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The ProSeal™ laryngeal mask airway is an effective alternative to laryngoscope-guided tracheal intubation for gynaecological laparoscopy

Y. LIM*, S. GOEL†, J. R. BRIMACOMBE‡

Department of Women's Anaesthesia, KK Women's and Children's Hospital, Singapore, Department of Anaesthesia, Mumbai Hospital, Mumbai, India and James Cook University, Department of Anaesthesia and Intensive Care, Cairns Base Hospital, Cairns, Queensland, Australia

SUMMARY

We tested the hypothesis that the ProSeal™ laryngeal mask airway is superior to laryngoscope-guided tracheal intubation for gynaecological laparoscopy. One-hundred and eighty consecutive patients (ASA grade 1-2, aged 18-80 y) were divided into two equal-sized groups for airway management with the ProSeal™ laryngeal mask airway or tracheal tube. Induction was with fentanyl/propofol, maintenance with sevoflurane and muscle relaxation with atracurium. The following primary variables were tested: time to achieve an effective airway, ventilatory capability, peak airway pressure before and after pneumoperitoneum, duration of surgery and pneumoperitoneum and haemodynamic responses. Data about gastric size, airway trauma and sore throat were collected. The number of attempts for successful insertion were similar, but effective airway time was shorter for the ProSeal™ laryngeal mask airway (20±2s vs 37±3s, P<0.001). All devices were successfully inserted within three attempts. There was no episode of failed ventilation or hypoxia. The haemodynamic stress responses to insertion and removal were greater for the tracheal tube than the ProSeal™ laryngeal mask airway. The duration of surgery, duration of pneumoperitoneum and intra-abdominal pressures were similar. Gastric size was similar at the start and end of surgery. There were no differences in the frequency of complications or sore throat.

We conclude that the ProSeal™ laryngeal mask airway is a similarly effective airway device to conventional laryngoscope-guided tracheal intubation for gynaecological laparoscopy, but is more rapidly inserted and associated with an attenuated haemodynamic response to insertion and removal.

Key Words: ProSeal laryngeal mask airway, tracheal intubation, gynaecological laparoscopy, ventilation

Although there is evidence that the classic laryngeal mask airway (classic LMA) is a safe and effective airway device for gynaecological laparoscopy, most clinicians prefer to use a tracheal tube (TT) as they consider ventilation and airway protection to be mandatory and do not consider that the classic LMA fulfils these requirements[1,2]. The ProSeal™ laryngeal mask airway (PLMA; Laryngeal Mask Company, Henley-on-Thames, U.K.) is an improvement of the classic LMA with a modified cuff to increase the seal and a drain tube to provide a channel for regurgitated fluid, prevention of gastric insufflation and insertion of a gastric tube[3,4]. Maltby et al[5] in 2003 and Piper et al[6] in 2004 showed that the PLMA was as effective as a TT for gynaecological laparoscopy, with some advantages in terms of ease of insertion, haemodynamic responses and airway protective reflex activity. In the following randomised non-crossover trial we test the hypothesis that the PLMA is a superior airway device to conventional laryngoscope-guided tracheal intubation in anaesthetised paralysed patients undergoing gynaecological laparoscopy.

METHODS

After ethics committee approval and written informed consent, we studied 180 consecutive patients (American Society of Anesthesiologists grade 1-2, aged 18-80 y) scheduled for elective gynaecological laparoscopy. Patients were randomized into two groups of equal size for airway management with either the PLMA or TT. Randomisation was by opening an opaque sealed envelope containing the

* M.Med. (Anaesth), Associate Consultant, Department of Women's Anaesthesia, KK Women's and Children's Hospital.
† M.D., Consultant Anaesthetist, Department of Anaesthesia, Mumbai Hospital.
‡ M.D., James Cook University, Department of Anaesthesia and Intensive Care, Cairns Base Hospital.

Address for reprints: Prof. J. Brimacombe, Department of Anaesthesia and Intensive Care, Cairns Base Hospital, The Esplanade, Cairns, Qld. 4870.

