USM J/P- 06

BAHAGIAN PENYELIDIKAN & PEMBANGUNAN
CANSELORI
UNIVERSITI SAINS MALAYSIA

Laporan Akhir Projek Penyelidikan Jangka Pendek

1) Nama Penyelidik: Profesor Madya (Dr.) Nik Abdullah Bin Nik Mohamad

Nama Penyelidik-Penyelidik Lain (Jika Berkaitan): Dr. Norhafidzah bt. Hj. Ghazali

2) Pusat Pengajian/Pusat/Unit : Pusat Pengajian Sains Perubatan, Kampus Kesihatan

3) Tajuk Projek: A Comparison of the Laryngeal Tube with the Laryngeal Mask Airway during Spontaneous Ventilation in Paediatric Anaesthesia

A randomized prospective study was conducted involving 80 premedicated paediatric patients of ASA 1 and 2, aged between 2 to 10 years. These children were divided into 2 groups, group LT (n=40) received laryngeal tube and group LMA (n=40) received laryngeal mask as airway device. After a standardized inhalational induction of anaesthesia with servoflurane followed by fentany 1.5 $\mu g.kg^{-1}$, the laryngeal tube or the laryngeal mask airway was inserted and the patients breathed spontaneously throughout the surgery. Anaesthesia was maintained with nitrous oxide, oxygen, and servoflurane. The airway device was removed at the end of surgery when the patient is fully awake. We recorded the speed of insertion and the number of attempts needed to successfully secure the airway. The quality of ventilation as assessed by incidence of oxygen desaturations, frequencies of airway manipulations throughout the surgery and the end-tidal CO_2 at various time intervals were recorded. The haemodynamic changes such as systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate at different time intervals were recorded. We have also recorded the incidence of complications postoperatively.

We found that there were significant more time required for successful insertion and more number of attempts for LT group as compared to the LMA group. The number of manipulations of device or patients after first attempt and the recordings of $ETCO_2$ recorded at various time intervals was higher with the LT and the difference was significant. However both groups had no statistical difference in episodes of desaturation and haemodynamic parameters during anaesthesia. We found no statistically significant difference in the incidence of complications postoperatively between the two groups.

We conclude that during spontaneous ventilation in paediatric patients undergoing general anaesthesia the laryngeal tube is not as reliable in providing a satisfactory airway and we consider it is not a suitable alternative to the laryngeal mask airway.

(b) Faedah-Faedah Lain Seperti Perkembangan Produk, Prospek Komersialisasi Dan Pendaftaran Paten.
(Jika ada dan jika perlu, sila guna kertas berasingan)

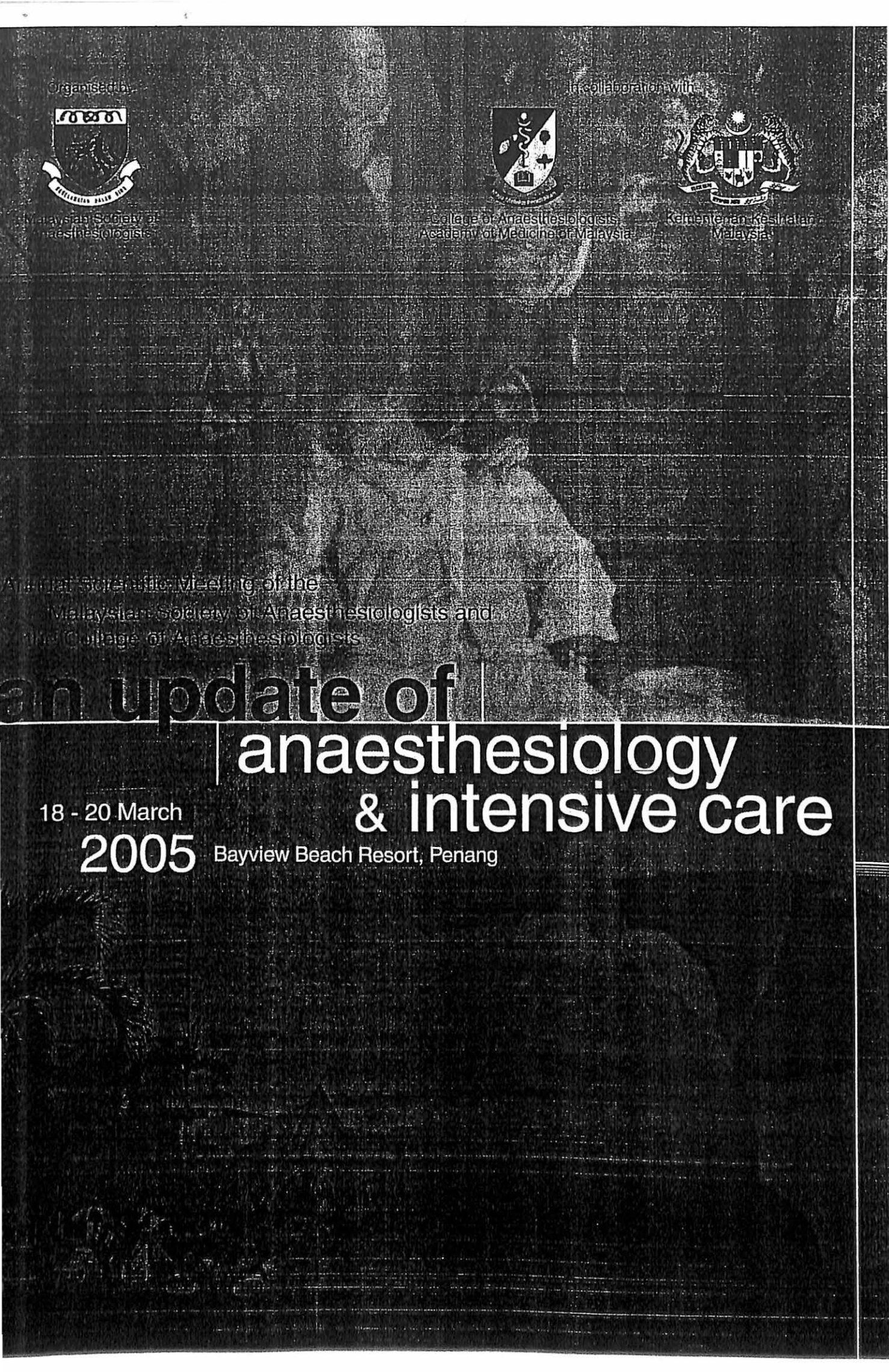
Kajian ini menunjukan bahawa alat baru ini (laryngeal tube) tidak berupaya menjadi pilihan alternatif kepada laryngeal mask airway sebagai alat untuk penghantaran gas pembiusan/ penghantaran bekalan oksigen dan pembuangan karbon dioxide semasa pemberian bius untuk kanak kanak. Walaupun efektif untuk pengunaan pesakit dewasa, didapati pengunaan nya didalam pembiusan kanak kanak tidak memberi kesan yang baik saperti mana pengunaan Laryngeal mask yang nyata berkesan. Hasil kajian ini memberi kesedaran bahawa alat baru ini tidak harus digunakan untuk penjagaan airway kanak kanak semasa pembiusan dan pembedahan.

