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. Mahamarowi Bin Omar

Dr. Noor Zairul Muhamad

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

3) Tajuk Projek: Comparison of the Use of the Laryngeal Tube (VBM) and Laryngeal Mask Airway under Anaesthesia During Spontaneous Ventilation

4) (a) Penemuan Projek/Abstrak
(Perlu disediakan makluman di antara 100 – 200 perkataan di dalam Bahasa Malaysia dan Bahasa Inggeris. Ini kemudiannya akan dimuatkan ke dalam Laporan Tahunan Bahagian Penyelidikan & Pembangunan sebagai satu cara untuk menyampaikan dapatan projek tuan/puan kepada pihak Universiti).

ABSTRAK (BAHASA MALAYSIA):

Tujuan kajian ini dijalankan adalah untuk menilai samaada "laryngeal tube (VBM)" yang baru direka adalah alat bantuan pernafasan yang cepat, boleh diharapkan dan mudah digunakan. Kami telah membandingkan penggunaan "laryngeal tube (VBM)" dan "laryngeal mask airway" keatas pesakit dewasa yang bernafas secara spontan semasa pembiusan dijalankan keatas mereka dan telah mengukur tahap kesenangan untuk memasukkan alat, insiden kecederaan pada saluran pernafasan dan sakit kerongkong serta perubahan tindak balas kardiovaskular yang berlaku semasa memasukkan alat –alat ini. Kajian rawak secara prospektif ini telah dijalankan terhadap 121 orang pesakit yang telah menerima rawatan primedikasi sebelum pembiusan dilakukan dan terdiri daripada kelas ASA I dan II serta berumur diantara 18 tahun sehingga 65 tahun. Pesakit-pesakit ini telah dibahagikan kepada 2 kumpulan iaitu kumpulan yang menggunakan "laryngeal tube (VBM)" dan kumpulan yang mengunakan "laryngeal mask airway" sebagai alat bantuan pernafasan semasa pembedahan elektif dijalankan. Selepas induksi pembiusan dilakukan dengan menggunakan fentanyl 1.5 □g.kg^{-1} dan propofol 2 mg.kg^{-1}, saiz 3 atau 4 "laryngeal tube (VBM)" atau "laryngeal mask airway" telah dimasukkan dan pesakit akan bernafas secara spontan di bawah bius semasa pembedahan dijalankan tanpa menggunakan ubat kelumpuhan otot (muscle relaxant). Pembiusan di kekalkan menggunakan nitrus oxida, oksigen dan isoflurane. Alat bantuan pernafasan ini akan dikeluarkan selepas pembedahan, setelah pesakit sedar sepenuhnya. Kecepatan, kesenangan dan jumlah percubaan yang diperlukan untuk memasukkan alat pernafasan ini dengan jaya telah direkodkan. Insiden kecederaan saluran pernafasan, sakit kerongkong serta perubahan tindakbalas kardiovaskular

(b) Senaraikan Kata Kunci yang digunakan di dalam abstrak:

Bahasa Malaysia	Bahasa Inggeris
saluran pernafasan	airway
"laryngeal tube"	laryngeal tube
"laryngeal mask airway"	laryngeal mask airway
bius	anaesthesia
pernafasan spontan	spontaneous ventilation
kesenangan memasukan alat	easiness of insertion
kecederaan saluran pernafasan	airway trauma

5) Output Dan Faedah Projek

(a) Penerbitan (termasuk laporan/kertas seminar)
(Sila nyatakan jenis, tajuk, pengarang, tahun terbitan dan di mana telah diterbit/dibentangkan).

Pembentangan pertama:

Jenis: Pembentangan Oral

Tajuk: Comparison of The Use of The Laryngeal Tube (VBM) and Laryngeal Mask Airway under Anaesthesia During Spontaneous Ventilation

Pengarang: N. M. Nik Abdullah, M. Noor Zairul, O. Mahamarowi, M. Z. Rhendra Hardy, J. Kamarudin

Tahun: 2003

Pembentangan di13th Asean Congress of Anaesthesiologists, 15-19 October 2003, Surabaya, Indonesia

Pembentangan kedua:

Jenis Pembentangan Oral

Tajuk: Comparison of the Use of The Laryngeal Tube (LT) and Laryngeal Mask Airway (LMA) under Anaesthesia During Spontaneous Ventilation

Pengarang: M. Noor Zairul, N. M. Nik Abdullah, A. H. Azmi, M. Z. Rhendra Hardy, G. Ghazaime, O. Mahamarowi, J. Kamarudin,

Tahun: 2004

Pembentangan di 9th National Conference On Medical Sciences, 22-23 May 2004, Kota Bharu, Kelantan

seperti tekanan darah sistolik, tekanan darah diastolik, tekanan darah purata (MAP) dan kadar denyutan jantung pada masa yang berbeza juga telah direkodkan. Kekerapan episod memanipulasikan alat pernafasan ini semasa pembedahan dijalankan serta bacaan "end-tidal CO_2" pada masa yang berbeza juga direkodkan.

Didalam kajian ini, kami mendapati bahawa tiada perbezaan statistik yang signifikan bagi masa serta jumlah percubaan yang diperlukan untuk memasukkan alat ini dengan jaya bagi kedua-dua alat bantuan pernafasan ini. Kami berjaya mencapai 75.4% kejayaan memasukkan alat ini dalam satu cubaan, keatas pasakit bagi kumpulan "laryngeal tube (VBM)". Tiada perbezaan didalam insiden kecederaan salur pernafasan dan sakit kerongkong didalam kajian ini diantara 2 kumpulan yang dikaji. Kedua-dua kumpulan juga tidak berbeza secara statistik didalam tindak balas kardiovaskular semasa pembiusan dijalankan. Walaupun episod memanipulasikan alat pernafasan ini semasa pembedahan dijalankan serta bacaan "end-tidal CO_2" adalah tinggi didalam kumpulan "laryngeal tube (VBM)" berbanding kumpulan "laryngeal mask airway", ia adalah tidak relevan secara klinikal didalam kajian ini. Kesimpulannya, kami berpendapat bahawa semasa pembiusan menggunakan kaedah pernafasan spontan, alat bantuan pernafasan baru iaitu "laryngeal tube (VBM)" adalah sesuai sebagai alat bantuan pernafasan alternatif terhadap "laryngeal mask airway" yang sedia ada.

ABSTRACT (BAHASA INGGERIS)

The purpose of this study is to assess whether the newly developed laryngeal tube (VBM) is a fast, reliable and easy device for airway management. We compared the use of the laryngeal tube (VBM) with the laryngeal mask airway in spontaneously ventilating adult patient undergoing general anesthesia and measured the easiness of insertion, incidence of airway trauma and sore throat and also the haemodynamic responses to insertion of these devices. A randomized single blinded prospective study was conducted involving a total of 121 premedicated, ASA I or II patients, aged 18 to 65 years and were divided into 2 groups either laryngeal tube (VBM) or laryngeal mask airway group as for airway management during elective surgery. After a standardized induction of anaesthesia with fentanyl 1.5 □g.kg^{-1} and propofol 2 mg.kg^{-1}, a size 3 or 4 laryngeal tube (VBM) or laryngeal mask airway was inserted and the patients breathed spontaneously throughout the surgery with no muscle relaxants given. Anaesthesia was maintained with nitrous oxide, oxygen and isoflurane. The airway device was removed at the end of surgery with the patients fully awake. The speed and ease of insertion and the number of attempts needed to successfully secure the airway were recorded. The incidence of airway trauma, sore throat and haemodynamic changes such as systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate at different time intervals were recorded. Episodes of airway manipulations intraoperatively and end-tidal CO_2 at various time intervals were also recorded.

