COMPARISON OF THE BASKA® FESS MASK WITH THE LMA SUPREME™: OROPHARYNGEAL LEAK PRESSURES IN PARALYZED ANAESTHETIZED ADULT PATIENTS

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ABSTRACT

Background

The Baska® mask is a novel supraglottic airway device (SAD) with a number of innovations. Baska FESS mask is a modification of the Baska mask with a connector that can be turned to face south. This randomized controlled trial compared the Baska FESS to the Supreme™ Laryngeal Mask Airway® (SLMA) in paralysed patients under general anaesthesia in term of oropharyngeal leak pressures (OLP).

Methods

We recruited 100 adult patients with ASA I to III underwent elective surgical procedures from October 2015 to March 2016 at the University Malaya Medical Centre, Kuala Lumpur. Patients with BMI > 35 kg m-2, with risk of regurgitation or aspiration were excluded. We recorded the oropharyngeal leak pressure (OLP) as primary outcome. We also compared number of insertion attempts, ease of insertion, success rates, time to insertion, gastric drain functionality, haemodynamic response, fibreoptically determined laryngeal view grade and complications of usage.

Results

The mean (SD) oropharyngeal leak pressure for the Baska FESS was 32.59 (5.49) cmH2O, which was greater than the SLMA 26.65 (6.40) cmH2O ($P<0.001$). The overall insertion success rates were 100% for both groups with comparable first attempt insertion (Baska FESS 91.8% versus SLMA 98%, $P=0.200$). The SLMA was found to be faster and easier to insert than the Baska FESS ($P<0.001$ and $P=0.046$). The grade of fibreoptic view was better with the Baska FESS than the SLMA ($P=0.025$). The occurrence of complications was low in both groups.

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Conclusions

The Baska FESS has significantly higher oropharyngeal leak pressure and better fibreoptic views. But SLMA is easier and faster to insert with better gastric drain functionality.

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ABSTRAK

Latar Belakang

Baska® mask adalah alat rongga pernafasan supraglotik dengan beberapa inovasi baru. Baska FESS mask adalah pengubahsuaian Baska mask dengan penyambung yang boleh dipusing ke arah selatan. Percubaan terkawal rawak ini membandingkan tekanan kedap orofarinks (OLP) antara Baska FESS dengan LMA Supreme (SLMA) pada pesakit di bawah bius penuh.

Metodologi

Kami telah mengumpul 100 pesakit dewasa dengan ASA I hingga III menjalani prosedur pembedahan elektif dari Oktober 2015 hingga Mac 2016 di Pusat Perubatan Universiti Malaya, Kuala Lumpur. Pesakit yang mempunyai BMI> 35 kg m-2, dengan risiko muntah atau aspirasi telah dikecualikan. Kami telah merekodkan tekanan kedap orofarinks (OLP) sebagai keputusan utama. Kami juga mencatatkan bilangan percubaan, kesenangan perletakan, kadar kejayaan, masa perletakan, fungsi salur gastrik, respon hemodinamik, gred pandangan fibreoptic dan komplikasi.

Keputusan

Min (SD) tekanan kedap orofarinks (OLP) untuk Baska FESS adalah 32.59 (5.49)cmH2O, lebih tinggi daripada SLMA 26.65 (6.40)cmH2O (P <0.001). Kadar kejayaan perletakan adalah 100% bagi kedua-dua kumpulan dengan kejayaan percubaan pertama yang serupa (Baska FESS 91.8% berbanding SLMA 98%, P = 0.200). SLMA didapati lebih cepat dan lebih mudah untuk diletak daripada Baska FESS (P <0.001 dan P = 0.046). Gred pandangan fibreoptic adalah lebih baik dengan Baska FESS daripada SLMA (P = 0.025). Kejadian komplikasi adalah rendah dalam kedua-dua kumpulan.

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Kesimpulan

Baska FESS mempunyai tekanan kedap orofarinks (OLP) yang lebih tinggi dan pandangan fibreoptic yang lebih baik. Tetapi SLMA adalah lebih mudah dan lebih cepat untuk diletak serta mempunyai fungsi salur gastric yang lebih baik.

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I also take this apportunity to thank all 100 participants who willingly join in this study. And also my anaesthetic colleagues, staff nurses and the academic staffs for their helps in the completion of the study.

Finally, my wife for her never ending support and encouragement throughout. Thank you.

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LIST OF SYMBOLS AND ABBREVIATIONS

ASA	:	American Society of Anesthesiologists
BMI	:	Body mass index
DBP	:	Diastolic blood pressure
ENT	:	Ear, nose & throat surgery
ETCO2	:	End tidal carbon dioxide
HR	:	Heart rate
LMA	:	Laryngeal Mask Airway
MAC	:	Minimum alveolar concentration
MAP	:	Mean arterial pressure
OLP	:	Oropharyngeal leak pressure
SBP	:	Systolic blood pressure
SLMA	:	Supreme™ Laryngeal Mask Airway®
SAD	:	Supraglottic airway device

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LIST OF APPENDICES

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CHAPTER 1: INTRODUCTION

Supraglottic airway devices (SAD) play an essential role in the modern anesthetic practice. These devices have become part and parcel in general anesthesia and have evolved so much since the introduction of classic laryngeal mask airway into clinical practice in 1988. Since then various newer SADs have been introduced and extensively in use.

All newer generation of SADs are designed to have improved airway seal, gastric access and protection from aspiration. One of them is Supreme™ Laryngeal Mask Airway® (SLMA) which is also the commonly used LMA in our institution. SLMA is a second generation SAD which forms an effective First Seal™ with the oropharynx (oropharyngeal seal) and an innovative Second Seal™ with the upper oesophageal sphincter (the oesophageal seal) which can minimise gastric insufflation and reduce the risk of aspiration[1]. In addition, it has fixed curve tube and guiding handle to facilitate insertion and fixation. It is single use to prevent disease transmission. It has other features like the airway tube incorporates a drain tube within its lumen to shorten and straighten its path, oval-shaped to match the shape of the mouth and to reduce rotation in the pharynx, the inner cuff has been strengthened to prevent airway obstruction from infolding and epiglottic fins have been added to prevent airway obstruction from epiglottic downfolding.

