COMPARISON OF CLINICAL PERFORMANCE OF LMA PROTECTOR™ *CUFF PILOT*™ AND LMA SUPREME™ AMONG ANAESTHETISED, NON-PARALYSED PATIENTS

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INTRODUCTION

The inception of supraglottic airway (SGA) has revolutionized the anaesthetist's airway armamentarium. It was invented by Dr Archie Ian Jeremy Brain in 1982 and was commercially made available in 1987.[1] It offers the advantage of avoiding endotracheal intubation, shorter insertion time, lower incidence of post-operative pharyngeal pain and better haemodynamic stability during induction and emergence.[2] An ideal SGA placement should provide sufficient perilaryngeal seal to allow ventilation of the lungs without injuring pharyngeal mucosa and able to prevent or provide early detection of gastric aspiration. It can be classified based on its function into 1st, 2nd and 3rd generation[3] or via its sealing mechanism.[4]

LMA Supreme™ is a single use, second generation SGA introduced in 2005. It is made of polyvinyl chloride (PVC). It has the advantage of anatomically shaped airway tube, presence of an integral bite block and a drain tube to facilitate placement of gastric tube.[5] According to manufacturer, it is a high volume low pressure cuff which can generate high seal pressure up to 37 cmH_2O.[6]

LMA Protector™ is the latest second generation SGA introduced in 2015. It is a single use device made of silicon and is both latex and phthalate free. It is similar to LMA Supreme™ that has a dynamic curve, which conforms to the anatomical contour of the pharynx, hence allowing rapid insertion. LMA Protector™ also has an integral bite block and dual gastric access. In addition, LMA Protector™ *Cuff Pilot*™ has an integrated cuff pressure monitor to ensure the SGA is properly inflated.[7]

The common complications of SGA are malposition, sore throat, dysphagia and laryngeal nerve injury.[8] Instruction leaflet for LMA Supreme™ states a maximum cuff volume of 20 ml, 30 ml and 40 ml of air for size 3, 4, and 5 respectively. It also recommends maximum intra-cuff pressure of 60 cmH_2O.[5] However, inflating the maximum recommended cuff volume often results in intra-cuff pressure higher than 60 cmH_2O.[9,10] Saraçoğlu *et al*. reported that professional experience does not contribute to obtaining optimal cuff pressure without measuring it.[11] Hence, this calls for a need to introduce cuff manometer into our routine anaesthetic practice.

The new LMA Protector™ *Cuff Pilot*™ was designed to reduce the risk of overinflating. It has a cuff pilot valve to allow user to monitor the intra-cuff pressure of the SGA through visual means that are colour coded. Optimal intra-cuff pressure of 40-60 cmH_2O will place the cuff pilot valve in green zone whereas underinflating and overinflating will place it either in yellow or red zone respectively. As it is made of silicone, it also offers more flexibility and potentially less traumatic than LMA Supreme™.[12]

A search of 'LMA Protector, laryngeal mask airway protector' in PubMed Central only yielded six results, whereas 'laryngeal mask airway supreme' yielded 160 results in PubMed and 188 results in PubMed Central respectively. Only two papers mentioned LMA Protector™'s clinical performance whereas another three were case reports. Hence, this calls for more study on LMA Protector™ *Cuff Pilot*™ especially in regards to its clinical performance.

OBJECTIVES

Primary objective:

To assess the oropharyngeal leak pressure (OLP) of LMA Protector™ *Cuff Pilot*™ and LMA Supreme™.

Secondary objectives:

1. To compare the mean time to insertion between LMA Protector™ *Cuff Pilot*™ and LMA Supreme™.
2. To compare the ease of gastric tube insertion between LMA Protector™ *Cuff Pilot*™ and LMA Supreme™.
3. To compare the laryngeal view of LMA Protector™ *Cuff Pilot*™ and LMA Supreme™.
4. To compare the complications in patients using LMA Protector™ *Cuff Pilot*™ and LMA Supreme™.

STUDY HYPOTHESIS

We hypothesised that LMA Protector™ *Cuff Pilot*™ has similar OLP to LMA Supreme™, is easily inserted with faster insertion time, and lesser complication.