We found that there was no statistically significant difference in time required for successful insertion and number of attempts for both groups. We were able to achieve a clear airway in 75.4% patients in LT group at the first attempt. There were no difference in incidence of airway trauma and sore throat between laryngeal tube and laryngeal mask airway. Both groups had no statistical differences in haemodynamic parameters during spontaneous ventilation under anaesthesia. Although, the incidence of airway manipulations and end – tidal CO_2 were higher with laryngeal tube (VBM) compared to the laryngeal mask airway but it is not likely to be clinically relevant in this study. We conclude that during spontaneous ventilation, the laryngeal tube (VBM) is a suitable alternative to the laryngeal mask airway.

(b) Senaraikan Kata Kunci yang digunakan di dalam abstrak:

Bahasa Malaysia	Bahasa Inggeris
saluran pernafasan	airway
"laryngeal tube"	laryngeal tube
"laryngeal mask airway"	laryngeal mask airway
bius	anaesthesia
pernafasan spontan	spontaneous ventilation
kesenangan memasukan alat	easiness of insertion
kecederaan saluran pernafasan	airway trauma

5) Output Dan Faedah Projek

(a) Penerbitan (termasuk laporan/kertas seminar)
(Sila nyatakan jenis, tajuk, pengarang, tahun terbitan dan di mana telah diterbit/dibentangkan).

Pembentangan pertama:

Jenis: Pembentangan Oral

Tajuk: Comparison of The Use of The Laryngeal Tube (VBM) and Laryngeal Mask Airway under Anaesthesia During Spontaneous Ventilation

Pengarang: N. M. Nik Abdullah, M. Noor Zairul, O. Mahamarowi, M. Z. Rhendra Hardy, J. Kamarudin

Tahun: 2003

Pembentangan di13th Asean Congress of Anaesthesiologists, 15-19 October 2003, Surabaya, Indonesia

Pembentangan kedua:

Jenis Pembentangan Oral

Tajuk: Comparison of the Use of The Laryngeal Tube (LT) and Laryngeal Mask Airway (LMA) under Anaesthesia During Spontaneous Ventilation

Pengarang: M. Noor Zairul, N. M. Nik Abdullah, A. H. Azmi, M. Z. Rhendra Hardy, G. Ghazaime, O. Mahamarowi, J. Kamarudin,

Tahun: 2004

Pembentangan di 9th National Conference On Medical Sciences, 22-23 May 2004, Kota Bharu, Kelantan

Pembentangan ketiga:

Jenis pembentangan: Penulisan dissertasi untuk memenuhi pra-syarat keperluan untuk dianugerah Ijazah Sarjana Perubatan (Anestesiologi)

Tajuk:	Comparison of the Use of The Laryngeal Tube (LT) and Laryngeal Mask Airway (LMA) under Anaesthesia During Spontaneous Ventilation
Pengarang:	Dr. Noor Zairul Bin Muhamad
Supervisor:	Prof. Madya Dr. Nik Abdullah Bin Nik Mohamad
Co-Supervisor:	Dr. Mahamarowi Bin Omar
Tahun:	Mei 2004

USM J/P-06 - 3

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

Kajian ini mengesahkan bahawa alat baru ini (laryngeal tube) berupaya menjadi pilihan alternatif kepada laryngeal mask airway sebagai alat untuk penghantaran gas pembiusan dan juga memastikan pesakit mendapat cukup bekalan oksigen dan pembuangan karbon dioxide semasa pengalami pembiusan untuk 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

iii) Lain-Lain : Jururawat sebagai pembantu semasa menjalankan aturcara untuk kajian

USM J/P-06 - 4

6. Peralatan Yang Telah Dibeli:

Epson Printer
Kodak digital camera
Handy drive
Canon Scanner

Pembiayaan menaja Penyelidik Bersama (Co-Researcher), Dr. Mahamarowi Bin Omar menghadiri 13th ASEAN Congress of Anaesthesiologists, Surabaya, Indonesia untuk pembentangan hasil penyelidikan ini secara Oral Presentation

Tambang Perjalanan Udara	RM 1263.00
Penginapan (Subsidi):	RM 1440.00 (240X6)
Subsisten:	RM600.00
Yuran Pendaftaran:	USD225/-

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T/TANGAN PENGERUSI
J/K PENYELIDIKAN
PUSAT PENGAJIAN

PROFESSOR ABDUL AZIZ BABA
Chairman of Research & Ethics Committee
School of Medical Sciences
Health Campus
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan

25/8/06

USM J/P-06 - 5

The title page.

Comparison of the use of the laryngeal tube (VBM) and laryngeal mask airway under anaesthesia during spontaneous ventilation

M. Noor Zairul, N. M. Nik Abdullah, O. Mahamarowi

Department of Anaesthesiology, School of Medical Sciences, Universiti Sains Malaysia, Kubang Kerian, Kelantan, 16150 Malaysia.

Summary

Background and objective: The purpose of this study is to assess whether the newly developed laryngeal tube (VBM) is a fast, reliable and easy device for airway management. We compared the use of the laryngeal tube (VBM) with the laryngeal mask airway in spontaneously ventilating adult patient undergoing general anaesthesia and measured the easiness of insertion, incidence of airway trauma and sore throat and also the haemodynamic responses to insertion of these devices.

Method: A randomized single blinded prospective study was conducted involving a total of 121 premedicated (n=121), ASA I or II patients, aged 18 to 65 years and were divided into 2 groups either laryngeal tube (VBM) or laryngeal mask airway group as for airway management during elective surgery. After a standardized induction of anaesthesia with fentanyl 1.5 $\mu g.kg^{-1}$ and propofol 2 $mg.kg^{-1}$, a size 3 or 4 laryngeal tube (VBM) or laryngeal mask airway was inserted and the patients breathed spontaneously throughout the surgery with no muscle relaxants given. Anaesthesia was maintained with nitrous oxide, oxygen and isoflurane. The airway device was removed at the end of surgery with the patients fully awake. The speed and ease of insertion and the number of attempts needed to successfully secure the airway were recorded. The incidence of airway trauma, sore throat and haemodynamic changes such as systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate at different time intervals were recorded. Episodes of airway manipulations intraoperatively and end-tidal CO_2 at various time intervals were also recorded.

Results: We found that there was no statistically significant difference in time required for successful insertion and number of attempts for both groups. We were

able to achieve a clear airway in 75.4% patients in LT group at the first attempt. There were no difference in incidence of airway trauma and sore throat between laryngeal tube and laryngeal mask airway. Both groups had no statistical differences in haemodynamic parameters during spontaneous ventilation under anaesthesia. Although, the incidence of airway manipulations and end – tidal CO_2 were higher with laryngeal tube (VBM) compared to the laryngeal mask airway but it is not likely to be clinically relevant in this study.

Conclusions: We conclude that during spontaneous ventilation, the laryngeal tube (VBM) is a suitable alternative to the laryngeal mask airway.

Keywords.