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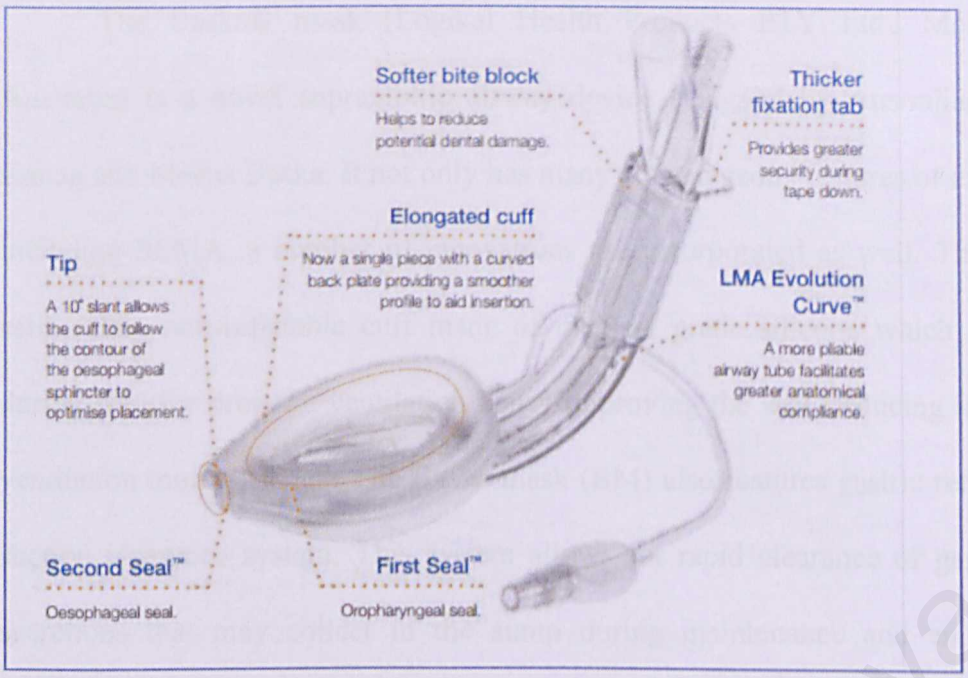

Figure 1.1: The LMA® Supreme™

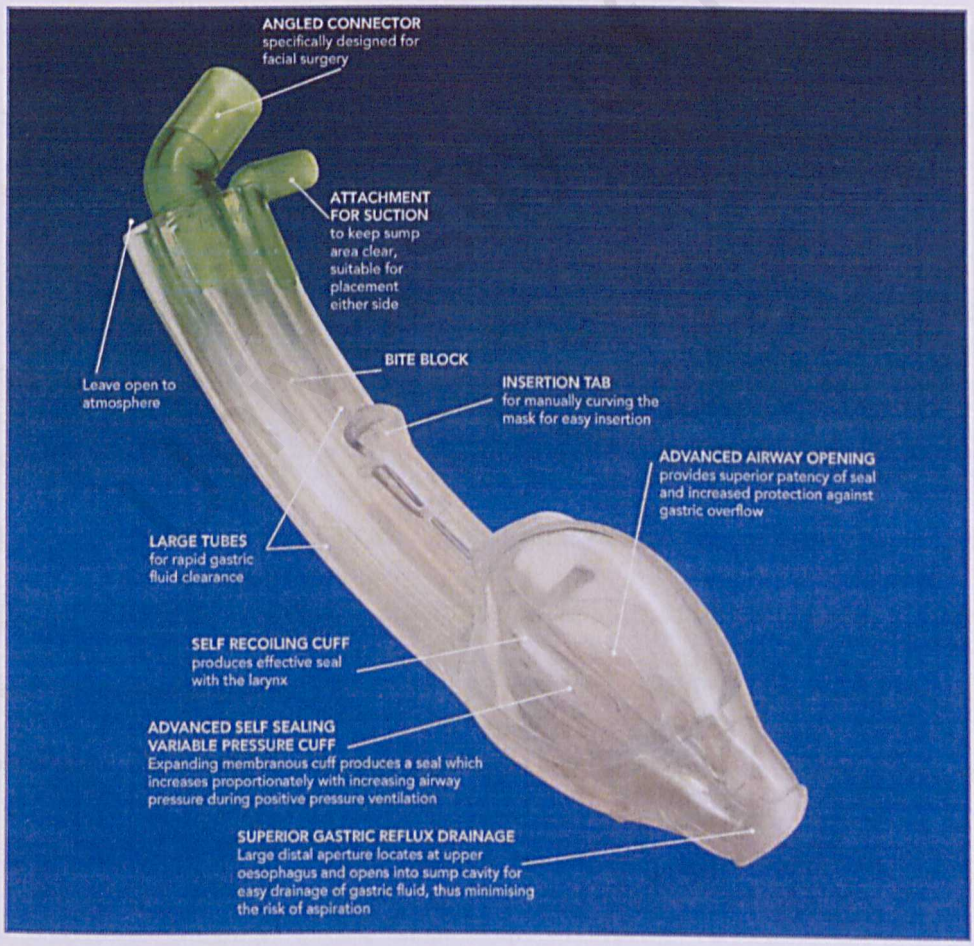

Figure 1.2: The Baska® FESS mask

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The Baska® mask (Logikal Health Products PTY Ltd., Morisset, NSW, Australia) is a novel supraglottic airway device designed by Australian anesthetists Kanag and Meena Baska. It not only has many advantageous features of existing SADs, including SLMA, a number of innovations are incorporated as well. These include a self-sealing non-inflatable cuff made of medical grade silicone which self 'inflates' during positive pressure ventilation hence improving the seal, reducing leak and make ventilation more efficient. The Baska mask (BM) also features gastric reflux high flow suction clearance system. This system allows for rapid clearance of gastric fluids or secretions that may collect in the sump during maintenance and emergence from anesthesia which can reduce the risk of pulmonary aspiration. There is an extended hand-tab for manually curving the mask to facilitate insertion. The Baska FESS mask is a modification of the BM with a connector that can be turned to face south, thereby facilitating surgical access for head and neck procedures. The Bask FESS comes in 4 sizes for patients ranging between 30 to >100 kg. It is inserted in the neutral head position, which may reduce the need for neck manipulation.[2, 3]

These two devices had drawn our attention with their claimed advantages and benefits. In view of growing numbers of SADs being utilized in our centre, a study was designed to assess the clinical performance of The Baska FESS and The SLMA in paralysed anaesthetised patients. Our primary outcome measure was oropharyngeal leak pressure (OLP). Secondary outcomes included number of insertion attempts, ease of insertion, success rates, time to insertion, gastric drain functionality, haemodynamic response, fibreoptically determined laryngeal view grade and complications of usage.