(c) Latihan Gunatenaga Manusia

i) Pelajar Siswazah: Melibatkan Doktor Pasca Siswazah yang menyediakan dissertasi bagi memenuhi syarat untuk penganugerahan Sarjana Perubatan (Anestesiologi), USM.

ii) Pelajar Prasiswazah: Melibatkan Pelajar Prasiswazah sebagai pemerhati. Memberi tunjuk ajar mengenai peralatan baru dan juga kaedah penyelidikan

iii) Lain-Lain : Jururawat sebagai pembantu semasa menjalankan aturcara untuk kajian. Meningkatkan pendedahan jururawat serta memberi pendedahan mengenai kaedah penyelidikan


Organised by:
Malaysian Society of Anaesthesiologists
In collaboration with:
College of Anaesthesiologists, Academy of Medicine of Malaysia
Kementerian Kesihatan Malaysia
Annual Scientific Meeting of the
Malaysian Society of Anaesthesiologists and
The College of Anaesthesiologists
an update of
anaesthesiology
& intensive care
18 - 20 March
2005
Bayview Beach Resort, Penang

UNIVERSITI SAINS MALAYSIA
JABATAN BENDAHARI
KUMPULAN WANG PENYELIDIKAN GERAN USM(304)
PENYATA PERBELANJAAN SEHINGGA 31 MAC 2006

Jumlah Geran:	RM	Tiada Rekod	Ketua Projek:	PROF(MIN ABDULLAH N. MOHAMAD	
Peruntukan 2004 Tahun 1	RM	3,000.00	Tajuk Projek:	A Comparison of the Laryngeal Tube LT with the Laryngeal Mask Airway (LMA) during Spontaneous Ventilation Pediatric Anesthesia	
Peruntukan 2005 Tahun 2	RM	0.00			
Peruntukan 2006 Tahun 3	RM	0.00	Tempoh:	01 April 04- 31 Mac 06	
			No.Akaun:	304/PPSP/6131328	

Vot	Subseksyen	PTJ	Projek	Nombor	Peruntukan Projek	Perbelanjaan Terkumpul Hingga Tahun Lalu	Peruntukan Semasa	Tanggungan Semasa	Bayaran Tahun Semasa	Belanja Tahun Semasa	Baki Projek
304	21000	PPSP	6131328		-	-	-	-	-	-	-
304	14000	PPSP	6131328		-	-	-	-	-	-	-
304	15000	PPSP	6131328		-	-	-	-	-	-	-
304	21000	PPSP	6131328		-	-	-	-	-	-	-
304	22000	PPSP	6131328		-	-	-	-	-	-	-
304	23000	PPSP	6131328		-	-	-	-	-	-	-
304	24000	PPSP	6131328		-	-	-	-	-	-	-
304	25000	PPSP	6131328		-	-	-	-	-	-	-
304	26000	PPSP	6131328		-	-	-	-	-	-	-
304	27000	PPSP	6131328		3,000.00	2,990.00	10.00	-		2,990.00	10.00
304	28000	PPSP	6131328		-	-	-	-	-	-	-
304	29000	PPSP	6131328		-	-	-	-	-	-	-
304	32000	PPSP	6131328		-	-	-	-	-	-	-
304	35000	PPSP	6131328		-	-	-	-	-	-	-
					3,000.00	2,990.00	10.00	-	-	2,990.00	10.00

A COMPARISON OF THE LARYNGEAL TUBE WITH THE LARYNGEAL MASK AIRWAY DURING SPONTANEOUS VENTILATION IN PAEDIATRIC ANAESTHESIA

TABLE OF CONTENTS

1. INTRODUCTION

Many patients undergoing general anaesthesia do not require endotracheal intubation. Previously airway management in spontaneously ventilating patients for short elective procedures has been managed by use of facemask and laryngeal mask airway. The laryngeal tube (VBM, Medizintechnik GmbH, Germany) is a new airway device recently introduced into clinical practice. The design is based on the oesophageal obturator airway and it is designed to be inserted blindly into the oesophagus. The laryngeal tube consists of an airway tube with a small cuff at the tip (distal cuff) and a larger cuff in the middle of the tube (proximal cuff). The two low-pressure cuffs are inflated through a single pilot tube and balloon. The transmission of gases between the airway tube and the larynx takes place via a ventilation outlet,two openings which lie between these two cuffs. When the device is inserted, it lies along the length of the tongue and the distal tip is positioned in the hypopharynx. The proximal cuff stabilizes the tube in the oropharynx and the distal cuff seals the oesophageal inlet. At the proximal end of the tube there is a thick black line in the center where when correctly positioned lies at the level of upper incisor teeth. There are two thinner lines above and below the thick line which indicates the range of depth where the tube can be repositioned to allow sufficient ventilation. There is a standard 15 mm connector on the proximal end of the tube for attachment to a breathing system. There are six sizes of LT designated 0 to 5.Size 0 to 3 are used in paediatric anaesthesia.

The first case report regarding the use of laryngeal tube (LT) in adult patients was published in 1999.Since then studies have been conducted in mannequins to evaluate its use in emergency airway management. Following that further studies were conducted in anaesthetized adult patients during intermittent positive pressure ventilation as well as spontaneous ventilation. Three studies have been published so far to evaluate the use of laryngeal tube in paediatric anaesthesia. (Richebe et al, 2001, Gaitini et al. and Genzwuerker et al, 2003) and demonstrated encouraging results. A study by Zairul et al, 2003 on adult patients found that during spontaneous ventilation under anaesthesia the laryngeal tube form a suitable alternative to the laryngeal mask airway. Hence in this study we propose to compare the efficacy of the laryngeal tube with that of the laryngeal mask airway in paediatric patients breathing spontaneously under general anaesthesia.

