BASKA MASK VERSUS ENDOTRACHEAL TUBE IN LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE RANDOMIZED TRIAL

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FACULTY OF MEDICINE
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ABSTRACT

Objectives: Evaluating the efficacy and safety of Baska mask as an alternative to endotracheal tube in patients undergoing general anaesthesia for laparoscopic cholecystectomy. Comparing the time to effective insertion, ventilatory performance, hemodynamic response and complications related to the airway.

Methods: This is a prospective randomized controlled trial (RCT), single-blinded (patient) involving adult patients going in for laparoscopic cholecystectomy in the University of Malaya Medical Centre (UMMC), Kuala Lumpur. A total of 59 patients, age ranging from 18 – 75 years old, ASA classification I to III were recruited in the study. Patients were randomized into two groups – Baska mask and endotracheal intubation. Several parameters were evaluated intraoperatively – time to effective airway insertion, time to orogastric tube insertion, ventilatory parameters and hemodynamic parameters. Immediate postoperative complications which include aspiration, laryngospasm, airway trauma and emergence cough were recorded. The incidence of sore throat, dysphonia, dysphagia, nausea and vomiting were recorded at 1 hour and 24 hours.

Results: Baska mask showed significantly shorter time to insertion with high first attempt insertion rate. Orogastric tube insertion is faster with the Baska mask with lesser associated complications. The Baska group showed consistently high oropharyngeal leak pressure throughout and performed comparably like the endotracheal tube with regards to ventilation. Hemodynamic response during airway insertion was significantly lesser with the Baska mask. The incidence of emergence cough, sore throat and dysphonia was significantly lesser in the Baska group compared to the endotracheal tube group.

Conclusion: The Baska mask is a suitable and safe alternative to endotracheal intubation in selected patients going for laparoscopic surgery.

Key words: Baska mask, endotracheal tube, laparoscopic surgery

ABSTRAK

Objektif: Menguji keberkesanan dan keselamatan tiub pernafasan *"Baska mask"* sebagai alternatif kepada tiub endotrakea bagi pesakit-pesakit yang menjalani pembiusan am untuk pembedahan buang hempedu secara laparoskopik. Membandingkan masa yang diperlukan untuk tiub dimasukkan, kecekapan ventilasi, kesan terhadap hemodinamik, dan komplikasi kepada liang pernafasan.

Kaedah: Ini merupakan kajian rawak terkawal yang melibatkan pesakit-pesakit dewasa yang menjalani pembedahan buang hempedu laparoskopik di Pusat Perubatan Universiti Malaya. 59 pesakit berumur 18-75 tahun, berklasifikasi ASA I-III dibahagikan kepada dua kumpulan – *"Baska mask"* dan tiub endotrakea. Beberapa parameter direkodkan – masa diperlukan untuk memasukkan tiub pernafasan dan orogastrik, kecekapan ventilasi dan kesan terhadap hemodinamik. Komplikasi sejurus pembedahan seperti aspirasi, pengecutan akut dan kecederaan liang pernafasan, dan batuk ketika sedar daripada bius turut dicatat. Kadar kejadian sakit tekak, perubahan suara, kesukaran menelan, loya dan muntah direkodkan pada jam pertama dan 24 jam selepas pembedahan.

Keputusan: Masa diperlukan untuk memasukkan tiub pernafasan "Baska mask" adalah lebih cepat dengan kadar kejayaan kali pertama yang tinggi. Masa untuk memasukkan tiub orogastrik bagi "Baska mask" juga adalah lebih pantas dengan kadar komplikasi yang lebih rendah. *"Baska mask"* menunjukkan *"oropharyngeal leak pressure"* yang tinggi dan prestasi yang setara dengan tiub endotrakea. Kesan hemodinamik adalah lebih rendah dengan *"Baska mask"*. Kadar kejadian batuk semasa sedar dari pembiusan, sakit tekak dan perubahan suara lebih rendah bagi *"Baska mask"*.

Kesimpulan: Tiub pernafasan *"Baska mask"* adalah alternatif sesuai dan selamat untuk tiub endotrakea bagi pesakit tertentu yang menjalani pembedahan laparoskopik.

Kata kunci: "Baska mask", tiub endotrakea, pembedahan laparoskopik

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LIST OF SYMBOLS AND ABBREVIATIONS

ASA	:	American Society of Anaesthesiologists
SAD	:	Supraglottic airway device
LMA	:	Laryngeal mask airway
SLIPA	:	Streamlined liner of the pharynx airway
ETT	:	Endotracheal tube
BMI	:	Body mass index
RCT	:	Randomized controlled trial
SD	:	Standard deviation
IPPV	:	Intermittent positive pressure ventilation
MAC	:	Minimum alveolar concentration
MV	:	Minute ventilation
SpO2	:	Pulse oximetry
etCO2	:	End tidal carbon dioxide
OLP	:	Oropharyngeal leak pressure
SBP	:	Systolic blood pressure
DBP	:	Diastolic blood pressure
HR	:	Heart rate

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1. INTRODUCTION

Laparoscopic surgeries have gained popularity over the years in different surgical disciplines all over the globe. They are minimally invasive and thus, lead to better cosmesis, less perioperative pain and reduced hospital stay. Cholecystectomy, for example, is one of the few procedures which is done mainly laparoscopically nowadays especially in developed countries. Laparoscopic cholecystectomy is regarded as the gold standard for surgical treatment of gallstone disease and about ninety percent of cholecystectomies in the United States are done laparoscopically.

For the anaesthetists, laparoscopy imposes substantial physiologic alteration to the patient. Capnoperitoneum inflicts significant load on the respiratory and cardiovascular system. The diaphragm is pushed upwards, which may lead to insufficient ventilation, increased risk of regurgitation, which in turn, increases risk of aspiration.

Traditionally, general anaesthesia with endotracheal intubation has been regarded as the gold standard by most anaesthetists. However, there are emerging interests with regards to the use of supraglottic airway devices (SAD) in laparoscopic surgeries in the recent years. The newer generations of SADs, which possess improved safety profile thanks to the incorporated gastric port and higher oropharyngeal leak pressure, are among others the reasons why they are increasingly popular.

1.1 Background

Since the introduction of the Classic® LMA by Archie Brain in 1988, a growing number of newer SADs with different designs and features have been available in the market. The improvisation to the initial design was aimed to increase safety, with features that might reduce the risk of aspiration. The list of the desirable features of SADs is long, and it is doubtful whether a single device will ever fulfill them all.

The Baska Mask is an internationally patented SAD that was designed by Australian anaesthetists, Kanag and Meena Baska. It is a novel SAD with many salient features. It has brought together several desirable features possessed by other SADs.

The mask is made of medical grade silicone and is designed in such a way that during IPPV, the seal apposes to the glottis incrementally to augment seal pressure with increasing airway pressure. The cuff is non-inflatable, self-sealing and self-recoiling with variable pressure. Its soft and moulded surface renders this device a lower propensity for oropharyngeal tissue trauma or nerve injury.

The manufacturer of the Baska mask claims that it obviates the need for an orogastric tube and replaces this with a sump and two drains. The mask posseses a large distal aperture that sits on the upper end of oesophagus and opens into the sump cavity behind the mask, which in turn is connected with two cylindrical tube vents running the entire length of the main stem of the device. One of these tube vents is connected to high pressure, high flow suction, while the other is left open to ambient to equilibrate the pressure in the sump cavity to atmospheric. This system allows for rapid clearance of gastric fluids or secretions that may collect in the sump during maintenance and emergence from anesthesia. Orogastric tube however, can be inserted easily through one of the cylindrical tube vents should the need arise.

The device is kink-resistance, with an integrated bite block throughout the entire length of the airway tube to reduce the patient biting and obstructing the airway. The oval-shaped airway tube matches the shape of the mouth and reduces rotation within the pharynx. The special hand tab attached to the cuff can be used by the operator to adjust the position of the device during insertion without the need of manipulation of the head and neck.

Several studies have evaluated the performance of Baska Mask for various types of surgery and had reported high first-attempt success rate, easy insertion and a good oropharyngeal leak pressure above 30 cm H2O with lower incidence of postoperative complications such as sore throat, dysphonia and dysphagia. There are studies comparing older SADs with ETT, however, none has compared the performance of Baska mask with endotracheal tube in surgery requiring mandatory positive pressure ventilation with muscle paralysis.

The aim of this study was to compare the clinical efficacy (i.e. ease of insertion and success rate) of the Baska mask and the endotracheal tube and to establish the safety profile of the use of the Baska mask in laparoscopic surgery in selected population. The study also compared the hemodynamic response and the incidence of anaesthetic-related postoperative complications between the two groups.

1.2 Hypothesis

The Baska mask maybe safely used as an alternative airway device in laparoscopic cholecystectomy in selected patients. The study aimed to show that the Baska mask is not inferior to the endotracheal tube with regards to the ease of insertion and first time success rate, with a good safety profile (i.e. oropharyngeal leak pressure). Aside from that, the study also aimed to demonstrate that there is lesser hemodynamic response and anaesthetic-related postoperative complications in the Baska mask group compared to the endotracheal tube.

2. LITERATURE REVIEW

To date, there are no studies published yet in comparing the performance of Baska mask to the gold standard endotracheal tube in laparoscopic surgeries. There were, however, several observational studies and randomized controlled trials comparing Baska mask and other supraglottic airways.

Zundert and Gatt[1] in 2012 first evaluated the performance of the Baska mask in an observational study. They recruited 50 samples going for various surgeries. They reported easy insertion with high first time insertion rate and high oropharyngeal leak pressure of more than 30 cm H2O.

