2\)O. 

All the patients were asked to fast overnight and received famotidine 40 mg and diazepam 10mg orally at 10.00 p.m. one night prior to surgery. Patients were randomly allocated to three equal groups of 35 patients each by the computer-generated chit system on the day of surgery. LMA supreme\(^TM\) was used in group LS, LMA proseal\(^TM\) was used in group LP and I-Gel was used in group IG. Half an hour before surgery, all patients received glycopyrrolate 4mcg/kg IM and ranitidine 1mg/kg as an intravenous infusion. An anaesthesiologist having an experience of at least 25 insertions of the particular supraglottic device was assigned for the insertion of device. Size of the selected supraglottic device was determined as per user manual guidelines and was decided on the weight of the patients. For the Supreme and ProSeal groups, sizes 3 and 4 were used for weights of 30-50 kg and 50-70 kg respectively. For the I-Gel group, the recommendation was for sizes 3 and 4 to be used for weights of 30-50kg and 50-90kg respectively.
intermittent injection vecuronium or injection atracurium as and when required. N₂O was avoided till the examination of gastric distension on laparoscopic view at 30 minutes after insertion of the device. Heart rate, systolic, diastolic blood pressure, mean blood pressure, SPO2, EtCO₂ were monitored throughout the procedure. Peak airway pressure measured at 15 and 30 minutes after the insertion of the device were noted. An effective ventilation was defined as EtCO₂ <45 and SPO2 >95%. Intra-abdominal insufflations pressure was maintained below 12mmHg. Airway sealing pressure or oropharyngeal leak pressure (OLP) was measured (at a cuff pressure of 60cm of H₂O in PLMA and LMA S) by closing expiratory valve of the circle system at a fixed gas flow 3 lit/minutes and at 15 and 30 minutes after insertion of the device. Cuff pressure of the PLMA and SLMA was checked every 15 minutes till the end of surgery and was maintained at 60cm of H₂O. The anatomical position of the device was assessed by introducing a flexible fiberoptic bronchoscope into the airway tube to a position 1cm proximal to the terminal end of the airway tube. The scoring of fiberoptic examination view was done as suggested by Brimacombe1. Positioning of the drain tube was assessed by passing the fiberoptic bronchoscope through the drain tube 1cm proximal to its terminal end.11 Distension of stomach was assessed on laparoscopic view by surgeon at 30 minutes after insertion of the device as grade 1 (no distension), grade 2 (mild distension) and grade 3 (gross distension). Any intraoperative adverse effects like laryngospasm, bronchospasm or haemodynamic instability was recorded. At the end of the procedure anaesthesia was discontinued, neuromuscular blocked was reversed with neostigmine 0.05mg/kg and Glycopyrrolate 0.01mg/kg i.v and the device was removed. Blood staining on device, tongue, lip and dental trauma were recorded. Patients were assessed after regaining consciousness and after 24 hours for the symptoms of pharyngolaryngeal morbidity like sore throat, dysphagia, and dysphonia.

Statistical analysis

Continuous variables were presented as Mean ± SD. Categorical variable were expressed in actual number and percentages. Continuous variables were compared between 3 groups by performing one-way Analysis of variance (ANOVA). Multiple comparisons were performed by Bonferroni t-test. Categorical variable was compared by applying chi²-statistics. For small number, Fisher exact test was applied wherever applicable. P<0.05 was considered as statistical significant and P<0.001 was considered as highly significant. Statistical software STATA version 10.0 was used for statistical analysis.

RESULTS

There were no significant differences between the 3 groups as regards the demographic and clinical characteristics (Table 1).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group LS</th>
<th>Group LP</th>
<th>Group IG</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>28.14±7.57</td>
<td>29.51±7.33</td>
<td>29.94±8.26</td>
<td>0.5144</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>50.77±8.8</td>
<td>50.14±7.11</td>
<td>51.71±8.91</td>
<td>0.7393</td>
</tr>
<tr>
<td>Sex (Male/Female)</td>
<td>18/17</td>
<td>15/20</td>
<td>17/18</td>
<td>0.765</td>
</tr>
<tr>
<td>Mallampatti grading I/II</td>
<td>19/16</td>
<td>13/22</td>
<td>18/17</td>
<td>0.229</td>
</tr>
</tbody>
</table>

The most common surgery performed in all three groups was laparoscopic appendicectomy. All groups matched well according to type of surgical procedure (Table 2).