2. OBJECTIVES AND DEFINITIONS

2.1 OBJECTIVES

(i) To compare the easiness of insertion between laryngeal tube and laryngeal mask airway

(ii) To compare the quality of ventilation between laryngeal tube and laryngeal mask airway

(iii) To compare the haemodynamic parameters between laryngeal tube and laryngeal mask airway at different time intervals

(iv) To compare the incidence of complications between laryngeal tube and laryngeal mask airway

2.2 NULL HYPOTHESIS

There are no difference in easiness of insertion, quality of ventilation, haemodynamic parameters and incidence of complications between laryngeal tube and laryngeal mask airway during spontaneous ventilation in paediatric anaesthesia.

2.3 DEFINITIONS

(i) Easiness of insertion is defined as less time taken to insert the airway and less number of attempts required for a successful first tidal lung volume

(ii) Quality of ventilation is defined as number of further manipulations of device or patients after insertion to maintain sufficient ventilation and any episodes of desaturation throughout the procedure.

(iii) Hemodynamic parameters are defined as measurement of systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate at different time intervals

(iv) Complications are defined as intra and postoperative unfavorable effects like laryngospasm, airway trauma (blood on airway device), vomiting and coughing

3. LITERATURE REVIEW

3.1 LARYNGEAL TUBE (VBM)

3.1.1 History

The laryngeal tube (VBM) was designed by Volker Bertram in Sulz, Germany. It received its US patent in November 1996. It was developed as a variant of the oesophageal obturator airway and is designed to be inserted blindly into the oesophagus. The laryngeal tube (VBM) is an alternative to ventilation with face mask, laryngeal mask or for procedures where tracheal intubation is not necessary.

The first case report regarding the use of laryngeal tube (VBM) was published in 1999. Since then, many studies have been conducted to evaluate its role in emergency airway management out of hospital resuscitation and to secure a patent airway during spontaneous and controlled ventilation during general anaesthesia. It has also been tested for use in paediatric patients under anaesthesia and shown encouraging results. It is now commercially available for clinical practice.

3.1.2 Characteristics of the laryngeal tube (VBM)

The laryngeal tube (VBM) is a reusable curved shaped, single lumen, latex free, and silicone tube with two low-pressure cuffs connected to a single pilot balloon. The proximal (pharyngeal) cuff stabilizes the tube and blocks the naso and oropharynx. The oesophageal cuff when inflated blocks the entry of oesophagus hence reduces possibility of gastric ventilation and aspiration. Due to the short tube and S-shape, a blind insertion is possible without any instruments and it causes no irritation of vocal cords and trachea. The aperture between the two cuffs provides the route for ventilation. This ventilation hole lies in front of the larynx for efficient ventilation and it allows suctioning and bronchoscopy with fibrescope.

There are three markings called teeth marks on the proximal end of the tube, which provides a visual indicator to the user as to the final position after insertion. The thick middle line is for orientation and if necessary the laryngeal tube can be repositioned between the two thinner lines to allow sufficient ventilation. There is a standard colour-coded 15 mm connector on the proximal end of the tube for immediate identification of different sizes and for attachment to a breathing system.

3.1.3 (a) Size selection

Six sizes are now available ranging from size 0 to size 5 with specific colour-coded connector. Choosing the correct size of the tube depends on the patient's height and weight. For newborn less than 6 kilogram, the appropriate size is size 0, size 1 is for infant from 6 to 15 kilogram and size 2 is for children from 15 to 30 kilogram. Size 3 to 5 depends on the patient's height. Size 3 is used for teenager and small adult up to 155 centimeter, size 4 is for height between 155 centimeter to 180 centimeter and size 5 is for adult more than 180 centimeters.

Table 3.1: Sizes of laryngeal tube (VBM) in relation to patients' weight and height

Size	Patient	Weight/height	Color code connector
0	Newborn	Less than 6 kilogram	Transparent
1	Infant	6-15 kilogram	White
2	Child	15-30 kilogram	Green
3	Adult, small	Less than 155 centimeter	Yellow
4	Adult, medium	155-180 centimeter	Red
5	Adult, large	More than 180 centimeter	Purple

In 3 previous studies done on paediatric patients undergoing anaesthesia, the investigators use the laryngeal tube based on the weight, as per manufacturer's instruction. No studies have been done to correlate the height with the size used. Gaitini LA et al., 2001 in their study on 20 children found that 60% of the children were adequately ventilated with the LT size according to the manufacturer recommendations. In 40% of patients satisfactory ventilation was obtained only after replacing the initial LT size with a size superior than that recommended.

There are six colour-coded connector which determined the size of the laryngeal tube. The transparent connector for size 0, white connector for size 1, green connector for size 2, yellow connector for size 3, red connector for size 4 and purple connector for size 5.

3.1.2 (b) Cuff volumes and pressure

Both cuffs are high volume cuffs and are connected to a single pilot balloon. Both cuffs are inflated to 60-70 cmH_2O pressures using the pressure gauge manometer as recommended by manufacturer. If a cuff pressure gauge is not available the cuffs may

also be inflated by mean of a syringe which is provided with the laryngeal tube (VBM) package.

A study by Genzwuerker HV et al., 2003 demonstrated that with mean cuff pressure of 68.0(60-100) cmH2O, auscultation over the stomach was negative in all their paediatric patients. The mean tidal volume was 191.9 ml during controlled mechanical ventilation resulting in a peak airway pressure of 15.9 cmH2O. An earlier study by Richebe P et al. on 70 children demonstrated gastric ventilation in 13% of their cases with the average cuff inflation pressure of 63 cmH2O.

Table 3.2: Size of the laryngeal tube (VBM) in relation to volume and pressure needed to inflate the cuff

Size	Cuff volume (ml)	Cuff pressure (cmH_2O)
0	10	60-70
1	20	60-70
2	35	60-70
3	60	60-70
4	80	60-70
5	90	60-70

3.1.3 Indications to laryngeal tube (VBM) use

The laryngeal tube (VBM) is now used for short elective surgical procedures under spontaneous or positive pressure ventilation. It is an alternative to face mask, laryngeal mask airway and endo-tracheal tube for fasted patients or those considered to have a low risk of aspiration of gastric contents. It has also been used in emergency conditions such as in pre hospital emergency use, during the management of difficult or failed airway and as a means to secure an immediate airway in cardiopulmonary resuscitation (CPR).