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CHAPTER 2: LITERATURE REVIEW

In general anesthesia, endotracheal tube (ETT) is commonly used to maintain an open airway and allow unobstructed breathing. The ETT has been proven to be a reliable method of securing the airway and is considered the standard of care for protecting the airway from aspiration.[4] Nevertheless, design of the ETT has not been changed for decades, on the other hand, SADs are still developing and new devices are being invented and extensively trialed to improve the safety features of SAD.[5]

The laryngeal mask airway (LMA), developed by Brain, provides an alternative for airway management during general anesthesia.[6] The SAD has gained popularity owing to its ease of insertion and low complication risks. SAD has statistically and clinically significant lower incidence of laryngospasm during emergence, postoperative hoarse voice, and coughing than when using an ETT.[7] Furthermore, estimated risk of clinically significant aspiration associated with the SADs is extremely low (< 1 in 10,000).[8] A recent meta-analysis in 2009 of over 65 thousand cases worldwide showed that the LMA had similar risk for aspiration and gastric insufflation as the endotracheal tube.[9] In SAD, the OLP plays an important role as an indicator of the degree of airway protection.[10] A high OLP will reduce the risk of pulmonary aspiration and provide effective positive pressure ventilation.

SLMA is a safe, efficacious and easy-to-use disposable SAD in general anesthesia.[11] The BM, as compared to SLMA, is rather new. Only few clinical trials were published to look at the claimed advantages of the new features. Initial experience with BM has demonstrated it to be a suitable airway device for procedures less than 2 hours or when endotracheal intubation is not required.[12, 13] When comparing with the classic LMA, the BM was shown to be more difficult to insert, requiring more insertion

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attempts and taking longer to insert.[14] However, in another study by Sharifa, BM takes significantly shorter placement time as compared to Proseal LMA.[15] Both studies showed BM has more superior OLP and no difference in complication rates.[14,15] With improving safety features in new LMA, it is even possible for LMA becoming a suitable alternative to tracheal intubation , even in high risk patients. Recently, BM was safely used in a patient with gastroesophageal reflux which has high risk of regurgitation. This was first case of laparoscopic Nissen fundoplication performed with a BM, reported in Spanish Journal of Anesthesiology and Resuscitation 2016.[16]

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CHAPTER 3: METHOLOGY

After approval from the University of Malaya Medical Ethics Committee (UMREC Number: 20163-2317) and prospective trial registration on the Australian New Zealand Clinical Trials Registry (Trial Number: ACTRN12616001263482), a total of 100 adult patients (18-70 years old) scheduled for elective surgical procedures under general anesthesia that were amenable to supraglottic airway management were recruited in University of Malaya Medical Centre. The exclusion criteria were patients of ASA physical status IV, surgery in the non-supine position, known or predicted difficult airway, the morbidly obese with BMI > 35 kg m-2, patients with increased risk of gastric aspiration (such as inadequate fasting time, pregnancy, expected operation time >3 hours, upper gastrointestional tract surgery, hiatus hernia), patient with active upper respiratory tract infection or pneumonia and patients with neck injury.

Patients were randomized into 2 groups: "Baska FESS" and "SLMA" using a computer generated random number table. After recruitment, sealed opaque envelopes were opened by the enrolling investigators to reveal the group allocation. Participants were blinded to their group allocation.

All patients were fasted overnight and no premedications were given to them. Patients were in supine position with the head resting on a jelly doughnut. Standard monitoring (i.e. pulse oximetry, electrocardiograph and non-invasive blood pressure) was instituted before induction of anaesthesia. After pre-oxygenation with high flow oxygen for three minutes, anaesthesia was induced with intravenous fentanyl 1-2 μ kg-1, propofol 2-3 mg kg-1 and rocuronium 0.5 mg kg-1. If coughing, gagging or body movement occurred during insertion, a further dose of propofol 0.5 mg kg-1 was given to achieve an adequate depth of anaesthesia. Induction of anaesthesia was confirmed by

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loss of verbal contact with the patient, loss of eyelash reflex and relaxation of the jaw. After insertion, the cuff of the SLMA will be inflated with air to attain a cuff pressure of 60 cmH2O as measured with a handheld aneroid manometer. The Baska FESS does not need inflation of the cuff. All SAD insertions were performed by experienced staff anaesthesiologists, who had performed at least five clinical Baska FESS insertions prior to trial commencement.

The size of the airway was chosen in accordance with the manufacturers' recommendations. For the SLMA, a size 3 was used if < 50 kg, a size 4 if 50–70 kg and a size 5 if 70–100 kg. Size selection of the Baska FESS was based on the manufacturer's recommendation of weight-based estimate (Size 3: 30-50kg, Size 4: 50-70kg, Size 5: 70-100kg) plus clinical judgment. Both the SLMA and the Baska FESS were prepared and lubricated according to manufacturer's guidelines.

Successful establishment of effective ventilation was determined by the appearance of the first square end-tidal carbon dioxide (ETCO2) trace. Otherwise, the device was completely removed for another insertion attempt. Three insertion attempts were allowed. Each "attempt" was defined as re-insertion of the SAD into the mouth. When insertion attempts more than three times or the entire process of insertion exceeded 120 seconds, it was considered as insertion failure. This included the time the airway device was removed from the mouth and any bag-mask ventilation in between. In case of failure of both devices, the airway was secured according to the decision of the attending anaesthesiologist.

The SAD was fixed by taping over the patient's cheek once it was in place. A gel plug was placed in the proximal one centimeter of the gastric drain outlet and the suprasternal notch test was done to confirm placement (gently tapping the suprasternal

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notch causes the gel to pulsate, confirming the tip location behind the cricoid cartilage). Oropharyngeal leak pressure (OLP) was measured after closing the adjustable pressure limiting (APL) valve with a fresh gas flow of 3 L min-1, noting the airway pressure at equilibrium or when there was audible air leak from the throat. Maximum pressure allowed was 40 cm H20. The epigastrium was also auscultated when measuring the OLP to detect any air entrainment in the stomach. Following this, the device's anatomic position was evaluated by flexible video endoscopy using the Brimacombe and Berry scoring system.[17] This is graded from 1 to 4: Grade 1, vocal cords not seen; Grade 2, vocal cords and anterior (down folded, lingual surface) epiglottis seen; Grade 3, vocal cords and posterior (laryngeal surface) epiglottis seen; Grade 4, only vocal cords seen.

For both the SADs, a gastric tube was inserted through the gastric drain outlet. These gastric tubes were pre-lubricated with a water soluble lubricant. Ease of insertion was graded 1 to 3 (1-easy, 2-moderate, 3-difficult). Time to insertion of the gastric catheter was also noted. Confirmation of correct placement of the gastric catheter was through detection of injected air by auscultation of epigastrium, and aspiration of gastric contents. Gastric decompression was done and the amount of gastric fluid aspirated was noted.

The number of insertion attempts and time to establish effective ventilation (interval from when the SAD entered the mouth to first ETCO2 trace) was recorded. The ease of insertion of SAD was subjectively assessed on a 3 point scale (1= easy, 2 = moderate, 3 = difficult). Blood pressure and heart rate (every 2.5 minutes for the first five minutes from induction of anesthesia) was recorded as well.