AIRWAY, laryngeal tube, laryngeal mask airway; ANAESTHESIA, spontaneous ventilation; OUTCOME ASSESSMENT, easiness of insertion, airway trauma, sore throat, haemodynamic.

Introduction.

The laryngeal tube (VBM, Medizintechnik GmbH, Sulz, Germany), a new airway device, has been recently introduced into clinical practice. It has been developed to secure a patent airway during spontaneous breathing or controlled ventilation. The design of the laryngeal tube is based on the oesophageal obturator airway and it is designed to be inserted blindly into the oesophagus. The prototype laryngeal tube consisted of an airway tube with a small cuff attached to the tip (distal cuff) and a larger cuff in the middle of the tube (proximal cuff). The cuffs are inflated through a single pilot tube and balloon, through which the cuff can be monitored. There is a standard 15-mm connector on the proximal end of the device so that it can be attached to a breathing system.

The laryngeal tube device is made of silicone and is reusable after sterilization in an autoclave. Two oval holes located between the cuffs allowed lung ventilation. 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 provides a seal by forming a plug in the upper pharynx and the distal cuff seals the oesophageal inlet. A black line on mid-part of the tube indicates adequate depth of insertion when aligned with the teeth. The tip is made of soft silicone to minimize oropharyngeal injury. Six sizes are available, suitable for neonates to adults.

The first case report regarding the use of the laryngeal tube was published in 1999 [2]. It has been shown to provide a clear airway during controlled ventilation in anesthetized patients, and has been suggested to have a potential role during

cardiopulmonary resuscitation because of its ease of insertion and a good airtight seal [14]. The manufacturers claimed that it is also an effective device during spontaneous ventilation as well [4]. In this study, we compared the use of the laryngeal tube (VBM) and laryngeal mask airway under aesthesia during spontaneous ventilation.

Method.

After obtaining approval from the Institutional Research Ethics Committee and written informed consents, we studied 121 patients (ASA I or II, aged from 18-65 years) undergoing elective surgery that did not require tracheal intubation and mechanical ventilation. Exclusion criteria included patients at risk of pulmonary aspiration of gastric contents and those with features suggestive of possible difficult intubation (for example Mallampati III-IV classification, a receding chin, protruding front teeth and limited neck extension). This was a prospective randomized controlled trial. The patients were then allocated randomly to one of two groups. In one group, the laryngeal tube was used and, in the other, the laryngeal mask airway. Randomization was by use of sealed opaque envelopes containing the letters LT or LMA.

All the patients were fasted overnight and received oral midazolam 0.15 $mg.kg^{-1}$. In the anaesthetic room, an electrocardiograph, a pulse oximeter and non –invasive blood pressure monitor were attached and i.v. cannula was inserted. A firm head pad was placed under the patient' occiput. After the patients had breathed oxygen through a facemask for a minimum of 3 minutes, anaesthesia was induced with a sleep dose of propofol 2.0 $mg.kg^{-1}$ i.v, supplemented with fentanyl 1.5 $\mu g.kg^{-1}$. Further increments of propofol 0.5 $mg.kg^{-1}$ were repeated every 30 s, if required, to achieve adequate anaesthetic depth. The laryngeal tube or laryngeal mask airway was inserted after loss of eyelash reflex.

In the LT (n= 61) group the laryngeal tube was inserted following the manufacturers instructions [4]. Before insertion, cuffs were deflated and a water soluble lubricant (KY jelly) applied to the cuffs. The patient's head was extended on the neck ("sniffing position"). The tip of the laryngeal tube was placed against the hard palate behind the upper incisors and the device was slid down in the centre of the mouth until a resistance was felt or the second bold black line on the tube had just passed between upper and lower teeth. The cuffs were inflated using a cuff inflator (VBM, Germany) until the intracuff pressure reached 80-90 cmH_20 and then slightly reduced to 60-70 cmH_20. A size 3 was used for patients below 155 cm, a size 4 for that height above 155 cm. In the LMA group (n=60), a laryngeal mask airway was used. A size 3 was used in females and a size 4 mask for males. The back of the cuff was lubricated with KY jelly; the mask was placed by method described in the manufacturer's instruction manual [8]. Twenty millilitres of air were injected into size 3 and 30 ml into the size 4 laryngeal mask airway.

In both groups, the breathing system was connected to the device. We immediately assessed adequacy of ventilation by gentle squeezing the reservoir bag, observing the presence of end-tidal carbon dioxide waveforms and chest movement. If it was not possible to ventilate the lungs, in the case of the laryngeal tube the position was adjusted by gently pushing or pulling the device (whereas no such manoeuvre was allowed for the laryngeal mask) and adequacy of ventilation re-assessed. If it was not possible to ventilate the lungs, or if end –tidal CO_2 and or chest movement did not indicate a patent airway, the laryngeal tube or laryngeal mask airway was removed, and reinserted after a supplement dose of propofol (up to 1 $mg.kg^{-1}$). If still not possible to insert or ventilate through the laryngeal tube or laryngeal mask airway

after three attempts, a failure was recorded and the study terminated. The airway was then secured in the most suitable manner determined by the anaesthetist.

After successful placement of the laryngeal tube or laryngeal mask airway, anaesthesia was maintained with 66% nitrous oxide in oxygen and isoflurane (1 to 2 minimum alveolar concentrations). Ventilation of the lung was manually assisted until respiratory efforts were regular. The patients breathed spontaneously throughout the procedure and no muscle relaxants were given. Intermittent fentanyl boluses were given for inadequate analgesia. All patients were monitored with electrocardiograph, pulse oximeter, non invasive blood pressure monitor, capnograph, inspired oxygen and volatile agents' analyzers. After commencement of surgery, patients' demographic data will be recorded; these were included age, sex, weight, height, ASA status, Mallampati airway examination, duration of surgery and anaesthesia and also the emergence time. The haemodynamic parameters (systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate) were measured and recorded prior to induction, after induction, two minutes after insertion of devices, prior to surgical incision, two minutes after incision, prior to airway removal, two minutes after airway removal, on admission to recovery room and finally, on discharge from recovery bay. All patients were also observed for any sign of partial or complete airway obstruction and this was diagnosed clinically and observation of the shape of the end-tidal CO_2. The end tidal CO_2 were recorded after insertion of devices, prior to surgical incision, two minutes after incision and prior to removal of the laryngeal tube or laryngeal mask airway. If partial or complete airway obstruction was noted, airway manipulations (pushing the airway in or out to find the ideal position, further extension of the head and chin lift or jaw tilt) were used in an attempt to clear the

airway. Failing that, the devices were removed and the airway was secured by other means.

The number of manipulations of each device during insertion and maintenance was recorded for each device. Time of insertion was defined as from the removal of the facemask to successful delivery of the first tidal volume. The number of attempts required to insert the laryngeal tube or laryngeal mask airway successfully was recorded. Any episode of desaturation was also recorded. At the end of surgery the laryngeal tube and laryngeal mask airway was removed with the patient fully awake. At removal of airway device, the presence or absence of blood on the device was examined. Post operative complications (hoarseness, sore throat, coughing, nausea, vomiting) were assessed and recorded at the time discharging the patient from the recovery ward and twenty four hours later.