3.1.4 Contraindications to laryngeal tube (VBM) use

(i). Patient who is at risk for pulmonary aspiration of gastric contents such as morbidly obese, history of gastro-oesophageal reflux and full stomach patient.
(ii) Patients with obstructed upper airways
(iii) Procedures of long duration (more than 2 hours)

3.1.5 Advantages of laryngeal tube (VBM)

(i) Anaesthetist convenience

The insertion of laryngeal tube is easy with no special technique required (minimal learning curve). The device can be easily inserted either in extended or neutral head position and requires minimal mouth opening during insertion. A study by Genzwuerker et al., Oct 2003 on 57 paediatric patients showed that LT was placed successfully in 55 patients (96.5%) with 90.9% during first attempt and 9.1% during second attempt.Richebe P.et al found that the head was maintained in extension to make the insertion easier in 83% of cases using size 0, 30% in children using size 2 and 3 and for maintainence of anaesthesia position required was neutral for more than 85% of patients. Harald V.Genzwurker, 2000 conducted a study on 50 physicians and nurses and he found that during 500 insertions of the laryngeal tubes (VBM), correct placement and sufficient ventilation were achieved 478 times in first attempt (95.6%).

Another study by Asai et al., 2002 on the efficacy of the laryngeal tube by inexperienced personnel found that the insertion of the laryngeal tube was easier than the insertion of the laryngeal mask airway, therefore they decided that the laryngeal tube has a potential role in providing a clear airway during cardiopulmonary resuscitation.

The laryngeal tube (VBM) does not require maintenance, leaving the anaesthetists free to attend monitoring and record keeping (hands-free)

(ii) Patient safety and tolerance

The laryngeal tube (VBM) insertion is atraumatic and easy with minimal damage to the oropharyngeal structures and minimal incidence of sore throat compared to tracheal intubation. Genzwuerker et al., 2003 found minor traces of blood in 2 cases out of 57 paediatric patients studied. They also found that only one patient complained of mild sore throat post removal of LT. A study by Riechebe et al. on 70 paediatric patients also found the incidence of moderate postoperative pharyngeal pain in 1 patient.

The soft cuffs of the laryngeal tube (VBM) adjust better to the anatomy (patient comfort). The large proximal cuff stabilizes the laryngeal tube and patient can be moved without creating leaks. Asai et al., 2000 demonstrated that the distal cuff of the laryngeal tube provided a good seal towards the oesophagus and therefore a better protection against regurgitation. Genzwuerker et al, 2003 also found negative finding on the auscultation of stomach in all his paediatric patients.

In a study by Genzwuerker et al, 2003 on 57 boys undergoing anaesthesia, they found the incidence of laryngospasm in one case however sufficient ventilation was possible after deepening of anaesthesia. Richebe P et al. in their earlier study found the one incidence of stridor and 2 laryngospasm out of their 70 paediatric patients. However none of these children had incidence of oxygen desaturation.

(iii) Cost Effectiveness

The laryngeal tube (VBM) can be used on its own following induction of general anaesthesia, during maintenance and as a recovery airway until patient is fully awake, reducing the need for additional airway devices, e.g. oral airways, laryngoscopes, suction apparatus etc. The price is cheaper compared to laryngeal mask airway. The need for additional drugs, e.g. neuromuscular blocking agents is also minimized. The ease of insertion reduces the anaesthetic time with minimal risk of damage to the teeth, caps and crowns and therefore more comforting to the patient and the medico-legal budget of the hospital.

The laryngeal tube (VBM) is made from silicone (latex free) and is designed as a reusable device. With proper cleaning, sterilization and handling, the laryngeal tube may be expected to withstand repeated steam autoclaving at 134° C (273° F) up to 50 times. Continued use beyond 50 times is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure of the device.

3.1.6 Performance tests

All of the non clinical tests described below must be conducted before each use of the device. Failure of any one test indicates that the device has passed its useful life and should be replaced.

(i) Visual Inspection

Examine the transparency of the airway tube. The device should not be used when there is discoloration of the airway tube as this impairs the ability to see and effectively remove foreign particles during cleaning or to see regurgitated fluids during use.

Examine the surface of the device for damage, including cuts, tears, or scratches. Do not use if the airway tube is damaged in any way. Examine the interior of the tube to ensure that it is free from blockages or loose particles. Flex the tube up to, but not beyond 180°; should the tube kink, the device should be discarded. Examine the 15 mm connector, it should fit tightly into the outer end of the airway tube, ensure that it cannot easily be pulled off by hand using reasonable force.

(ii) Inflation and Deflation

Insert syringe into the inflation line and fully deflate the cuffs so that the cuff walls are tightly flattened. Remove the syringe from the inflation line and cuff wall should remains deflated. Inflate the cuffs from complete vacuum to the recommended maximum inflation volume; leaking and deflation will be evident within 2 minute. Examine the symmetry of the inflated cuffs, there should be no uneven bulging seen. Finally examine the inflation pilot balloon, the balloon shape should be elliptical not spherical.

(iii) Pre-insertion Preparation

Prior to insertion of the laryngeal tube (VBM), evacuate the cuffs completely with the syringe so that they lie smoothly on the tube. Lubricate the cuffs with a water-soluble lubricant, such as K-Y jelly. Lubricants containing xylocaine are not recommended for use as xylocaine can delay the return of the patient's protective reflexes prior to removal of the device airway and preservatives used may also cause allergic reaction towards patients.

Insertion of the laryngeal tube (VBM) requires an anesthetic depth similar to that, which allows placement of an oropharyngeal airway. The optimal induction agent would produce jaw relaxation and attenuation of airway reflexes, allowing insertion within 3060 seconds of loss of consciousness.

3.1.7 Insertion and Removal of laryngeal tube (VBM)

(i) Insertion (Figure 2.1)

Step 1- Hold the laryngeal tube like a pen in the area of the black teeth marks or at the connector. The head is either extended or in neutral position. Both cuffs have to be completely deflated and lubricated with before insertion.

