**Evaluation of the clinical performance of LMA Protector in the moderately obese patients.**

Introduction

Supraglottic airway device (SGAD) is useful in obese patients, as this group of patients have a higher incidence of difficult intubation1,2. However, airway management with SGADs in obese patients can also be challenging. Managing the intra operative ventilation of obese patients with SGAD has also shown to improve lung volumes of obese patients post operatively in comparison to those intubated.3 Nevertheless, to ensure safety in using SGADs in obese patients, the SGADs should have high oral leak pressure (OLP) and have features that can ensure low risk of aspiration.

LMA protector (Teleflex Medical, Co. Westmeath, Ireland) is the latest innovation of second-generation laryngeal masks and it is FDA approved. The airway tube and cuff of the LMA Protector are made of medical grade silicone. It also has an enlarged air-inflatable cuff with an anatomically shaped tube, enabling it to sit better in the post cricoid area, above the oesophageal sphincter. These features result in the LMA Protector yielding a high OLP. 4 In addition, it has dual gastric channels that emerge as separate ports proximally. A suction tube can be attached to the male drainage port around the laryngeal region or a well-lubricated gastric tube may be passed through the female drainage port to the stomach. The high OLP combined with the dual gastric ports should offer better protection from aspiration for patients.

Currently, there is paucity in studies using SGADs in obese patients. In this preliminary observational study we would like to assess the clinical performance of the LMA protector in the moderately obese patients (30 kg/m2≤ BMI≤35kg/m2).

Methodology

After approval from the hospital’s Institutional Review Board, we will recruit a total of 30 patients scheduled for elective surgical procedures under general anaesthesia that are amenable to supraglottic airway management in our tertiary hospital. We will include patients who are moderately obese (30 kg/m2≤ BMI ≤ 35 kg/m2) and will exclude patients of ASA physical status IV, at high risk of regurgitation or aspiration for example those with symptomatic gastro-esophageal reflux, hiatus hernia, respiratory tract pathology eg. preoperative sore throat, patients with previous head and neck surgery with deformity or radiotherapy to the neck with hypopharyngeal involvement, and patients with inadequate mouth opening to permit insertion of device.

Patients are not premedicated. They are positioned supine on the operating table, with the head resting on a head ring. Standard monitoring will be instituted before induction of anaesthesia, for example, pulse oximetry, electrocardiograph and non-invasive blood pressure. Pre-oxygenation is carried out with high flow oxygen for three minutes prior to induction of anaesthesia.

The LMA Protector cuff is completely deflated and a water-based lubricant is applied to the posterior part of cuff and airway tube. The LMA protector size 4 is utilized for all subjects. After pre-oxygenation, anaesthesia will be induced with fentanyl 1.5 to 2 mcg/kg, propofol 2 to 3 mg/kg and anaesthesia maintained with sevoflurane (end tidal concentration of 2 to 3%) in oxygen until the jaw is considered relaxed at the discretion of the investigators. Neuromuscular blockade is used if indicated. Under direct vision, the tip of the device is pressed flat against the hard palate and the LMA Protector is inserted until definite resistance is felt.The cuff is then inflated with air until the marker of the pilot balloon sits within the green zone (indicative of 40-60cmH20) with an upper limit of clear zone pressures of not more than 70cmH20). The amount of air to achieve this will be recorded, and the intra-cuff pressure is doubly confirmed with a handheld aneroid manometer (Portex® Pressure Gauge; Smiths Medical Intl Ltd, Kent, UK) to achieve an intra-cuff pressure of 60cmH2O.

The appearance of the first square end-tidal carbon dioxide (ETCO2) trace denotes successful establishment of effective ventilation. Otherwise, the device is completely removed for another insertion attempt. Three insertion attempts are allowed. Each “attempt” is defined as re-insertion of the airway device into the mouth. We define “insertion failure” of the device as one comprising >3 unsuccessful attempts or if the entire process of insertion exceeds 120 seconds. This includes the time the airway device is removed from the mouth and any bag-mask ventilation in between. In case of failure to insert the LMA Protector, the airway will be secured according to the decision of the attending anaesthesiologist.

Once the airway device is in place, the tube is fixed by taping over the patient’s cheek. A gel plug is placed in the proximal one centimeter of the male gastric drain outlet whilst closing the female port of the gastric drain and the suprasternal notch test is done to confirm placement (gently tapping the suprasternal notch causes the gel to pulsate, confirming the tip location behind the cricoid cartilage). Then, a 14 French gauge gastric tube is inserted through the female port gastric drain. These gastric tubes are pre-lubricated with a water-soluble lubricant. Ease of insertion was graded 1 to 3 (1-easy, 2-difficult, 3-impossible). Time to insertion of the gastric catheter will also be noted. Confirmation of correct placement of the gastric catheter is through detection of injected air by auscultation of epigastrium, and aspiration of gastric contents. Gastric decompression is done and the amount of gastric fluid aspirated is noted, and will be checked against fasting duration.

The anatomical airway position of the LMA Protector is then assessed by fiberoptic examination via the airway channel and scored as follows: 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 [3].

The oropharyngeal leak pressure (OLP) is 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 is an audible air leak from the throat. Maximum pressure allowed is 40 cm H20. The epigastrium is also auscultated when measuring the OLP to detect any air entrainment in the stomach.

We record the number of insertion attempts and time to establish effective ventilation (interval from when the LMA Protector enters the mouth to first ETCO2 trace), the ease of insertion of airway, subjectively assessed on a 5 point scale (1= easy, 2 = not so easy, 3 = difficult, 4= very difficult, 5= impossible), blood pressure and heart rate every minute for the first five minutes from induction of anaesthesia, manoeuvers required to optimize positioning or ventilation with the airway devices: adjusting head and neck position, depth of insertion, applying jaw lift, and changing device size. Maintenance of anaesthesia is achieved with an oxygen: air mixture in sevoflurane 1-2 MAC. The airway device is removed upon return of spontaneous breathing and eye opening of the patient. The airway device is then inspected for presence of visible blood. Forty five minutes later, an independent observer will assess patients for post-operative sore throat, dysphonia or dysphagia.

All airway insertions were performed by experienced staff anaesthesiologists with >10 year experience with supraglottic airway management, who had perfomed at least 10 insertions LMA protector prior to trial commencement. 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 the same investigator.

**Statistical analysis**

Data will be analysed by using SPSS xxx TM (SPSS Inc., Chicago, IL, USA). We used means and standard deviation to describe continuous data; median, interquartile ranges (IQR) and ranges for non-parametric data; and percent- ages for categorical data

References:

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