PROSEAL LARYNGEAL MASK AIRWAY VERSUS ENDOTRACHEAL TUBE FOR DELIVERING POSITIVE PRESSURE VENTILATION DURING LAPAROSCOPIC SURGERY

BY
DR. MARINI OTHMAN

Dissertation Submitted In
Partial Fulfillment of the Requirements for
The Degree of Masters of Medicine
(Anaesthesiology)

UNIVERSITI SAINS MALAYSIA

UNIVERSITI SAINS MALAYSIA
MAY 2007

TO

My Parents
My Beloved Husband

and

Dearest Children

ACKNOWLEDGEMENT

Bismillahirrahmanirrahim

I would like to take this opportunity to grant my heartiest gratitude and extend my appreciation to the following persons who have helped me right from the start until the completion of my dissertation:

- Associate Professor Dr. Nik Abdullah Nik Mohamad, Head and Lecturer of Anaesthesiology and Intensive Care Unit, Universiti Sains Malaysia for his valuable advice and guidance towards this study.
- Dr. Shamsul Kamaruljan, Lecturer of Anaesthesiology and Intensive Care Unit, Universiti Sains Malaysia for his guides, valuable comments and support as a supervisor for this study.
- Dr. Ruwaida Isa, Clinical Specialist, Department of Anaesthesiology and Intensive Care, Hospital Kota Bharu for initiating me with ideas for the study and her continuous support and advice.
- All the lecturers and medical officers, Department of Anaesthesiology and Intensive Care Unit, University Sains Malaysia for their helpful assistance.
- To my parents; Othman bin Ab. Rahman and Ramlah Hamat for their vigilant prayers and love that makes me as who I am today.
- Last but not least, my dearest husband Dr. Mat Zuki Mat Jaeb, my children; Muhd. Amir Firdaus, Muhd. Arif Hakimi, Muhd. Amin Baihaqi, Sofia Mardhiah and Aleesa Solehah who inspired me with their endless support and love in ensuring the completion of this study.

ABSTRAK

Tujuan kajian ini dijalankan adalah untuk menilai samada "Proseal Laryngeal Mask Airway" (PLMA), alat bantuan pernafasan semasa bius yang baru di pasaran boleh menjadi alternatif yang baik kepada alat bantuan pernafasan Tiub Endotrakea (ETT) dalam membantu memberikan ventilasi tekanan positif semasa pembedahan laparoskopi. Kami membandingkan perubahan hemodinamik (kadar denyutan jantung, tekanan darah sistolik, tekanan darah diastolik dan tekanan darah purata) yang direkodkan pada jarak masa tertentu sepanjang pembedahan, kualiti pernafasan pesakit yang menggunakan kedua-dua alat intubasi yang dikaji melalui rekod peratusan oksigen saturasi dalam darah (SpO_2) dan rekod kadar karbon dioksida dalam udara hembusan ($ETCO_2$) juga komplikasi yang dialami semasa dan selepas pembedahan yang berkaitan dengan penggunaan kedua alatan ini. Kami menjalankan kajian prospektif ke atas 64 pesakit yang menjalani pembedahan laparoskopi.

Para pesakit dibahagikan kepada dua kumpulan; kumpulan yang menggunakan PLMA dan yang menggunakan ETT sebagai alat bantuan pernafasan. Setiap kumpulan mempunyai 32 subjek Selepas induksi pembiusan, intubasi menggunakan PLMA atau ETT dilakukan dan alatan ini disambungkan ke mesin bantuan pernafasan (ventilator) yang akan membekalkan ventilasi tekanan positif kepada pesakit pada kadar pernafasan dan jumlah isipadu gas yang ditetapkan. Pembiusan kemudian dikekalkan menggunakan gas Nitrus Oksida, Oksigen dan Isoflurane. Selepas pembedahan tamat, alatan pernafasan di keluarkan dalam keadaan pesakit sedar sepenuhnya. Perubahan hemodinamik direkodkan pada jarak waktu ditetapkan, bersama-sama perubahan SpO_2 dan $ETCO_2$.

Komplikasi yang berlaku sewaktu pembedahan (pesakit batuk, muntah, "bronchospasm", desaturasi dan kebocoran gas pernafasan) direkodkan sekiranya ada.

Sekiranya terdapat darah pada alatan pernafasan semasa proses ekstubasi, ianya juga direkodkan. Kemudian kami merekodkan komplikasi selepas pembedahan sekiranya ada iaitu batuk berterusan, muntah dan sakit tekak.

Kajian kami mendapati tiada perbezaan statistik pada kadar denyutan nadi yang direkodkan pada jarak waktu tertentu antara kedua-dua alat yang dikaji. Terdapat perbezaan statistik pada tekanan darah sistolik dan tekanan darah purata yang direkodkan pada minit pertama, minit ke-5, minit ke-10 dan minit ke-15 selepas intubasi, dimana kumpulan PLMA merekodkan tekanan darah yang lebih rendah berbanding kumpulan ETT. Untuk tekanan darah diastolik, kadar yang lebih rendah untuk kumpulan PLMA hanya signifikan secara statistik pada minit ke-10 dan ke-15 selepas intubasi. Apabila membandingkan SpO2 dan ETCO2, tiada terdapat perbezaan statistik di antara kedua-dua kumpulan kajian.

