PROSEAL LARYNGEAL MASK AIRWAY: A STUDY OF 100 CONSECUTIVE CASES OF LAPAROSCOPIC SURGERY

Dr. Bimla Sharma¹ Dr. Chand Sahai² Dr. Abhijit Bhattacharya³ Dr. V. P. Kumra⁴ Dr. Jayashree Sood⁵

SUMMARY

Tracheal intubation and controlled ventilation is the gold standard for the anaesthetic management of a patient undergoing laparoscopic surgery. The ProSeal laryngeal mask airway (PLMA), a modified version of the Classic laryngeal mask airway (LMA), is being considered as an alternative airway device for a wide range of laparoscopic surgical procedures. The aim of the study was to assess the use of the PLMA as a ventilatory device in anaesthetised paralysed patients for various elective laparoscopic procedures. This prospective study comprised 100 patients between the age of 18-85 years, of either sex, belonging to physical status ASA I-III. We assessed haemodynamic responses to insertion of the PLMA, ventilatory parameters, ease of gastric tube placement, gastric insufflation and any postoperative complications. The statistically analysed results showed that the PLMA caused minimum haemodynamic responses to insertion, was a reliable airway management device ensuring adequate ventilation and providing an effective glottic seal in all but one patient. It allowed easy passage of gastric tube. There were three cases of oesophageal regurgitation but no incidence of pulmonary aspiration. Sore throat was reported in three patients.

Keywords : Equipment, Masks anaesthesia; Laparoscopic surgery; airway, Pressure, Regurgitation, Pulmonary aspiration.

Introduction

Laparoscopic surgery is an evolving subspecialty and is not only limited to minor gynaecologic surgery or cholecystectomy but has extended to procedures such as appendectomy, hernia repairs (inguinal, epigastric and incisional), advanced gastrointestinal, urologic and gynaecologic procedures.

The problems common to all such procedures are a) carbon dioxide insufflation in the body-intraperitoneal or extraperitoneal b) raised abdominal pressure and c) potential danger of regurgitation and pulmonary aspiration. The anaesthesiologist must ensure a patent airway and adequate ventilation. Till date the cuffed tracheal tube was considered as ideal for providing a safe glottic seal especially for laparoscopic procedures under general anaesthesia. But over a period of time new airway devices have been added to the anaesthesiologist’s armamentarium.

The ProSeal laryngeal mask airway (PLMA) is one of such new devices. It is a modification of the Classic Laryngeal Mask Airway (LMA). The cuff of the PLMA is specially designed with an aim to provide a more effective seal around the glottis than the Classic LMA and the drain tube provides a bypass channel for regurgitated gastric contents. The Classic LMA is not a very popular device for positive pressure ventilation for fear of gastric distension, aspiration of gastric contents and inadequate ventilation. The PLMA offers several advantages over the Classic LMA. It provides a better glottic seal at lower mucosal pressures and isolates the alimentary tract from the respiratory tree. It is superior to the Classic LMA for providing positive pressure ventilation and, at a given intracuff pressure, provides twice the seal pressure of the Classic LMA.

Methods

With institutional ethics committee approval, written informed consent was obtained from 100 patients of physical status ASA I – III, aged 18-85 years of either sex, scheduled for elective laparoscopic surgery. It was a prospective study conducted over a period of five months. Patients with a known difficult airway, cervical spine disease, body mass index >35 kgm², mouth opening <2.5 cm and patients who were at risk of aspiration: full stomach, hiatus hernia or gastro-oesophageal reflux disease were excluded from the study. The investigators were consultant anaesthesiologists, each with more than twenty years experience and well versed in the use of the LMA. They were trained to insert the PLMA according to a
protocol provided by the manufacturer, each carried out ten
insertions in patients before commencing the trial. Routine
elective laparoscopic surgical procedures included for the
study were: cholecystectomy, appendectomy, hemia repair
(incisional, umbilical and inguinal) and gynaecologic surgical
procedures such as laparoscopic assisted vaginal hysterectomy
and total laparoscopic hysterectomy.