Anesthesia was maintained with oxygen: air mixture in sevoflurane (1-2 MAC). At the end of surgery, patient was reversed, the SAD was removed upon return of

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spontaneous breathing and eye opening of the patient. The SAD was then inspected for presence of visible blood. The patient was assessed, 45 minutes later, by a blinded independent observer for postoperative sore throat, dysphonia or dysphagia. Contemporaneous data collection of airway insertion times, ventilatory parameters and complications of placement (desaturation < 95%, gross regurgitation or aspiration [defined as fluid in the ventilation tube], bronchospasm, mucosal, lip, tongue or dental injury) were done by an unblinded observer was not involved in the study.

The primary outcome of the study was oropharyngeal leak pressure (OLP). Sample size was based on previous studies involving BM that demonstrated a mean (SD) OLP of 29.98 (8.51) {ref: Sharifa ASA, Anesth Pain & Intensive care 2013}[15]. In order to detect a difference of 20%, prospective power analysis at 90% power and 0.05 level of significance showed that a sample of 47 patients would be required. Therefore, we have recruited total 100 patients to account for dropouts and protocol breaches. Student's t-test analysis was used for OLP, insertion times, numbers of insertion and haemodynamic response. The grade of fibreoptic view and ease of insertion were compared by Fisher exact analysis. Complications between the groups were compared by Fisher's exact test and also chi-square test. All statistical analyses were performed using IBM SPSS software version 22. A p value of < 0.05 is considered statistically significant.

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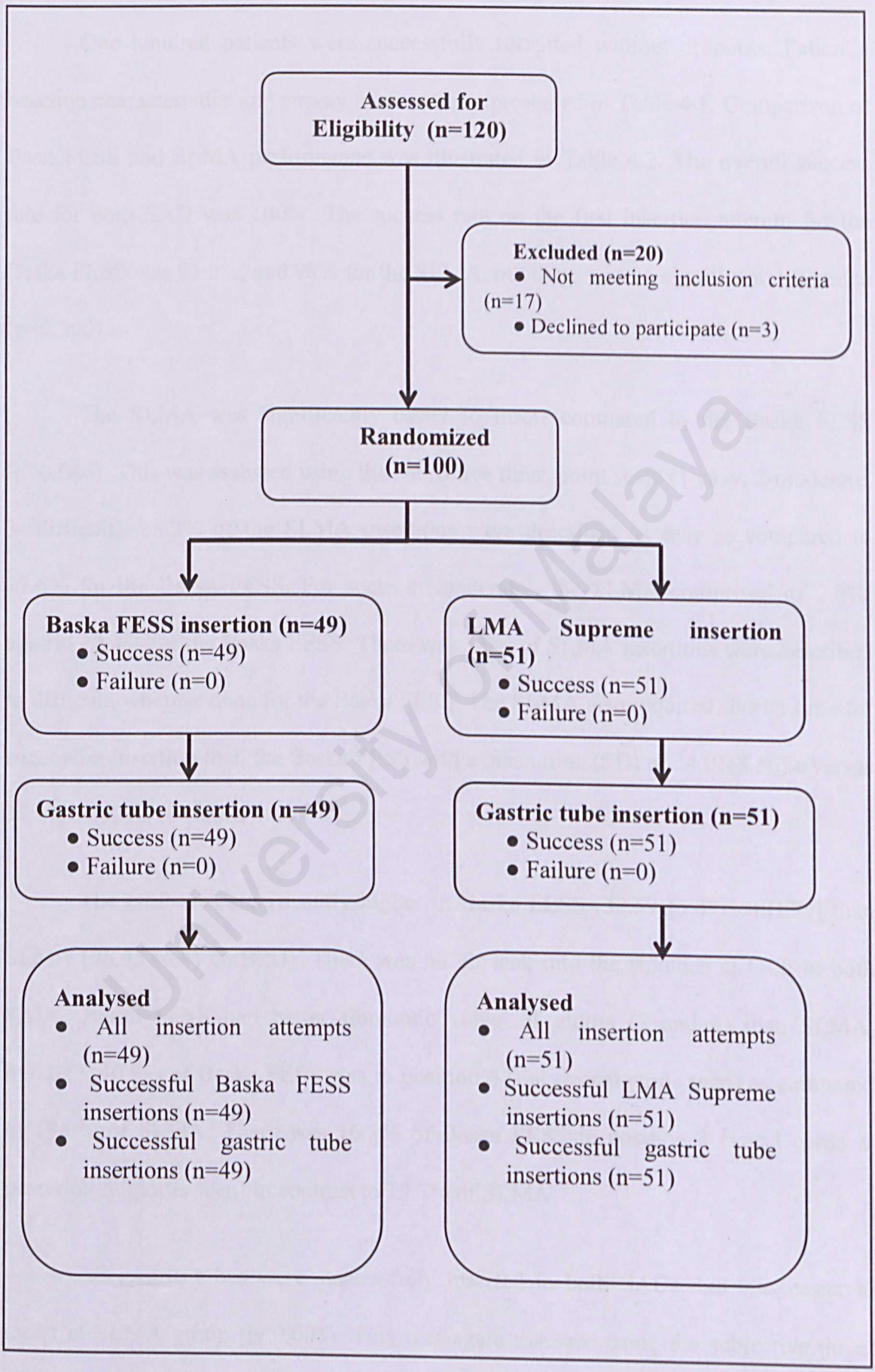
Figure 3.1 Consort diagram illustrating the workflow from recruitment till data analysis.



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One hundred patients were successfully recruited without dropouts. Patient's baseline characteristics and airway features were presented in Table 4.1. Comparison of Bask FESS and SLMA performance was illustrated in Table 4.2. The overall success rate for both SAD was 100%. The success rate on the first insertion attempt for the Baska FESS was 91.8%, and 98% for the SLMA, but there was no significant difference (p=0.200).

The SLMA was significantly easier to insert compared to the Baska FESS (p=0.046). This was assessed using the subjective three-point scale (1-easy, 2-moderate, 3- difficult). 88.2% of the SLMA insertions were described as easy as compared to 77.6% for the Baska FESS. For scale 2 (moderate), the SLMA comprised of 7.8%, against 22.4% for the Baska FESS. There was 3.9% of SLMA insertions were described as difficult, whereas none for the Baska FESS. The SLMA also required shorter time for successful insertion than the Baska FESS with a mean time (SD) of 24.01(8.50) s versus 37.37(20.39) s, (p<0.001).

The OLP was significantly higher in Baska FESS [32.59 (5.49) cmH2O] than SLMA [26.65 (6.4) cmH2O]. There was no air leak into the stomach at OLP in both SADs. Baska FESS had better fibreoptic views of glottis (3 and 4) than SLMA, p=0.025. 40.8% of Baska FESS was in position 4 (only vocal cords seen) as compared to 19.6% of SLMA. There was 16.3% of Baska FESS in position 3 (vocal cords & posterior epiglottis seen) in contrast to 13.7% of SLMA.