Tidak ada perbezaan statistik di antara insiden batuk, regurgitasi, desaturasi, "bronchospasm" dan kebocoran gas dari alatan pernafasan. Kajian kami juga mendapati tiada perbezaan statistik di antara insiden terdapatnya kesan darah pada alatan pernafasan semasa ianya dikeluarkan selepas pembedahan selesai. Bagi komplikasi selepas pembedahan, kami mendapati bagi insiden batuk berterusan dan muntah selepas pembedahan, tiada perbezaan statistik bagi kedua kumpulan. Bagaimanapun, terdapat perbezaan statistik antara kedua-dua kumpulan bagi insiden sakit tekak di mana kumpulan ETT mempunyai peratusan yang lebih tinggi dengan $p = 0.001$.

Kami membuat kesimpulan bahawa PLMA adalah alternatif yang baik terhadap penggunaan ETT semasa pembedahan laparoskopi di mana ianya mempunyai kelebihan dari segi kestabilan hemodinamik, memberikan kualiti pernafasan yang baik kepada pesakit sepanjang pembedahan dan tidak menunjukkan terdapatnya lebih insiden komplikasi semasa dan selepas pembedahan berbanding ETT.

ABSTRACT

The purpose of our study is to assess whether the new Proseal Laryngeal Mask airway (PLMA) can be a suitable alternative to the standard use of Endotracheal Tube (ETT) as an airway adjunct to deliver positive pressure ventilation during laparoscopic surgeries. We compared haemodynamic changes (by measuring heart rates, systolic blood pressures, diastolic blood pressures and mean arterial pressures at different time intervals) throughout the surgery, the quality of airway maintenance by measuring SpO2 and ETCO2 and recorded intra operative as well as post operative complications related to use of both airway devices. We performed a prospective single blinded study on 64 patients undergoing laparoscopic surgical procedures. These patients were randomized using block randomization and divided into two groups; PLMA and ETT group. Both groups have 32 patients. After standardized induction of anaesthesia, PLMA or ETT was inserted and the patient was connected to ventilator that delivered positive pressure ventilation at set tidal volume and rate. Anaesthesia was maintained with Nitrous oxide, Oxygen and Isoflurane. Both airway devices were removed at the end of surgery with the patients fully awake. The haemodynamic changes were recorded at different time intervals, together with SpO2 and ETCO2 changes. The incidences of intra operative complications (coughing, regurgitation, bronchospasm, desaturation and gas leaking) were recorded if present. The presence of blood upon airway device removal that indicates airway trauma was also recorded. Then we recorded post operative complications if present (persistent cough, vomiting and sore throat).

We found that there were no statistical differences in HR changes measured at different time intervals between PLMA and ETT. However there were statistically significant decrease in systolic blood pressures and mean arterial pressures for PLMA group at 1 minute, 5 minute, 10 minute and 15 minute post intubation. For diastolic blood pressures, the lower values in PLMA group were only significant at 10 and 15 minutes post intubations. Comparing SpO2 and ETCO2 monitoring, generally there were no significant statistical differences for both groups studied.

Our findings on intra operative complications were that both groups have no statistical difference in the incidence of coughing, regurgitation, desaturation, bronchospasm and gas leaking. For presence of blood upon airway devices removal, we found no statistical difference between PLMA and ETT groups. The incidence of post operative persistent coughing and vomiting were also found to be statistically insignificant for both groups, however incidence of post operative sore throat was significantly higher in ETT group compared to PLMA with p value of 0.001.

Therefore we concluded that for laparoscopic surgery with positive pressure ventilation, PLMA is a suitable alternative to standard ETT use and may offer advantages in terms of haemodynamic changes, with lower incidences or no statistically significant peri operative complications related to its use.

TABLE OF CONTENTS

LIST OF PICTURES/ TABLES

LIST OF FIGURES

ABBREVIATIONS

ASA	American Society of Anaesthesiologists
BMI	Body mass index
BTL	Bilateral Tubal Ligation
CO2	Carbon Dioxide
CO	Cardiac Output
CPR	Cardiopulmonary Resuscitation
CVP	Central Venous Pressure
DBP	Diastolic Blood Pressure
ENT	Ear, nose and throat
ETCO2	End Tidal Carbon Dioxide
ETT	Endotracheal Tube
FG	French Gauge
FRC	Functional Residual Capacity
HR	Heart Rate
ID	Internal Diameter
I: E	Inspiratory: Expiratory Ratio
GEB	Gum Elastic Bougie
IPPV	Intermittent Positive Pressure Ventilation
IV	Intravenous
LMA	Laryngeal Mask Airway
LT	Laryngeal Tube
MAP	Mean Arterial Pressure

N2O	Nitrous Oxide
O2	Oxygen
PaO2	Partial Pressure of Oxygen
PaCO2	Partial Pressure of Carbon Dioxide
PLMA	Proseal Laryngeal Mask Airway
SBP	Systolic Blood Pressure
SD	Standard Deviation
SpO2	Oxygen Saturation
SVR	Systemic Vascular Resistance
T.O.F	Train–of-Four
VR	Venous Return

1. INTRODUCTION

Laparoscopic technique now is gaining popularity in surgical practice. It is preferred over open technique simply because of smaller incision involved hence smaller surgical scar, faster recovery time for patients; shorter hospital stays post operatively with less pain (Reddick et al., 1989). Among surgical procedures that incorporate laparoscopic technology are laparoscopic cholecystectomy, appendicectomy, splenectomy, adrenalectomy, bilateral tubal ligation (BTL), cystectomy and laparoscopic dye insufflation. Open surgical technique has also been associated with high incidence of chronic pain due to adhesions; therefore by incorporating laparoscopic technique this complication can be avoided.