The patients were premedicated with oral alprazolam
0.25 mg, the night prior to surgery and this was repeated
two hours preoperatively. The following parameters were
monitored: electrocardiogram, pulse oximetry, respiratory
gases, blood pressure (non invasive), tidal volume and airway
pressures. All the patients received injection midazolam
1mg, glycopyrrrolate 0.2 mg, ranitidine 50 mg and
metoclopramide 10 mg intravenously 45 min before surgery.
Anaesthesia was induced with fentanyl mg/kg−1, and propofol
2-3 mg/kg−1 thiopentone sodium 3-5 mg/kg. Maintenance of
anaesthesia was achieved with propofol infusion 2-3 mg/kg−1/hr−1/inhalational anaesthetic agent (Isoflurane / Sevoflurane)
with 66% nitrous oxide in oxygen. Neuromuscular blockade
was achieved with vecuronium bromide 0.08-0.1 mg/kg−1 for
insertion of the device and 0.1 mg/kg−1/hr−1 for maintenance
of blockade. Three minutes were allowed for full relaxation
of the jaw before placing the device.

A size 3,4 or 5 PLMA (size 3,4 in females and size
4, 5 in males) was used, as decided by the independent
investigator. The mask was inserted using the index finger
or the introducer tool as recommended by the
manufacturer.3,4 In a few select cases, laryngoscopy aided
placement was carried out e.g. partial dentition, or where
the PLMA cuff was too bulky for the oral cavity. The cuff
was inflated to a pressure of 60 cm H2O which was
maintained at this pressure throughout the procedure with
a cuff pressure monitor (VBM anaeroid meter, Germany).
Closed circle breathing system with soda lime was used.
Correct placement of the device was confirmed by:

* manual ventilation
* expired tidal volume of more than 8 ml/kg−1
* square wave capnography
* no audible leak from the drain tube with peak airway
pressures less than 20 cm H2O. A leak below 20 cm
H2O was taken as significant and suggested a
malposition.1
* The gel displacement test1, done by placing a blob of
gel at the tip of the drain tube and noting the airway
pressure at which it was ejected.

Positive pressure was started with a tidal volume of
8 ml/kg−1. The time interval between picking up the PLMA
and obtaining an effective airway was recorded. In the
event of partial or complete airway obstruction or a
significant leak, the mask was removed and reininsertion
attempted. A maximum of three insertion attempts were
allowed before the placement of the device was considered
a failure. An alternative device either an LMA or a tracheal
tube was used in such a situation and the number of attempts
to secure the airway was noted.

Oropharyngeal seal pressure was determined by
closing the expiratory valve of the circle system at a fixed
gas flow of 5 litre min−1 and recording the airway pressure
at which equilibrium was reached.5 The airway pressure
was not allowed to exceed 40 cm H2O. A flexible fibreoptic
scope (Olympus LF-2) was introduced into the airway and the drain tubes for viewing and scoring the laryngeal
and oesophageal structures. The fibreoptic position was
graded on the following scoring system: 1= clear view of
vocal cords; 2= only arytenoids visible; 3= only epiglottis
visible; 4= no laryngeal structures visible.5 The view
from the drain tube was catalogued as: hypopharynx
(mucosal); oesophageal sphincter open (clear view down
the oesophagus); others (glottis, epiglottis, arytenoids).6

A gastric tube, whenever needed, (Size 14-16) was
then passed through the drain tube. Ease of placement
of the gastric tube was recorded and its correct placement
confirmed by injection of air and epigastric auscultation.
Presence or absence of any gastric contents and its pH
was recorded.

Ease of insertion of the device was also recorded.
An easy insertion was defined as the one in which there
was no resistance to insertion in the pharynx in a single
maneuver. In a difficult insertion there was resistance to
insertion or more than one maneuver was required for the
correct placement of the device.

Intraoperatively the following parameters were
noted:

* Heart rate, systolic, diastolic and mean blood pressure
before induction, and at 1 and 5 min after insertion
of device and after achieving carboperitoneum /
insufflating carbon dioxide and then at every 5 min
intervals.
* Saturation (SpO2) and end tidal CO2 (EtCO2), at a
tidal volume of 8 ml/kg−1, FIO2 0.33 respiratory rate
of 12 b.p.m & 1/E of 1:2 were observed.

Protocol to maintain SpO2 > 95% and EtCO2< 6
Kpa was observed by adjusting the FIO2, respiratory
rate and the tidal volume. If SpO2 fell below 97%,
FIO₂ was increased and if the SpO₂ did not improve, the tidal volume was increased to 12 mlkg⁻¹. If EtCO₂ increased above 5.6 kPa, respiratory rate was increased to 14 b.p.m., then 16 b.p.m. followed by tidal volume increase up to 12 mlkg⁻¹.