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computer-generated allocation. Patients were excluded if they had a predicted (Mallampati III/IV) or known difficult airway; were at risk of aspiration (not fasted, gastro-oesophageal reflux); or had a body mass index greater than 30 $kg.m^{-2}$. Airway management was by two anaesthetists with more than five years training, both of whom were proficient with the PLMA (>500 uses, first attempt failure rate <10%).

Patients were not premedicated. A standard anaesthesia protocol was followed and routine monitoring was applied. Anaesthesia was induced with the patient supine and with their head on a standard pillow, 7 cm in height. After three minutes' preoxygenation, anaesthesia was induced with fentanyl 2 $\mu g.kg^{-1}$ intravenous (IV) and propofol 2 $mg.kg^{-1}$ IV. Muscle relaxation was achieved with atracurium 0.5 $mg.kg^{-1}$ IV. The lungs were manually inflated via a face mask using 2 to 3% sevoflurane in 100% oxygen until the train-of-four count was zero. A Guedel airway was not used. Sevoflurane 2 to 3% in 40% oxygen and air was used for maintenance of anaesthesia.

The PLMA size was according to the manufacturer's weight-based recommendations. A 7.0 mm internal diameter (ID) TT was used. The PLMA was inserted using the digital technique and the cuff inflated with air to an intracuff pressure of 60 cm H_2O. The volume of air required to achieve this pressure was recorded. The TT was inserted after the best possible views of the vocal cords had been obtained using a size 3 Macintosh blade. The cuff was inflated with the minimum volume of air required to form an effective seal for ventilation. All devices were fixed by taping the tube to the face.

Three attempts were allowed before airway device insertion was considered a failure. A failed attempt was defined as removal of the airway device from the mouth. An effective airway was defined as a square-wave capnograph trace during manual ventilation. The time between picking up the airway device and obtaining an effective airway was recorded as the effective airway time. If an effective airway could not be achieved within three insertion attempts, an alternative airway device or a different size was used, but no further data were collected.

In the PLMA group, a size 14 French gauge orogastric tube was inserted through the drain tube if there was no air leak up the drain tube during positive pressure ventilation. Gastric tube placement was graded as easy, difficult or failed. Advancement of the gastric tube along the drain tube was permitted to a maximum of three times. Correct gastric tube placement was determined by suction of fluid or detection of injected air during epigastric auscultation. In the PLMA group, oropharyngeal leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 $l.min^{-1}$ and noting the airway pressure (maximum allowed 40 cm H_2O) at which equilibrium was reached[7].

Patients underwent volume-controlled ventilation at tidal volumes of 10 $ml.kg^{-1}$ with the respiratory rate adjusted to maintain normocapnoea. Intraoperative analgesia was obtained with morphine 0.1 $mg.kg^{-1}$. The surgeon, who was blinded to the airway management technique, graded gastric size at the start and end of surgery on an ordinal scale of 0 (completely collapsed) to 10 (grossly distended). Peak airway pressures were recorded by a blinded observer, before and during pneumoperitoneum. Muscle relaxation was reversed using neostigmine and atropine. Anaesthesia was discontinued when the train-of-four count was three or greater and the airway device was removed when the patient was able to open their mouth to command. Any blood staining on the airway device was documented.

The following additional data were collected: heart rate and blood pressure at (i) insertion and (ii) removal of the airway device and at 2.5 and 5 minutes thereafter, duration of surgery and pnemoperitoneum, and respiratory rate, minute volume and end-tidal CO_2 during pneumoperitoneum. Episodes of hypoxia (arterial oxygen saturation (SpO_2) <91%) or inadequate ventilation (end-tidal carbon dioxide tension (E_TCO_2) >50 mmHg) before, during or after pneumoperitoneum were recorded. Patients were asked about the presence/absence of sore throat (constant pain, independent of swallowing) one to two hours postoperatively. Patients were unaware of the insertion technique used. Unblinded trained observers collected all data during anaesthesia (other than the data about gastric size collected by the surgeon) and blinded trained observers collected postoperative data.