Results were presented as mean and standard deviation (S.D) or mean and percentile. The Statistical Package for the Social Science (SPSS) version 10.0 for windows was used in statistical analysis. The data from two groups were analyzed using the independent t-test for continuous variables or the Chi square for categorical data. Haemodynamic data were analyzed using ANOVA for repeated measurements. Differences were considered statistically significant when $P < 0.05$.

Results

A total of 121 patients who had undergone elective surgery under spontaneous ventilation were studied and randomly assigned into 2 groups. Sixty one patients used Laryngeal tube (VBM) and another sixty patients used laryngeal mask airway (LMA) as an airway device during spontaneous ventilation under anaesthesia. Two patients in LMA group were excluded from these studies because of inability to insert the device after three attempts during intubation and one patient under laryngeal tube (VBM) group was excluded for unexpected prolonged surgery (more than 2 hours).

Patients' characteristics, duration of anaesthesia and surgery and dose of propofol and fentanyl administered are shown in Table 1. The two groups were well matched. Time taken for successful insertion of the device, the number of attempts needed to successfully insert the laryngeal tube or laryngeal mask airway is shown in Table 2. Table 3 shown the relationship of height and number of insertion attempts. Adverse respiratory complications are shown in Table 4 and table 5 represent the incidence of airway trauma. Apart from airway obstruction needing manipulations there were no patient recorded an oxygen saturation of less than 95%. The incidence of intraoperative airway manipulation and the relationship of height and episode of airway manipulations are shown by Table 6 and Table 7 respectively.

Haemodynamic data and end- tidal CO_2 are presented in Figures 1-5. There were no differences in the systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate between the two groups. The end- tidal CO_2 was significantly higher in the laryngeal tube group (by ANOVA for repeated measurements).

Table 1. Characteristics of patients, dose of Propofol and Fentanyl, emergence time and duration of procedures. Values are given as mean (SD).

Parameters	Group LT (n=61)	Group LMA (n=60)	p value
Age ; years	36.0(14.6)	37.0(13.1)	0.708
Weight ; kg	61.1(14.8)	60.2(8.6)	0.741
Height ; cm	160.1(7.5)	160.0(6.4)	0.929
Propofol ; mg	125.6(19.2)	130.0(2.3)	0.262
Fentanyl ; μg	88.8(14.9)	90.4(14.3)	0.559
Duration of anaesthesia ; min	71.9(52.5)	62.4(26.5)	0.216
Duration of surgery ;min	57.3(45.6)	50.4(26.8)	0.323
Emergence time ; min	7.8(2.9)	8.1(4.2)	0.694

Table 2. Time to insertion of device, number of insertion attempts and rate of successful insertion. Values are given as mean (SD) or number (proportion).

Parameters	Group LT (n=61)	Group LMA (n=60)	p value
Time to successful insertion; seconds	20.6(7.9)	21.7(5.0)	0.376
Number of attempts			
1	46	45	
2	14	13	0.973
3	1	-	
>3	-	2	
Successful insertion; yes: no	61:0(100:0)	58:2(96.7:3.3)	0.496

Table 3. Relationship of height and number of insertion attempts.

Airway type			**Height(in meter)**		Total
			Same or > 155 cm	<155 cm	
LMA (p=0.100)	**number of attempt**	1	40	5	45
		2	12	1	13
	Total		52	6	58
LT (p=0.004)	**number of attempt**	1	38	8	46
		2	6	8	14
		3	0	1	1
	Total		44	17	61

Table 4. Adverse respiratory complications. Values are given in number (proportion)

	Group LT (n=60)	Group LMA (n=58)	p value
Sore throat; yes: no	11:49(18.3:81.7)	9:49(15.5:84.5)	0.684
Hoarseness; yes: no	2:58(3.3:96.7)	0:58(0:100)	0.496
Coughing; yes: no	6:54(10:90)	10:48(17.2:82.8)	0.251
Nausea; yes: no	0:60(0:100)	0:58(0:100)	-
Vomiting; yes: no	0:60(0:100)	0:58(0:100)	-

Table 5. Airway trauma (presence of blood on airway devices used).Values are given in number (proportion).

	Group LT (n=60)	Group LMA (n=58)	p value
Airway trauma; yes: no	1:59(1.7:98.3)	2:56(3.4:96.6)	0.615

Table 6. The incidence of intra operative airway manipulation. Values are given in number (proportion).

	Group LT (n=61)	Group LMA (n=58)	p value
Intra operative airway manipulations; Yes: No	22:39(36.1:63.9)	7:51(12.1:87.9)	0.002

Table 7. Relationship of height and episode of intra operative airway manipulations. Values are given in number (proportion).

Airway			Episode of airway manipulations		Total
			Yes	No	
Group LMA (p=0.091)	Height	≥ 155 cm	5	47	52
		< 155cm	2	4	6
		Total	7	51	58
Group LT (p=0.004)	Height	≥ 155 cm	11	33	44
		< 155cm	11	6	17
		Total	22	39	61

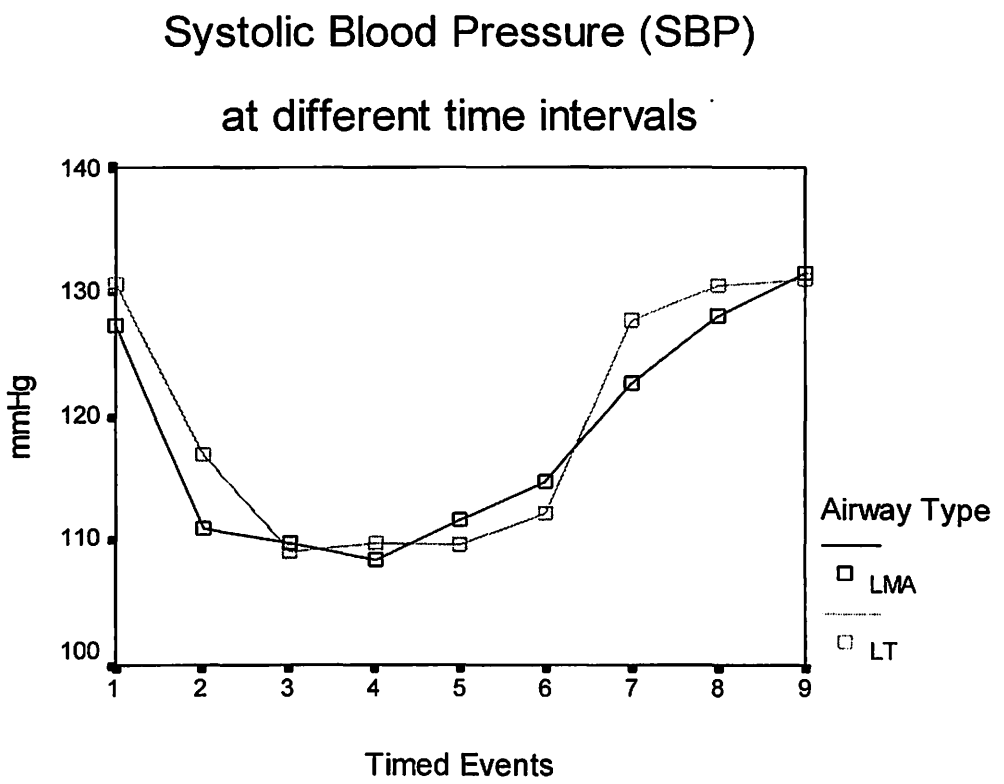

Figure 1. Systolic blood pressures (SBP) at different time intervals. No significant difference between the two groups (p=0.287).