MATERIALS AND METHODS

This prospective, single blinded, randomised controlled trial will be submitted for the approval of the Research Committee of Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Centre (UKMMC) and the Medical Research & Ethics Committee, UKMMC.

Patient information sheet (in Malay and English) will be given out and explained to patients. Written informed consent will be obtained from patients recruited into the study, which will be conducted by a single operator who has experience in insertion of both LMAs.

Study Site:

This proposed study will be carried out in operation theatres of Universiti Kebangsaan Malaysia Medical Centre.

Inclusion Criteria:

1. Patients aged 18-65 years old.
2. Patients planned for general anaesthesia without muscle relaxant usage via SGA.

Exclusion Criteria:

1. Patients with body mass index (BMI) > 35 kg/m^2.
2. Patients with likelihood of difficult intubation (Simplified Airway Risk Index score ≥ 4).[13]
3. Patients with increase risks of aspiration (gastro-oesophageal reflux disease, obstetric patients, hiatus hernia).

Methodology:

Patients who consented to the study will be randomized into 2 groups, Group P or Group S using an online Random Sequence Generator (https://www.random.org/sequences/). Patients in Group P will have LMA Protector™ *Cuff Pilot*™ inserted during general anaesthesia whereas patients in Group S will receive LMA Supreme™. The selection of SGA sizes will be done according to manufacturer's recommendation based on participant's weight. At the operating theatre, patients will be placed in supine position with a head rest. Standard monitoring consisting of pulse oximeter, non-invasive blood pressure (NIBP) and 3 lead electrocardiogram (ECG) will then be applied.

Both groups will receive similar induction regime which are: preoxygenation to achieve end-tidal fractional oxygen concentration > 0.85; intravenous (IV) fentanyl 1-2 mcg/kg; IV propofol 1.5-2.5 mg/kg and anaesthesia maintained with sevoflurane at minimum alveolar concentration (MAC) of 0.8-1.2 via manual mask ventilation with adjustable pressure limiting (APL) valve closed at < 20 cmH_2O. Each SGA will be fully deflated and its posterior surface will be lubricated with water-based gel prior to placement. SGA will be inserted once participant's both pupils are in the centre and loss of motor response to jaw thrust. Both LMA Protector™ *Cuff Pilot*™ and LMA Supreme™ will be inserted using the single-handed rotational technique in the semi-sniffing position as recommended by manufacturer.

After insertion, the cuff in Group P will be insufflated with air till the cuff pilot valve is located in the centre of the green zone (estimated cuff pressure between 40-60 cmH_2O). In Group S, the cuff will be insufflated with air in accordance to manufacturer's recommendation to 60 cmH_2O by using a hand-held analog cuff pressure gauge (VBM *Medizintechnik GmbH,* Germany). The time to insertion - that is defined as duration from picking up the study device to presence of capnography tracing - will be recorded. The number of attempts will also be recorded. Any participant which require more than three attempts will be considered a fail attempt and will subsequently be managed appropriately by the attending anaesthetist.

After placement, a size 12-F gastric tube will be lubricated at the distal tip with water based lubricant and then inserted via the gastric channel of both groups. The number of attempt to insert a gastric tube will be recorded. Correct placement of the gastric tube will be determined by the detection of injected air through epigastric auscultation.

The position of SGA after insertion in relation to laryngeal inlet will be verified by passing an intubating bronchoscope to a position just proximal to the end of the SGA. The laryngeal view obtained at this point will be scored according to Keller *et al.*: Grade 1, clear view of the vocal cords; Grade 2, view of the arytenoids only; Grade 3, view of the epiglottis only; Grade 4, no laryngeal structures visible.[14]

Oropharyngeal leak pressure (OLP) will be assessed by setting the APL valve of the circle system at 40 cmH_2O with fresh gas flow of 3 L/min. The OLP will be determined by observing the airway pressure at equilibrium until an audible noise is heard over the mouth with a stethoscope. For safety reasons, the maximum allowable OLP is 40 cmH_2O.