Alexiev et al[2] in 2012 also performed observational study in 30 low risk female patients. They reported overall success rate for device insertion was 96.7% (95% CI 82.8–99.9%), while the success rate for the first insertion attempt was 76.7% (95% CI 57.7–90.1%). The device was easy to insert, with a mean (SD) difficulty score of 0.9 (1.6) on a 10-cm scale. The mean (SD) airway leak pressure was 35.7 (13.3) cmH2O. The incidence of throat pain, dysphonia and dysphagia was low.

Zaballos et al[3] in 2014 evaluated the performance of Baska mask in an observational study in paralysed patients needing intermittent positive pressure ventilation (IPPV). They reported easy insertion with consistently high oropharyngeal leak pressure throughout and low complications.

In 2013, Al-Rawahi et al[4] compared Baska mask and Proseal laryngeal mask airway for general anaesthesia with IPPV. They enrolled 52 patients going for elective surgery in supine position. Their findings showed that the placement time and the seal is better with the Baska mask compared to Proseal, but there was no difference in laryngo-pharyngeal morbidity.

The earliest study comparing the efficacy of a supraglottic airway device with the gold standard endotracheal tube (ETT) dates back to 1993 when Swann et al[5] compared the use of Classic® LMA with ETT in gynaecological laparoscopy. Between 1993 to 2013, there were 17 different randomized controlled trials conducted which compared various types of supraglottic airways and endotracheal intubation in laparoscopic surgeries.

The supraglottic airways that were studied before included classic LMA, Combitube, Laryngeal tube, ProSeal LMA, Supreme LMA and SLIPA (streamlined liner of the pharynx airway). Each study recruited between 60 to 200 patients. The type of laparoscopic surgeries included gynaecological laparoscopy, laparoscopic cholecystectomy, laparoscopic inguinal hernia repair and laparoscopic gastric banding.

A recent meta-analysis by Park et al[6] has revealed that the performance of supraglottic airway devices (SAD) and endotracheal tubes (ETT) are comparable in laparoscopic surgery in term of success rate on the first attempt, insertion time and oropharyngeal leak pressure. Besides, the incidence of laryngospasm, cough at device removal, dysphagia or dysphonia, sore throat, and hoarseness were higher in the ETT group than in the SAD group. Therefore, they propose that SGAs might be clinically more useful as effective airways in laparoscopic surgery.

Fotedar et al[7] in 2018 performed observational study with Baska mask in ASA 1 patients going for elective laparoscopic cholecystectomy. They found that the Baska mask functioned reasonably well with high first time insertion success rate. Haemodynamics were stable during the insertion with oxygen saturation and end tidal carbon dioxide (etCO2) within normal range throughout.

3. METHODOLOGY

This is a prospective randomized controlled trial (RCT), single-blinded (patient) involving adult patients going in for laparoscopic cholecystectomy in the University of Malaya Medical Centre (UMMC), Kuala Lumpur.

Inclusion criteria:

1) Elective surgery for laparoscopic cholecystectomy including daycare, short stay and inpatient surgery
2) Age 18 – 75 years old
3) American Society of Anaesthesiologists (ASA) classification – class I and II
4) Body mass index (BMI) ≤ 35

Exclusion criteria:

1) Known gastroesophageal reflux
2) History of difficult intubation or difficult anaesthesia
3) Features of facial, laryngeal and pharyngeal anatomy problem

3.1 Sample Size

Sample size was calculated using the open source software. To achieve α=0.05 and power (1-β) >80%, total sample size of sixty patients with n=30 for each arm. The analysis utilizes Mann Whitney test, Fischer's exact test, Chi Square test and repeated measures ANOVA.

3.2 Randomization

Subjects are randomized into two groups for the RCT – group 1: Baska® mask, group 2: endotracheal tube (ETT). A web-based randomizer is used to randomize the patients into these two groups. This is a single-blinded study and complete blinding is not possible as the researcher needs to perform the insertion of the airway (BASKA® mask or Endotracheal tube) to the patient. A single researcher with clinical anaesthetic experience of more than five years, performed the airway insertion. The operations were performed by qualified surgeons in hepatobiliary surgery.

3.3 Steps

1. All patients underwent comprehensive review by the anaesthetist (researcher) on the day of operation. The inclusion and exclusion criteria are thoroughly reviewed before the decision to recruit was made.
2. Patient information sheet was given to the patient and written consent was taken.
3. Intravenous cannula was inserted in the waiting lounge (for daycare or short stay surgery patients) and "Group & Screen" (GSH) was sent to the lab. For inpatients, these have been done in the ward the day prior.
4. The patient was randomized according to the randomization table into either of the two groups: 1) Baska mask 2) Endotracheal tube. The researcher is unblinded, but the patient and surgeon were blinded.
5. Theatre:
    a) Standard AAGBI monitoring applied: 3-lead ECG, non-invasive blood pressure monitoring (NIBP), pulse oximetry (SpO_2)

b) Hemodynamics data (blood pressure and heart rate) were recorded at baseline pre-induction. They were then recorded immediately pre-intubation (after induction), immediately after intubation and every minute for five minutes, and every ten minutes thereafter until the end of surgery.

c) Induction was initiated with preoxygenation with 100% oxygen. Patients received IV Fentanyl 2 mcg/kg, IV Propofol 3 mg/kg and IV Rocuronium 0.6 mg/kg. Sevoflurane vaporizer then was turned on between 2-4% aiming minimum alveolar concentration (MAC) 1 -1.2. Patient was mask ventilated with or without oropharyngeal airway. After 180 seconds, loss of eyelash reflex and full jaw relaxation, either BASKA mask insertion or endotracheal intubation was performed according to randomized allocation.

d) Time to effective airway insertion was recorded. This is defined as time from picking up the airway device (for Baska mask) or laryngoscope (for endotracheal tube), insertion and until occurrence of the first square-waveform capnogram. Correct position also was confirmed by equal chest movement and breath sound bilaterally, normal rectangular shape of the capnograph tracing and the absence of gastric insufflation over stomach.

e) The number of attempts, ease of insertion and complications during the placement of airway (such as desaturation, coughing, gagging, airway spasm and patient movement) were recorded.

f) Placement and performance tests were done for the Baska mask arm before allowing to proceed with the surgery. These include:

   i) Gastric tube bubble test

   ii) Suprasternal notch test

   iii) Insertion of gastric tube

iv) Oropharyngeal leak pressure measurement

v) Maximum volume minute ventilation test

A fibreoptic bronchoscope is then used to grade the fibreoptic view of the airway based on Brimacombe grading.

g) Ryle's tube insertion was mandatory for both arms of patient. For the Baska mask, it was inserted through one of the cylindrical vent and for the ETT group, it was inserted nasogastric. The size of Ryle's tube was standardized to 14 French for both arms. Ryle's tube insertion (from time of picking up tube to confirmation of placement with auscultation), ease of insertion and complications pertaining to Ryle's tube insertion were recorded.

h) Ventilatory parameters are recorded for both at the following occasions:

i) immediately following airway insertion

ii) immediately prior to peritoneal insufflation

iii) after peritoneal insufflation

iv) after peritoneal insufflation and reverse trendeleburg positioning

v) after peritoneal desufflated and patient supined

i) For the Baska mask arm, efficacy of airway seal is assessed by measuring oropharyngeal leak pressure at similar time frame as described above.

j) Anaesthesia was maintained with oxygen/air mixture with Sevoflurane at MAC of 1.0-1.2 throughout the operation. Tidal volume is set at 6-8ml/kg and the ventilatory parameters were adjusted aiming end tidal CO2 at 35-45 mmHg. Neuromuscular blockade was maintained with IV Rocuronium boluses as needed. Intraoperative analgesia - intermittent intravenous Fentanyl bolus of 0.5mcg/kg, intravenous Morphine ≤0.05 mg/kg, intravenous Paracetamol 1g and intravenous Parecoxib 40mg (provided no contraindication). All patients received intravenous Ranitidine 50 mg and Dexamethasone 0.10 mg/kg after induction, as well as intravenous Ondansetron 0.10mg/kg before reversal of anaesthesia.

k) Intra-abdominal pressure was standardized to be kept between 12 -16 mm Hg. The surgeon was requested to evaluate the gastric distension by using a gastric distension score at the time of insertion of laparoscope and just prior to removal (0-empty, 1-2 – nearly empty, 3-4 – mild distension, surgeon careful to distension, 5-6 – moderate distension with occasional need to push away, 7-8 – severe distension, constantly need to push away and requires more tilting, 9-10 – heavy distension, impossible operation). Surgical and peritoneal insufflation times were documented. Estimated blood loss, total fluid given and necessity for blood products were recorded.

l) After completion of surgery, Sevoflurane vaporizer was turned off and flow was switched to 100% oxygen. Neuromuscular blockade was reversed with IV Neostigmine 2.5mg and IV Atropine 1 mg. Baska® Mask or ETT will be removed when the patients emerge from anaesthesia as evidenced by production of adequate tidal volume, ability to open eye, facial grimace and ability to follow simple instruction. After Baska mask removal and tracheal extubation, 5L/min oxygen was administered to patients via facemask.

m) Blood pressure and heart rate were recorded immediately after extubation and every minute for five minutes following it.

n) Patients were monitored in the recovery area. Postoperative complications such as incidence of sore throat, dysphagia, dysphonia, airway trauma, nausea, vomiting, airway spasm, aspiration and emergence cough were recorded at two time frames – immediate (within one hour post-extubation) and at 24 hours (either through telephone call or ward visit). Complications were recorded as present/absent unless a specific grading is used for certain complications as mentioned below.

o) Occurrence and grade of coughing were assesed in the operating room from the discontinuation of anesthetic drugs to 5 minutes after extubation. The grade of coughing was measured in 4 grades, where an additional no cough grade was added to the 3-grade scale used in the study of Minogue et al. (Grade 0 - no cough, Grade 1 - single cough, Grade 2 - more than one episode of non-sustained [≤ 5 s] coughing, Grade 3 - sustained [> 5 s] bouts of coughing).

p) The scale used to evaluate postoperative sore throat is a four graded scale: 0 = no sore throat, 1 = mild sore throat (less than with a cold), 2 = moderate sore throat (as with a cold) and 3 = severe sore throat (more severe than with a cold).

q) Postoperative hoarseness (dysphonia) was scored as: 0 = no hoarseness, 1 = mild hoarseness (noticed by the patient only), 2 = severe hoarseness (noticed at the time of the interview by the personnel) and 3 = aphonia (inability to speak).

r) Postoperative nausea and vomiting were graded (0 - no nausea and vomiting, 1 - nausea without vomiting, 2 - nausea with vomiting < three episodes, 3 - nausea with vomiting > three episodes) and documented within first hour post-operative and at 24 hours after surgery.

s) Patients were discharged to the ward according to standard criteria for inpatient, discharged home according to the daycare criteria for daycare patients, or admitted to the day surgery ward for short stay surgery patients.

t) Collected data were keyed in to and analyzed statistically with SPSS® software version 24 (IBM).