Key to timed events:

1. Before induction
2. After induction and before insertion
3. 2 minutes after insertion
4. Prior to surgical incision
5. 2 minutes after surgical incision
6. Prior to removal of airway
7. 2 minutes after airway removal
8. On admission to recovery room
9. On discharge from recovery room.

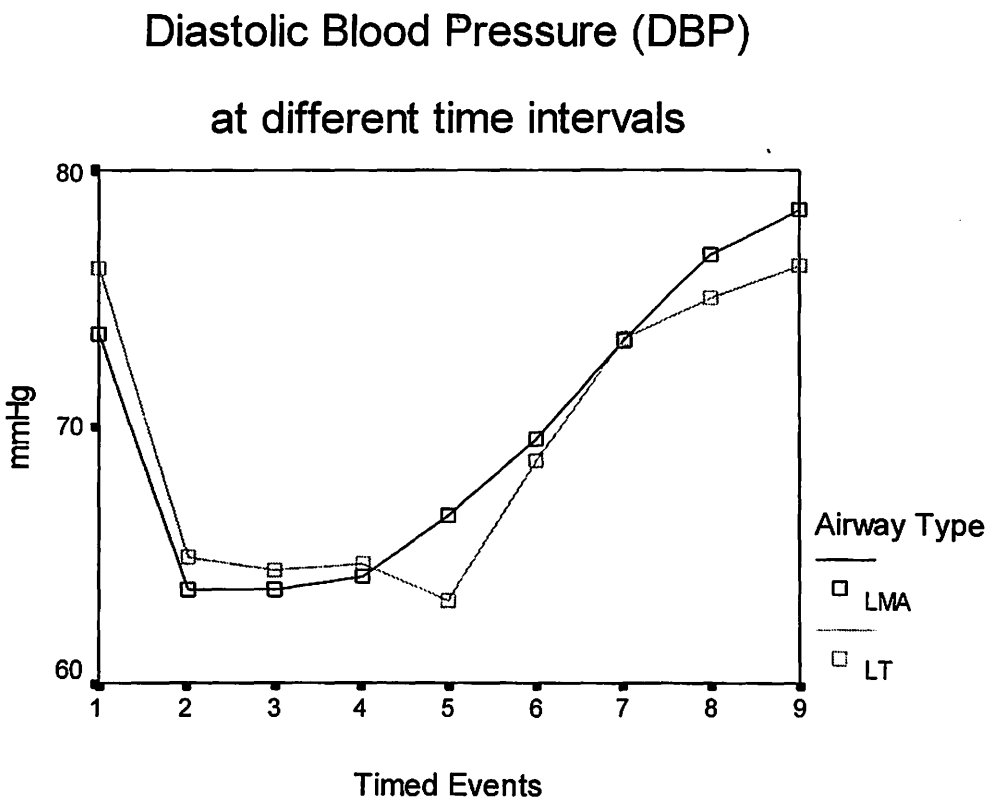

Figure 2. Diastolic blood pressures (DBP) at different time intervals. No significant difference between the two groups (p=0.767).

Key to timed events:

1. Before induction
2. After induction and before insertion
3. 2 minutes after insertion
4. Prior to surgical incision
5. 2 minutes after surgical incision
6. Prior to removal of airway
7. 2 minutes after airway removal
8. On admission to recovery room
9. On discharge from recovery room.

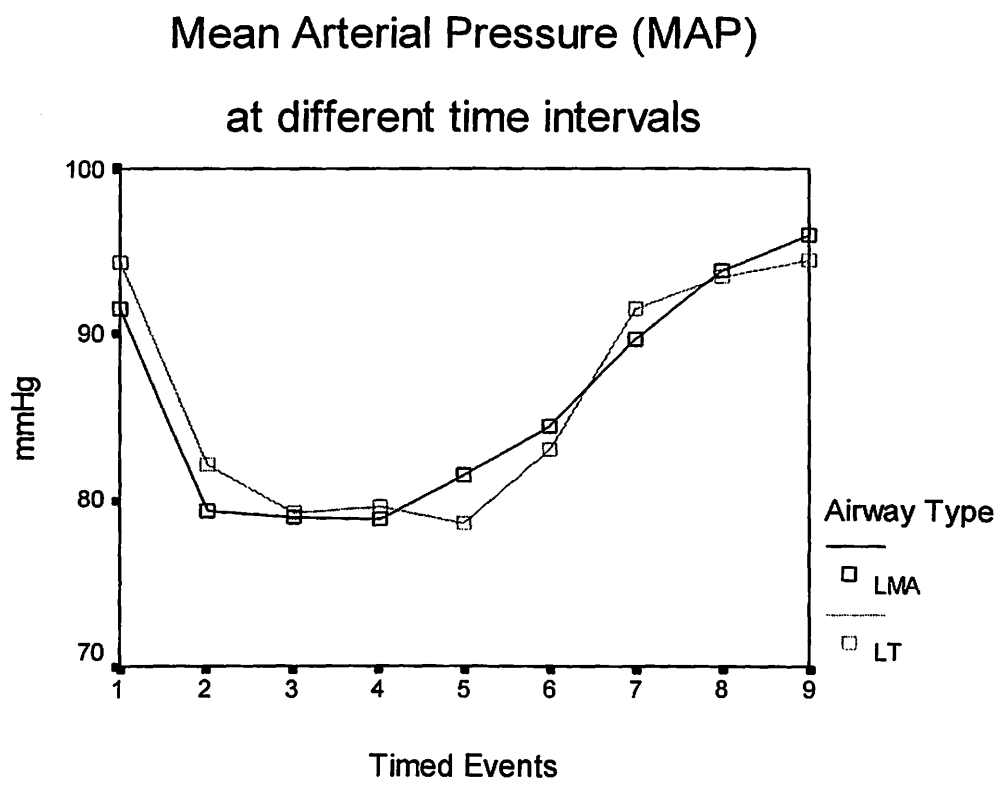

Figure 3. Mean arterial pressures (MAP) at different time intervals. No significant difference between the two groups (p=0.829).

Key to timed events:

1. Before induction
2. After induction and before insertion
3. 2 minutes after insertion
4. Prior to surgical incision
5. 2 minutes after surgical incision
6. Prior to removal of airway
7. 2 minutes after airway removal
8. On admission to recovery room
9. On discharge from recovery room.