All gastric tubes were successfully inserted in both SADs, but was easier to insert in SLMA group (p<0.001). This was again assessed using the subjective three-

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point scale (1-easy, 2-moderate, 3- difficult). 96.1% of the gastric tube insertions in SLMA were described as easy as compared to 63.3% for the Baska FESS. The SLMA group had only 3.9% gastric tube insertions described as moderate and none for difficult. In contrast, 26.5% and 10.2% of gastric tube insertions in Baska FESS group were rated as moderate and difficult respectively. Ease of gastric tube correlated well with time to successful insertion of gastric tube in with SLMA group was easier and faster to insert. The mean time (SD) for the SLMA group was 16.33 (6.21) in comparison to the Baska FESS group which was 26.86 (16.00), $p<0.001$.

Comparing both SADs, there were no significant difference in the overall complications (Baska FESS 22.4% vs SLMA 33.3%, $p=0.226$). However, the incidence of mucosal injury for patients in the SLMA group was significantly higher compared to the Baska FESS (19.6% vs 6.1%, $p=0.045$). The incidence of other complications, summarised in Table 4.3, were similar and insignificant.

The patients' haemodynamic response (difference of systolic and diastolic blood pressure, mean arterial pressure, and heart rate with baseline readings) to either SAD insertion did not differ significantly as shown in table 4.4.

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Table 4.1 Characteristics of patients (n=100). Data stated as mean (SD) or number [proportion]

	Baska FESS (n = 49)	**LMA Supreme (n = 51)**
Age, years	38.57 (13.35)	41.33 (13.33)
Sex, n (%)		
Male	16 [32.7%]	16 [31.4%]
Female	33 [67.3%]	35 [68.6%]
Height, cm	161.55 (8.66)	158.45 (7.79)
Weight, kg	62.24 (12.86)	60.13 (12.74)
Body mass index, kg m^{-2}	23.71 (4.76)	24.10 (4.08)
ASA class, n (%)		
1	30 [61.2%]	36 [70.6%]
2	19 [38.8%]	13 [25.5%]
3	0	2 [3.9%]
Mallampati score		
I	31 [63.3%]	28 [54.9%]
II	16 [32.7%]	22 [43.1%]
III	2 [4.1%]	1 [2.0%]
Thyromental distance		
>6.5 cm	46 [93.9%]	47 [92.2%]
<6.5 cm	3 [6.1%]	4 [7.8%]
Sternomental distance		
>12.5 cm	49 [100%]	51 [100%]
Interincisor distance		
>4 cm	49 [100%]	51 [100%]
Head and neck movement		
Normal	49 [100%]	51 [100%]
Ability to prognath		
Yes	49 [100%]	51 [100%]
Types of surgery		
Orthopedic	8 [16.3%]	10 [19.6%]
General surgery	29 [59.2%]	23 [45.1%]
Gynaecology	6 [12.2%]	10 [19.6%]
Urology	4 [8.2%]	7 [13.7%]
Ear, nose and throat (ENT)	2 [4.1%]	1 [2.0%]
Duration of anaesthesia; minutes	63.92 (31.85)	59.12 (36.38)
Fasting time; hours	10.14 (2.20)	10.25 (1.59)

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Table 4.2 Comparison of Baska FESS and LMA supreme. Data stated as mean (SD) or number [proportion]

	Baska FESS (n = 49)	**LMA Supreme (n = 51)**	***p* value**
Size of airway used			0.236
3	24 [49.0%]	31 [60.8%]	
4	25 [51.0%]	20 [39.2%]	
Ease of insertion			0.046
1-easy	38 [77.6%]	45 [88.2%]	
2-moderate	11 [22.4%]	4 [7.8%]	
3-difficult	0	2 [3.9%]	
Insertion attempt success rate			0.200
first	45 [91.8%]	50 [98.0%]	
second	4 [8.2%]	1 [2.0%]	
Time to successful insertion of LMA; s	37.37 (20.39)	24.01 (8.50)	<0.001
Oropharyngeal leak pressure (OLP), cm H_2O	32.59 (5.49)	26.65 (6.40)	<0.001
Fibreoptic view of glottis			0.025
1-vocal cords not seen	3 [6.1%]	1 [2.0 %]	
2-vocal cords & anterior epiglottis seen	18 [36.7%]	33 [64.7%]	
3-vocal cords &posterior epiglottis seen	8 [16.3%]	7 [13.7%]	
4-only vocal cords seen	20 [40.8%]	10 [19.6%]	
Ease of gastric tube insertion			<0.001
1-Easy	31 [63.3%]	49 [96.1%]	
2-Moderate	13 [26.5%]	2 [3.9%]	
3-Difficult	5 [10.2%]	0	
Time to successful insertion of gastric tube; s	26.86 (16.00)	16.33 (6.21)	< 0.001
Gastric volume aspirated; ml	1.06 (3.53)	2.75 (8.00)	0.175

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Table 4.3 Complications arising from SAD insertion (n=100). Data stated as number [proportion].

	Baska FESS (n=49)	**SLMA (n=51)**	***p* value**
Complications of placements			0.226
Yes	11 [22.4%]	17 [33.3%]	
No	38 [77.6%]	34 [66.7%]	
Desaturation (SPO_2< 95%)	0	0	
Gross regurgitation / aspiration	0	0	
Bronchospasm	0	0	
Lip injury	0	0	
Tongue trauma	0	0	
Dental injury	0	0	
Mucosal injury	3 [6.1%]	10 [19.6%]	0.045
Sore throat	10 [20.4]	10 [19.6%]	0.920
Dysphonia	0	2 [3.9%]	0.495
Dysphagia	0	1 [2.0%]	1.000

Table 4.4 Hemodynamic changes to SAD insertion. Data stated as mean (SD).