Step 2- Insert the tip of the laryngeal tube against the hard palate; make sure that the tongue is not pushed back. In case of problems a lateral insertion might be useful. Slide the laryngeal tube smoothly along the midline of the mouth into the hypopharynx until the middle black line is level with the teeth.

Step 3- Inflate the cuffs with the Cuff Pressure Gauge to 60-70 cmH_2O. Both cuffs are inflated with only one inflation line. If in an emergency situation where no cuff pressure gauge is available, the cuffs can also be inflated by means of the included syringe (follow the inflation volumes in the instructions of use).

Step 4- The laryngeal tube (VBM) is now in place and the patient can be ventilated. Connect breathing circuit and check the lung ventilation by auscultation and chest movement. If ventilation is not sufficient reposition the tube to distal or proximal between the thin teeth marks. With the VBM bite block the Laryngeal tube can be protected and fixed safely. The internal ramp at the ventilation outlet will direct devices into the trachea such as fiber optic scope, tube exchanger and suction catheter.

(ii) Common problems with insertion

(a) Leak pressure more than airway pressure- measure the leak pressure and make sure that it is higher than the airway pressure to avoid gastric insufflation with its risk of regurgitation.

(b) Level of anesthesia- make sure that anaesthesia is deep enough to avoid airway closure. The laryngeal tube is a pharyngeal airway device, which is placed before the vocal cords. Too light anesthesia could result in closure of the vocal cords and airway obstruction.

(c) Insertion- lateral insertion can be useful in case of insertion problems. A study conducted by S. A. Khan et al., 2003 found a better method of laryngeal tube insertion with better success rate by aided anterior mandibular displacement or jaw thrust.

(iii) Removal of laryngeal tube (VBM)

The laryngeal tube (VBM) should be well tolerated until the return of protective reflexes. Onset of swallowing indicates reflexes are almost restored. Remove the laryngeal tube when patient is able to open mouth on command., Make sure that both cuffs are completely deflated before removal of the laryngeal tube.

3.1.8 Caring for laryngeal tube (VBM)

(i) Cleaning

Clean the laryngeal tube by thoroughly washing the cuffs and the tube with only soap and warm water or mild alkaline cleaning agents such as a diluted (8-10% w/w) sodium bicarbonate solution until all visible foreign matter is removed. Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex), ethylene oxide, phenol-based cleaners or iodine- containing cleaners for cleaning or sterilizing. Such substances are absorbed by device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Thoroughly rinse with water to eliminate all residues of the cleaning agents. Visibly check to ensure that no foreign matter is present.

b) Sterilization

Steam autoclaving at 134° C is the only recommended method of sterilization for laryngeal tube (VBM). Ensure that the tube is completely dry, inside and outside. Both cuffs must be completely evacuated prior to autoclaving using a syringe because any air or moisture left in the cuffs will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage to the cuffs and/or pilot balloon. The laryngeal tube may be placed in an appropriate autoclave-proof bag. After autoclaving, allow to cool to room temperature before use.

3.2 LARYNGEAL MASK AIRWAY

3.2.1 History and Development of laryngeal mask airway

The development of the laryngeal mask airway began in 1981 at the Royal London Hospital, Whitechapel,in the East End of London by British anaesthesiologist, Professor Archie Brain. The prototype laryngeal mask airway was based on the modification of the Goldman Dental Mask. It was first used by Dr Brain on human patient in 1981 and was subsequently used successfully in a pilot study on 23 patients.In 1983, Dr Brain reported the first use of laryngeal mask airway in a failed intubation. It became commercially available in the United Kingdom in 1988 and was used in more than 500 British hospitals within first 12 months of its availability in the United Kingdom.In august 1991, it was approved as a substitute for the face mask during elective anaesthesia by the Food and Drug Administration of United States.

The laryngeal mask airway is a novel device that fills the gap in airway management between use of a facemask and tracheal intubation. (Brain AIJ, 1995). It is relatively simple to insert and have a role in management of the difficult or failed intubation.

When it was first invented, Dr Archie Brain raised the question,is there a better way to combine an anatomical airway and an artificial airway? The facemask falls short, stopping at the mouth and nares while the endotracheal tube goes too far into the trachea. The use of cuff in the ETT produce a high pressure to the smooth epithelial surface of the respiratory tree and may provoke undesirable autonomic responses .The laryngeal mask is simple to use, traumatic to insert, helpful in overcoming an obstructed airway and better fits the ideal connection between the anatomical and artificial airway. Since its introduction, the laryngeal mask airway has achieved increased popularity in paediatric practice. Its use is increasing in many clinical settings, especially day-case surgery and short procedures in which intubation is not necessary.

3.2.2 Components of the laryngeal mask airway

The LMA is made up of medical-grade silicone rubber that is latex free. This allows the LMA to withstand repeated autoclaving. The device has a shaft ranging from 5.25 to 12 mm in internal diameter, depending on the size of the LMA. The shaft is fused at a 30° angle to a distal elliptical spoon –shaped mask with an inflatable rim. The shaft is marked with a longitudinal black line along the posterior aspect, which gives a guide to the location of the spoon-shaped mask in the larynx. If the posterior black line is perpendicular to the middle of patient upper lips after insertion of the mask into the patient mouth., meaning that the mask is in the correct location in the larynx where the opening of the tube is facing the vocal cord.

The shaft opens into concavity of the ellipse via a fenestrated aperture with three orifices to prevent the epiglottis from falling back and blocking the lumen. The adequacy of the seal is dependent on the correct placement and appropriate size. It is less dependent on the cuff filling pressure.

The LMA also has an inflation pilot balloon with valve and inflation line. At the opening of the shaft (proximal end), there is a standard 15 mm connector that connects to a breathing circuit. A range of sizes are now available ranging from size 1 to size 6.To choose the appropriate size will depend on the patient's weight.

Currently, there are 8 sizes of the LMA available ranging from size 1 to size 6. Tham et al., 1994, suggested that the relationship with sex, weight, height and pharyngeal geometry in children was inconsistent when predicting the size of LMA. Ideally, the optimal LMA should be easy to insert, have an oropharyngeal leak pressure sufficient for positive pressure ventilation, a pharyngeal mucosal pressure less than capillary perfusion pressure and enable instruments to pass easily into the respiratory tracts.