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Group LS</th>
<th>Group LP</th>
<th>Group IG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lap. appendicectomy</td>
<td>22</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>Lap. cholecystectomy</td>
<td>9</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Lap. TAPP</td>
<td>4</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>35</td>
<td>35</td>
</tr>
</tbody>
</table>

Table 3 shows distribution of patients according to ease of insertion of device. Number of attempts taken for insertion of device was comparable and statically non-significant, (chi²=0.8996 and P=0.638.). There was a significant difference between the insertion time in group LS and group IG (P=0.016). No significant difference in insertion time was found between group LS and group LP (P=1) and between group LP and group IG (P=0.074). All the three devices were comparable with respect to device and head position manipulations. The mean time required to insert nasogastric tube through the device in group LS, LP and IG was 14.28±4.70, 14.57±5.24 and 12.94±4.07 respectively and difference was statistically non-significant, (F=1.20, P=0.3057).

There was no significant difference between the three groups with respect to peak airway pressure at 15 and 30 minutes after insertion. It was observed that the mean peak airway pressure was well within the normal limits in all 3 devices even after carboperitoneum (Table 4).
Oropharyngeal leak pressure (OLP) is considered as a marker of safety of the SGDs. OLP at 15 and 30 minutes after insertion was found to comparable in all the study groups. Oropharyngeal leak pressures were higher with LMA Proseal followed by LMA Supreme and then by I-gel, (Table 4).

Table 3: Data showing ease of insertion of device.

<table>
<thead>
<tr>
<th>No. of attempts</th>
<th>Group LS</th>
<th>Group LP</th>
<th>Group IG</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30 (85.71%)</td>
<td>29 (82.85%)</td>
<td>27 (77.14%)</td>
</tr>
<tr>
<td>2</td>
<td>5 (14.28%)</td>
<td>6 (17.14%)</td>
<td>8 (22.85%)</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Device manipulations**

- Pushing: 5, 7, 7
- Pulling: 2, 1, 5

**Head position manipulations**

- Extension: 4, 5, 5
- Flexion: 4, 1, 5

Table 4: Comparison of mean peak airway pressure and oropharyngeal leak pressure at 15 and 30 minute after insertion.

<table>
<thead>
<tr>
<th>Peak Airway Pressure</th>
<th>Group LS</th>
<th>Group LP</th>
<th>Group IG</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 15 minute</td>
<td>15.77±2.55</td>
<td>14.71±2.19</td>
<td>14.97±1.68</td>
</tr>
<tr>
<td>At 30 minute</td>
<td>16.65±1.25</td>
<td>16.14±1.26</td>
<td>16.05±1.39</td>
</tr>
</tbody>
</table>

**Oropharyngeal leak pressure**

- At 15 minute: 24.82±4.01, 26.14±3.82, 24.80±3.99
- At 30 minute: 25.37±4.01, 26.48±4.0, 25.48±3.99

As there is no defined lower safe limit of OLP, if the OLP is found to be on lower side in case of I gel during controlled ventilation, it is advisable to be more watchful and monitor the clinical parameters of ventilation as the fiberoptic grading of laryngeal inlet may be less.

All the groups were comparable with respect to view of the esophageal inlet assessed by fiberoptic bronchoscopy through drain tube, (P=0.601). In present study no gastric insufflation was found (grade 1) in 30 patients in group LS and 31 patients of group LP and IG each. Mild (grade 2) distension was found in 5 patients in group LS and 4 patients of group LP and IG each. None of the patient in any group had grade 3 gastric distension on laparoscopic view. All the study groups were comparable with respect to gastric distension grading on laparoscopic view.

Malrotation was present in 4 patients of group LS, 5 patients of group LP and 7 patients of group IG and the incidence was statistically comparable. However, incidence of malrotation was more in I gel despite of having more number of patients with better grading on fiberoptic assessment. Malrotation of the device seems to decrease mean OLP by 2.87cm of H2O in LMAS and by 4.48cm of H2O in I gel but does not seem to affect OLP in PLMA. The difference between the mean peak airway pressures at 30 minutes and mean OLP at 30 minutes in

Figure 1: Correlation between mean OLP at 30 minutes and the fiberoptic view of the laryngeal inlet.