The primary variables tested were time to achieve an effective airway, ventilatory capability, peak airway pressure before/after pneumoperitoneum, duration of surgery/pneumoperitoneum and haemodynamic responses. Secondary variables were gastric size, airway trauma and sore throat. Sample size was based upon a projected difference of 5% between the groups for successful ventilation (E_TCO_2<50 mmHg). The primary variable requiring the largest sample size was ventilatory capability. The sample size allowed a projected difference of 5% or less to be detected between the groups for all of the primary variables for a type I error of 0.05 and a power of 0.8. The distribution of data was determined using Kolmogorov-Smirnov analysis[8]. Statistical analysis was with Student's t test for parametric data and the Mann Whitney U test for non-parametric data. Serial

data were analysed by repeated measure analysis of variance. Data are presented as mean±SD (range) unless otherwise stated. Significance was taken as $P<0.05$.

RESULTS

All patients were included in the analysis. The parametric data were normally distributed. There were no differences in demographic or surgical data (Table 1). The number of attempts for successful insertion were similar, but the effective airway time was shorter for the PLMA (Table 2). All devices were successfully inserted within three attempts. There were no differences in respiratory parameters during pneumoperitoneum. There were no episodes of hypoxia or failed ventilation before, during or after pneumoperitoneum. The haemodynamic responses to insertion and removal were greater for the TT than the PLMA (Table 3). Gastric size was similar at the start and end of surgery. There were no significant differences in the frequency of sore throat. Oropharyngeal leak pressure for the PLMA was 27±4 cm H_2O. Orogastric tube insertion was easy in 80 patients but difficult in 10 patients.

TABLE 1
Demographic and surgical data

	ProSeal LMA	Tracheal tube
n	90	90
Demographic		
Age, y	41±10	38±12
Height, cm	156±6	158±8.0
Weight, kg	62±13	62±16
BMI, kg/m^2	26±5	25±7
ASA 1/2 ; n	68/21	67/23
Mallampati score 1/2, n	80/10	77/13
Surgical		
Type, n		
Ovarian cystectomy	62	60
Adhesiolysis	3	0
Tubal ligation	14	14
Vaginal hysterectomy	5	8
Myomectomy	6	8
Duration of surgery, min	73±37	81±32
Duration of pneumoperitoneum, min	58±39	63±31
Intra-abdominal pressure, cm H_2O	13±2	13±1
Gastric size*		
At the beginning of surgery	4 (2-7)	4 (2-6)
At the end of surgery	4 (2-8)	4 (2-6)

Values are mean±SD or mean (range) or numbers.
No significant differences between groups.
*Ordinal scale of 0 (completely collapsed) to 10 (grossly

TABLE 2
Insertion, ventilation and complications

	ProSeal LMA	Tracheal tube
n	90	90
Insertion		
Effective airway time, s	20±2	37±3*
Insertion success, n		
First attempt	86	85
Second attempt	4	4
Third attempt	0	1
Failed	0	0
Ventilation		
Peak airway pressures, cm H_2O		
Before pneumoperitoneum	18±4	18±4
After pneumoperitoneum	26±4	24±6
Respiratory rate, bpm	12±2	12±2
Minute ventilation, L	5.8±3.7	6.0 ±3.2
End-tidal CO_2, mmHg	36±5	38±9
Complications		
Hypoxia	0 (0)	0(0)
Blood staining	6 (7)	5 (6)
Sore throat	18 (20)	25 (28)

Values are mean±SD or numbers (percentage).
*$P<0.001$.

TABLE 3
Haemodynamic responses to insertion and removal

	ProSeal LMA	Tracheal tube	*P* value
n	90	90	
Insertion			
Systolic blood pressure, mmHg			
Baseline	112±23	110±19	NS
Time 2.5 min	105±19	121±18	<0.001
Time 5.0 min	104±26	109±15	NS
Heart rate; bpm			
Baseline	77±14	80±12	NS
Time 2.5 min	67±12	88±9	<0.001
Time 5.0 min	68±15	86±14	<0.001
Removal			
Systolic blood pressure, mmHg			
Baseline	118±18	116±16	NS
Time 2.5 min	123±17	126±22	NS
Time 5.0 min	117±18	127±13	<0.001
Heart rate; bpm			
Baseline	74±15	75±20	NS
Time 2.5 min	74±14	81±22	NS
Time 5.0 min	78±14	84±19	0.048

Values are mean±SD or numbers (percentage).