3.2.3 Indications to laryngeal mask airway use

Laryngeal mask can be used in both children and adults. In operation theatre, it is mainly used in a well fasted patients undergoing short procedures .It has also been used in the management of the difficult or failed airway. In 1991,Benumof reviewed the difficult airway algorithm and included the laryngeal mask airway in the "cannot intubate and cannot ventilate" scenerio. In prehospital care the LMA can be used when the patient is profoundly unconscious with loss of protective pharyngeal and laryngeal reflex and intubation is not possible due to restricted access or for other technical reasons.. It has also been included in the European Cardiopulmonary Resuscitation algorithm on immediate airway management during CPR. Currently it is increasingly being used for pediatric and neonatal resuscitation.

3.2.4 Contraindications to laryngeal mask airway use

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 esophageal reflux, morbid obesity, intestinal obstruction, delayed gastric emptying). Other contraindications include poor lung compliance or high airway resistance, glottic or subglottic airway obstruction and limited mouth opening (<1.5 mm).

3.2.5 Advantages and Disadvantages of laryngeal mask airway

(i) Advantages

- Ideal for elective outpatient/daycase procedures
- Can be used for spontaneously breathing patients as well as with assisted and controlled ventilation
- Not equipment invasive
- No muscle relaxant necessary
- Lower incidence of sore throat
- Reusable

- Latex free

(ii) Disadvantages

- No protection from gastric regurgitation
- Possibility of stomach insufflations at ventilation pressures higher than 20 cmH_20
- Easy to torque out of position
- Expensive device
- Insertion requires experience and skill (learning curve)

3.2.6 Advantages of the Laryngeal Tube (VBM) over the Laryngeal Mask Airway

(a) Insertion of laryngeal tube (VBM) is easier with no special technique required (minimal learning curve)
(b) Laryngeal tube requires minimal mouth opening during insertion
(c) Minimal head movement during insertion with laryngeal tube, extended or neutral position
(d) Soft cuffs of the laryngeal tube adjust better to the anatomy (patient comfort)
(e) Distal cuff of laryngeal tube grants a good seal towards the esophagus and therefore a better protection against regurgitation.
(f) Reduced risk of gastric ventilation even with higher ventilation pressures compared to LMA (higher sealing pressure)
(g) Large proximal cuff stabilizes the laryngeal tube; patient can be moved without creating leaks
(h) Less airway trauma, no blood after laryngeal tube removal
(i) Lower incidence of sore throat when using laryngeal tube
(j) Bite block with elastic neck strap and syringe are included in the laryngeal tube (VBM) package (size 3, 4, 5)
(k) Price- cheaper than LMA

3.2.7 Laryngeal Mask Airway insertion and removal

(i) Insertion of laryngeal mask airway

The laryngeal mask airway is inserted blindly into the pharynx, forming a low-pressure seal around the laryngeal inlet and permitting gentle positive-pressure ventilation with the administration of inhaled anesthetics through a minimally stimulated airway. Dr Brain's initial contemplation of this laryngeal mask airway was to mimic the placement of food into the hypopharynx, hence establishing the placement of a device, which could then serve as an airway. Prototype insertion methods involved rotation through 180^0 and the early use of an introducer to prevent down folding of the epiglottis.

The current recommended technique was found to be less traumatic and have a 98% success rate. Although the insertion is relatively simple, proper attention to details will improved success rate.An ideally positioned cuff is bordered by the base of the tongue superiorly, the pyriform sinuses laterally and the upper oesophageal sphinter inferiorly (Morgan & Mikhail,1992).The epiglottis often lies within the bowl of the mask but the device function satisfactorily with the epiglottis in the upright horizontal or down folded position. Nandi et al., 1991 demonstrated radiological findings of epiglottis down folding in 66% of cases.

The Insertion of the laryngeal mask does not require laryngoscope. The mask is lubricated with a non- local anesthetic-containing lubricant and is fully deflated to form a thin, flat wedge shape

A variation on the insertion technique has been described in paediatric cases. There are many anatomical differences between paediatric and adults, which include relatively large tongue, higher and more anterior larynx and a more acute angle between the floor of the mouth and the pharyngeal lumen..Mc Nicol, 1991 inserted the device upside down with the laryngeal aperture pointing cephalad. As the laryngeal mask entered the pharynx, it was rotated through 180°.Other maneuvers to aid in insertion include slight inflation of the cuff, a jaw thrust and by using laryngoscope.

(ii) Removal of the laryngeal mask airway

Removal of the LMA should be done once the patient is awake and can open the mouth on command.(Brain AIJ,1991).If this route is chosen, use of a bite block is recommended to avoid the common complication of attempted biting on the LMA. The laryngeal mask cuff protects the larynx from pharyngeal secretions hence reducing the risk of inducing laryngospasm. Onset of swallowing indicates reflexes are almost restored. Brain has stated previously that it is best to leave the cuff inflated until the mask is ejected spontaneously. Usually suction is unnecessary because correctly used LMA protects the larynx from oral secretions.

3.2.8 Caring for the laryngeal mask airway

(i) Cleaning

The LMA should be thoroughly washed with mixture of warm water and diluted sodium bicarbonate solution until all visible foreign matter is removed. The device should be cleaned using a small soft bristle brush. The cuff and airway tube are thoroughly rinsed in warm flowing tap water to remove cleaning residues. Carefully inspect the device to ensure that all visible matter has been removed.

(ii) Sterilization

Steam autoclaving is the recommended method for sterilization of the LMA. Prior to it, the cuff must be fully deflated and dry. After autoclaving, allow the LMA to cool to room temperature before use.

3.2.9 Complications after laryngeal mask airway removal

Many authors agree that children have an increased incidence of airway complications when recovering from anaesthesia compared with the adult population. Parry et al, 1997 conducted a prospective audit on the. recovery phase of anaesthesia with the LMA in paediatric patients and they found that 90% of the children had a totally uneventful recovery period with no airway complications. In those cases where complications occurred, the commonest problem was either coughing or retching followed by laryngospasm. They found no episodes of aspiration or loss of airway.

3.2.9(a) Coughing/bucking

Coughing is the most common complication seen after LMA removal. Bucking is a more forceful and often protracted cough that physiologically mimics a valsalva maneuver. Coughing and bucking are not only unpleasant but can also be harmful. They can cause abrupt increases in intracranial and intraocular pressures. The increased in intrathoracic pressure will decrease the venous return to the right atrium. Mason et al., 1990 studied the use of LMA in 200 paediatric patients and found that the incidence of coughing to be highest on the list followed by biting, laryngospasm, retching and vomiting.