The choice of anesthetic technique for laparoscopic surgery is mostly limited to general anesthesia because of patient discomfort associated with creation of pneumoperitoneum (intraperitoneal carbon dioxide insufflation) and the extent of position changes associated with the procedure. High intra abdominal pressures during laparoscopic surgery may increase risk of passive regurgitation of gastric contents (Cunningham et al., 1993).

Therefore to date, the goal standard airway management for laparoscopic surgeries is tracheal intubation using cuffed ETT to facilitate ventilation and prevent aspiration.
The Endotracheal Tube (ETT) is the standard and recommended item used in positive pressure ventilation and the gold standard procedure for airway management. But its use

is not without complications. Among the complications of ETT insertions are (Divatia JV. and Bhowmick K., 2005):

1. Failed intubations
2. Spinal cord and vertebral column injuries
3. Trauma to lips, teeth, tongue and nose
4. Haemodynamic instability (tachycardia, hypertension, bradycardia and arrythmias)
5. Raised intracranial pressures and intraocular pressures
6. Laryngospasm and bronchospasm
7. Oesophageal and bronchial intubations

Studies have been done to look for other alternative to ETT use in laparoscopic surgery. Classic Laryngeal Mask Airway (Classic LMA) has been suggested following two prospective studies (Maltby et al., 2000 and Ilzuka et al., 2000) and a retrospective survey (Verghese et al., 1996) as a suitable alternative in order to minimize complications related to laryngoscope and ETT use.

Among advantages of LMA compared to ETT are (Reissman et al., 2000 and Sidaras et al., 2001):

- LMA avoids the reduction in diameter that happens when one tube (the ETT) is inserted into the lumen of another (the trachea).
- LMA tube is shorter and wider compared to ETT.
- The LMA airflow resistance is between one-sixth and half of the ETT.

- The insertion doesn't require use of laryngoscope, therefore avoids trauma related to laryngoscope.
- The insertion doesn't require use of muscle relaxant, therefore reducing incidence of complications related to its use.
- LMA is the airway of choice for short procedures not requiring muscle paralysis.
- LMA can also be used for longer operations with controlled ventilations as well.
- LMA provides haemodynamic stability at induction, intubation and during emergence compared to ETT.
- Minimal increase in intraocular pressure after insertion.
- Reduced anaesthetic requirement for airway tolerance.
- Lower frequency of coughing during emergence.
- Improved oxygen saturation during emergence.
- Lower incidence of sore throat in adults.
- Impairment of mucociliary clearance, as measured by mucous transport velocity is less than the endotracheal tube.This may have implications for reducing the risk of retention of secretions, atelectasis and pulmonary infections.
- A cost analysis study proved that the LMA was the most cost-efficient airway choice if it is reused 40 times and each anaesthetic lasted for >40 min (Brimacombe J., 2004a).

The main complication of using LMA relate to the airway seal pressure of its cuff. The LMA cuff seal pressure is the inflation pressure above which gas can escape around the cuff. This is lower than with a tracheal tube, so there is a greater risk of gastric insufflations, gastro-oesophageal reflux and aspiration of regurgitated gastric contents when using LMA (Sidaras et al., 2001).

But these problems can now be overcome by using the LMA with oesophageal vent- The ProSeal Laryngeal Mask Airway (PLMA) (Brain et al., 2000).

The advantages of PLMA compared to ETT are (Brain et al., 2000):

- It has additional drainage tube placed laterally to the airway tube, designed to allow insertion of gastric tube and to vent gas or liquid from the upper esophagus.
- All above LMA advantages.

Compared to Classic LMA, PLMA forms a more effective seal and has drainage tube, therefore is a more effective ventilatory device for laparoscopic surgery than the LMA (Lu et al., 2002). Use of PLMA in laparoscopic surgery and positive pressure ventilation needs further evaluation regarding the superiority or vice versa comparing to conventional methods (ETT) (Maltby et al., 2003).

1.1 Objectives

I. To compare haemodynamic stability between use of PLMA and ETT during positive pressure ventilation under general anaesthesia in laparoscopic surgery.

II. To compare quality of airway maintenance during laparoscopic surgery between both devices (PLMA and ETT) and prove that PLMA is comparable to endotracheal tube intubation in term of airway maintenance quality.

III. To compare incidences of perioperative complications related to use of both devices (PLMA and ETT), namely:

   a. Coughing (intraoperatively)
   b. Regurgitation (intraoperatively)
   c. Desaturation
   d. Bronchospasm
   e. Gas leaking
   f. Trauma (presence of blood upon airway device removal)
   g. Persistent cough (postoperatively)
   h. Vomiting (postoperatively)
   i. Post operative sore throat

1.2. Study Hypothesis

Proseal LMA can provide better haemodynamic stability during its insertion and removal as well as during creation of pneumoperitoneum with less trauma associated with its use and non inferior quality of airway maintenance compared to endotracheal tube intubation.