Intraoperatively, anaesthesia will be maintained with sevoflurane at MAC of 0.8 to 1.2 in a mixture of 50% oxygen and 50% medical air with total flow of 2 L/min. Subsequent anaesthetic management including analgesia and anti-emetic will be in accordance to the discretion of the anaesthetist-in-charge.

SGA will be removed once patient awake and obeying simple commands. Presence of blood stain over the SGA will be recorded. Participants will be followed up in the recovery

and 6 hours after discharged from recovery to assess for presence of sore throat and hoarseness of voice.

STATISTICAL ANALYSIS

Sample size calculation:

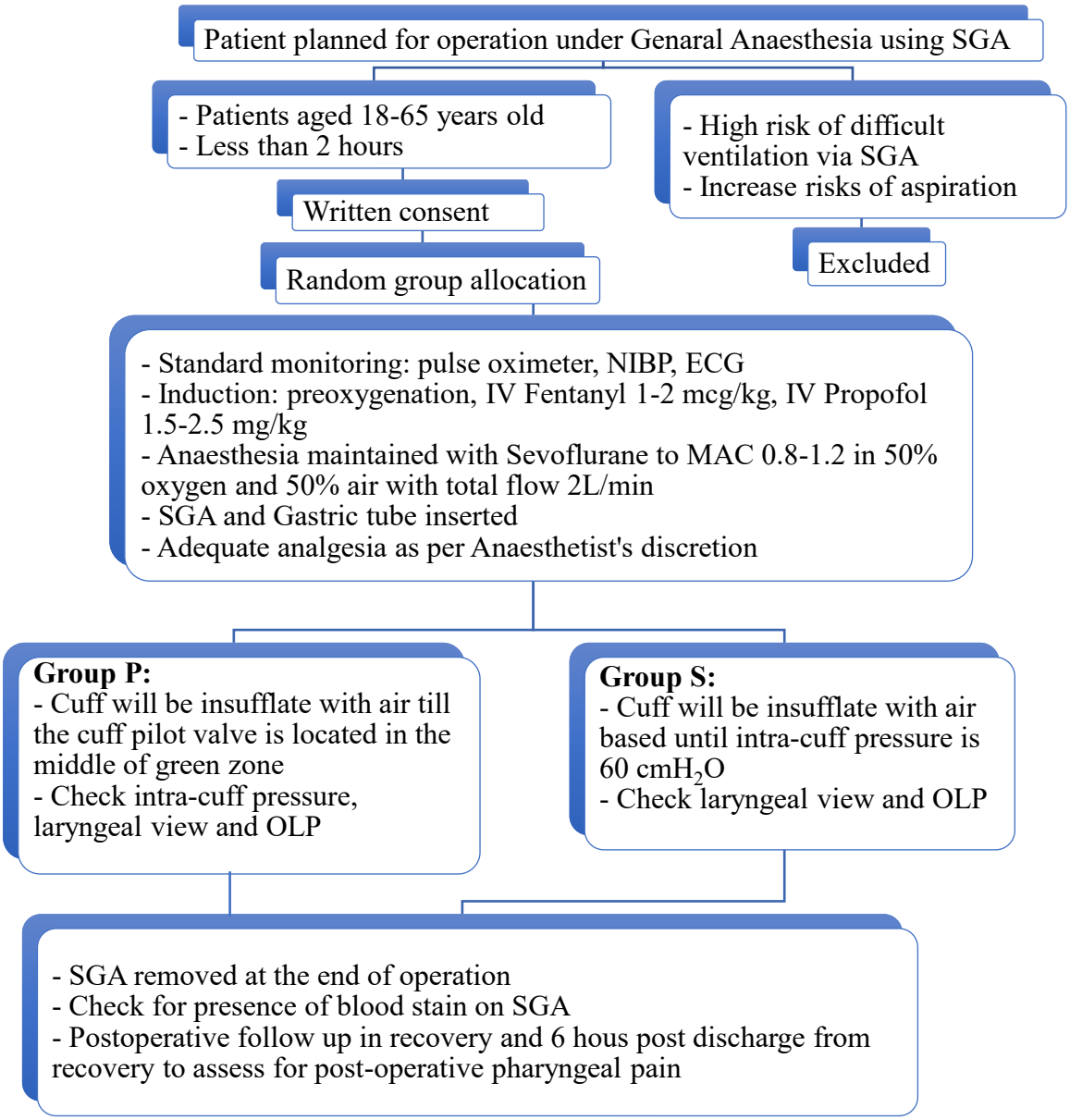
For the primary objective, we need 26 participants in each group to detect the difference of 4.5 cmH_2O (20.7 vs 25.2 cmH_2O) [15] with standard deviation of 5.7 at 80% power and alpha value of 0.05 using Power and Sample Size Calculation version 3.1.2.[16] With anticipation of 15% dropout rate, we decided to take a total of 60 participants.