4. RESULTS

A total number of 60 samples were collected over a period of one year (July 2017 until August 2018) and the data were analysed in this analysis. One sample from the Baska® mask arm had to cross over to the endotracheal tube group as in spite of reinsertion and readjustment of the Baska, it did not pass the maximal volume ventilation performance test despite having oropharyngeal leak pressure >30 cm H2O (suspected folding of the membrane of the cuff – however, fibreoptic bronchoscope was not immediately available to diagnose the glottic view and decision was made to switch to endotracheal tube to proceed with surgery). This sample was thus dropped from the analysis. Therefore, a total number of 59 samples were ultimately analysed which comprise, n=29 (48.3%) in the Baska® mask arm and n=30 (50.0%) in the ETT group.

4.1 Socio-demographic Data

Mean age of the recruited patients was 49.5 ± 15.6. The youngest patients recruited in the Baska and ETT arms were respectively, 20 and 29 years old, while the oldest patients were respectively, 74 and 73 years old. There were no significant differences in the demographic characteristics between the two groups in terms of age, weight, height and body mass index. In both groups, two-third of the patients were female and one-third of the patients were male.

Variables	Airway		Whole group	p-value
	Baska (n=29)	ETT (n=30)		
Age, Mean ± SD	46.4 ± 15.5	52.5 ± 15.4	49.5 ± 15.6	0.139
Weight, Mean ± SD	65.3 ± 13.3	69.4 ± 13.9	63.4 ± 13.6	0.249

Height, Mean ± SD	158.0 ± 7.8	161.1 ± 8.1	159.6 ± 8.1	0.146
BMI, Mean ± SD	25.9 ± 4.2	26.4 ± 4.5	26.2 ± 4.3	0.660
Gender, n (%) Male Female	 8 (40.0) 21 (53.8)	 12 (60.0) 18 (46.2)	 20 (33.9) 39 (66.1)	 0.314
ASA, n (%) 1 2 3	 11 (50.0) 18 (50.0) 0	 11 (50.0) 18 (50.0) 1 (100.0)	 22 (37.3) 36 (61.0) 1 (1.7)	 >0.999
Comorbids, n (%) DM: Y/N HPT: Y/N Dyslipidemia: Y/N BA: Y/N Smoker: Y/N Hyperthyroidism: Y/N CKD: Y/N Gastritis: Y/N	 7 (36.8)/22 (55.0) 8 (33.3)/ 21(60.0) 2 (20.0)/27 (55.1) 2 (50.0)/27 (49.1) 2 (100.0)/27 (47.4) 0/29 (50.0) 0/29 (50.0) 1 (100.0)/28 (48.3)	 12 (63.2)/ 18 (45.0) 16 (66.7)/14 (40.0) 8 (80.0)/22 (44.9) 2 (50.0)/28 (50.9) 0/30 (52.6) 1 (100.0)/29 50.0) 1 (100.0)/ 29 50.0) 1 (100.0)/30 (51.7)	 19 (32.2)/40 (67.8) 24 (40.7)/35 (59.3) 10 (16.9)/49 (83.1) 4 (6.8)/55 (93.2) 2 (3.4)/57 (96.6) 1 (1.7)/ 58 (98.3) 1 (1.7)/ 58 (98.3) 1 (1.7)/ 58 (98.3)	 0.192 0.044 0.080 >0.999 0.237 >0.999 >0.999 0.492

Table 1

In both groups, one-third of the recruited patients were ASA I and two-third were ASA II. There were slightly more hypertensives in the ETT group compared to the Baska group (p = 0.044) and five of the hypertensives in the ETT group were on beta-blockers (while in the Baska group, none was on beta-blockers). This probably explains the significant difference in the baseline heart rate between the two groups (p=0.017). There were no significant differences in baseline systolic and diastolic BP between the two groups.

Variable	Airway		Whole group	p value
	Baska (n=29)	ETT (n=30)		
Baseline Systolic BP (SBP)	145.0 ± 21.4	146.2 ± 18.6	145.6 ± 19.8	0.818
Baseline Diastolic BP (DBP)	82.4 ± 10.7	84.1 ± 10.5	83.3 ± 10.5	0.535
Baseline Heart Rate (HR)	79.8 ± 16.91	69.9 ± 13.7	74.8 ± 16.0	0.017

Table 2

4.2 Airway Parameters

Several data regarding airway parameters were collected and analysed. They include the Mallampati class, thyromental distance, interincisor distance, presence of dentures and neck movement. There were no significant differences between the two groups.

Variables	Mallampati Class			p-value
	I	II	III	
Baska	9 (37.5%)	15 (62.5%)	0 (0%)	0.227
ETT	4 (18.2%)	17 (77.3%)	1 (4.5%)	

Table 3

Variables	Thyromental Distance		p-value
	<60mm	≥60mm	
Baska	3 (10.3)	26 (89.7)	0.472
ETT	6 (20.0)	24 (80.0)	

Table 4

Variables	Interincisor Distance		p-value
	<40mm	≥40mm	
Baska	4 (13.8)	25 (86.2)	0.424
ETT	2 (6.7)	28 (93.3)	

Table 5

Variables	Dentures			p-value
	Double	Single	None	
Baska	3 (10.3)	1 (3.4)	25 (86.2)	0.687
ETT	3 (10.0)	3 (10.0)	24 (80.0)	

Table 6

Variables	Neck Movement	
	Yes	No
Baska	29 (100.0)	0
ETT	30 (100.0)	0

Table 7

4.3 Time to effective airway, ease of insertion and complications

Time to effective airway was recorded for each patient. This was defined as the time from picking up the airway (for the Baska mask group) and laryngoscope (for ETT group), insertion and occurrence of square-wave capnogram. Baska mask group had statistically significant shorter time to effective airway compared to the ETT group.

The mean time to effective airway for the Baska group was 26.6 ± 4.7 seconds, as compared to the ETT group, 67.4 ± 96.8 seconds. The ETT group had longer insertion time and wider standard deviation, as there were several occurrences when endotracheal intubation was unanticipatedly difficult, requiring multiple attempts and videolaryngoscopy. Levene's test for normality showed that equality of variance cannot be assumed. Therefore, non-parametric test (Mann-Whitney) was used to analyze the data for time to effective airway, which showed median (IQR) in the Baska group as 25.43 (5.35) and in the ETT group as 45.52 (18.22) [p <0.001].

Variables	Time to effective airway (sec) Mean rank	Median (IQR)	p-value
Baska	15.79	25.43 (5.35)	<0.001*
ETT	43.73	45.52 (18.22)	

*Mann Whitney

Table 8

There was no significant difference in the first attempt airway insertion rate, which was 96.6% for Baska® group and 86.7% for ETT group (p = 0.704).

Variables	Ease of airway insertion				p-value
	1st attempt	2nd attempt	3rd attempt	4th attempt	
Baska	28 (96.6)	1 (3.4)	0	0	0.704*
ETT	26 (86.7)	2 (6.7)	1 (3.3)	1 (3.3)	

*Fisher's Exact Test

Table 9

There were no significant differences in the rate of airway insertion complication between the two groups (p = 0.704). Intervention was defined as change in the size of the Baska mask and the need to use videolaryngoscopy in the ETT group. There was one intervention in the Baska group and two interventions in the ETT group.

Variables	Airway insertion complications				p-value
	None	Intervention	Gagging	Airway trauma	
Baska	28 (96.6)	1 (3.4)	0	0	0.704
ETT	16 (86.7)	2 (6.7)	1 (3.3)	1 (3.4)	

*Fisher's Exact Test

Table 10

4.4 Time to Ryle's tube insertion, ease of insertion and complications

Ryle's tubes were inserted for both groups. Time to insertion, ease of insertion and complications associated with the insertion were recorded. The mean time to Ryle's tube insertion for the Baska group was 29.3 ± 5.6 seconds and for the ETT group, 67.4 ± 96.8 seconds. The insertion of Ryle's tube was easier in the Baska group with first attempt successful insertion of 93.1% as compared to in the ETT group, 46.7% ($p < 0.001$). In the ETT group, 16.7% achieved successful insertion on second attempt, and 36.7% only on third attempt requiring assistance of laryngoscopy and Magill forceps.