Hemodynamic changes	**Minute**	**Baska FESS (n=49)**	**SLMA (n=51)**	***p* value**
Difference of SBP, mean; mmHg	2.5	19.18 (15.45)	16.14 (16.32)	0.340
	5	23.84 (19.54)	21.61 (24.24)	0.615
Difference of DBP, mean; mmHg	2.5	13.14 (10.25)	13.14 (10.96)	0.998
	5	15.53 (12.61)	16.69 (12.28)	0.643
Difference of MAP, mean; mmHg	2.5	14.50 (10.68)	14.04 (11.51)	0.840
	5	17.08 (13.33	18.00 (14.81)	0.745
Difference of HR, mean; beats per minute	2.5	7.08 (6.91)	6.71 (6.40)	0.778
	5	7.57 (5.60)	7.49 (7.58)	0.952

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CHAPTER 5: DISCUSSION

In our study, we found that both the Baska FESS and SLMA had 100% success rate of insertion. The first attempt success rate for the Baska FESS was 91.8% which was almost as good as 98% of SLMA. High overall and first time success rate of the Baska mask insertion is agreed in other studies. [13,14]

The Baska FESS was slower and more difficult to insert compared to the SLMA. This was consistent with the study by Alexiev, comparing the Baska mask with classic LMA, in which the Baska mask was proved to be more difficult and slower to insert.[12] However, this was not in agreement with other studies. The Baska mask was proven to be easier to insert with short insertion time of 16s in two studies.[13,15] The Baska Mask being devoid of an inflatable cuff, should have faster insertion time as no time is needed for cuff inflation and volume adjustment as required in the SLMA. Hence, the inconsistent findings of time and ease of insertion in the Baska mask can be due to different familiarity of the anaesthetists with the SADs. Clinical significance of the differences in the time of insertion (37s versus 24s, $p < 0.001$) in the Baska FESS and SLMA is arguable as the overall successful insertion for both SADs is equally high. Another new feature in the Baska mask is having a tab for manually curving the mask to facilitate insertion should improve the insertion experience. This was demonstrated in our study, none of the Baska FESS insertion was described as scale 3 (difficult) in contrast to 2 difficult insertions in the SLMA group.

Although, the Baska Mask was designed without inflatable cuff, the OLP was significantly higher as compared to the SLMA, 32.59 (5.49) cmH2O versus 26.65 (6.40) cmH2O. This is comparable to previous studies in which the OLPs for Baska Mask were 29.98 (8.51) cmH2O and 35.7 (13.3) cmH2O. [12,15] The mean difference of 5.94 cmH20 OLP in between the two SADs may be of clinical relevant especially during

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positive ventilation as high OLP confers better airway protection. Hence, the Baska Mask may be more suitable than SLMA as a possible alternative to endotracheal tube in controlled ventilation. Higher OLP in Baska Mask could be attributed to its self-sealing non-inflatable cuff which will be moulded to take up the shape of the supraglottic airway and self 'inflated' when the pressure increases with positive pressure ventilation, offering better seal.

Fibreoptic view of glottis was found better in Baska FESS. Similar result was demonstrated in the Baska mask evaluation study done by Van ZT. [13] The value of fiberoptic position as a means of assessing anatomic position has been questioned. This is because there is no association between the fibreoptic scores with the ventilation function of the SADs. [18,19] However, SAD with good fibreoptic scores could be a better choice of airway conduit in difficult airway management and failed intubation as the fibreoptic view of vocal cord is more reliable. Further careful evaluation is required to validate this.

Gastric tube insertion via the drain tube was successful in all patients. It was easier to insert in SLMA and required shorter insertion time than Baska FESS. Again this has not much of clinical significant. Gastric tube insertion in Baska mask is not reported in any other study, therefore no comparison can be made. One of the innovations of Baska mask is it obviates the need for a gastric tube. This is by incorporating an inlet that fits into the upper oesophagus, and the dorsal surface of the cuff is moulded to direct any oropharyngeal contents away from the glottis and towards the side channels to which suction can be attached to facilitate aspiration of this space.[12] These features, even without gastric tube insertion, may reduce the risk of pulmonary aspiration of secretions or gastric contents that accumulate in the supraglottic area.

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The overall complications were similar in both SADs. No inflatable self-recoiling membranous cuff of Baska mask was expected to have less postoperative laryngopharyngeal morbidity when comparing to SLMA. However, we did not detect significant difference in overall complications. This was also observed by others in which there is no relationship between cuff pressure and laryngopharyngeal complaints.[20] Nonetheless, mucosal injury was found to be higher in SLMA group. This was probably because of the inbuilt tab in the Baska mask that permits to increase its angulation for easy negotiation of the oropharyngeal curve during placement.

Maintaining the airway using LMA is associated with less cardiovascular responses compared to direct laryngoscopy and tracheal intubation. [21] This was well demonstrated in the study by Hashem J comparing SLMA with tracheal intubation. [22] In our study, we found that there was no difference in hemodynamic changes to both SADs insertion. Hence, Baska FESS is equally as good as SLMA as an alternative airway maintenance techniques in attenuating hemodynamic stress responses like hypertension, tachycardia, and arrhythmias associated with tracheal intubation.

There were some limitations in our study. First, blinding of anesthetic medical officers to the SADs being used is not possible, hence there would be observer-expectancy bias. Secondly, post operative sore throat will be affected by the amount of analgesics administered intra-operatively which was not standardized. Third, sizes of both SADs were determined by manufacturer's recommendation of weight-based estimate. But size of the Baska FESS can also be decided by clinical judgment. The results might be affected by this subjective estimation. Lastly, In our study, neuromuscular blocking agent was used, the OLP may differ from spontaneously breathing patient, and results of this study may not be applied.

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CHAPTER 6: CONCLUSION

In conclusion, the Baska FESS is more suitable than SLMA for maintenance of anaesthesia in paralyzed patients as it has higher OLP and better fibreoptic views. Both have high success rate of insertion and similarly low complications. However, our findings showed that the SLMA might be slightly easier and faster to insert.

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APPENDICES

Appendix A: Data Collection Form

Comparison of *Baska FESS* vs LMA *Supreme*

Subject number _____

OT number : _____
Date : _____
Anaesthetist: _____

1. Demographics and Type of Surgery

Age _____ yrs Height _____ cm Weight _____ kg BMI _____ kg/m2

ASA ☐ 1 ☐ 2 ☐ 3

Surgery/Procedure
- ☐ Orthopaedics
- ☐ General surgery
- ☐ Gynaecology
- ☐ Others: _____
- ☐ Urology
- ☐ ENT

Anaesthesia time
Start: _____ hrs End: _____ hrs Duration: _____ min

2. Airway Assessment

Mallampati score	☐ I ☐ II	☐ III ☐ IV		Interincisor distance	☐ >4cm	☐ ≤4cm	
Thyromental distance	☐ >6.5cm	☐ ≤6.5cm		Head/neck movement	☐ Normal(>90°)	☐ Abnormal(<80°)	
Stemomental distance	☐ >12.5cm	☐ ≤12.5cm		Ability to prognath	☐ Yes	☐ No	

3. Airway ☐ *Baska FESS* ☐ *LMA Supreme* (please tick the appropriate box)

Size of airway ☐ 3 ☐ 4 ☐ 5

Ease of airway insertion _____
(1-easy, 2-moderate, 3-difficult)

No. of attempts ^ required

☐	1 attempt
☐	2 attempt
☐	3 attempt
☐	Failure of insertion (reason):
☐	Alternative airway:
☐	No. of attempts:

Time to insertion * _____ sec

Oropharyngeal leak pressure (OLP) & Fibreoptic laryngeal view grade

Head and neck position	cmH20	Glottic view
Neural		
30° neck flexion		
45° extension		
45° lateral rotation		

Glottis view: (1-vocal cords not seen; 2-vocal cords and anterior epiglottis seen; 3-vocal cords and posterior epiglottis seen; 4- only vocal cords seen)

Air leak into stomach * Yes / No

Haemodynamic response to insertion

Time	SBP	DBP	MAP	HR
0min				
2.5min				
5min				

Time to gastric tube insertion _____ sec

Ease of gastric tube insertion _____
(1-easy, 2-moderate, 3-difficult)

Fasting time (solids) (H2O not counted) _____ hrs

Gastric volume aspirated _____ mls

4. Complications of placement

- ☐ Desaturation (SpO2 <95%)
- ☐ Gross regurgitation/aspiration (fluid in ventilation tube)
- ☐ Bronchospasm
- ☐ Difficulty in ventilation
- ☐ Lip injury
- ☐ Tongue trauma
- ☐ Mucosal injury (visible blood on airway after removal)
- ☐ Post-op sore throat (mild / moderate / severe)
- ☐ Dysphonia/hoarse voice (mild / moderate / severe)
- ☐ Dysphagia (mild / moderate / severe)
- ☐ Dental injury

Definitions

*Time to insertion	- interval when Baska Mask or SLMA inserted into patient's mouth to 1st ETCO2
^Each attempt	- defined as complete removal of airway device from mouth and reinsertion
Failed insertion	- defined as entire insertion procedure >120secs ***OR*** >3 insertion attempts
#OLP	- maximum airway pressure reached after closing APL valve at gas flow of 3L/min
*Air leak into stomach	- presence of gastric insufflation on auscultation of epigastrium at OLP

Chen YS v1. 25 March 2016

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Appendix B: Patient Information Sheet

MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE

PATIENT INFORMATION SHEET

Version No.: 2
Version Date: 19-5-2016

Please read the following information carefully, do not hesitate to discuss any questions you may have with your Doctor/Investigator

1. Study Title:

An evaluation of the Baska Fess mask and comparison with the Supreme Laryngeal Mask in different head and neck positions

2. Introduction (Scientific basis of the study)

Patients undergoing anaesthesia need an endotracheal tube or supraglottic airway after anaesthesia. The baska mask is a new supraglottic airway with improved features such as a cuff that self-inflates, and a channel for drainage of stomach contents to reduce risk of vomiting.

3. What is the purpose of this study?

This study will be conducted to investigate the safety and efficacy of the Baska FESS mask, and to compare its performance with the current "gold standard", the Supreme LMA. As a secondary outcome, we will also evaluate the Baska Fess mask in different head and neck positions and compare it with the Supreme LMA.

4. What are the procedures to be carried out?

You will be randomized into either the Baska FESS mask or Supreme LMA group.

Anaesthesia will be administered as per protocol.

Once sufficient depth of anaesthesia is achieved, the supraglottic airway device will be inserted by a trained anaesthetist.

The required data will be recorded:

- **Time for insertion**
- **Ease of insertion**
- **Number of tries needed for successful insertion**
- **Oropharyngeal leak pressure**
- **Glottic view on fiberoptic bronchoscopy**
- **Ease of insertion of gastric tube**

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- Complications encountered

The planned surgery will be performed by the respective surgical team.

Anaesthesia will be reversed at the end of the procedure and the supraglottic airway device will be removed.

You will be monitored in our post-anaesthesia care unit until fit for discharge to the ward.

5. How long will I be involved in this study?
The time when you are in the operation theatre till discharge back to the ward

6. Who should not enter the study (exclusion criteria)?

Patients undergoing surgery in the non-supine position

Patients with known or anticipated difficult airway

Patients who are morbidly obese with BMI>35kg/m2

Patients who have increased risk of gastric aspiration (such as inadequate fasting time, pregnancy, expected operation time >3 hours, upper gastrointestional tract surgery, hiatus hernia)

Patients with active upper respiratory tract infection or pneumonia

Patients with neck injury, at risk for neck instability (such as rheumatoid arthritis or Down's syndrome) or reduced range of neck movement

Patients with vertebral artery occlusion

7. How many patients/research subjects will be recruited into this study?

100

8. Who will have access to the subjects medical records or research data?

The research data and relevant medical records will only be accessible by members of the research team.

9. Will the records/data be kept confidential?

Yes

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10. What will be the benefits of the study to the subject?

None. However the outcome of this study may benefit the patients undergoing anaesthesia in the future.

11. What are the possible drawbacks (side effects, etc.)?

You may experience a similar incidence of side effects of general anaesthesia with a laryngeal mask airway such as the following:

- **inability to achieve a seal and ventilate**
- **regurgitation and aspiration**
- **stomach gas insufflation**
- **malposition/dislodgement of the airway device**
- **airway spasm**
- **cough**
- **injuries to the upper airway (e.g. bleeding, dislodgement of teeth, gum/tongue swelling)**

12. Is the investigatory product derived from a source that may be cultural sensitive, eg: bovine or porcine? (if applicable)

None

13. What payments or reimbursement will research subjects receive?

No payments or reimbursement will be given

14. Can I refuse to take part in the study?

Yes. Your decision to refuse will not affect your medical care

15. Who should I contact if I have additional questions during the course of the study?

Associate Prof. Dr. Ina Ismiarti	**012 2353134**
Dr Foo Li Lian	**012-9889011**
Dr Chen Yi Shang	**012 2769069**
Dr Lee Chong En	**013-8832729**

BK-MIS-1116-E03

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Appendix C: Patient Consent Form

UNIVERSITY MALAYA MEDICAL CENTRE

CONSENT BY PATIENT FOR CLINICAL RESEARCH

Version No.: 1
Version Date: 25-3-2016

I, ... Identity Card No. .....
(Name of Patient)
of .....
(Address)
hereby agree to take part in the clinical research (clinical study/questionnaire study/drug trial) specified below:

Title of Study: A evaluation of the Baska Fess mask and comparison with the Supreme Laryngeal Mask in different head and neck positions

the nature and purpose of which has been explained to me by
Dr. .....
(Name & Designation of Doctor)

and interpreted by .....
(Name & Designation of Interpreter)

..... to the best of his/her ability in ..... language/dialect.

I have been told about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as per patient information sheet). After knowing and understanding all the possible advantages and disadvantages of this clinical research, I voluntarily consent of my own free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning any reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date: ..... Signature or Thumbprint .....
(Patient)

IN THE PRESENCE OF

Name .....)
)
Identity Card No. .....) Signature .....
(Witness for Signature of Patient)
Designation .....)