Statistical test:

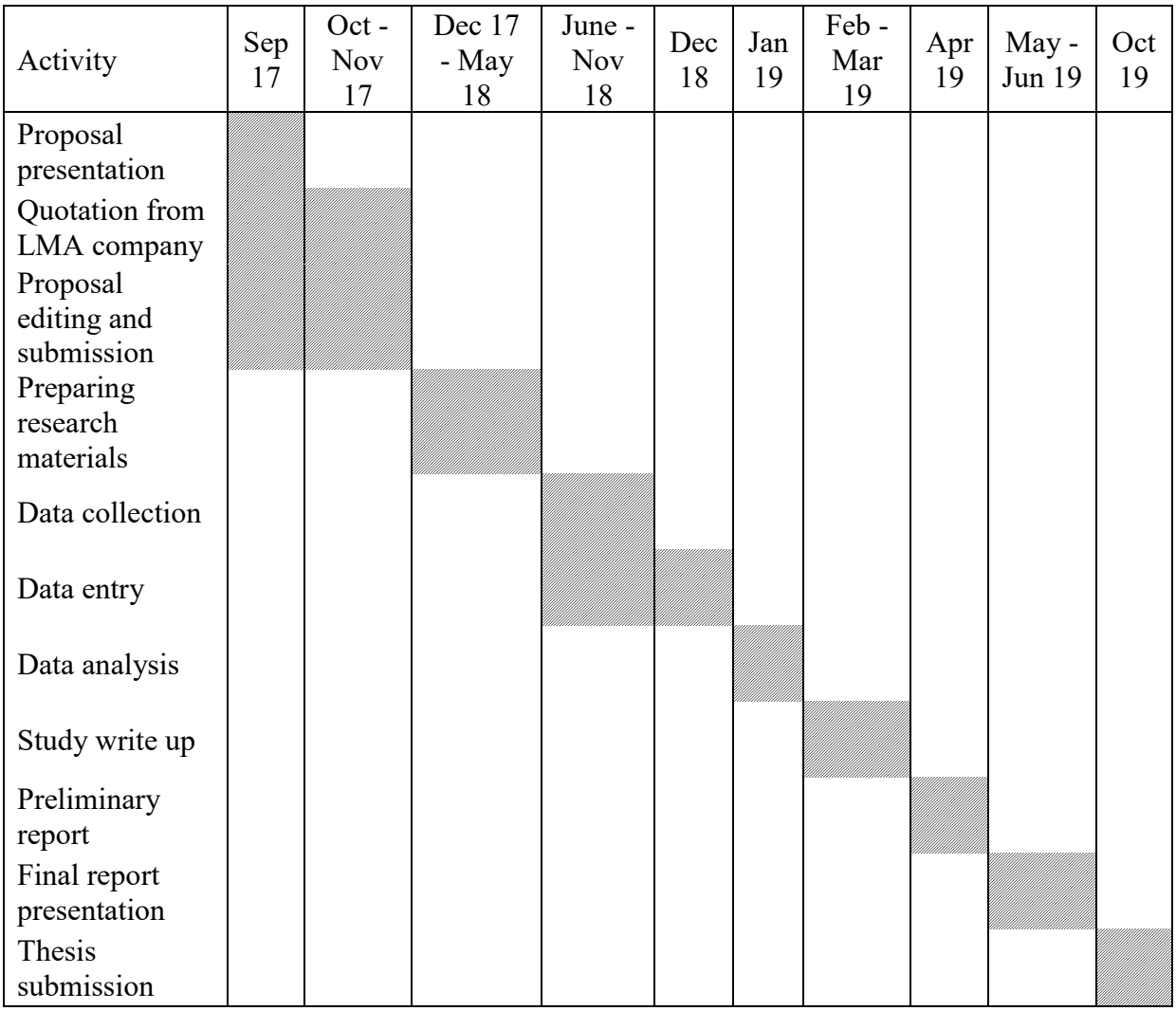
All data will be entered into Microsoft Excel 2016 and analysed in Statistical Package for Social Science (SPSS) version 20.0. Result for the respective objectives will be analysed using the following statistical test and as appropriate. A value of $p < 0.05$ will be considered statistically significant.