There was no significant difference in the fiberoptic view of the laryngeal inlet between the three study groups but the number of patients with grade 4 view of laryngeal inlet fiberoptic was more in I gel than LMA Proseal and LMA supreme. Correlation between mean OLP at 30 minutes and fiberoptic view shows that mean OLP decreased as the fiberoptic grading of laryngeal inlet worsened from grade 4 to grade 2 without affecting the ventilation clinically. This decrease in OLP with decrease in fiberoptic grading was more in case of I gel (Figure 1).
cases of malrotation was 6.5, 11.2 and 5.15 respectively in group LS, LP and IG respectively. It was observed that the difference between OLP and peak airway pressure at 30 minutes in malrotation was more for group LP than group LS and IG. This may be the reason why gastric distension occurred only in 20% cases of malrotation in PLMA against 50% in LMAS and 42.8% in I gel.

Fiberoptic assessment of the oesophageal inlet revealed grade 2 view i.e. open hypo pharynx in 1 case of LMA S and 1 case of PLMA. In both the patients gastric distension was present. So there was 100 % association between grade 2 view of oesophageal inlet and gastric insufflation in our study. In addition LS case also had malrotation. However more numbers of cases are required to determine the association between OLP, fiberoptic view of laryngeal and esophageal inlet, malrotation of the device and gastric distension. Mean OLP at 30 minutes in patients with gastric distension was 20.4, 21.5 and 17.5 in group LS, LP and IG respectively. This OLP is much less than the overall OLP in 35 patients in each group. (25.37±4.01, 26.48±4.0 and 25.48±3.99 in group LS, LP and IG respectively). This shows that OLP has an inverse relationship with gastric insufflation.

Table 6 shows the adverse effects related to device and all the adverse effects were found to be non-significant between the study groups.

Table 6: Adverse effects related to device.

<table>
<thead>
<tr>
<th>Adverse effect</th>
<th>Group LS</th>
<th>Group LP</th>
<th>Group IG</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchospasm</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Blood on device</td>
<td>4</td>
<td>8</td>
<td>5</td>
<td>0.402</td>
</tr>
<tr>
<td>Cough</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>0.916</td>
</tr>
<tr>
<td>Sore throat</td>
<td>3</td>
<td>6</td>
<td>6</td>
<td>0.093</td>
</tr>
<tr>
<td>Hoarseness</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>0.715</td>
</tr>
<tr>
<td>Dysphonia</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
</tr>
</tbody>
</table>

DISCUSSION

As regards the insertion criteria in the studied patients, it was found that the rate of the first attempt insertion was higher in LMAS patients compared to both LMAP and I gel. Other two devices, (LMAS >I gel (10.57) or LMA Supreme (9.05). The significance of this difference has to be determined and verified by conducting a study with larger number of patients.

We have maintained intracuff pressure constant at 60 cm H2O in group LS and LP. However, it was reported that increasing the intracuff pressure to 80cm H2O favourably increases the OLP without an increase in the incidence of postoperative airway morbidity. The overall ease of insertion of LMAS was found to be easier and better than the other two devices, (LMAS >I-gel (10.57) or LMA Supreme (9.63). The difference between the mean OLP and mean peak airway pressure at 30 minutes was higher in LMA Proseal (11.26) than I-gel (10.57) or LMA Supreme (9.63). The significance of this difference has to be determined and verified by conducting a study with larger number of patients.

The bulky design of I-gel makes insertion time longer than LMA S. Insertion of the nasogastric tube was possible in first attempt in all the cases which suggest that the tip of the device was not folded in any of the case. The mean time required to insert NGT through the device was statistically non-significant and comparable between the three study groups. However, time taken to insert NGT was comparatively less with I gel. This is corroborative with the study conducted by Chauhan et al.15

SPO2 and EtCO2 may be considered as a marker of adequate ventilation. In our study, we defined adequate ventilation as SPO2 >95% and EtCO2 <45mmHg. In all the patients ventilation was adequate according to the defined criteria. We found no significant difference with respect to peak airway pressure at 15 and 30 minutes after insertion but significant difference found in the distribution of peak airway pressures at 30 minutes between three groups. Number of patients with peak airway pressure more than 15cm H2O was significantly higher in group LS than the other two groups. The peak airway pressure was increased over a period of 15 minutes by 0.88, 1.43 and 1.08 in group LS, LP and IG respectively which was not significant. The device which offered less resistance to the ventilation was LMA Proseal followed by I-gel and then by LMA Supreme. The present study was comparable with various studies.8,16-22