A period of three minutes was allowed between adjustments of FIO₂, tidal volume and respiratory rate. When SpO₂ was 94–90% the oxygenation was graded as suboptimal and failed if it was < 90%. With EtCO₂ readings, suboptimal ventilation was between <6.0 to 7.3 kPa or failed if the reading was >7.3 kPa.

- Peak airway pressures were recorded once the abdominal pressure reached 15 mmHg. For most abdominal laparoscopic procedures, the intra-abdominal pressures were kept between 12 to 14 mmHg.
- Ease of placement of gastric tube through the drain tube.
- Episodes of gastric insufflation noted during the laparoscopic procedure by the surgeon were recorded.

Intraoperative analgesia was achieved with intravenous fentanyl boluses of 10-20 mg and intramuscular diclofenac sodium (50–75 mg). The following intraoperative complications were documented: aspiration-regurgitation, hypoxia (SpO₂ < 90%), hypercarbia, bronchospasm, airway obstruction, gastric insufflation, blood staining of the device, and tongue-lip-dental trauma. Residual blockade was reversed with 1.2 mg atropine and 2.5 mg neostigmine.

After the completion of procedure, the PLMA was removed when the patient was able to open the mouth on command. Any blood detected on the device on removal and duration of anaesthesia was recorded. Secretions, if present, over both the ventral and dorsal aspect of the PLMA were noted and pH tested with a litmus paper sensitive to changes of 0.5 unit pH from pH 2.5 to 8.5. Postoperatively, the patients were monitored for heart rate, blood pressure, SpO₂ and respiratory rate, and any incidence of nausea and vomiting. Patients were questioned directly about sore throat in the recovery room. Enquiry about the same was made 24 hrs later.

Results

The different procedures that were carried out are shown in table 1. The characteristics of the 100 patients are shown in table 2. The mean (range) age, height, weight and BMI were 44.04 (13-85) yr, 159.46 (121.92 182.88) cm, 63 (40-110) kg, 24.5 (16.7-45.8)kgm⁻² respectively. However, there were two exceptions as two patients with BMI of >35 were included in the study. The male:female ratio was 57:43. Time taken for the placement of the device was mean 13.51 and range (5-33) sec.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of cases(%)</th>
</tr>
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<tbody>
<tr>
<td>Cholecystectomy</td>
<td>40</td>
</tr>
<tr>
<td>Inguinal Hernia</td>
<td>25</td>
</tr>
<tr>
<td>Gynaecological</td>
<td>6</td>
</tr>
<tr>
<td>Appendectomy</td>
<td>5</td>
</tr>
<tr>
<td>Incisional Hernia</td>
<td>5</td>
</tr>
<tr>
<td>Umbilical Hernia</td>
<td>3</td>
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<tr>
<td>Diagnostic Laparoscopic(Gen Surgery)</td>
<td>3</td>
</tr>
<tr>
<td>Cyst, Anterior Abdominal Wall</td>
<td>1</td>
</tr>
<tr>
<td>Lipoma chest</td>
<td>1</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Procedure Placement</th>
<th>37, 51, 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion attempts: 1/2/3 (n)</td>
<td>80, 14, 06</td>
</tr>
<tr>
<td>Failed insertions: ET, LMA</td>
<td>03, 02, 01</td>
</tr>
<tr>
<td>Easy</td>
<td>72</td>
</tr>
<tr>
<td>Difficult</td>
<td>6</td>
</tr>
<tr>
<td>With Inserter</td>
<td>8</td>
</tr>
<tr>
<td>Without Inserter</td>
<td>7</td>
</tr>
<tr>
<td>Laryngoscope aided</td>
<td>1</td>
</tr>
<tr>
<td>With inserter</td>
<td>8</td>
</tr>
<tr>
<td>Without inserter</td>
<td>3</td>
</tr>
</tbody>
</table>
Fibreoptic position of the airway tube showed grade 1 in 57, grade 2 in 3 (6.12%), grade 3 in 2 (2.72%) and grade 4 in 1 (1.36%) patients respectively [Table 4]. There was down-folding of epiglottis in 5 patients. The fibreoptic view from the drain tube revealed an open upper oesophageal sphincter in 1 patient.