DISCUSSION

Effective airway time was shorter with the PLMA than the tracheal tube, but the number of attempts required for successful insertion was similar. Maltby et

al[5] found no differences in insertion success, but Piper et al[6] found insertion easier with the PLMA, though insertion times were similar. Interestingly, all these groups used non-guided techniques for insertion and it is likely that success rates would have been higher and airway morbidity less if guided techniques, such as the use of a gum elastic bougie[9], had been used. We consider the time saving of 17 seconds with the PLMA to be clinically significant, as this might reduce the frequency of hypoxia at induction, particularly if facemask ventilation is difficult.

Ventilation was similarly successful during pneumoperitoneum. Again, this supports the findings of Maltby et al[5] and Piper et al[6]. Maltby et al[5] also found that ventilation was successful for the obese subpopulation. Successful use of the PLMA in grossly and morbidly obese patients has been reported[10]. We found that oropharyngeal leak pressure was 27 cm H_2O for the PLMA, which is similar to previous studies[3,9]. The efficacy of the seal is on average 10 cm H_2O higher than the classic LMA.

Haemodynamic responses to placement and removal were lower for the PLMA than the TT. This supports the findings of Piper et al[6] and is not surprising because haemodynamic responses are attenuated with insertion of the classic LMA compared with tracheal intubation and extubation[11]. The clinical importance of these differences is doubtful because patients undergoing gynaecological laparoscopy tend to be young and free of cardiovascular disease. Indeed, there is only anecdotal evidence that the haemodynamic stress response is harmful to patients with cardiovascular disease[12,13].

Gastric insufflation was not detected in either group. This supports the findings of Maltby et al[5] who also assessed gastric size by direct vision. An advantage of the PLMA over the classic LMA is that gastric insufflation is prevented provided the distal cuff is correctly positioned and the drain tube is patent, a benefit compounded by the fact that the drain tube provides information about malposition. We recommend that the gastric tube should be left on free drainage or low-grade suction during the procedure to ensure maximal emptying.

The frequency of sore throat was similar. This supports the findings of Piper et al[6]; however, sore throat was not a primary variable in either study. Laryngoscope-guided tracheal intubation is associated with a higher frequency of sore throat than the classic LMA[14]. We did not document the frequency of coughing during emergence but both Malty et al[5] and Piper et al[6] found that coughing occurred more frequently with the TT during emergence. We found that gastric tube insertion was successful in all patients after three attempts. The failures were related to the distal cuff being folded over or inadequate lubrication.

Viira and Myles[2] in a recent critically appraised topic found limited evidence to support or refute the hypothesis that the classic LMA was safe for gynaecological laparoscopy. They noted that the reported incidence of aspiration, or more serious morbidity associated with the use of the classic LMA, was very low. In a meta-analysis, including data from 4842 patients, one of the authors (JB) concluded that it was safe and effective[1]. The PLMA offers advantages over the classic LMA for gynaecological laparoscopy in terms of ventilatory capability[3] and probably airway protection[15]. The combined findings of Maltby et al[5], Piper et al[6] and the current study suggest that the PLMA is a reasonable alternative to conventional tracheal intubation for gynaecological laparoscopy, with some advantages in usage.

Our study has a number of limitations. First, most intra-operative data were collected unblinded, a possible source of bias. Second, all insertions were by experienced anaesthetists and our findings may not apply to those with less experience. Third, we did not attempt to insert a gastric tube in the TT group. However, Piper et al[6] found that gastric tube insertion was easier with the PLMA than the TT.

We conclude that the PLMA is a similarly effective airway device to conventional tracheal intubation for gynaecological laparoscopy, but is more rapidly inserted and associated with an attenuated haemodynamic response to insertion and removal.

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