

Original Research Article

Comparison between the Use of LMA™ and SLIPA™ in Patients Undergoing Minor Surgeries.

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Abstract

Supraglottic airway devices have been used as safe alternatives to endotracheal intubation in appropriate types of surgery. This was a prospective, randomised, single blind study comparing the use of LMA™ and SLIPA™ in terms of ease of insertion, haemodynamic changes and occurrence of adverse effects (e.g. blood stains on the device upon removal and sore throat). A total of 62 ASA I or II patients, aged between 18 to 70 years were recruited for this study. Patients were randomised into two groups; LMA™ and SLIPA™ group. Following induction of anaesthesia, an appropriate sized LMA™ or SLIPA™ was inserted after ensuring adequate depth of anaesthesia. Anaesthesia was maintained with oxygen, nitrous oxide and sevoflurane. The ease of insertion was graded and haemodynamic changes were recorded at 2 minute intervals up to 10 minutes after insertion of the airway devices. The presence of blood stains upon airway device removal at the end of surgery and incidence of sore throat was also recorded. No difficult insertion was experienced in either of these devices. Insertion was either easy [LMA™ 87.1% versus SLIPA™ 80.6% ($p = 0.49$)] or moderate [LMA™ 12.9% versus SLIPA™ 19.4% ($p = 0.16$)]. Throughout the study period, the haemodynamic changes that occurred in both groups were not statistically different. Traces of blood were noted on the surface of the device in 9.7% of patients in the SLIPA™ group versus 6.5% of patients in the LMA™ group. The incidence of sore throat was recorded in 12.9% versus 19.4% of patients in the SLIPA™ and the LMA™ groups respectively. These findings were not statistically significant. In conclusion, this study showed no significant differences between the use of LMA™ and SLIPA™ in terms of ease of insertion, haemodynamic changes and adverse effects in patients undergoing minor surgical procedures.

Keywords: LMA, SLIPA, supraglottic airway, insertion, ease, haemodynamics

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Introduction

The laryngeal mask airway (LMA™) was first introduced in United Kingdom in 1988 and in United States of America in 1992 as an alternative to the face masks (1). It has been used in most elective and outpatient surgical procedures. It has since been recognised as a valuable rescue airway tool in both adult and paediatric resuscitation especially when managing a difficult airway. It is a relatively

expensive device designed for multiple uses and as such requires time consuming maintenance procedures such as cleaning and autoclaving. The risk of cross-infection still remains despite cleaning and autoclaving of the airway device after use (2).

The Streamlined Liner of Pharyngeal Airway, SLIPA Medical Ltd., UK (SLIPA™) made of soft plastic is designed for single use and has the potential to replace the LMA™ (3). It is a hollow, preformed,

boot-shaped airway which anatomically engages in the pharynx and palate (4). The SLIPA™ is designed without an inflatable cuff as its shape resembles the anatomy of the pharynx closely (5). The risk of pulmonary aspiration is reduced by the presence of a 50 ml empty internal space within the device which allows removal of pharyngeal secretions (3). Insertion of the device can be done without the assistance of other devices and it is relatively cheaper than the LMA™ (6, 7). In Europe in 2008, the estimated cost of a single use LMA™ and SLIPA™ was about £80 (MYR520) and £2.80 (MYR18.20), respectively (7).

Many clinical studies and researches have been conducted on various supraglottic airway devices in the United States of America, United Kingdom, Europe, Australia, India, Korea, Japan and Saudi Arabia to assess their clinical uses, efficacy and safety for both anaesthetic as well as emergency airway management (4, 7-13). They concluded that the ease of insertion, haemodynamic changes, seal pressure, and gastric insufflation were comparable for both SLIPA™ and LMA™ supraglottic airway devices (9-11).

Over the past five years, the number of countries using the SLIPA™ has grown dramatically. This is due to its simplicity and ease of use. The use of SLIPA™ in Malaysia is still relatively new as it is not readily available in the country. Therefore, there is lack of familiarity of the device amongst Malaysian health care providers. So far, there are no studies published locally on its usage and efficacy.