<table>
<thead>
<tr>
<th>Table - 4 : Fibreoptic Grading.</th>
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</thead>
<tbody>
<tr>
<td>Airway tube</td>
</tr>
<tr>
<td>Not attempted</td>
</tr>
<tr>
<td>Grade 1</td>
</tr>
<tr>
<td>Grade 2</td>
</tr>
<tr>
<td>Grade 3</td>
</tr>
<tr>
<td>Grade 4</td>
</tr>
<tr>
<td>Drain tube</td>
</tr>
<tr>
<td>Not attempted</td>
</tr>
<tr>
<td>Hypopharynx seen</td>
</tr>
<tr>
<td>UOS seen</td>
</tr>
</tbody>
</table>

The mean airway seal pressure was 28.04 cm H₂O. One patient achieved a seal pressure of 19 cm H₂O, in 80 patients it was between 20-29 cm H₂O, 14 patients had between 30-39 cm H₂O, while 5 patients had a seal pressure of more than 40 cm H₂O.

There was optimal oxygenation in all the cases before and after CO₂ insufflation in the body as shown in table 5. There was one case of failed ventilation in a patient of incisional hernia after CO₂ insufflation where ETCO₂ exceeded 7.3kPa. Here the PLMA was changed to the Classic LMA and the case proceeded uneventfully.

<table>
<thead>
<tr>
<th>Table - 5 : Peak airway pressure, Oxygenation &amp; Ventilation</th>
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<tbody>
<tr>
<td>PLMA</td>
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<tr>
<td>Peak airway pressure (cm H₂O)</td>
</tr>
<tr>
<td>Before CO₂ insufflation</td>
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<tr>
<td>After CO₂ insufflation</td>
</tr>
<tr>
<td>Optimal/suboptimal/failed oxygenation (n)</td>
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<tr>
<td>Before CO₂ insufflation</td>
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<tr>
<td>After CO₂ insufflation</td>
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<tr>
<td>Optimal/suboptimal/failed ventilation (n)</td>
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<tr>
<td>Before CO₂ insufflation</td>
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<td>After CO₂ insufflation</td>
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</table>

There were no significant haemodynamic changes at 1 and 5 min after insertion of the device (P< 0.05 was taken as significant), as shown in table 6. Mean heart rate changed from 91.38 of pre-induction to 92.16 at 1 min and 92.18 at 5 min after insertion. The mean arterial pressure changed from 91.7 of pre-induction to 91.99 at 1 min and 95.76 at 5 min after insertion. The changes observed in systolic and diastolic blood pressures at different time intervals and P values are shown in the table.

<table>
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<th>Table - 6 : Haemodynamic Parameters</th>
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Gastric tube placement was not attempted in 26 cases, and successfully placed in 74 (98.55%) patients with first attempt success rate of 100%. Fluid was aspirated from the gastric tube in 15 out of 74 patients (20.27%). Mean gastric aspirate was 1.74 ml (range 4 to 30 ml) with pH ranging from 2.5 to 7.5. Gastric insufflation was noted in 3 patients. Regurgitation of gastric contents through the drain tube was noticed in 3 patients but there were no cases of regurgitation into the mask as detected by the litmus paper technique. There was no case of pulmonary aspiration.

Excessive secretions were noted in 18 patients, leak in 13 patients, and blood staining on the cuff following removal in 9 patients. Bronchospasm was seen in 5 patients. Sore throat was reported in 3 patients and tongue-lip-dental trauma was noted in 4 patients.

Discussion

A relatively new device, the PLMA is an improved version of the Classic LMA and offers some added safety features over the Classic LMA such as providing a better glottic seal at low mucosal pressures and a drain tube to vent out air and regurgitant material from the stomach.1-4

We studied the ProSeal LMA in 100 patients undergoing laparoscopic surgery. The PLMA was easy to insert with a high success rate (80%) on the first attempt. We used sizes 3, 4 and 5 for our study. Earlier studies have been done with sizes 4 and 5 only.1-8 Size 3 is appropriate for most of our female population. The insertion success rates, insertion time, fibreoptic position of the airway tube and drain tube, and ease of placement of gastric tube were in conformity with earlier reported studies.1-4 There were minimum haemodynamic responses to insertion.4
We used the PLMA in varied surgical procedures, the majority being laparoscopic cholecystectomies, followed by laparoscopic inguinal hernia repairs. The procedures included intraperitoneal as well as extraperitoneal CO₂ insufflation in the body. Following peritoneal insufflation, CO₂ is absorbed transperitoneally, and the rate at which this occurs depends on the gas solubility, the perfusion of the peritoneal cavity, and the duration of the pneumoperitoneum. Maltby and colleagues found that end-tidal CO₂ and pulmonary CO₂ elimination increased between the eighth and tenth minutes, regardless of site and duration of insufflation. The CO₂ absorption is more following extraperitoneal rather than intraperitoneal insufflation. Increasing the minute ventilation by 15-25% is necessary to maintain normocarbia under well functioning physiological mechanisms.