Oropharyngeal leak pressure is considered as a marker of safety of the SGD. For adequate delivery of the air and anaesthetic gases, OLP should always be more than peak airway pressure. In all the cases peak airway pressure was lower than the OLP at any given time of surgery. This suggests the efficacy and safety of these devices during controlled ventilation in laparoscopic surgeries. The difference between the mean OLP and mean peak airway pressure at 30 minutes was higher in LMA Proseal (11.26) than I-gel (10.57) or LMA Supreme (9.63). The significance of this difference has to be determined and verified by conducting a study with larger number of patients.

We have maintained intracuff pressure constant at 60 cm H2O in group LS and LP. However, it was reported that increasing the intracuff pressure to 80cm H2O favourably increases the OLP without an increase in the incidence of postoperative airway morbidity. In present study muscle relaxant was used so the effect of the pharyngeal muscle tone on OLP had no significance. The difference between the mean OLP and mean peak airway pressure at 15 minutes was higher in LMA Proseal (11.43) than I-gel (9.83) or LMA Supreme (9.05). Similarly, the difference between the mean OLP and
mean peak airway pressure at 30 minutes was higher in LMA Proseal (11.26) than I-gel (10.57) or LMA Supreme (9.63). Present findings compare with study of Lopez et al. The OLP less than 20 cm of H2O was observed in 5 cases of LMA S, 2 cases of LMA P and 3 cases of I gel, this was comparable with study of Teoh WHL et al. Present OLP falls well within this range. We found higher oropharyngeal leak pressure with LMA Proseal followed by LMA Supreme and then by I-gel, when comparing LMA S with LMA Proseal show statistically insignificant difference. OLP of LMA S was always within the normal limits i.e. more than the peak airway pressure. This finding was corroborative with other study. Although the OLP of the I-Gel was found to be lower than that of LMA Proseal and Supreme. The possible explanation for this may be the non-inflatable cuff of I gel is less able to conform to the variable pharyngeal anatomy than an inflatable cuff of LMA S or LMA Proseal. The same findings were observed by various authors.

In 1993 Brimacombe et al first proposed the grading to assess the position of the LMA by putting a fiberoptic scope into the hypopharynx and graded the fiberoptic view of laryngeal inlet. Since then various studies on LMAs used this grading to assess the efficacy and safety of this device in addition to OLP. Table 7 shows the relationship between mean OLP at 30 minutes and the fiberoptic view of the laryngeal inlet. There was no significant difference in the fiberoptic view of the laryngeal inlet between three groups. However more number of patients should be studied to test the significance of this difference in the three study groups. The double silicon cuff of PLMA has greater elasticity and molding ability than the polyvinyl cuff of other two devices. This property of PLMA may be considered as a possible explanation for this may be the non-inflatable cuff of I gel is less able to conform to the variable pharyngeal anatomy than an inflatable cuff of LMA S or LMA Proseal. The same findings were observed by various authors.

Table 7: Relationship between mean OLP at 30 minutes and the fiberoptic view of the laryngeal inlet.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Mean OLP in Group LS</th>
<th>Mean OLP in group LP</th>
<th>Mean OLP in group IG</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>26.54 (n=22)</td>
<td>27.04 (n=24)</td>
<td>26.28 (n=28)</td>
</tr>
<tr>
<td>3</td>
<td>23.6 (n=10)</td>
<td>25.66 (n=9)</td>
<td>23 (n=5)</td>
</tr>
<tr>
<td>2</td>
<td>22.66 (n=3)</td>
<td>23.50 (n=2)</td>
<td>20.5 (n=2)</td>
</tr>
<tr>
<td>1</td>
<td>0 (n=0)</td>
<td>0 (n=0)</td>
<td>0 (n=0)</td>
</tr>
<tr>
<td>0</td>
<td>0 (n=0)</td>
<td>0 (n=0)</td>
<td>0 (n=0)</td>
</tr>
</tbody>
</table>

In all the devices, OLP decreases as the fiberoptic grading of laryngeal inlet worsens from grade 4 to grade 2 without affecting the ventilation clinically. This decrease in OLP was more in case of I-gel. As there is no defined lower safe limit of OLP, in the clinical practice if the OLP is found to be on lower side in case of I-gel, it is advisable to be more watchful and meticulously monitor the clinical parameters of ventilation as the fiberoptic grading of ventilation may be less.