Variables	Ease of Ryle's tube insertion			p-value
	1st attempt	2nd attempt	3rd attempt	
Baska	27 (93.1)	2 (6.9)	0	<0.001*
ETT	14 (46.7)	5 (16.7)	11 (36.7)	

*Fisher's Exact Test

Table 11

This explains the significantly longer Ryle's tube insertion time in the ETT group with wider standard deviation. Levene's test for normality performed showed that equality of variances could not be assumed. Non-parametric (Mann Whitney) test was therefore used to analyze the time to Ryle's tube insertion. The time to insertion of Ryle's tube was significantly faster ($p < 0.001$) in the Baska group, 28.70 (6.57) seconds than in the ETT group, 66.53 (129.20) seconds.

Variables	Time to Ryle's tube insertion (sec) Mean rank	Median (IQR)	p-value
Baska	20.52	28.70 (6.57)	<0.001*
ETT	39.17	66.53 (129.20)	

*Mann Whitney

Table 12

The complications associated with the Ryle's tube insertion were significantly higher in the ETT group as compared to the Baska group. This is explained by the need for multiple attempts and instrumentation for insertion of the Ryle's tube.

Variables	Ryle's tube insertion complications			p-value
	None	Oral/lip trauma	Nasal bleed	0.005*
Baska	29 (100.0)	0	0	
ETT	22 (73.3)	6 (20.0)	2 (6.7)	

*Fisher's Exact Test

Table 13

4.5 ***Baska mask placement and performance tests, oropharyngeal leak pressure and fibreoptic views***

For the Baska group, placement and performance tests were done and fibreoptic view of the vocal cords was recorded. Apart from the sample that was dropped from the analysis, all (n=29) had passed the placement and performance tests before proceeding with surgery. The mean oropharyngeal leak pressure (OLP) was 33.6 ± 2.2 cm H2O.

The fibreoptic views revealed that 58.6% of the Baska masks inserted had grade 4 view (only vocal cords seen), 24.1 % had grade 3 view (vocal cords plus posterior epiglottis seen), 13.8% grade 2 view (vocal cords plus anterior epiglottis seen), and 3.4% (n=1) had grade 1 view (vocal cords not seen). Despite the differences in the fibreoptic views, there was no significant effect to the oropharyngeal leak pressure and the ventilator parameters throughout the surgery.

Variable		n (%)
Gastric Bubble Test	Yes	29 (100.0)
	No	0
Suprasternal Notch Test	Yes	29 (100.0)
	No	0
Gastric Tube Insertion	Yes	29 (100.0)
	No	0
Oropharyngeal Leak Pressure (initial) cm H2O	Mean ± SD	33.6 ± 2.2
Maximum volume Ventilation Test	Yes	29 (100.0)
	No	0
Fibreoptic view	1 - Vocal cords not seen	1 (3.4)
	2 - Vocal cords plus anterior epiglottis seen	4 (13.8)
	3 - Vocal cords plus posterior epiglottis seen	7 (24.1)
	4 - Only Vocal cords visible	17 (58.6)

Table 14

The oropharyngeal leak pressure was measured for the Baska mask group at five different time frames as mentioned in the methodology.

i) immediately following airway insertion

ii) immediately prior to peritoneal insufflation

iii) after peritoneal insufflation

iv) after peritoneal insufflation and reverse trendeleburg positioning

v) after peritoneal desufflated and patient supined

There was no significant difference in the mean oropharyngeal leak pressure across different time interval (p = 0.806).

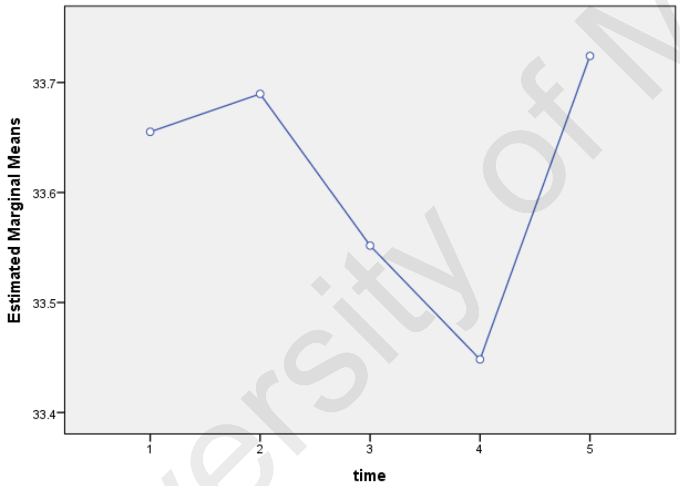

Diagram 1: Mean oropharyngeal leak pressure (cm H2O) across five time frames.

4.6 Ventilatory parameters

Ventilatory parameters were recorded at five different time frames as mentioned earlier in the methodology. There was no significant difference in pulse oximetry readings regardless of time (p = 0.567) and at each time interval.

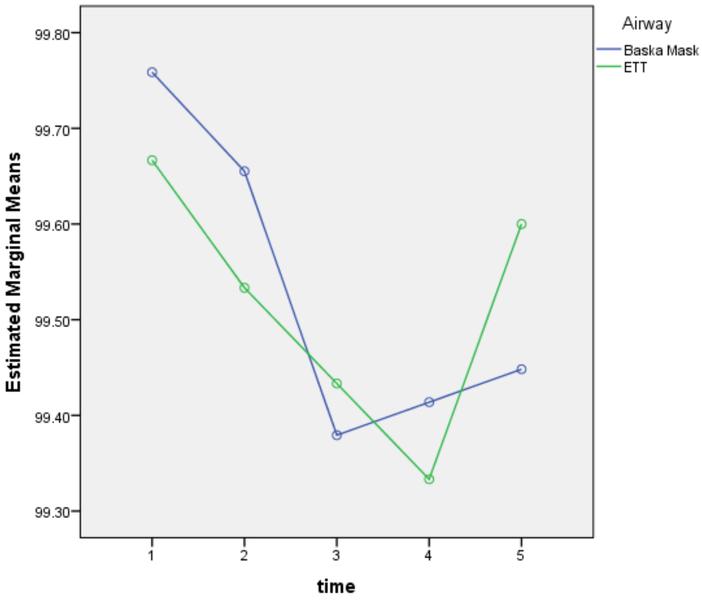

Diagram 2: Pulse oximetry (SpO2) values (%) across five time frames

There was no significant difference in end tidal CO2 (etCO2) values between Baska and ETT groups, regardless of time ($p = 0.567$). Based on time, there was significant difference in mean etCO2 between Baska and ETT group ($p = 0.032$). Baska group had statistically significantly higher etCO2 at time interval 2 (just before peritoneal insufflation) compared to ETT, with mean etCO2 36.90 ± 3.39 for Baska group and 35.13 ± 2.74 for the ETT group ($p = 0.032$). This however is not clinically significant – both the values are still within the normally accepted range.

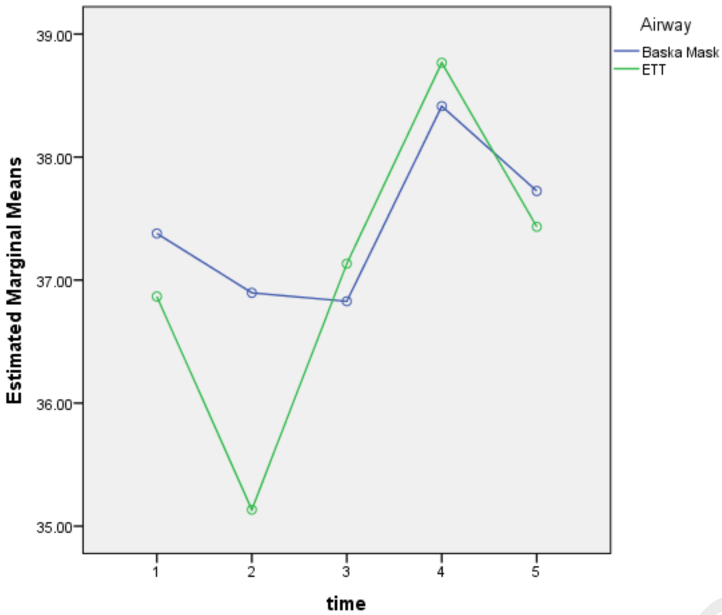

Diagram 3: End tidal CO2 (etCO2) (mm Hg) across five time frames

There was no significant difference in mean of minute ventilation (MV) between Baska and ETT group regardless of time ($p = 0.214$) and based on time ($p = 0.569$).

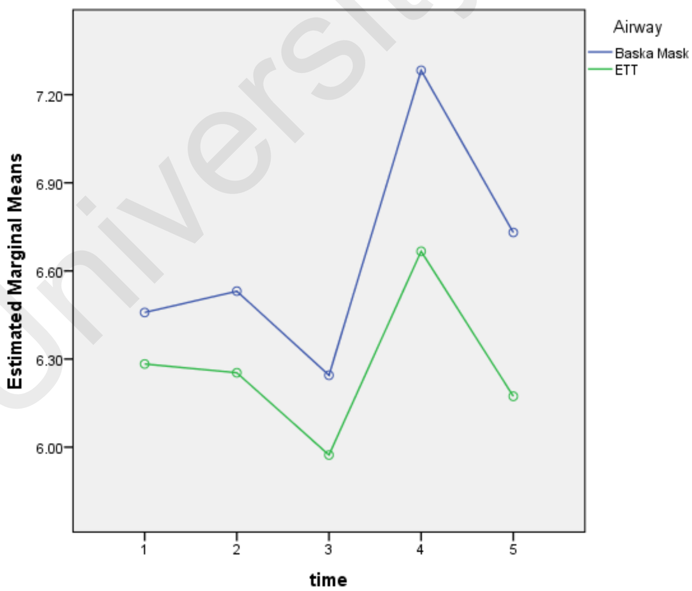

Diagram 4: Minute ventilation (MV) (litres per minute) across five time frames

There was significant difference in mean of peak airway pressure between Baska and ETT group regardless of time (p = 0.024). ETT group had significantly higher mean of peak airway pressure (18.79 cm H2O) compared to BASKA group (17.59 cm H2O). There was no significant difference in mean of peak airway pressure between Baska and ETT group based on time (p = 0.025).