3.2.9 (b) Laryngospasm

Laryngospasm is a protective reflex, involves reflex closure of the glottis by adduction of the true or false cords. It can be life threatening when it occurs after airway removal. Stimulation of a variety of sites from the nasal mucosa to the diaphragm can evoke laryngospasm.Most commonly it is due to reaction to a foreign body or substance eg. blood or saliva near the glottis. Suzuki and Sasaki., 1977 found that laryngospasm is due to prolonged adduction of the vocal cords mediated via the superior laryngeal nerve and cricothyroid muscle. It has been suggested that laryngospasm can be prevented by removal of airway under deep anaesthesia while the laryngeal reflexes are depressed especially for patient with high risk for bronchospasm.

3.2.9(c) Sorethroat

Postoperative sore throat following anaesthesia with LMA is multifactorial. Its incidence can be influenced by the method of insertion, the depth of anaesthesia at the time of insertion, the correct size of LMA, the number of attempt at placement and the presence of humidified moist exchanger in the circuit.

3.2.9(d) Dysphonia

The LMA and LT do not transverse the vocal cord, hence the incidence of dysphonia is less than that induced by tracheal intubation. Nevertheless direct contact of the LMA with

the vocal cord and the arytenoid cartilage may occur in some cases and dysphonia may occur, albeit with varying incidence.

3.2.9(e) Aspiration

The overall incidence of regurgitation and aspiration with LMA is unknown. Brimacombe J, et al., 1994 found the incidence of aspiration with the LMA is 2.3 per 10,000 patients which is comparable to the facemask (2.6 per 10,000 patients) or tracheal tube (1.7 per 10,000 patients). A.I.J Brain, 1995 demonstrated that IPPV via LMA is not associated with a greater incidence of aspiration.

3.2.9(f) Vocal cord paralysis

Unilateral vocal cord paralysis may cause persistent hoarseness after extubation. Bilateral vocal cord paralysis may produce upper airway obstruction. Vocal cord paralysis is usually secondary to injury of the recurrent laryngeal nerve resulting in unopposed superior laryngeal nerve mediated adduction of the vocal cords.

Mechanisms proposed for vocal cord paralysis include misplacement of the LMA tip between the false vocal cords causing pressure on the vocal folds and lead to paresis, hyperextension of the neck resulting in stretching of vagus nerve, local diffusion of the lignocaine jelly applied to the LMA cuff, reaction to products used for cleaning and pressure neuropraxia by the over inflated cuff due to diffusion of nitrous oxide.

4. METHODOLOGY

After obtaining approval from the University research ethics committee and written informed consents from the parents, we studied 80 paediatric patients (ASA 1 or 11,aged from 2-10 years) undergoing short elective surgery that did not require tracheal intubation. Exclusion criteria included patients at risk of pulmonary aspiration of gastric contents and those with features suggestive of possible difficult intubation.

This was a prospective randomized controlled trial. All children were fasted and received syrup promethazine 0.5mg/kg as premedication 1 hour prior to surgery. They were randomized to receive either a laryngeal tube or laryngeal mask airway by the use of sealed envelopes containing the letters LT or LMA. In the operation room, all patients received standard monitors such as electrocardiograph, pulse oxymeter, non-invasive blood pressure monitor, inspired oxygen and volatile agent analyzers.

General anaesthesia were induced identically in both groups by inhalational technique using servoflurane 8% in Nitrous oxide/oxygen. Fentany 1.5 $\mu g.kg^{-1}$ was given once intravenous access was obtained. The concentration of volatile agent will be reduced down to 3% when the child was no longer physically moving. The facemask was maintained for at least 1 minute. The LT or LMA will be inserted after adequate depth was achieved as assessed by loss of eyelash reflex, verbal response, jaw relaxation and absence of movement. The same investigator inserted the airways in all 80 patients.

In the LT group, the laryngeal tube was inserted based on the weight as recommended by the manufacturer' instruction manual. Size 0 for newborn up to 6 kg, size 1 for children from 6-15 kg, size 2 for children from 15-30 kg and size 3 for children above 30 kg. Before insertion both cuffs were deflated and lubricated with a water soluble lubricant (KY jelly) With the head extended on the neck, the tip of the LT was placed against the hard palate behind the upper incisors and the device was slid down in the center of the mouth until resistance was felt or the bold middle line had just passed between upper and lower teeth. The cuffs were inflated using a cuff pressure gauge manometer supplied by the manufacturer to the pressure of 60-70 cmH2O.

In the LMA group, LMA size 2 was used for children from 6.5 kg up to 20 kg, size 2½ for 20-30 kg and size 3 for 30 kg upwards. The back of the cuff was lubricated with KY jelly and the mask was inserted by method described in the manufacturer's instruction booklet. The cuff was inflated with 10 ml of air for size 2,14 ml for size 2½ and 20 ml for size 3.

In both groups, the breathing system was connected to the device. We assessed the adequacy of ventilation by observing the tracing of $ETCO_2$ waveforms and chest movement. After successful placement of LT or LMA anaesthesia was maintained with 2 to 3 MAC of servoflurane and 66% nitrous oxide in oxygen. Ventilation will be manually assisted until respirations are regular. The end-tidal CO2 was maintained between 45-65 mmHg. The children breathed spontaneously throughout the procedure and no muscle relaxant was administered. Intermittent fentanyl boluses were given intravenously if

analgesia was inadequate. Regional block such as caudal block was used as appropriate for pain relief.

When the insertion of LT or LMA was unsuccessful at first attempt, manipulations like jaw thrust or chin lift was done and further attempt was made. If it was not possible to ventilate the lungs or if $ETCO_2$ or chest movement did not indicate a patent airway, in case of LT, the position was adjusted by gently pushing or pulling the device and adequacy of ventilation was reassessed. (no such manoeuver was allowed for LMA).If it was still not possible to insert or ventilate through the laryngeal tube or laryngeal mask after three attempts , it was recorded as a failure and the study was terminated. The airway was then secured in the most suitable manner determined by the attending anaesthetist.