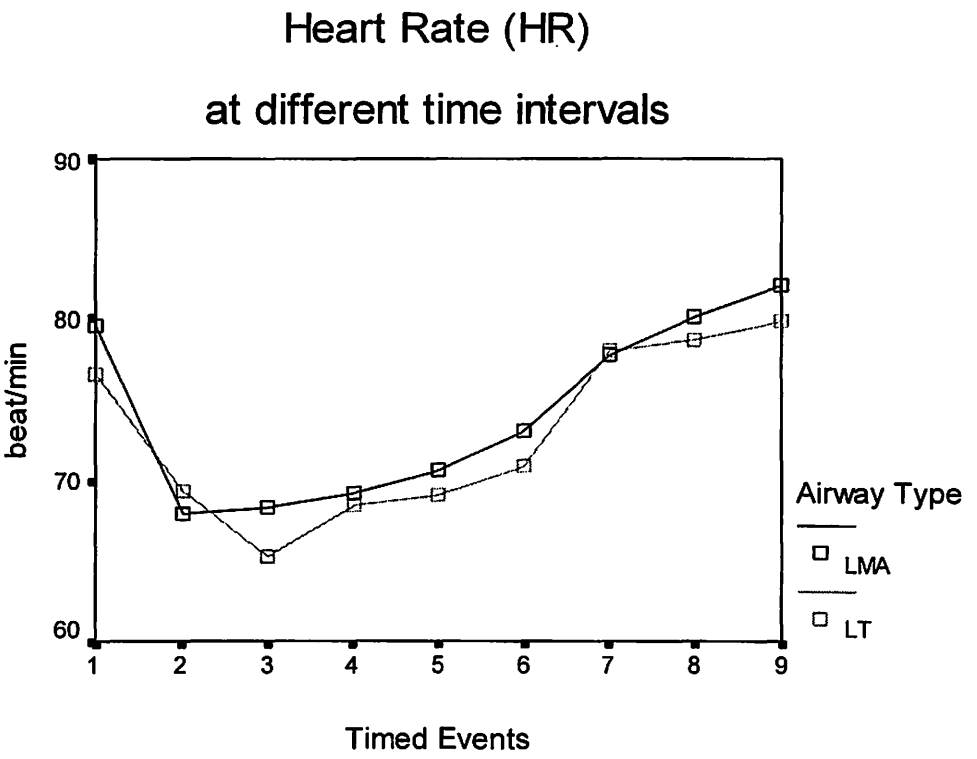

Figure 4. Heart rate (HR) at different time intervals. No significant difference between the two groups (p=0.361).

Key to timed events:

1. Before induction
2. After induction and before insertion
3. 2 minutes after insertion
4. Prior to surgical incision
5. 2 minutes after surgical incision
6. Prior to removal of airway
7. 2 minutes after airway removal
8. On admission to recovery room
9. On discharge from recovery room.

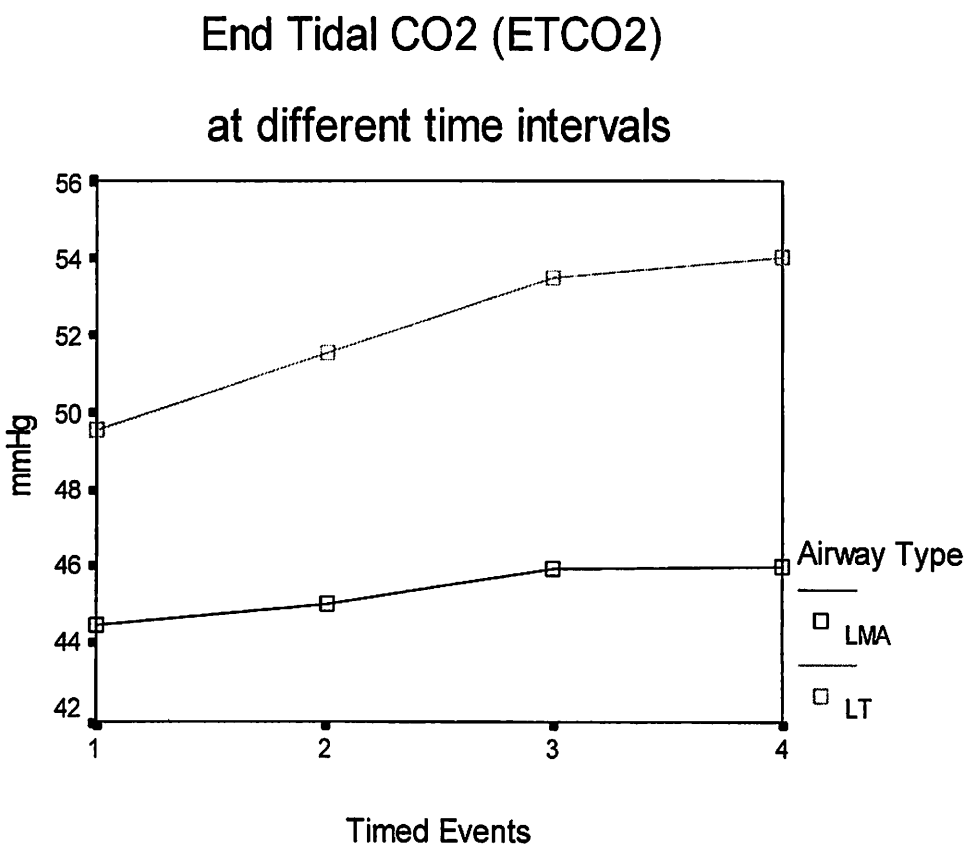

Figure 5. End Tidal Carbon Dioxide ($ETCO_2$) at various time intervals. The end-tidal CO_2 is significantly higher in the laryngeal tube group than the laryngeal mask airway group, by ANOVA for repeated measurements (p=0.010).

Key to timed events:

1. Post airway insertion
2. Pre surgical incision
3. Post surgical incision
4. Before anaesthetic turned off

Discussion

The recently introduced laryngeal tube (VBM) was found to be a fast, reliable and easy device for airway management [16] and it insertion has been reported to be generally easy in anesthetized patients [6, 12]. Despite relative lack of experience with the device, Dorges et al, 2000 could insert the device and obtained adequate ventilation in all of 30 patients (100%), whereas Asai T et al, 2000 reported the success rate were 94% and 100% in two studies, at first attempt of insertion. When used by intensive care unit nurses, it was shown to be a valid alternative for emergency airway management in the experimental model used (manikin) and 50 inexperienced personnel could insert the laryngeal tube (VBM) in 478 of 500 times at the first attempt [16]. Therefore, it appears that insertion of the laryngeal tube is easy (in patients) even for inexperienced personnel.

In this study, we tested the use of laryngeal tube (VBM) as an airway device in spontaneous breathing patients under anaesthesia. It was easy and quick to insert in most of the patients with mean time of successful airway insertion of 20.6 $\pm$ 7.9 seconds. This finding has however no significant difference statistically compared to laryngeal mask airway with p =0.376. In LMA group, the mean time required for successful insertion was 21.7 seconds with a SD of 5.0. Although the laryngeal tube was easy and quick to insert, 24.6 % of the patients required more than one attempt for successful insertion. This finding was almost similar with the study conducted by C.L.Chiu et al. [9] who reported 70% of the patients had successful insertion of the laryngeal tube (VBM) with one attempt. However, the finding was in contrast with the other two studies that showed 94% [6] and 100% [12] success rate with one

attempt. The differences between our study and Dorges [12] and Asai [6] studies were; in Asai study [6] vecorunium was used to facilitate the insertion of laryngeal tube and controlled ventilation, our patients did not receive any neuromuscular blocking drugs and were breathing spontaneously. Dorges and colleagues [12] did not mention the use of a neuromuscular blocker in their study. However, with 10-15 $mg.kg^{-1}.h^{-1}$ of propofol infusion as maintenance of anaesthesia, they were able to provide controlled ventilation throughout the study period of 10 minutes. It is possible that the laryngeal tube is slightly more difficult to insert without muscle relaxation. Although in LT group, the success rate was 75.4% with single attempt, it was no statistical difference compared to LMA group (p=0.973).