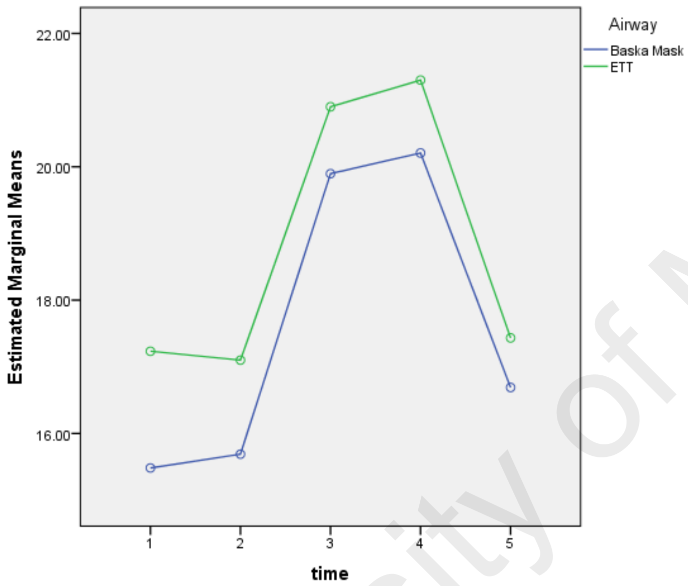

Diagram 5: Peak airway pressure (cm H2O) across five time frames

4.7 Hemodynamics data

Hemodynamics data were recorded to compare the hemodynamic response to the insertion and removal of the airway in both groups. Baseline systolic and diastolic BP (SBP and DBP) and heart rate were taken for each patient. There were no significant differences in SBP and DBP in both groups. However, the baseline HR was significantly higher in the Baska group (79.8 ± 16.91) compared to the ETT group (69.9 ± 13.7) [p = 0.017]. There were slightly more hypertensives in the ETT group compared to the

Baska® group (p = 0.044) and five of the hypertensives in the ETT group were on beta-blockers (while in the Baska® group, none was on beta-blockers). This probably explains the significant difference in the baseline heart rate between the two groups (p=0.017).

Variable	Airway		Whole group	p value
	Baska (n=29)	ETT (n=30)		
Baseline Systolic BP (SBP)	145.0 ± 21.4	146.2 ± 18.6	145.6 ± 19.8	0.818
Baseline Diastolic BP (DBP)	82.4 ± 10.7	84.1 ± 10.5	83.3 ± 10.5	0.535
Baseline Heart Rate (HR)	79.8 ± 16.91	69.9 ± 13.7	74.8 ± 16.0	0.017

Table 15

The hemodynamics data were recorded during the period of intubation/airway insertion over predetermined time frames, which were, 1 – baseline, 2 – post-induction, 3 – post-intubation, 4-7 – every minute, 8-11 – every 10 minutes.

There was significant difference in mean of intubation SBP between BASKA and ETT group regardless of time (p=0.012). ETT group had significantly higher intubation SBP mean (128.28) compared to BASKA group (118.58). Significant difference in mean of intubation SBP between BASKA and ETT group based on time (p=0.004). The significant differences between the groups are presented in the table below. ETT group had significantly higher mean of intubation SBP compared to BASKA group.

Time	Mean(sd)		p-value
	BASKA	ETT	
2	118.93(20.56)	130.77(24.62)	0.050
3	119.14(19.79)	149.30(27.73)	<0.001
4	111.45(22.87)	132.77(29.75)	0.003
5	107.52*18.12)	127.67(28.65)	0.002
6	110.90(18.61)	122.40(22.07)	0.035

Table 16

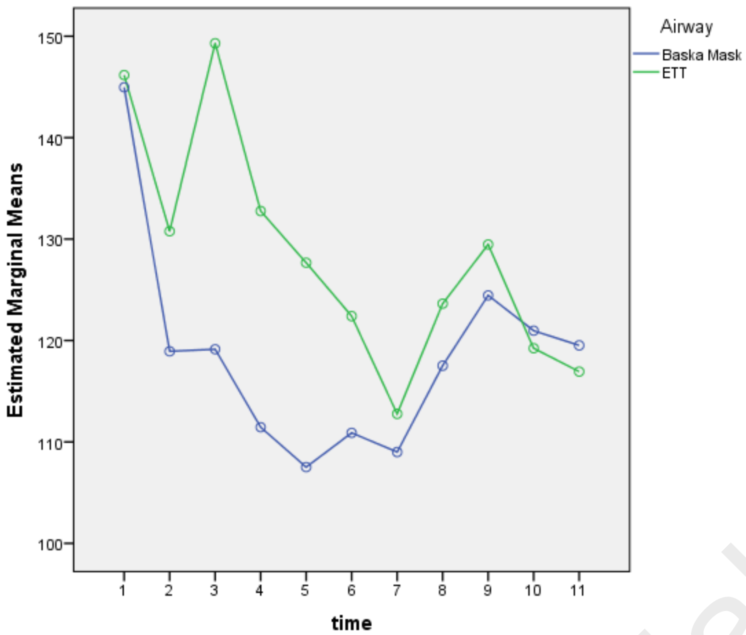

Diagram 6: Systolic BP (SBP) measurements across different time frames (1 – Baseline, 2 – post- induction, 3 – post-intubation, 4-7 – every minute, 8-11 – every 10 minutes)

There was significant difference in mean of DBP between BASKA and ETT group regardless of time (p=0.030). ETT group had significantly higher intubation DBP mean (76.95) compared to BASKA group (70.48). Based on time, there was also significant difference in mean of intubation DBP between BASKA and ETT group (p=0.011). The significant differences between the groups are presented in the table below. ETT group had significantly higher mean of intubation DBP compared to BASKA group.

Time	Mean(sd)		p-value
	BASKA	ETT	
3	69.24(12.97)	88.30(18.54)	<0.001
4	68.45(12.37)	80.33(20.40)	0.009
5	64.55(14.43)	75.23(17.69)	0.014
6	64.90(11.92)	75.00(16.91)	0.011

Table 17

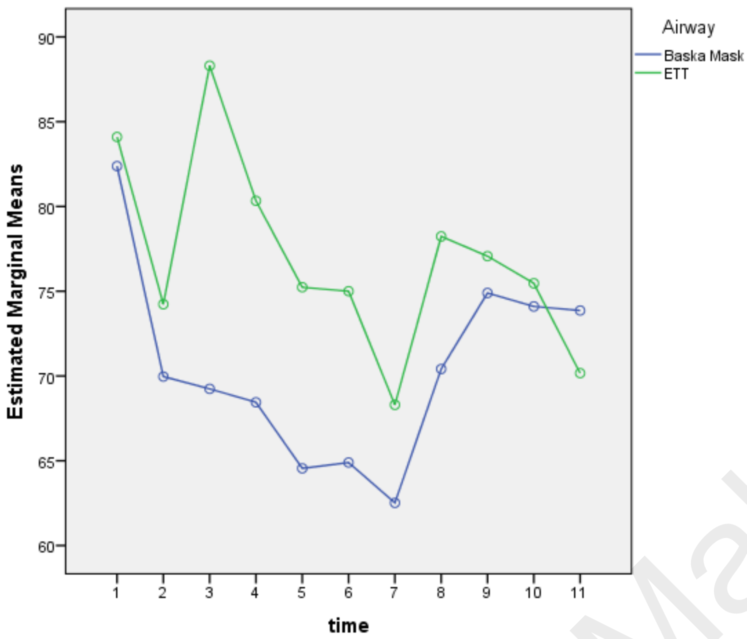

Diagram 7: Diastolic BP (DBP) measurements across different time frames (1 – Baseline, 2 – post- induction, 3 – post-intubation, 4-7 – every minute, 8-11 – every 10 minutes)

With regards to heart rate during intubation, there was overall significant difference in mean of intubation heart rate within BASKA and ETT group based on time (p=0.003). As mentioned earlier, there was significant difference in the baseline heart rate between the two groups (Baska - 79.8 ± 16.91 compared to the ETT - 69.9 ± 13.7) [p = 0.017]. From the post hoc test, both BASKA and ETT groups showed significant difference in mean of intubation heart rate based on time. The significant pair within the group is presented in the table below.