I confirm that I have explained to the patient the nature and purpose of the above-mentioned clinical research.

Date ..... Signature .....
(Attending Doctor)

CONSENT BY PATIENT FOR CLINICAL RESEARCH	R.N. Name Sex Age Unit		**BK-MIS-1117-E02**

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KEIZINAN OLEH PESAKIT UNTUK PENYELIDIKAN KLINIKAL

Nombor Versi: 1
Tarikh Versi: 25-3-2016

Saya,..... No. Kad Pengenalan .....
(Nama Pesakit)

beralamat.....
(Alamat)

dengan ini bersetuju menyertai dalam penyelidikan klinikal (pengajian klinikal/pengajian soal-selidik/percubaan ubat-ubatan) disebut berikut:

TajukPenyelidikan: A evaluation of the Baska Fess mask and comparison with the Supreme Laryngeal Mask in different head and neck positions

yang mana sifat dan tujuannya telah diterangkan kepada saya oleh Dr.....
(Nama & Jawatan Doktor)

mengikut terjemahan .....
(Nama & Jawatan Penterjemah)

..... yang telah menterjemahkan kepada saya dengan sepenuh kemampuan dan kebolehannya di dalam Bahasa / loghat.....

Saya telah diberitahu bahawa dasar penyelidikan klinikal dalam keadaan methodologi, risiko dan komplikasi (mengikut kertas maklumat pesakit). Selepas mengetahui dan memahami semua kemungkinan kebaikan dan keburukan penyelidikan klinikal ini, saya merelakan/mengizinkan sendiri menyertai penyelidikan klinikal tersebut di atas.

Saya faham bahawa saya boleh menarik diri dari penyelidikan klinikal ini pada bila-bila masa tanpa memberi sebarang alasan dalam situasi ini dan tidak akan dikecualikan dari kemudahan rawatan dari doktor yang merawat.

Tarikh: ..... Tandatangan/Cap Jari .....
(Pesakit)

DI HADAPAN

Nama .....)
)
No. K/P.....) Tandatangan .....
) *(Saksi untuk Tandatangan Pesakit)*
Jawatan .....)

Saya sahkan bahawa saya telah menerangkan kepada pesakit sifat dan tujuan penyelidikan klinikal tersebut di atas.

Tarikh: ..... Tandatangan .....
(Doktor yang merawat)

KEIZINAN OLEH PESAKIT UNTUK PENYELIDIKAN KLINIKAL	No. Pend. Nama Jantina Umur Unit		BK-MIS-1117-E02

University of Malaya

CONSENT BY RESPONSIBLE RELATIVE FOR CLINICAL RESEARCH

Version No.: 1
Version Date: 25-3-2016

I, ... Identity Card No.....
(Name)
of .....
(Address)

hereby agree that my relative .....
I.C. No.....
(Name)
participate in the clinical research (clinical study/questionnaire study/drug trial) specified below:-
Title of Study: A evaluation of the Baska Fess mask and comparison with the Supreme Laryngeal Mask in different head and neck positions

the nature and purpose of which has been explained to me by Dr. .....
(Name & Designation of Doctor)

and interpreted by .....
(Name & Designation of Interpreter)

..... to the best of his/her ability in ..... language/dialect.

I have been informed of the nature of this clinical research in terms of procedure, possible adverse effects and complications (as per patient information sheet). I understand the possible advantages and disadvantages of participating in this research. I voluntarily give my consent for my relative to participate in this research specified above.

I understand that I can withdraw my relative from this clinical research at any time without assigning any reason whatsoever and in such situation, my relative shall not be denied the benefits of usual treatment by the attending doctors. Should my relative regains his/her ability to consent, he/she will have the right to remain in this research or may choose to withdraw.

Date: ..... Relationship to Patient ..... Signature or Thumbprint .....

IN THE PRESENCE OF

Name .....)
)
Identity Card No. .....) Signature .....
) *(Witness)*
Designation .....)

I confirm that I have explained to the patient's relative the nature and purpose of the above-mentioned clinical research.

Date ..... Signature .....
(Attending Doctor)

UNIVERSITY MALAYA MEDICAL CENTRE

KEIZINAN OLEH WARIS YANG BERTANGGUNGJAWAB UNTUK PENYELIDIKAN KLINIKAL

Nombor Versi: 1
Tarikh Versi: 25-3-2016

Saya,..... Kad Pengenalan .....
(Nama Waris yang bertanggungjawab)

beralamat.....
(Alamat)

dengan ini bersetuju supaya saudara saya..... menyertai
(Nama Pesakit)

dalam penyelidikan klinikal (pengajian klinikal/pengajian soal-selidik/percubaan ubat-ubatan) disebut berikut:

TajukPenyelidikan: A evaluation of the Baska Fess mask and comparison with the Supreme Laryngeal Mask in different head and neck positions

yang mana sifat dan tujuannya telah diterangkan kepada saya oleh Dr.....
(Nama & Jawatan Doktor)

.....mengikutterjemahan .....
(Nama & Jawatan Penterjemah)

..... yang telah menterjemahkan kepada saya dengan sepenuh kemampuan dan kebolehannya di dalam Bahasa / loghat.....

Saya telah diberitahu bahawa dasar penyelidikan klinikal dalam keadaan metodologi, risiko dan komplikasi (mengikut kertas maklumat pesakit). Saya mengetahui dan memahami semua kemungkinan kebaikan dan keburukan penyelidikan klinikal ini. Saya merelakan/mengizinkan saudara saya menyertai penyelidikan klinikal tersebut di atas.

Saya faham bahawa saya boleh menarik balik penyertaan saudara saya dalam penyelidikan klinikal ini pada bila-bila masa tanpa memberi sebarang alasan dalam situasi ini dan tidak akan dikecualikan dari kemudahan rawatan dari doktor yang merawat. Sekiranya saudara saya kembali berupaya untuk memberi keizinan, beliau mempunyai hak untuk terus menyertai kajian ini atau memilih untuk menarik diri.

Tarikh: ..... Pertalian dengan Pesakit ..... Tandatangan/Cap Jari Waris yang bertanggungjawab .....

DI HADAPAN

Nama .....)
)
No. K/P.....) Tandatangan .....
) *(Saksi untuk Tandatangan Waris yang Bertanggungjawab)*
Jawatan.....)

Saya sahkan bahawa saya telah menerangkan kepada waris yang bertanggungjawab sifat dan tujuan penyelidikan klinikal tersebut di atas.

Tarikh: ..... Tandatangan .....
(Doktor yang merawat)

KEIZINAN OLEH WARIS PESAKIT UNTUK PENYELIDIKAN KLINIKAL	No. Pend. Nama Jantina Umur Unit		**BK-MIS-1117-E02**

University of Malaya