For LT group, a size 3 laryngeal tube (VBM) was used for patient with height less than 155 cm and size 4 for patient with height $\geq$ 155cm as recommended by manufacturer [4]. From statistical analysis, it was shown that the height of patient plays a role in determining the number of attempts for successful insertion with p value of 0.004. In LT group, 17 patients were < 155cm in height and 9 (52.9%) of them required more than one attempt for successful insertion of the device. There was no significant difference in LMA group in the relation between height and number of attempts (p=0.100). Asai and colleagues [5] postulated that the distance between the teeth and the oesophageal inlet correlated more with height than with weight and found that ventilation was often inadequate in patients whose heights were less than 155cm if the selection of the size were based on the weight of the patient. Since the number of attempts required for successful insertion was higher for patient with height < 155cm in our study. It is wise for the manufacturer to review the appropriate size of laryngeal tube (VBM) for appropriate height especially for Asian population.

In our opinion, all patients whose height was more than 150 cm and using size 4 laryngeal tube (VBM) have a better outcome in term of number of attempts for successful insertion but a further bigger study would be needed to re-evaluate of appropriate size of the laryngeal tube (VBM) based on height of the patient.

In this study the successful insertion of device was 100% in LT group and 96.7% in LMA group but there were no significant differences between the two groups with p value of 0.496. These results showed that the laryngeal tube (VBM) can provide a fast, easy and reliable device for a patent airway in spontaneous breathing under anaesthesia as frequently as the laryngeal mask airway.

The complications during emergence and recovery were few and mostly minor [11]. We studied the incidence of airway trauma in both groups by presence of blood on airway devices used during extubation at the end of surgery and found that the incidence of airway trauma was not significantly different between the two groups in this study with the p value of 0.615. The incidence of airway trauma was 1.7% in LT group whereas 3.4% seen in LMA group. The incidence of airway trauma in LT group was not correlated with the number of attempt and there was no statistical difference with p value of 0.562. The tip of the laryngeal tube (VBM) was made of soft silicone in order to minimize oropharyngeal injury [4] and these advantages could explain the possible reason for the finding in our study. It seems in LMA group, there was significant difference in incidence of airway trauma with the number of attempts to successful insertion (p=0.047). Although our study involved spontaneous breathing patients under anaesthesia, the findings were similar to that study conducted in paralyzed patients [11]. These findings showed that the laryngeal tube (VBM) offered

an equivalent safety to laryngeal mask airway as atraumatic airway device apart from providing a better seal in the oropharynx than the laryngeal mask [7].

The manufacturer claimed that the incidence of sore throat was lower when using the laryngeal tube (VBM) compared to laryngeal mask airway [4]. A study in anesthetized and controlled ventilation patients were shown that the incidence of sore throat was similar in number, in severity and in the number of patients affected; these differences did not reach statistical significance [11].

In our study, it was found that the incidence of sore throat for both groups was not significant statistically (p=0.684). For LT group, 11 of them complained of mild form of sore throat while staying in recovery room but none of them had experienced sore throat 24 hours later. A similar finding was also seen in LMA group post extubation. The incidence of sore throat in this study seems to correlate with the number of attempts in both groups with p value of 0.00 for LMA group and p value of 0.04 for LT group; however, it was not related with the episode of airway manipulations intra operatively for both groups (LMA group; p=0.296 and LT group; p=0.2). Other complications such as hoarseness and coughing did not reach statistical significance in this study. None of the patient from either groups complained of nausea or vomiting post operatively. Based on these findings, it shown that the laryngeal tube (VBM) was comparable with the laryngeal mask airway in the incidence of sore throat when used as an airway device in spontaneous breathing patient under anaesthesia and it was similar to the findings when used in a paralyzed and controlled ventilation patient.

Although a lot of clinical trial studies were conducted throughout the world on the laryngeal tube (VBM) as a new supraglottic airway device; only one study on haemodynamic responses while using LT and LMA under spontaneous breathing anaesthesia was reported by C. L. Chiu and colleagues [9]. Their study involved a total of sixty patients revealed no significance statistical difference in haemodynamic responses for both LT group and LMA group. One of the objectives in our study was to evaluate the haemodynamic responses while using the laryngeal tube (VBM) or LMA, but it involved much larger number of patients with a total of 121 participants. In this study, there was a significant decreased of systolic blood pressure after induction from baseline for both groups with $p= 0.015$. The decreased in systolic blood pressure after the induction could be explained by the intravenous drugs used for the induction; which were 2 $mg.kg^{-1}$ of propofol and 1.5 $\mu g.kg^{-1}$ of fentanyl. In the absence of nitrous oxide, propofol per se can reduce the blood pressure by a mean decrease 20% of cardiac output and 22% of stroke volume. The systolic blood pressure was found to be increased significantly for both groups at two minutes after airway removal ($p=0.028$). The precise mechanism responsible for the finding after extubation remains unclear, but the haemodynamic changes may be associated with the release of catecholamine. It seems the increased of the systolic blood pressure at two minutes after airway removal was a transient episode as the pressure returned to baseline values once patients were admitted to recovery room.

Apart from systolic blood pressure measurement, other haemodynamic parameters were also tested in the study and they included diastolic blood pressure (DBP), mean arterial pressure (MAP) and heart rate (HR). All of the parameters in both groups; although showed some reductions in measurements after induction, but did not reach

statistical significance. Obviously all the haemodynamic values were not increased at two minutes after airway insertion and based on these findings; we can say that the laryngeal tube (VBM) was comparable with the LMA in term of less haemodynamic responses after intubation; where it has been proved in many studies for LMA. All the haemodynamic parameters for both groups seem to be elevated in some degree at two minutes after surgical incision but did not reach statistical significance ($p > 0.05$).

This phenomenon can be due to pain stimulation that may some how trigger the sympathetic responses which lead to tachycardia and hypertension. All haemodynamic parameters except systolic blood pressure for both groups in these studies are to return to baseline at two minutes after removal of the devices. Looking at the results, we conclude that the laryngeal tube (VBM) was as effective as laryngeal mask airway in maintaining the haemodynamic response to insertion. A reduced haemodynamic effect response may be beneficial in patients with cardiovascular and cerebral disease.

In two previous studies by Miller et al [18] and Chiu et al [9] found that the laryngeal tube is associated with a high incidence of airway obstruction and that it is of limited use for spontaneous ventilation. Following these reports, a further modified version of the laryngeal tube was made with the latest version has two holes, instead of one; near the distal aperture, for lung ventilation and this is now the only version available. The manufacturer claims that with this modification, the incidence of airway obstruction has been dramatically reduced. In our study, the end tidal carbon dioxide ($ETCO_2$) was significantly higher in LT group compare to LMA group at all four timed intervals with p value of 0.000. We also noted that in LT group; on occasion, manual

ventilation of lungs was successful despite a subsequent need for airway manipulations to overcome the problems. This is in agreement with Miller et al. [18] who postulated that the burden of obstruction is easily overcome by manual ventilation, but not as easily by a patient's respiratory effort. During spontaneous breathing this increase in work of breathing by the patient may result in increased CO_2 production and less CO_2 elimination.

There were more intra operative airway manipulations required in the LT group compared to LMA group with a ratio of 22:7 case (p=0.002). If we look at the incidence of airway manipulation and height of the patient in LT group, it was significant statistically (p=0.004). Seventeen patients in LT group were shorter than 155cm and 11 (64.7%) of them required airway manipulations intraoperatively whereas only 50% happened in LMA group but none of the patient who required manipulations had episode of desaturation (SPO_2 <95%).