Comparison (time)	BASKA		Comparison (time)	ETT	
	Mean Difference (95%CI)	p-value		Mean Difference (95%CI)	p-value
4 vs 8	9.41(0.24,18.59)	0.039	3 vs 1	10.83(1.91,19.76)	0.006
			4 vs 1	10.80(2.16,19.44)	0.004
			5 vs 1	9.90(1.31,18.49)	0.011
			6 vs 1	10.73(2.34,19.12)	0.003
			3 vs 2	11.47(2.53,20.40)	0.003
			4 vs 2	11.43(2.42,20.45)	0.002
			5 vs 2	10.53(0.59,20.48)	0.028
			6 vs 2	11.37(2.57,20.16)	0.003
			3 vs 10	13.60(1.42,25.78)	0.016
			4 vs 10	13.57(2.33,24.80)	0.006
			5 vs 10	12.67(0.14,25.20)	0.045
			6 vs 10	13.50(1.25,25.75)	0.018
			8 vs 10	7.20(0.54,13.87)	0.023

Table 18

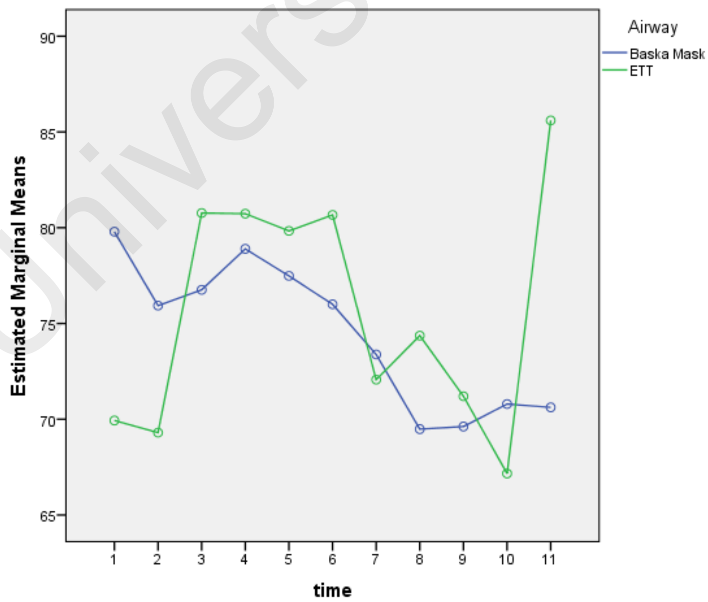

Diagram 8: Heart rate (HR) measurements across different time frames (1 – Baseline, 2 – post- induction, 3 – post-intubation, 4-7 – every minute, 8-11 – every 10 minutes)

During extubation, hemodynamics data were recorded across these time frames, which were – 1 – last recorded BP/HR intraoperatively, 2 – BP/HR immediately post-extubation, 3-7 – BP/HR every minute following extubation.

With regards to SBP during extubation, there was overall significant difference in mean of extubation SBP within BASKA and ETT group based on time (p<0.001). From the post hoc test, both BASKA and ETT groups showed significant difference in mean of extubation SBP based on time. The significant pair within the group is presented in the table below.

Comparison (time)	BASKA		Comparison (time)	ETT	
	Mean Difference (95%CI)	p-value		Mean Difference (95%CI)	p-value
2 vs 1	36.41(26.12,46.71)	<0.001	2 vs 1	33.93(22.36,45.50)	<0.001
3 vs 1	32.31(22.80,41.82)	<0.001	3 vs 1	20.38(10.54,30.22)	<0.001
4 vs 1	27.86(15.28,40.44)	<0.001	4 vs 1	17.10(6.51,27.70)	<0.001
5 vs 1	28.55(16.93,40.18)	<0.001	5 vs 1	18.69(7.96,29.42)	<0.001
6 vs 1	28.17(16.79,39.55)	<0.001	6 vs 1	17.14(3.99,30.28)	0.003
7 vs 1	28.72(16.54,40.91)	<0.001	7 vs 1	15.90(4.39,27.40)	0.002
2 vs 6	8.24(0.02,16.46)	0.049	2 vs 3	13.55(4.47,22.63)	0.001
			2 vs 4	16.83(6.42,27.24)	<0.001
			2 vs 5	15.24(5.58,24.90)	<0.001
			2 vs 6	16.79(6.42,27.17)	<0.001
			2 vs 7	18.03(8.75,27.32)	<0.001

Table 19

There was no significant difference in mean of extubation SBP between BASKA and ETT group regardless of time (p=0.668) and between the group at each time interval.

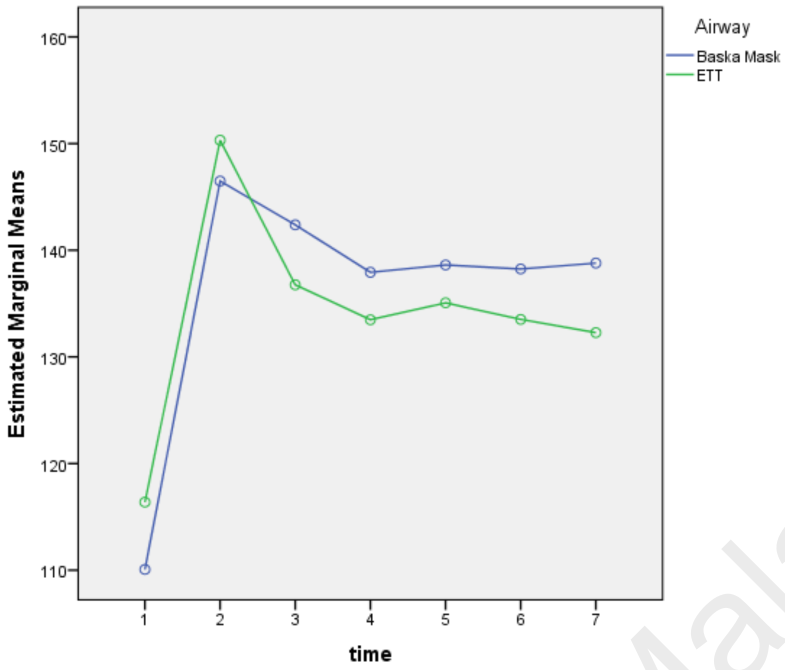

Diagram 9: Systolic BP (SBP) measurements during extubation (1 – last recorded SBP intraoperatively, 2 – SBP immediately post-extubation, 3-7 – SBP every minute following extubation).

With regards to diastolic BP (DBP) during extubation, there was overall significant difference in mean of extubation DBP within BASKA and ETT group based on time (p<0.001). From the post hoc test, both BASKA and ETT groups showed significant difference in mean of extubation DBP based on time. The significant pair within the group is presented in the table below.

Comparison (time)	BASKA		Comparison (time)	ETT	
	Mean Difference (95%CI)	p-value		Mean Difference (95%CI)	p-value
2 vs 1	16.55(9.59,23.51)	<0.001	2 vs 1	15.66(5.75,25.56)	<0.001
3 vs 1	13.07(5.39,20.75)	<0.001	2 vs 4	10.76(1.51,20.00)	0.012
4 vs 1	9.69(1.97,17.41)	0.005	2 vs 5	11.38(1.54,21.22)	0.014
5 vs 1	8.93(0.97,16.90)	0.017	2 vs 6	12.38(2.81,21.95)	0.004

6 vs 1	10.24(1.67,18.81)	0.009	2 vs 7	12.28(2.92,21.62)	0.003
2 vs 7	11.14(2.85,19.43)	0.002	3 vs 7	5.21(0.22,10.19)	0.034
3 vs 7	7.66(0.15,15.16)	0.042			

Table 20

There was no significant difference in mean of extubation DBP between BASKA and ETT group regardless of time (p=0.874) and based on time (p=0.349).

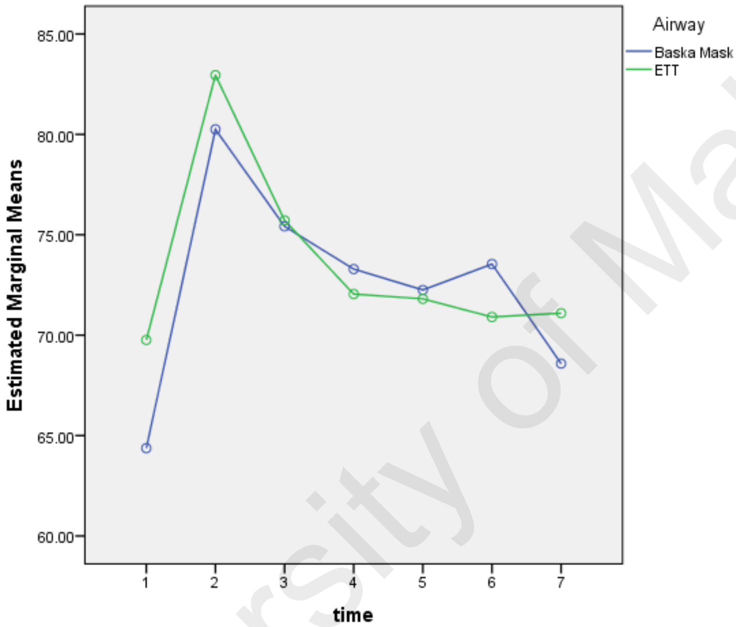

Diagram 10: Diastolic BP (DBP) measurements during extubation (1 – last recorded DBP intraoperatively, 2 – DBP immediately post-extubation, 3-7 – DBP every minute following extubation).

There was overall significant difference in mean of extubation heart rate within BASKA and ETT group based on time (p<0.001). From the post hoc test, both BASKA and ETT groups showed significant difference in mean of extubation heart rate based on time. The significant pair within the group is presented in the table below.

Comparison (time)	BASKA		Comparison (time)	ETT	
	Mean Difference (95%CI)	p-value		Mean Difference (95%CI)	p-value
2 vs1	16.59(9.16,24.02)	<0.001	2 vs 1	19.38(11.58,27.18)	<0.001
2 vs 3	11.62(5.05,18.19)	<0.001	2 vs 3	12.35(5.98,18.72)	<0.001
2 vs 4	14.62(8.35,20.89)	<0.001	2 vs 4	16.62(9.63,23.62)	<0.001
2 vs 5	13.55(6.00,21.10)	<0.001	2 vs 5	17.41(10.12,24.71)	<0.001
2 vs 6	14.48(8.19,20.78)	<0.001	2 vs 6	17.93(10.60,25.26)	<0.001
2 vs 7	15.28(9.14,21.41)	<0.001	2 vs 7	19.76(12.77,26.74)	<0.001
3 vs 4	3.00(0.59,5.41)	0.006	3 vs 4	4.28(0.15,8.40)	0.037
			3 vs 7	7.41(1.74,13.09)	0.003
			5 vs 7	2.35(0.14,4.55)	0.028

Table 21

There was no significant difference in mean of extubation heart rate between BASKA and ETT group regardless of time (p=0.849) and based on time (p=0.689).