1.3. Definitions

i. Haemodynamic parameters are objective measurements of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and heart rate (HR) at different time interval.

ii. Quality of airway maintenance is assessed by measuring peripheral oxygen saturation, end tidal carbon dioxide, peak airway pressures and tidal volumes achieved at different time interval. Good quality of airway maintenance is when SpO2>96%, ETCO2 ranges 35-45 mmHg, PIP not exceeding 35 and TV is maintained 6-12 mls/kg.

iii. Sore throat is defined as pain, irritation or discomfort in the throat.

iv. Airway trauma is injury caused to the upper airway structure following intubation. It may result from inadequate anaesthesia or muscle relaxation, stiffness of ETT used, excessive head and neck motion during intubation, and patient bucking and swallowing. It is indicated by presence of blood upon airway devices removal.

v. Bronchospasm is sudden onset of upper airway narrowing or closure resulting in inadequate or failed ventilation, triggered by certain stimuli eg. Surgical stimuli, presence of airway or tracheal tubes, secretions or aspirations.

vi. Coughing is a reflex partially under voluntary control. It is a deep inspiration followed by a forceful expiration against a closed glottis which is suddenly opened to allow explosive exhalation.

vii. Desaturation is when there is drop in percentage of Oxygen saturation of Hemoglobin, considered significant when it is less than 90%.

viii. Regurgitation is a reflex involving retrograde passage of gastric contents through the mouth.

ix. Gas leaking is presence of audible breath sounds heard over the mouth. Gas can also leaks into esophagus and this is confirmed by listening to the breath sounds over the epigastrium. If there is gas leaking through the drainage tube, there will be bubbling of lubricant placed on the proximal end of the drainage tube.

2. LITERATURE REVIEW

2.1. PROSEAL LARYNGEAL MASK AIRWAY

2.1.1. Introduction

The Laryngeal Mask Airway (*LMA*™ - now known as *LMA-Classic*™ or Classic LMA) was introduced into clinical practice in 1980s (Brain AIJ., 1983), and was approved by U.S Food and Drug Administration in 1991. It was approved as a substitute for the face mask during elective anaesthesia. Its introduction has brought about a revolution in anaesthesia as it fills the gap in airway management between tracheal intubation and use of the face mask.

It is relatively simple to insert and have a role in management of the difficult or failed intubation. The man behind the development of Classic LMA is a British anaesthesiologist, Dr. Archie Brain who first noticed the similarity between the general size and shape of a detached Goldman dental mask cuff and the available size and space in the pharynx as defined by his plaster of Paris molds. He suggested that the Goldman Dental Mask could be modified as to be positioned around the laryngeal inlet rather than over the nose. His initial study using a plaster of Paris casts of adult's cadaver pharynx indicated the optimal shape of the Classic LMA. A prototype was used on human patient in 1981, and a successful pilot study on 23 patients soon followed. The Classic LMA was first used in failed intubation in 1983 (Brain AIJ., 1983).

The Classic LMA became commercially available in the United Kingdom in 1988, and within 12 months was in use in more than 500 British hospitals and its use is increasing in many clinical settings, especially day-case surgery and short procedures in which intubation is unnecessary. Currently worldwide, the LMA airway is available in 60 countries and has been used in over 100 million surgeries since its introduction (Brimacombe J., 2004a).

The *LMA-ProSeal*™ (PLMA) is an advanced form of LMA that may be used for the same indications as the original Classic LMA. The PLMA is designed to provide additional benefits over the Classic LMA that extends the range of procedures for which an LMA is indicated (Brain et al, 2000).

The PLMA was first described by Brain and colleagues in 2000 (Brain et al., 2000). It is the most ingenious and versatile of the LMA devices and has great potential to improve patient safety. It supersedes LMA Classic in most clinical situations and challenges ETT in many clinical situations. During its development, Dr. Brain's goal was to construct a laryngeal mask with improved ventilatory characteristics that also offered protection against regurgitation and gastric insufflations, provided information about whether it was malpositioned and could be inserted without intraoral manipulation.

2.1.2. Characteristics of the Proseal Laryngeal Mask Airway

The ProSeal Laryngeal Mask Airway (PLMA) is a new wire-reinforced Laryngeal mask device with a larger, wedge-shaped cuff and a drainage tube. The design should improve the seal with the larynx (Brimacombe J., 2004a).

The PLMA has four main components: mask inflation line with pilot balloon, airway tube and drainage tube (Picture 1).

It is made from medical grade silicone and has modified features (Keller et al., 2000a):

1. A Dorsal cuff- pushes the ventral cuff into the periglottic tissues to improve the seal.
2. A Ventral cuff- larger proximally to improve seal. A revised cuff arrangement allows a higher seal than Classic LMA for a given intra-cuff pressure.
3. A Drainage tube- for passage of a gastric tube to vent regurgitated fluid and to provide information about device position. It also allows blind insertion of standard oro-gastric tubes, in any patient position, without the need to use Magill's forceps.
4. A double tube arrangement which reduces the likelihood of mask rotation and increases stability; the revised cuff profile together with the flexible tubes, result in the device being more securely anchored in place.
5. A built-in integral bite block which reduces the danger of airway obstruction or tube damage.
6. A locating strap or introducer on the anterior distal tube which also accommodates the index finger or thumb for manual insertion.
7. An introducer tool which comes together with the PLMA.
8. An accessory vent.
9. A wire-reinforced airway tube- prevents the double-tube configuration from being too stiff.
10. A deeper bowl than standard LMA.

11. The position of the drainage tube inside the cuff prevents the epiglottis occluding the airway tube. This eliminates the need for aperture bars.