Results	**Statistical analysis**
Assessing OLP	Student *t*-test
Comparing mean insertion time	Student *t*-test
Comparing ease of gastric tube insertion	Mann Whitney
Comparing laryngeal view	Mann Whitney
Comparing complications	Chi square

FLOW CHART


Patient planned for operation under Genaral Anaesthesia using SGA
- Patients aged 18-65 years old
- Less than 2 hours
- High risk of difficult ventilation via SGA
- Increase risks of aspiration
Written consent
Excluded
Random group allocation
- Standard monitoring: pulse oximeter, NIBP, ECG
- Induction: preoxygenation, IV Fentanyl 1-2 mcg/kg, IV Propofol 1.5-2.5 mg/kg
- Anaesthesia maintained with Sevoflurane to MAC 0.8-1.2 in 50% oxygen and 50% air with total flow 2L/min
- SGA and Gastric tube inserted
- Adequate analgesia as per Anaesthetist's discretion
Group P:
- Cuff will be insufflate with air till the cuff pilot valve is located in the middle of green zone
- Check intra-cuff pressure, laryngeal view and OLP
Group S:
- Cuff will be insufflate with air based until intra-cuff pressure is 60 cmH_2O
- Check laryngeal view and OLP
- SGA removed at the end of operation
- Check for presence of blood stain on SGA
- Postoperative follow up in recovery and 6 hous post discharge from recovery to assess for post-operative pharyngeal pain

GANTT CHART


Activity
Sep 17
Oct - Nov 17
Dec 17 - May 18
June - Nov 18
Dec 18
Jan 19
Feb - Mar 19
Apr 19
May - Jun 19
Oct 19
Proposal presentation
Quotation from LMA company
Proposal editing and submission
Preparing research materials
Data collection
Data entry
Data analysis
Study write up
Preliminary report
Final report presentation
Thesis submission

DATA COLLECTION SHEET

Study No: **Contact no:**

1. **Demographic Data:**

Name:

Age: Gender: Male / Female

RN: ASA: I / II / III

Weight: _____ kg Height: _____ cm

Diagnosis:

Operation:

2. **Please circle the supraglottic airway device (SGA) used:**

LMA Supreme™ / LMA Protector™ *Cuff Pilot*™

3. **Duration of Insertion**

Time	**Attempt No. 1**	**Attempt No. 2**	**Attempt No. 3**
Duration (seconds)			

4. **Laryngeal view grade: _____**

5. **Oropharyngeal Leak Pressure (OLP): _____** cmH_2O

6. **Gastric tube insertion attempt(s): _____**

7. **Total anaesthetic time (From induction to removal of SGA): _____**

8. **Postoperative Data**

a) Presence of blood stain on the SGA after removal: Yes / No

b) Pharyngeal pain within 6 hours post op: Yes / No

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SIMPLIFIED AIRWAY RISK INDEX (SARI)

(El-Ganzouri *et. al.*, 1996)

Assessment	**0 point**	**1 point**	**2 points**
Interincisor gap	≥ 4cm	< 4 cm	
Thyromental distance	> 6.5 cm	6-6.5 cm	< 6 cm
Modified Mallampati Score	I-II	III	IV
Neck Movement	> 90 º	80-90 º	< 80 º
Ability to prognath	Yes	No	
Weight	< 90 kg	90 - 110 kg	> 110 kg
History of difficult intubation	None	Questionable	Definite

Score:

< 4: unlikely to be difficult

≥ 4: likely will be difficult