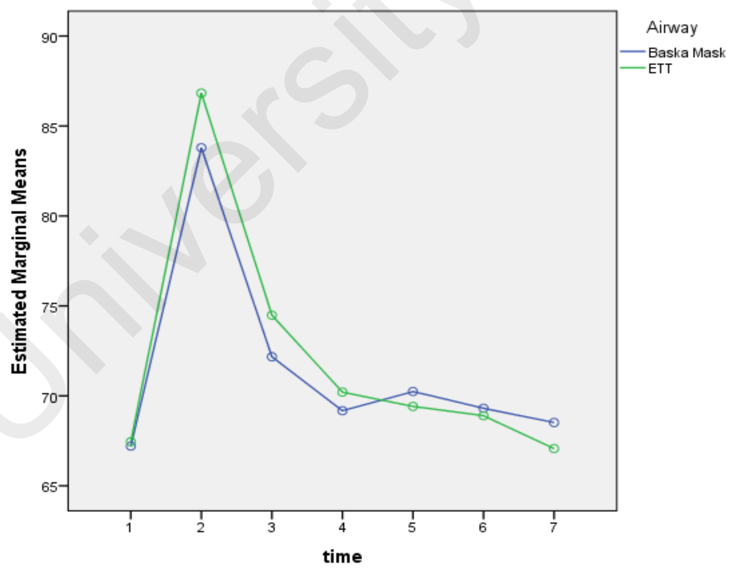

Diagram 11: Heart rate (HR) measurements during extubation (1 – last recorded HR intraoperatively, 2 – HR immediately post-extubation, 3-7 – HR every minute following extubation).

4.8 Surgical data

With regards to the surgery, gastric distension scores were recorded during the initial and at the end of surgery. In both groups, gastric distension score became lower at the end of the surgery compared to the initial part. There was no statistically significant difference in distension score between the two groups (p = 0.183). There were no significant differences in terms of duration of surgery, duration of peritoneal insufflation, blood loss and volume of intravenous fluid administered.

Baska

Variables	Mean ± SD	Mean Difference (95% CI)	p-value
Distension score (initial)	3.83 ± 1.87	1.76 (1.234, 2.283)	<0.001*
Distension score (end)	2.07 ± 0.96		

Table 22

ETT

Variables	Mean ± SD	Mean Difference (95% CI)	p-value
Distension score (initial)	4.03 ± 1.79	2.30 (1.671, 2.929)	<0.001*
Distension score (end)	1.73 ± 0.58		

Table 23

Difference between Distension score (Initial-End) between group

Variables	Mean difference (95% CI)	p-value
Baska	-0.52 (-1.345, 0.262)	0.183*
ETT		

*Independent t Test

Table 24

Duration of surgery

Variables	Duration of surgery (mins) Mean ± SD	Mean Difference (95% CI)	p-value
Baska	94.0 ± 51.7	-10.00 (-36.396, 16.398)	0.451*
ETT	104.0 ± 49.5		

*Independent t Test

Table 25

Duration of insufflation

Variables	Duration of insufflation (mins) Mean ± SD	Mean Difference (95% CI)	p-value
Baska	70.55 ± 51.3	-7.31 (-32.691, 18.062)	0.566*
ETT	77.87 ± 45.9		

*Independent t Test

Table 26

Blood loss

Variables	Blood loss (ml) Mean ± SD	Mean Difference (95% CI)	p-value
Baska	234.5 ± 103.6	-7.18 (-58.451, 44.083)	0.780*
ETT	241.7 ± 92.9		

*Independent t Test

Table 27

Fluid volume

Variables	Fluid volume (ml) Mean ± SD	Mean Difference (95% CI)	p-value
Baska	903.4 ± 308.8	-86.55 (-263.414, 90.311)	0.331*
ETT	990.0 ± 366.1		

*Independent t Test

Table 28

4.9 Complications

Device removal was significantly easier with the Baska group as compared to the ETT group (p <0.001). The presence of blood on airway device was seen in 23.3% of cases in the ETT group as compared to 0% in Baska group (p = 0.011).

Variables	Ease of device removal			p-value
	Very easy	Easy	Difficult	
Baska	22 (75.9)	6 (20.7)	1 (3.4)	<0.001*
ETT	8 (26.7)	20 (66.7)	2 (6.7)	

*Fisher's Exact Test

Table 29

Variables	Blood on device		p-value
	Yes	No	
Baska	0	29 (100.0)	0.011*
ETT	7 (23.3)	23 (76.7)	

*Fisher's Exact Test

Table 30

The occurrence of emergence cough was significantly more frequent in the ETT group as compared to the Baska group (p < 0.001). Only 2 samples (6.9%) recorded single emergence cough and 27 out of the total 29 (93.1%) did not have any emergence cough in the Baska group. In the ETT group, out of 30, 8 samples (26.7%) had single cough on emergence, 11 (36.7%) non-sustained cough less than 5 seconds, 1 (3.3%) sustained cough > 5 seconds and 10 (33.3%) had no cough on emergence.

There were 3 episodes (10.0%) of airway trauma in the ETT group and there was none in the Baska group – there was however no significant difference between the two groups (p = 0.237). The incidences of airway trauma in the ETT group maybe explained by the occurrence of unanticipated difficult airway and the need for laryngoscopy in some cases to insert Ryle's tube. There was one case of laryngospasm in each group (3.3%) – no significant difference between the two groups (p > 0.999). The case of laryngospasm in the ETT group had led to negative pressure pulmonary edema, which resolved with CPAP administration. The patient was monitored in a critical care unit and had an uneventful recovery. There were no episodes of bronchospasm or aspiration in both groups.

Variables	Emergence cough				p-value
	No cough	Single cough	Non-sustained cough	Sustained cough	
Baska	27 (93.1)	2 (6.9)	0	0	<0.001
ETT	10 (33.3)	8 (26.7)	11 (36.7)	1 (3.3)	

*Fisher's Exact test

Table 31

Variables	Airway trauma		p-value
	No	<3 episodes	
Baska	29 (100.0)	0	0.237
ETT	27 (90.0)	3 (10.0)	

*Fisher's Exact test

Table 32

Variables	Laryngospasm		p-value
	No	Yes	
Baska	28 (96.6)	1 (3.4)	>0.999
ETT	29 (96.7)	1 (3.3)	

*Fisher's Exact test

Table 33

Variables	Bronchospasm	
	Yes	No
Baska	0	29 (100.0)
ETT	0	30 (100.0)

Table 34

Variables	Aspiration	
	Yes	No
Baska	0	29 (100.0)
ETT	0	30 (100.0)

Table 35

There were significantly more occurences of sore throat at 1 hour and 24 hour in the ETT group as compared to the Baska group.

Variables	Sore throat at 1hour			p-value
	None	Mild	Moderate	
Baska	13 (44.8)	16 (55.2)	0	<0.001
ETT	4 (13.3)	14 (46.7)	12 (40.0)	

*Pearson Chi Square Test

Table 36

Variables	Sore throat at 24hour			p-value
	None	Mild	Moderate	
Baska	24 (82.8)	5 (17.2)	0	0.027
ETT	16 (53.3)	11 (36.7)	3 (10.0)	

*Fisher's Exact test

Table 37

There were more patients in the ETT group that developed mild and severe dysphonia at 1 hour in the ETT group compared to the Baska group ($p < 0.001$). At 24 hours, there was no significant difference between the two groups with regards to dysphonia ($p = 0.237$).

Variables	Dysphonia at 1hour			p-value
	No	Mild	Severe	
Baska	24 (82.8)	5 (17.2)	0	<0.001
ETT	11 (36.7)	12 (40.0)	7 (23.3)	

*Fisher's Exact test

Table 38

Variables	Dysphonia at 24hour			p-value
	No	Mild	Severe	
Baska	28 (96.6)	1 (3.4)	0	0.237
ETT	26 (86.7)	1 (3.3)	3 (10.0)	

*Fisher's Exact test

Table 39

2 cases (6.9%) of dysphagia at 24 hours were recorded in the Baska group and 1 case (3.3%) in the ETT group with no significant difference between the two groups ($p = 0.612$).

Variables	Dysphagia at 1hour		p-value
	No	Yes	
Baska	29 (100.0)	0	>0.999
ETT	29 (96.7)	1 (3.3)	

*Fisher's Exact test

Table 40

Variables	Dysphagia at 24hour		p-value
	No	Yes	
Baska	27 (93.1)	2 (6.9)	0.612
ETT	29 (96.7)	1 (3.3)	

*Fisher's Exact test

Table 41

There was no significant difference in the incidence of nausea and vomiting at 1 hour and 24 hours between the two groups.

Variables	Nausea & Vomitting at 1 hour			p-value
	No nausea/ vomitting	Nausea only	Vomitting <3 episodes	
Baska	25	3	1	0.492
ETT	27	3	0	0.612

*Fisher's Exact test

Table 42

Variables	Nausea & Vomitting at 24 hour			p-value
	No nausea/ vomitting	Nausea only	Vomitting <3 episodes	
Baska	26	1	2	0.492
ETT	28	1	1	0.612

*Fisher's Exact test

Table 43

5. DISCUSSION

Airway protection and the ability to ventilate in a condition of altered physiology have been the cornerstones in anaesthetizing patients for laparoscopic surgeries. Hence, for many years, endotracheal intubation has been regarded as the gold standard in laparoscopic surgeries.