The PLMA formed an effective seal around the glottis as reported by previous workers, allowing adequate oxygenation before and after CO₂ insufflation in all patients. A maximum number of patients (80%) in our study achieved peak airway pressures between 20-29 cm of H₂O. There was one case of failed ventilation in a patient of incisional hernia after carboperitoneum where the EtCO₂ exceeded 7.3kPa. Here an Intubating LMA replaced the PLMA and hernia after carboperitoneum where the EtCO₂ exceeded 7.3kPa. Here an Intubating LMA replaced the PLMA and the case proceeded uneventfully.

Maltby and colleagues, as well as other workers have reported adequate airway management and ventilation with the use of the Classic LMA during carboperitoneum for laparoscopic cholecystectomy whereas Lu et al do not recommend the use of the Classic LMA for the same. In another comparative study of the PLMA as an alternative to the tracheal tube for laparoscopic cholecystectomy, Maltby et al reported that both the devices (LMA & PLMA) provided equally effective pulmonary ventilation without clinically significant gastric distension in their non-obese patients.

We found that 20.27% of our study patients had residual gastric fluid with an average volume of 1.74 ml (range 4 to 30 ml) with pH ranging from 2.5 to 7.5. Brain and colleagues reported in a study the average residual gastric volume in patients undergoing minor procedures with the PLMA was 15 ml. None of these patients had reflux disease and therefore were not at risk of aspiration. All our patients, none of whom had a history of reflux disease, received metoclopramide, a prokinetic agent which markedly increases lower oesophageal sphincter tone. This could explain the small residual gastric volumes. We placed a gastric tube in all our patients with carboperitoneum to remove the residual gastric fluid, even though there is a possibility that this may render the LOS incompetent and precipitate regurgitation. Brimacombe recommends its use in cases of difficult insertions and also where displacement of the mask can occur intraoperatively. The Classic LMA, though popular in short gynaecological laparoscopic procedures, does not offer protection to the trachea against aspiration of regurgitated material.

Gastric insufflation was noted in 3 patients. Tracheal intubation was done in one patient with a view to avoid further gastric distension, which had occurred after PLMA insertion and positive pressure ventilation (PPV) but the maneuver proved unsuccessful. Similar instances have been noted by Maltby and other workers who reported an equal incidence of gastric insufflation in paralysed intubated patients and in those who were managed with either the Classic LMA or the ProSeal as the airway device. Stix et al noted oesophageal insufflation and gastric distension in two cases and cautioned that this can occur as a consequence of breach of the PLMA-UOS seal by PPV.

Patients undergoing laparoscopy might be considered to be at risk of developing the acid aspiration syndrome. However, the increased intra-abdominal pressure results in increase in the tone of the lower oesophageal sphincter, which allows maintenance of the pressure gradient across the gastro-oesophageal junction, and which might therefore reduce the risk of regurgitation.

Regurgitation of gastric contents through the drain tube was noted in 3 patients but there were no cases of regurgitation into the bowl of the PLMA as detected by the litmus paper technique. There was no case of pulmonary aspiration. Furthermore, the head-down position used in these cases should help prevent any regurgitated fluid from entering the airway.

Conclusions

Most anaesthesiologists, and the authors are no exception; definitely have more experience and confidence in tracheal intubation. The PLMA is emerging as an effective alternative to tracheal intubation, its applications and safety are still being evaluated. It is likely that the successful first time insertion of the PLMA will increase with more frequent use of the device. We suggest that the experienced anaesthesiologists use the PLMA and correct position of the device must be ensured before embarking on the surgical procedure. There should be no hesitation in using an alternative device in case there is a problem regarding adequate ventilation or oxygenation. It has a special role in patients with difficult intubation coming for elective surgery where its use will avoid unnecessary trauma to the airway. Our data showed that the PLMA is a safe airway device in patients undergoing laparoscopic surgery as judged by stable haemodynamics, good oxygenation and adequate ventilation. We consider that residual gastric fluid should be removed by gastric aspiration.
ANNOUNCEMENT

Dear Members,

In order to utilize optimally the spaces available in the journal and also to provide useful information to all our readers, newer sections on Applied Anatomy, Applied Physiology, History, Physics, Medico legal hints, How I do it, etc. have been started. Brief writeups on any of the above topics are invited.

– Editor