All components are latex free. The Laryngeal Mask Company recommends that the PLMA be used a maximum of 40 times before being discarded (Brimacombe J., 2004a). The PLMA is designed to be a minimally stimulating airway device. When fully inserted using the recommended insertion technique, the distal tip of the cuff presses against the upper oesophageal sphincter. Its sides face into the pyriform fossae and the upper border rests against the base of the tongue. The cuff is designed to be inflated to a low pressure (approximately 60cm H2O). Overinflation may not improve the seal, may be associated with mucosal ischaemia, may cause the device to be dislodged, and may cause the drain tube to collapse. If higher pressures are required to achieve a seal, it is recommended that a larger size PLMA be used. In general, it is recommended that the largest size which remains in place when inflated to a pressure of 60cm H2O should be used (Brimacombe J., 2004a).

2.1.3. Size Selection

Table 2.1: LMA size recommendations and inflation volumes (Brimacombe J., 2004a)

LMA size	Patient Weight (kg)	Increase in Size (%)	Maximum Inflation Volumes (ml)	Test Inflation Volumes (ml)
1	Neonates/ Infants up to 5 kg	-	4	6
1.5	5-10	21	7	10
2	10-20	21	10	15
2.5	20-30	18	14	21
3	30-50	15.7	20	30
4	50-70	14.4	30	45
5	70-100	13.8	40	60
6	>100	8.1	40	60

According to Kihara et al., 2004 size selection for the ProSeal Laryngeal Mask airway is equally effective using the manufacturer's weight-based formula or the sex-based formula in healthy, anaesthetized, paralyzed adult patients, but leakage of small volumes of air from the mouth occurs less frequently with the sex-based formula.

2.1.4. Indications for PLMA use

The PLMA is indicated for use in achieving and maintaining control of the airway. It may be used with spontaneous and Positive Pressure Ventilation (PPV) during routine and

emergency anaesthetic procedures in fasted patients. It is also indicated for securing the immediate airway in known or unexpected difficult airway situations.

The PLMA may be used to establish an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes requiring artificial ventilation. It has recently been included in the European Cardiopulmonary Resuscitation algorithm on immediate airway management during CPR, and in the American Society of Anaesthesiologist algorithm for management of difficult airway. It may also be used to secure an immediate airway when tracheal intubation is precluded by lack of available expertise or equipment, or when attempts at tracheal intubation have failed (Brimacombe J., 2004a).

ProSeal LMA has been increasingly used in difficult intubation cases. Cook and colleaques reported two cases in which the ProSeal LMA was used to initiate controlled ventilation in the intensive care unit and subsequently provide airway maintenance during percutaneous dilational tracheostomy. This device allowed mechanical ventilation and performance of a tracheostomy at the bedside without requiring placement of a tube inside the patient's trachea (Cook et al., 2003).

2.1.5. Contraindications for PLMA use

There is currently insufficient data to support the use of the PLMA in nonfasted patients. It is therefore contraindicated in non-fasted patients or patients who may have retained gastric contents until such time as data becomes available (Keller et al., 2000) except in

the "cannot intubate-cannot ventilate" situations in which the user must decide on the risk-benefit ratio of using this device.

When used in the profoundly unresponsive patient in need of CPR, the risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway in a potentially "non-fasted" patient.

Do not attempt to pass an oro-gastric tube through the PLMA in the following circumstances: gas leaking through the drain tube, or the presence of known or suspected oesophageal damage (Brimacombe J., 2004a).

The primary contraindication to elective use of the LMA is a risk of gastric contents aspiration (e.g. full stomach, hiatus hernia with significant gastro oesophageal reflux, morbid obesity, intestinal obstruction, delayed gastric emptying, poor history). Other contraindications include poor lung compliance or high airway resistance, glottic or subglottic airway obstruction and limited mouth opening (<1.5 mm) (Brimacombe J., 2004a)

2.1.6. Advantages of PLMA

When correctly positioned, the PLMA isolates the glottis from the upper oesophagus with possible implications for upper airway protection.

Based on studies done on cadaver model (Keller et al., 2000a), the correctly placed PLMA allows fluid in the oesophagus to bypass the pharynx and mouth when the drainage tube is open. Both LMA and PLMA with a closed drainage tube attenuate liquid

flow between the esophagus to bypass the pharynx. This study may have implications for airway protection in unconscious patients.

Evans and colleagues tested the ability of PLMA to isolate the airway from the digestive tract in 103 anaesthetized adult patients by filling the hypopharynx with methylene blue-dyed saline introduced down the drainage tube once the mask was in place. In 100 out of 103, the glottis was isolated successfully for the duration of the procedure. Leakage of saline into the bowl of the mask occurred in two patients in whom displacement of the mask was caused by upper airway events during the procedure (Evans et al., 2002a).

Compared to Classic LMA, PLMA is capable of achieving more effective seal and facilitates gastric tube placement, but more difficult to insert unless an introducer tool is used. When correctly positioned, the PLMA isolates the glottis from the upper oesophagus with possible implications for airway protection (Brimacombe et al., 2000.)

Proseal LMA has also been use as an adjunct airway in cases of difficult intubation. Awan et al., 2004 reported the use of the Proseal Laryngeal Mask Airway to establish and maintain the airway during emergency Caesarean section when tracheal intubation had failed with conventional laryngoscopy and mask ventilation was difficult. The PLMA allowed controlled ventilation without gas leak and facilitated drainage of the stomach.