The mechanisms to explain higher end tidal CO_2 level with higher incidence of airway manipulations has been postulated by Miller et al., 2001 in his report where it may be due to the effect of nitrous oxide that diffused into the cuffs which then lead to a rise in pressure and the cuff inflates further. As it does so, if it is slightly below or above the middle of the cricopharyngeus sphincter, it may pull the device inwards or push it further out. If it pulls inwards, the anterior aperture in the laryngeal tube may be obstructed in upper oesophagus. If it moves in the outward direction, the lower cuff may become obstructive to the laryngeal opening. In our opinion, the size of the laryngeal tube also plays an important role in order to avoid the airway obstruction and it seems with a proper size selection based on patient height's may reduce the

incidence of airway obstruction. If a smaller size laryngeal tube is used, the distal cuff may not be seated properly at the side and once the cuff is inflated it will obstruct the laryngeal opening. Inflation of lower cuff at improper place may cause the epiglottis to fold downwards and to close against the glottis. Again in LT group, if a smaller or inappropriate size been selected, it could end up with the oesophageal or oronasopharynx not fully sealed by both cuffs and because of the instability and with the effect of nitrous oxide that been used intraoperatively, it may lead outward migration of the tube which can caused obstruction to the ventilation holes and finally lead to airway obstruction.

Although various airway manipulations appear to successfully overcome airway obstruction in the laryngeal tube group, the end tidal CO_2 remained higher. This small difference in end tidal CO_2 is not likely to be clinically relevant since there were no episode of desaturation and no changes in haemodynamic parameter associated with the higher values in end tidal CO_2. However, special precaution must be taken, if we want to use it in patient who may encounter harmful effect of high end tidal CO_2 especially in patient with high intracranial pressure (ICP).

Based on all the results, we conclude that during spontaneous ventilation, the laryngeal tube (VBM) is a suitable alternative to the laryngeal mask airway.

Acknowledgements

We are grateful to Suria- Medik Sdn Bhd, Malaysia, who loaned us the laryngeal tubes and cuff inflation devices for the purpose of this trial.

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ORAL A1-1

COMPARISON OF THE USE OF THE LARYNGEAL TUBE (LT) AND LARYNGEAL MASK AIRWAY (LMA) UNDER ANAESTHESIA DURING SPONTANEOUS VENTILATION

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Objective :

To assess whether the newly developed laryngeal tube (LT) is comparable to laryngeal mask airway (LMA) in terms of easiness of insertion, haemodynamic response and complications in spontaneously ventilating adult patients undergoing general anaesthesia.

Methodology :

A randomized single blinded prospective study on 121 ASA I or II premedicated patients, aged 18 to 65 years. Patients were divided into 2 groups receiving either LT or LMA as for airway management during elective surgery. After induction of anaesthesia with fentanyl 1.5 ug.kg^{-1} and propofol 2 mg.kg^{-1}, a size 3 or 4 LT or LMA was inserted and the patients breathed spontaneously throughout the surgery. Anaesthesia was maintained with nitrous oxide, oxygen and isoflurane. The airway device was removed at the end of surgery with the patients fully awake. The speed and ease of insertion and the number of attempts needed to successfully secure the airway were recorded. The incidence of airway trauma, sore throat, systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate at different time intervals were recorded.

Results :

There was no significant difference in time required for successful insertion and number of attempts for both groups. A clear airway was achieved in 75.4% patients in LT group at the first attempt. There were no difference in incidence of airway trauma and sore throat between LT and LMA. Both groups had no statistical differences in blood pressure and heart rate changes.

Conclusions :

During general anaesthesia with spontaneous ventilation, the LT is a suitable alternative to the LMA.

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Comparison of The Use of The Laryngeal Tube (Vbm) and Laryngeal Mask Airway under Anaesthesia during Spontaneous Ventilation

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Abstract

Objectives The purpose of this study is to assess whether the newly developed laryngeal tube (VBM) is safe, atraumatic, simple to use and able to provide adequate ventilation and oxygenation to patient under anesthesia during spontaneous ventilation. We propose to compare the laryngeal tube (VBM) to the laryngeal mask airway as an alternative airway management tool in spontaneously ventilating adult patient undergoing general anesthesia. Interpretation of these results may demonstrate that the laryngeal tube (VBM) is a better alternative airway device than the laryngeal mask airway.
Methods A randomized single blinded prospective study was conducted involving a total of 120 ASA I or II premedicated patients which were divided into 2 groups either laryngeal tube (VBM) or laryngeal mask airway group as for airway management during elective surgery. After induction of anaesthesia with fentanyl (1.5 micrograms/ kg) and propofol (2 milligrams/kg), a size 3 or 4 laryngeal tube (VBM) or laryngeal mask airway was inserted and the patients were breathed spontaneously throughout the surgery. The airway device was removed at the end of surgery with the patients awake. Easiness of insertion, which included the time required to successfully insert the airway device and the number of attempt needed to achieve a patent airway, were recorded. Incidence of airway trauma, haemodynamic changes such as systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate at different time intervals and incidence of sore throat were also assessed.
Results From this study it was found there was no statistically significant for both groups in term of time required for successful insertion ($p > 0.05$) and number of attempts ($p > 0.05$). There were no difference in incidence of airway trauma ($p>0.05$) and sore throat between laryngeal tube and laryngeal mask airway ($p>0.05$). Both group had no difference in haemodynamic parameters during spontaneous ventilation under anaesthesia ($p> 0.05$).
Conclusion We conclude that laryngeal tube is a satisfactory alternative airway device for management of the airway in-patient breathing spontaneously under anaesthesia.

Key words: Laryngeal tube (VBM), spontaneous ventilation

COMPARISON OF THE USE OF THE LARYNGEAL TUBE (VBM) AND LARYNGEAL MASK AIRWAY UNDER ANAESTHESIA DURING SPONTANEOUS VENTILATION

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

UNIVERSITI SAINS MALAYSIA
MAY 2004

ACKNOWLEDGEMENT

Bismillahirrahmanirrahim

I would like to take this opportunity to extend my utmost appreciation and gratitude to the following persons who have helped me right from the beginning till 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 initiation, pertinent guidance, ongoing support and advice towards the progress of this study.
- Dr Mahamarowi Omar, Lecturer of Anaesthesiology and Intensive Care Unit, Universiti Sains Malaysia for his guides and valuable comments as a co - supervisor for this study.
- Suria-Medik Sdn Bhd Malaysia, particularly Mr. Budiman Harun Al-Rashid, for the support in supplying the needed paraphernalia for the study.
- All the lecturers and medical officers, Department of Anaesthesiology and Intensive Care Unit, Universiti Sains Malaysia for their helpful assistance.
- I would like to acknowledge the research grant, which was provided by Universiti Sains Malaysia, Penang that has resulted in this paper
- To my parents; Norsham Abd Ghafar and Muhamad Mahmud for their vigilant prayers and continuous faith in me.
- Last but not least, my dearest wife Dr Nazihah Mohamad, my children; Nur Sabrina, Muhammad Najmi and Muhammad Eirfan who inspired me with their endless support and love in ensuring the completion of this study.