Malrotation was present in 4 patients of group LS, 5 patients of group LP and 7 patients of group IG. All the study groups were comparable with respect to malrotation of the device (P=0.597). Incidence of malrotation of the device was higher with I gel compared to PLMA despite of having better fiberoptic view of laryngeal inlet. This was consistent with present study where the fiberoptic view was better with I-gel but with greater incidence of malrotation. However, malrotation of the device did not seem to affect the fiberoptic grading of the laryngeal inlet in present study. The positioning of the drain tube indicates the overall positioning of the LMA as well as the easy insertion of NGT and thus reflects on the safety of the device. If the device is correctly positioned, the tip of the cuff should rest at the oesophageal inlet. In present study, grade 1 was found in 34, 34 and 35 patients of group LS, LP and IG respectively. Grade 2 was found in 1 patient of group LS and LP each. No patient in any group had grade 3 or grade 4 view of the oesophageal inlet. The distension of stomach was assessed on laparoscopic view by surgeon at 30 minutes after insertion of the device. All the study groups were comparable with respect to gastric distension grading on laparoscopic view (P=0.916).

The difference between OLP and peak airway pressure at 30 minutes in malrotation was more for group LP than group LS and IG. The malrotation seems to decrease OLP in LMA S and in I gel but do not seem to affect OLP in PLMA. This may be the reason for lower incidence of gastric distension in group LP (20%) as compared to other two groups (50% in group LS and 42.8% in group IG). However more number of patients should be studied to test the significance of this difference in the three study groups. The double silicon cuff of PLMA has greater elasticity and molding ability than the polyvinyl cuff of the LMAS and fixed volume cuff of non-inflatable cuff of I-gel. This property of PLMA may be considered as beneficial especially in cases of malrotation over the other two devices. 1 case out of 5 cases of group LP with malrotation with fiberoptic grade 3 was associated with lowest OLP (21 cm of H2O) and mild gastric distension. 2 cases out of 7 cases of group IG with malrotation with fiberoptic grade 2 and 3 were associated with lower OLP (16 and 18 cm of H2O) and mild gastric distension. It seems that there was a direct correlation between fiberoptic grading of laryngeal inlet, OLP and gastric distension in group LP and IG. However, in group LS, no correlation was observed between inferior fiberoptic grading of laryngeal inlet, lower OLP and gastric distension in cases of malrotation. Hence OLP may not
be the proper criteria to decide safety of this device in case of malrotation.

Airway morbidity related with trauma and cuff pressure was statistically comparable in all the three study groups. However, trauma related blood on device was found to be more common with PLMA. Blood on the device indicates that the trauma may be during insertion of the device or while the device is in situ. Postoperative airway morbidity was more with LMA proseal in the form of blood on the device as compared to other devices. However, more number of cases should be studied to determine the exact correlation between OLP, fiberoptic grading of laryngeal and oesophageal inlet, malrotation of the device and gastric distension on laparoscopic view.

Limitations of the study

Only elective laparoscopic procedures were involved in the study. We did not test the safety and efficacy of these devices in emergency procedures where risk of aspiration is high. Also obese patients were excluded from the study and hence safety of these devices in obese patients requires to be studied further.

CONCLUSION

Adequate ventilation can be achieved with all the three devices in laparoscopic surgeries. Safety of these devices was found to be comparable but if oropharyngeal leak pressure is considered as a marker of safety of the device, LMA Proseal is a better option than the other two devices. Oropharyngeal leak pressure corresponds to the laryngeal fit of the device as assessed by the fiberoptic evaluation and has an inverse relationship with the gastric distension seen on laparoscopic view. Hence in clinical practice it is advisable to monitor peak airway pressure, OLP and laparoscopic view of gastric distension whenever these devices are used in laparoscopic surgeries.

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