Coulson et al., 2003 found that airway management in anaesthetized paralyzed adults is equally successful for the LMA and PLMA by inexperienced personnel following manikin-only training. That make PLMA is worthy of consideration as a tool for emergency airway management by inexperienced personnel. Another advantage of

Proseal LMA as reported by Keller et al., 2002 is as an effective temporary ventilatory device in grossly and morbidly obese patients before laryngoscope-guided tracheal intubation.

A case report by Evans and colleaques in 2002 described a case of 32-year old man undergoing elective change of dressing and POP application under spontaneous breathing anaesthesia with PLMA insertion. He developed passive acidic regurgitation intraoperatively which was suctioned out of the drainage tube. After operative procedures completed and following removal of the mask, pH testing showed that the dorsum of the mask had pH of 7 and the ventrum / bowl of the mask to be dry with a pH of 7. This case showed that the PLMA can protect the airway during the event of passive regurgitation during anaesthesia by allowing the regurgitated fluid to pass up the drainage tube without leaking into the glottis (Evans et al., 2002c).

Comparing the stability of PLMA in different head-neck position, Brimacombe and colleaques in 2003 found that the anatomical position of the PLMA is stable with different head-neck position. Head-neck flexion and rotation are associated with an increase, and head-neck extension a decrease in oropharyngeal leak pressure and intracuff pressure (Brimacombe et al., 2003a).

Maltby et al., 2003 compared PLMA, Classic LMA and Endotracheal tube intubation with respect to pulmonary ventilation and gastric distension during gynaecologic laparoscopy where 209 women were stratified into obese and non-obese group, and then randomized to receive PLMA, Classic LMA and ETT. The result was there were no

crossovers and no statistically significant differences between PLMA, Classic LMA and ETT groups for SpO2, ETCO2 or airway pressure before or during peritoneal insufflation in short (<15 min) or long (>15 min) periods of peritoneal inflation. This study concluded that a correctly placed PLMA or Classic LMA is as effective as endotracheal tube in positive pressure ventilation without clinically important gastric distension in non obese and obese patients.

2.1.7. Disadvantages of PLMA

There is currently no data documenting its significant adverse effects. Until such time as data becomes available, it should be assumed that a similar incidence and range of adverse events may occur with the PLMA as occurs with the Classic LMA.

A review of published literature suggests that the incidence of aspiration with the Classic LMA is low (~2:10,000) and is comparable to the incidence of aspiration associated with outpatient general anaesthesia using the facemask or endotracheal tube (Brimacombe J., 2004a). There have been no reports of death directly attributable to the Classic LMA in over 100 million uses of the device worldwide. The incidence of sore throat following Classic LMA use is approximately 10% (range 0-70%) and is usually mild and short-lived. Severe or prolonged sore throat, sometimes accompanied by dysphagia, has been reported in patients in whom an improperly cleaned or sterilised device has been used (Brimacombe J., 2004a). Unusual neurovascular events reported with Classic LMA use include rare cases of hypoglossal nerve injury, transient tongue numbness secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, and vocal cord paralysis. These complications could result from poor insertion techniques or excessive cuff

pressure. However, a clear relationship to the use of the Classic LMA has not been established (Brimacombe J., 2004a).

One of the distinguishing features of the PLMA is that it can cause upper airway obstruction, even when it is correctly inserted behind the cricoid cartilage. The most common cause of upper airway obstruction due to the PLMA was laryngeal obstruction. This refers to compression of supraglottic and glottic structures with resulting narrowing and compromise of the airway. A second, much less common form of airway obstruction was bilateral cuff infolding with or without downfolding of the epiglottis (Brimacombe et al, 2002a). Test that can be used to aid in the diagnosis of upper airway obstruction after PLMA is a hyperventilation test, the maximum minute ventilation test (Michael et al, 2002).

However, a case was reported by Brimacombe J and Keller C, 2003b; of gastric aspiration with the PLMA during a laparoscopic cholecystectomy secondary to an unidentified foldover malposition. Therefore it is imperative that the position and the patency of the drain tube be verified in all patients with the ProSeal laryngeal mask.
Another possible complication of PLMA based on a case report is mechanical closure of vocal cord following PLMA insertion (Brimacombe et al, 2002a). This event leads to near complete airway obstruction. Withdrawal of air from the cuff and /or moving the head and neck into the sniffing position resolved this problem
Nicholls and Patel in 2001 described the intracuff pressure changes in a 40 year old male undergoing a 5 hour mastoid procedure using 57-63% Nitrous Oxide. Intracuff pressure

increased fron 60 cmH2O at time zero to approximately 100 cmH2O after 1 hour and 115 cmH2O after 2 hours, and remained stable thereafter. This is a similar pattern to Classic LMA suggesting similar permeability.

2.1.8. Insertion and Removal of PLMA

Prior to insertion of the device, the cuff should be fully deflated to a flattened wedge shape. This shape facilitates atraumatic insertion and correct positioning in the patient. The correct cuff shape can be accomplished through use of the *LMA-ProSeal™ Cuff-Deflator* available from the distributor (Brimacombe J., 2004). There are few techniques of PLMA insertion namely digital technique, introducer guided insertion and gum-elastic bougie (GEB) guided insertion (Brimacombe et al., 2004b). Lubrication of the posterior surface of the cuff should be performed just before insertion to prevent drying of the lubricant. A water-soluble lubricant, such as K-Y Jelly, should be used. Do not use silicone-based lubricants as they degrade the PLMA components.