This study compared the performance of a novel supraglottic airway equipped with many new safety features, against the gold standard in laparoscopic surgeries, endotracheal intubation. The socio-demographic features, namely the age, gender, ASA classification and body mass index (BMI), were similar between the two groups. The airway parameters also did not show significant difference between the groups.

30 samples were recruited for the Baska group. All of the Baska masks inserted achieved good oropharyngeal leak pressure (OLP) >30 cm H2O. However, one sample was dropped from the analysis, as it did not achieve adequate ventilation during the performance test to allow it to proceed for laparoscopic surgery, despite readjustments, reinsertions and change of size. Folding of the membrane of the cuff was postulated to cause the problem (fibreoptic bronchoscope was not readily available at that time to diagnose the fibreoptic view of the Baska mask). The sample was therefore crossed over to endotracheal intubation to proceed with surgery.

Ultimately for the final analysis, 29 samples (49.2%) in the Baska group were compared with 30 samples (50.8%) in the ETT group. The primary outcome analysed in this study is to compare the time taken to successful airway placement and the rate of first time successful placement. The time taken for effective airway insertion was significantly shorter with the Baska masks (26.6 ± 4.7 seconds) as compared to the ETT (67.4 ± 96.8 seconds) [p <0.001 on Mann Whitney test]. The significantly longer time to effective airway insertion in the ETT group maybe explained by incidences of unanticipated difficult airway which required airway adjuncts like gum elastic bougie, and videolaryngoscope.

The first time successful airway placement was high in both groups (96.6% in Baska group vs 86.7% in ETT group) with no siginificant difference between them (p = 0.704). Complications related to airway insertion revealed 1 case of gagging (3.3%) and 1 case of airway trauma (3.3%) in the ETT group, while there were none in the Baska group. There was no statistical significant difference between the two groups (p = 0.704); more samples are likely needed to prove significant difference.

The time for successful Ryle's tube insertion was also significantly faster in the Baska group compared to the ETT group (mean insertion time 29.3 ± 5.6 seconds for the Baska group compared to 104.3 ± 89.1 seconds for the ETT group) [p < 0.001 on Mann Whitney test]. The rate of first time successful insertion of Ryle's tube was significantly higher in the Baska group (93.1%) compared to the ETT group (46.7%) [p < 0.001]. The rate of complications also was significantly higher in the ETT group (p = 0.005). Oral/lip trauma was reported at 20.0% and nasal bleed 6.7% in the ETT group, compared to none in the Baska group.

29 of the initially 30 samples recruited for Baska group passed all the placement and performance tests. The recorded mean oropharyngeal leak pressure (OLP) was 33.6 ± 2.2 cm H_2O and there was no significant difference in mean OLP across different time intervals (post-intubation, before peritoneal insufflation, after peritoneal insufflation, reverse Trendelenburg, after being supine) [p = 0.806]. 58.6% showed grade 4 fibreoptic view (only vocal cords seen), 24.1% grade 3 (vocal cords and posterior epiglottis seen),

13.8% grade 2 (vocal cords and anterior epiglottis seen), 3.4% grade 1 (vocal cords not seen). Despite the differences in the fibreoptic views, all of the Baska masks inserted showed good performance throughout the surgery with consistently high orophrangeal leak pressure.

The Baska group showed comparable performance with regards to ventilatory parameters throughout the surgery, when compared to the ETT group. There was no significant difference in pulse oximetry readings regardless of time ($p = 0.567$) and at each time interval. There was no significant difference in mean of minute ventilation (MV) between Baska and ETT group regardless of time ($p = 0.214$) and based on time ($p = 0.569$).

There was significant difference in mean of peak airway pressure between Baska and ETT group regardless of time ($p = 0.024$). ETT group had significantly higher mean of peak airway pressure (18.79 cm H_2O) compared to BASKA group (17.59 cm H_2O). This however was not clinically significant, as they were both within the clinically acceptable range. There was no significant difference in mean of peak airway pressure between Baska and ETT group based on time ($p = 0.025$). There was also no significant difference in end tidal CO_2 ($etCO_2$) values between Baska and ETT groups regardless of time ($p = 0.567$).

The haemodynamics data showed greater response in blood pressure and heart rate in the ETT group as compared to the Baska group. Systolic BP (SBP) and diastolic BP (DBP) pressor response was seen to be more significant in the ETT group compared to the Baska group (time interval 2 (post-induction) and 3 (immediately post-intubation) on diagram 6 and 7). The ETT group had significantly higher mean systolic and diastolic BP (SBP & DBP) overall during intubation. ETT group had significantly higher intubation SBP mean (128.28) compared to BASKA group (118.58). The ETT group also had significantly higher intubation DBP mean (76.95) compared to BASKA group (70.48). With regards to heart rate, there was significant difference of mean heart rate in the ETT group across the time intervals post-intubation (time interval 2 and 3 on diagram 8) from the post-hoc test. Overall, there was no significant difference of mean heart rate during intubation between the two groups ($p = 0.733$) and this is despite the baseline heart rate being significantly different between the two groups.

During extubation, both groups showed similar pressor response with regards to the SBP, DBP and HR (time interval 1 and 2 on diagram 9, 10 and 11). There were no significant differences in mean SBP, DBP and HR during extubation, regardless of time and based on time.

There were limitations to the haemodynamic data interpretation in this study. There were more hypertensives in the ETT group (66%) compared to the the Baska group (33%) [$p = 0.044$]. However, there was no significant difference in the baseline SBP and DBP. Baseline heart rate, however, was significantly different - 79.8 ± 16.91 bpm for the Baska group and 69.9 ± 13.7 bpm for the ETT group ($p = 0.017$). This is probably explained by the fact that, five out of the hypertensives in the ETT group were on Beta-blockers and there were none in the Baska group.

With regards to surgical parameters, the gastric distension scores were within acceptable range for the surgeon in both groups during both initial part and at the end of surgery. Gastric distension was not increasing in both groups and there was no significant difference between the groups. There were no significant differences in terms of duration of surgery, duration of peritoneal insufflation, blood loss and volume of intravenous fluid administered.

During extubation, device removal was significantly easier with the Baska group as compared to the ETT group ($p < 0.001$). The presence of blood on airway device was seen in 23.3% of cases in the ETT group as compared to 0% in Baska group ($p = 0.011$).

The incidence of emergence cough was significantly higher in the ETT group as compared to the Baska group ($p < 0.001$). Only 2 samples (6.9%) recorded single emergence cough and 27 out of the total 29 (93.1%) did not have any emergence cough in the Baska group. In the ETT group, out of 30, 8 samples (26.7%) had single cough on emergence, 11 (36.7%) non-sustained cough less than 5 seconds, 1 (3.3%) sustained cough > 5 seconds and 10 (33.3%) had no cough on emergence.

There were 3 episodes (10.0%) of airway trauma in the ETT group and there was none in the Baska group – there was however no significant difference between the two groups ($p = 0.237$). The incidences of airway trauma in the ETT group maybe explained by the occurrence of unanticipated difficult airway and the need for laryngoscopy in some cases to insert Ryle's tube. There was one case of laryngospasm in each group (3.3%) – no significant difference between the two groups ($p > 0.999$). The case of laryngospasm in the ETT group had led to negative pressure pulmonary edema, which resolved with CPAP administration. The patient was monitored in a critical care unit and had an uneventful recovery. There were no episodes of bronchospasm or aspiration in both groups.

There was significantly more laryngo-pharyngeal morbidity in the ETT group compared to the Baska group. Samples recruited in this study however, did not receive equianalgesic amount of opioids – this poses some limitation to the study. The incidence of sore throat at 1 hour immediately postoperatively and at 24 hours was significantly higher in the ETT group. There was higher incidence of dysphonia as well at 1 hour in the

ETT group as compared to the Baska group. At 24 hours, there was no significant difference between the two groups.

2 cases (6.9%) of dysphagia at 24 hours were recorded in the Baska group and 1 case (3.3%) in the ETT group. One of the cases of dysphagia within the Baska group maybe related to the protracted length of the surgery (290 minutes). The patient had full resolution of symptom within the next 48 hours following surgery. There was also no significant difference in the incidence of postoperative nausea and vomiting between the two groups.

6. CONCLUSION

Baska mask is a novel supraglottic airway which maybe a suitable alternative to the endotracheal tube in laparoscopic surgeries in selected patients. Both Baska mask and ETT had high first time success rate in insertion. The time needed to establish an effective airway, however, is shorter with the Baska mask as compared to the endotracheal intubation. The insertion of orogastric tube is much easier and faster in the Baska group with higher first attempt success rate with lesser complications related to the insertion as compared to the ETT group.

Both groups performed with similar efficacy with regards to maintaining ventilation and oxygenation in laparoscopic surgeries. The Baska masks recruited in the study maintained high mean oropharyngeal leak pressure more than 30 cm H2O with no significant changes throughout the surgery at different positions and time frames of the surgery.

The Baska group showed greater hemodynamic stability during the insertion of airway with significantly lesser hemodynamic response compared to the ETT group. Laryngo-pharyngeal morbidities postoperatively, in forms of emergence cough, dysphonia and sore throat, were significantly lesser in the Baska group in comparison to the ETT group.

In conclusion, the Baska mask proved to be a suitable and safe alternative to endotracheal tube in for airway management in selected adult elective laparoscopic surgeries.

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