After commencement of surgery, the patients were observed for any sign of partial or complete airway obstruction. If they were noted, airway manipulations (pushing the airway in or out to find the ideal position, further extension of the head, chin lift or jaw tilt)were used in attempt to clear the airway. Failing that the devices were removed and the airway was secured by other means.

Patients' demographic data was recorded which include age, sex, weight, height and ASA status. Duration of anaesthesia and duration of surgery were also recorded. The time to insert the airway device was taken, measured from removal of facemask to successful delivery of the first tidal lung volume. The number of attempts required to insert the airway device successfully was recorded. Any episodes of desaturation and intraoperative manipulation of the device or patient after initial insertion were recorded. The haemodynamic parameters (systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate) were recorded prior to induction,2 minutes after insertion of airway device, prior to surgical incision,2 minutes after surgical incision and prior to airway removal. The end-tidal CO2 were recorded after insertion of devices, prior to surgical incision, two minutes after incision and prior to removal of the devices.

At the end of surgery both airway devices was removed with the children fully awake.The emergence time was recorded as interval between switching off the volatile agent to eye opening or obeying verbal commands. At removal of airway device, the presence or absence of blood on the device was examined. Incidence of laryngospasm after airway insertion, during maintainence or during airway removal was recorded. Postoperative complications such as coughing and vomiting were assessed and recorded at the time of discharging the patient from recovery room. Postoperative analgesia was supplemented by suppository paracetamol or diclofenac if regional block was not given.

Results are presented as mean and standard deviation or median and percentile.The statistical package for the social science (SPSS) version 12.00 for windows was used in statistical analysis .The data from two groups were analysed using the independent t-test for continous variables or the chi square test for categorical data. Haemodynamic data were analyzed using ANOVA for repeated measurements. Differences were considered statistically significant when $p < 0.05$.

5. RESULTS

A total of 80 paediatric patients who had undergone elective surgery under spontaneous ventilation were studied and randomly assigned into 2 groups. 40 patients used laryngeal tube (VBM) and another 40 patients used laryngeal mask airway as an airway device.

5.1 DEMOGRAPHIC DATA

5.1.1 AGE

The mean age of patients in group LT was 5.2 years with a SD of 2.6 and group LMA was 4.9 years with a SD of 2.7. There was no statistical difference between groups according to age (p =0.537) (Table 5.1)

5.1.2 WEIGHT

Mean weight for LT group was 16.4 kg with a SD of 5.13 and group LMA was 16.1 kg with a SD of 5.2.There was no statistical difference between groups according to weight (p= 0.786) (Table5.1)

5.1.3 HEIGHT

Mean height for LT group was 108.0 cm with a SD of 17.2 and group LMA was 108.2 cm with a SD of 14.7. There was no statistical difference between groups according to height (p= 0.967). (Table 5.1)

5.1.4 DURATION OF ANESTHESIA, SURGERY AND EMERGENCE

The mean duration of anesthesia, surgery and emergence for LT group were 46.4 min with a SD of 16.9, 26.6 min with SD of 13.1 and 8.2 min with a SD of 3.1 respectively; group LMA were 49.9 min with a SD of 17.0, 32.8 min with SD of 16.0 and 6.7 min with a SD of 3.2.There were no significant statistical differences in duration of anesthesia, surgery and emergence between two groups of study (p= 0.360, p=0.062 and p=0.05). (Table 5.1)

Table 5.1 Characteristics of patients, duration of anaesthesia, surgery and emergence time. Values are given as mean (SD).

Parameters	Group LT (n=40)	Group LMA (n=40)	p value
Age (years)	5.2 (2.6)	4.9 (2.7)	0.537

Weight (kg)	16.4 (5.13)	16.1 (5.2)	0.786
Height (cm)	108.0 (17.2)	108.2 (14.7)	0.967
Duration of anesthesia (min)	46.4 (16.9)	49.9 (17.0)	0.360
Duration of surgery (min)	26.6 (13.1)	32.8 (16.0)	0.062
Emergence time (min)	8.2 (3.1)	6.7 (3.2)	0.050

5.1.5 GENDER

For LT group, total number of male patients was 32 (80.0%) and female patients was 8 (20.0%). In LMA group male patients was 35 (87.5%) and female patients was 5 (12.5%) There was no significant difference in gender between two groups in this study. (p=0.363) (Table 5.2 and Figure 5.1)

5.1.6 ASA (American Society of Anaesthesiologist)

For LT group, total number of ASA I patient was 38 (95.0%) and ASA II was 2(5%). In LMA group, 36 patients (90%) were ASA I and 4 patients (10.0%) were ASA II. There was no significant statistical difference between two groups in this study (p= 0.396). (figure 5.2)

Table 5.2 Number of patients according to gender. Values are given as number(proportion)

	Group LT (n=40)	Group LMA (n=40)	p value
Gender (Male: Female)	32:8 (80:20)	35:5 (87.5:12.5)	0.363

Figure 5.1 Gender distributions in groups

Table 5.3 Number of patient according to ASA (American Society of Anesthesiologists) in the group. Values are given in number (proportion)

	Group LT (n=40)	Group LMA (n=40)	p value
ASA (I:II)	38:2(95:5)	36:4(90:10)	0.396

Figure 5.2 ASA distributions in group

5.2 TIME TO SUCCESSFUL INSERTION

The mean time to successful insertion for LT was 18.2 seconds with a SD of 6.2 , group LMA was 13.9 seconds with SD of 6.8. There was significant difference in time to successful insertion between the two groups (p=0.004). (Table 5.4)

5.3 NUMBER OF INSERTION ATTEMPTS TO SECURE AIRWAY

In group LT, 19(47.5%) of the patients had successful insertion with the first attempt, 14(35%) patients had two attempts and 7 (17.5%) patients had successful insertion after third attempts. For group LMA, 37(92.5%) patients had successful insertion with a single attempt and 3(7.5%) patients required two attempts for the insertion of LMA. There was significant difference in the number of attempts to secure airway between the two devices in this study (p =0.000) (Table 5.4 and Figure 5.3)

Table 5.4 Time to insertion of device and number of insertion attempts. Values are given as mean (SD) or number (proportion)

Parameters	Group LT (n=40)	Group LMA (n=40)	p value
Time to successful insertion (seconds)	18.2(6.2)	13.9(6.8)	0.004
Number of attempts 1 2 3	 19(47.5) 14(35) 7(17.5)	 37(92.5) 3(7.5)	0.000