Place the tip of the *LMA-ProSeal™ Introducer* into the retaining strap at the rear of the cuff. Fold the tubes around the convex surface of the blade and fit the proximal end of the airway tube into the matching slot in the tool. Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it. Slide the cuff further inwards against the palate. You may push the jaw downwards momentarily to assist entry between the teeth. A high arched palate may require a slightly lateral approach. Look carefully into the mouth to verify that the tip of the cuff has not folded over.

An inadequate depth of anaesthesia may result in coughing and breath-holding during insertion. Should this occur, anaesthesia should be deepened immediately with

inhalational or intravenous agents and manual ventilation instituted. If difficulty persists with the chosen technique, one of the other techniques described should be used.

After insertion, inflate the cuff with just enough air to obtain an intra-cuff pressure equivalent to approximately 60cm H2O. Never over-inflate the cuff. Avoid prolonged intra-cuff pressures greater than 60cm H2O (Brimacombe et al., 2004a).

Removal of PLMA can be done before anaesthesia is discontinued (while the patient is still deep) or with the patient awake. Potential advantages of removal under anaesthesia are that (Brimacombe et al., 2004a):

i. The risk of triggering regurgitation may be reduced

ii. The drain tube is patent in case of regurgitation

However if muscle relaxant is used during positive pressure ventilation with PLMA, awake removal of PLMA should be done.

Potential advantages of removal when the patient is awake are that (Brimacombe et al, 2004a):

i. The stomach can be emptied during emergence

ii. Oropharyngeal secretions can be cleared if suction is applied during simultaneous PLMA and gastric tube removal

PLMA can be removed with the cuff inflated or fully deflated. Deakin et al., 2000 studied the quantity of secretion removed by inflated and deflated LMA and concluded that removal of LMA with the cuff inflated removes 0.5 gram more secretion than with the cuff deflated, however they believe that this difference is not likely to be clinically

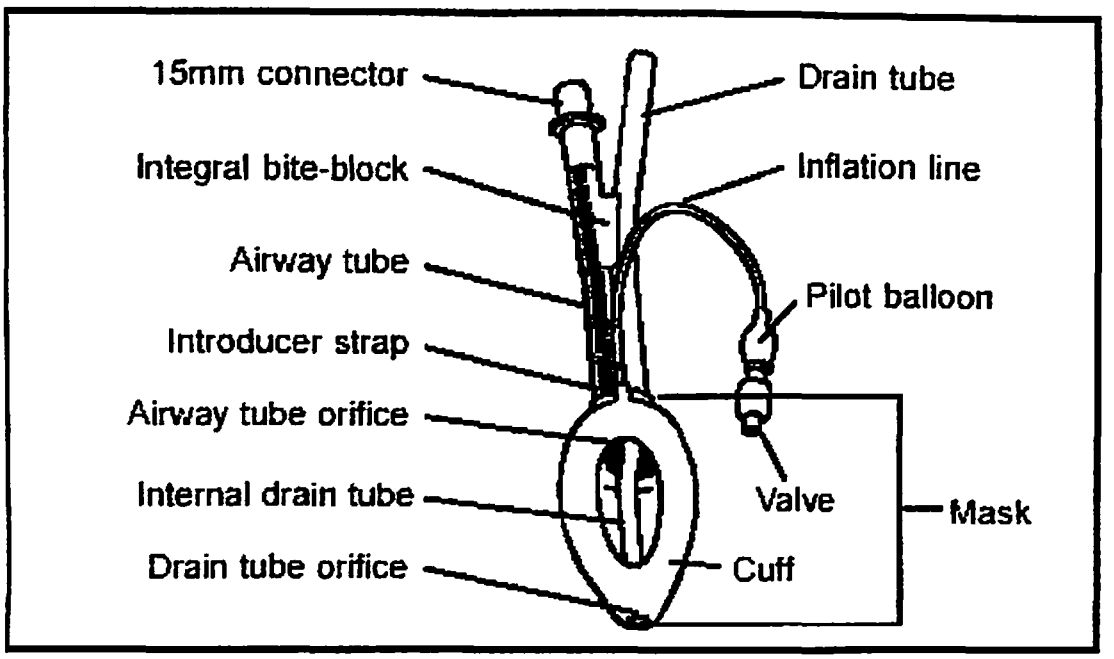
significant. Usually suction is unnecessary because correctly placed LMA protects the larynx from oral secretions.

2.1.9. Caring for the PLMA

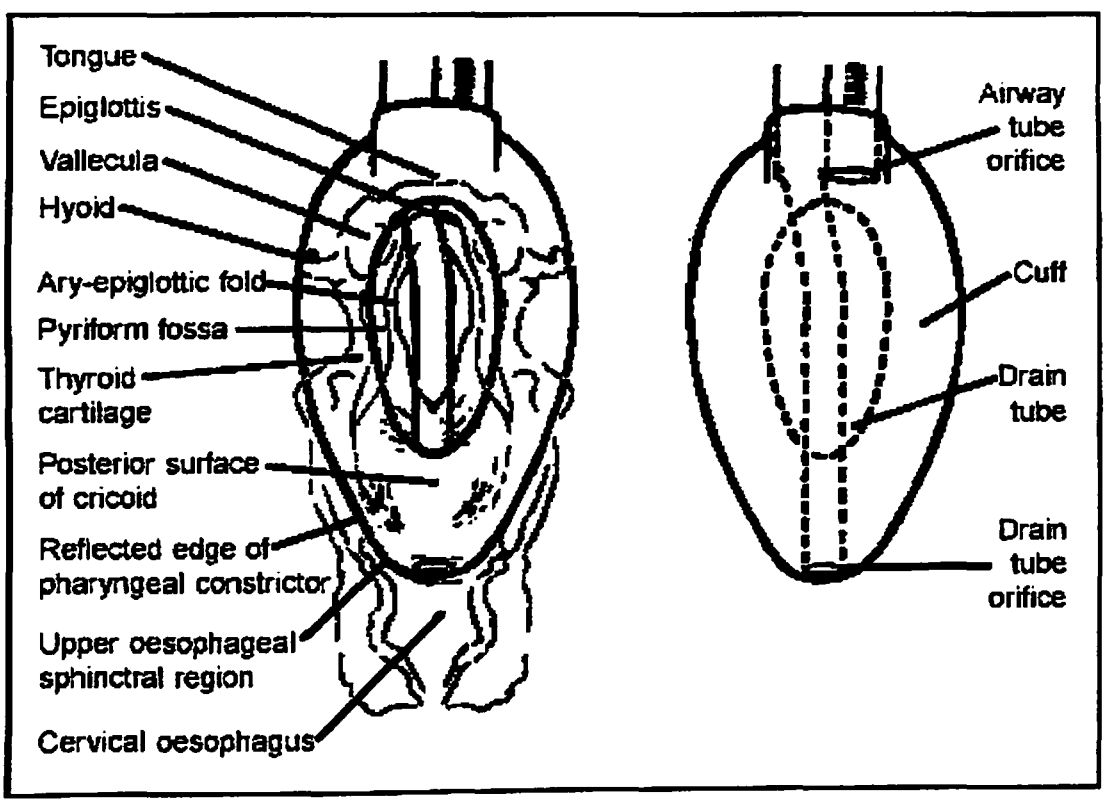
The guidelines for cleaning and sterilization are identical to the LMA Classic. However, the LMA Proseal has a complex shape and requires more attention. In particular, the finger strap and accessory vent form pockets where secretions can accumulate and both must be exposed and cleaned. The deflation tool will facilitate correct deflation. A dedicated cleaning brush has been designed specifically for the PLMA (Brimacombe et al., 2004a).

Study by Richards et al., 2006 recommended that reusable airway devices are cleaned in isolation and not by batch cleaning, this is because protein cross contamination of the Laryngeal Mask Airway occurs during batch cleaning and autoclaving.
Steam autoclaving is the only recommended method for sterilisation of the PLMA. After autoclaving, allow PLMA to cool to room temperature before use.

Picture 1: The components of Proseal Laryngeal Mask airway



Picture 2: Dorsal view of PLMA showing position in relation to pharyngeal airway



2.2. ENDOTRACHEAL TUBE

2.2.1. Introduction

Airway management is a fundamental aspect of anaesthetic practice and of emergency and critical care medicine. Endotracheal intubation (ETT) is a rapid, simple, safe and non surgical technique that achieves all the goals of airway management namely maintains airway patency; protect the lungs from aspiration and permits leak free ventilation during mechanical ventilation and remains the gold standard procedure for airway management (Divatia JV. and Bhowmick K., 2005).

The first description of current modern peroral tracheal intubation started in early part of 19th Century, by a Frenchman named Desault. He was part of the great tradition of innovators who took advantage of what appeared to be an adverse event and turn it into something positive. Desault was actually trying to place a feeding tube, and when he poured some bullion down the tube, he discovered that he had intubated the trachea rather than the oesophagus (Applebaum EL, 1976). Therefore, the discovery of this life saving modality of treatment was actually started as complication.

Nowadays, many special Endotracheal tubes available in the market and they are continuously improved to provide better protection of airway, with minimal complications. Examples of newer tracheal tubes are (Dorsch and Dorsch, 1994):

1. Armoured Tracheal Tube- Contain a spiral of metal wire or tough nylon. The spiral helps to prevent the kinking and occlusion of the tube when head/neck flex or rotate. An introducer should be used to aid intubation

2. RAE preformed tracheal tube - Has a preformed bend. Nasal RAE – Preformed bend toward the patient's forehead while oral RAE - Preformed bend toward the chin. It is easy to secure and can reduce risk of unintended extubation and provide more free area for surgical field.
3. Cole tube
4. Carden Bronchoscopy tube
5. Carden Laryngoscopy tube
6. Injectoflex
7. Microlaryngeal Tracheal Surgery Tube (MLT)
8. Laryngectomy tube
9. Endotrol Tracheal tube
10. Tubes with Monitoring Lumen
11. Laser shield tracheal
12. Laser flex tracheal tubes
13. Combitube- Double lumen tube designed to provide a patent airway during difficult and emergency situation. It has 2 cuffs, pharyngeal cuff 100ml and distal cuff 15ml. There are 8 ventilating eyes between the cuffs. It is inserted blindly (usually oesophagus) and if the tube enters the oesophagus, it will ventilate via number 1 lumen and if it enters the trachea, will ventilate via number 2 lumen.