This study was conducted to compare the use of LMA™ and SLIPA™ in terms of ease of insertion, haemodynamic changes and occurrence of adverse effects (traces of blood on the airway device upon removal and sore throat after surgery) in patients undergoing minor surgical procedures.

Materials and Methods

This was a prospective, randomised, single blind study. Following institutional ethics committee approval and obtaining informed consent, 62 patients were recruited with American Society of Anaesthesiologists (ASA) physical status I or II aged between 18 to 70 years who were scheduled for elective minor Orthopaedic, Gynaecological and General Surgical procedures under general anaesthesia in which the anticipated duration of surgery was less than two hours. Patients excluded were those with risk of pulmonary aspiration, morbid obesity (body mass index $> 35 \text{ kg/m}^2$), pregnancy,

history of gastro-oesophageal reflux, hiatus hernia, potential airway difficulty, pre-operative upper respiratory tract infection in the last 2 weeks and procedures involving the airway. Patients were fasted for at least 6 hours prior to surgery. Oral midazolam 3.75 - 7.5 mg, depending on age and weight of the patient, was given as night sedation as well as premedication prior to sending patients to the operation theatre. All device insertions were performed by a single investigator who had at least 5 years experience in using the LMA™ and had used the SLIPA™ at least 10 times before the study was initiated. Postoperative assessment was carried out by blinded independent observers in the recovery bay.

Patients were allocated using computer generated randomised numbers to one of two groups, the LMA™ group and SLIPA™ group. The appropriate size of the LMA™ was chosen according to standard practice i.e. according to body weight (size range from 3-5), whereas the size of SLIPA™ was chosen by matching the gender and height of the patient with the predetermined size from the manufacturer's guide (size range from 47-57). Water-based lubricant (K-Y jelly) was used for both devices. Standard monitoring for all patients included the electrocardiograph, non-invasive blood pressure monitor, pulse oximeter and capnograph. Pre-oxygenation was done with 100% oxygen for 3 minutes after which patients were induced with fentanyl (2 mcg/kg), propofol (2-3 mg/kg) and deepened with sevoflurane. Patients were not paralysed in this study. The respective supraglottic airway device was introduced into the pharynx after adequate anaesthetic depth had been achieved and this was confirmed by clinical assessment and on reaching a minimal alveolar concentration (MAC) value of 1. If the LMA™ was used, the cuff was inflated according to the manufacturer's guideline (1) after successful placement. Successful placement of the airway device, was verified by sufficient ventilation (8-10 ml/kg), $\text{SpO}_2 > 95\%$ and normal readings (35-45 mmHg) on the capnograph. Another 10 ml of air was added if substantial leakage occurred despite optimal placement of the LMA™. If the SLIPA™ was selected, a similar technique as the LMA™ was used for insertion into the pharynx. Following correct placement, patients were connected to a breathing circuit and initially given assisted ventilation. Subsequently, patients were allowed to breath spontaneously throughout the duration of anaesthesia.

Ease of insertion was rated as "easy", if successful placement was made at the first attempt within 15 seconds. If the first attempt was unsuccessful, mask

Table 1: Demographic data, values expressed as mean \pm SD or numbers where appropriate.

	Group LMA™ (n=31)	Group SLIPA™ (n=31)
Age (years)	43.8 \pm 15.5	46.0 \pm 15.9
Height (m)	157.1 \pm 4.5	158.2 \pm 3.9
Weight (kg)	58.2 \pm 5.5	60.1 \pm 5.6
BMI (kg/m ²)	23.5 \pm 1.5	24.0 \pm 1.7
Gender: Male/Female	13/18	15/16
ASA: I/II	17/14	21/10
Race: Malay/Chinese/Indian	14/12/5	15/13/3

ventilation was resumed and adequate anaesthetic depth re-established before subsequent attempts. Subsequently, ease of insertion was rated as “moderate” with successful placement at the second attempt; “difficult” with successful placement at the third attempt. If the third attempt failed, it would be rated as “impossible”; patients would then be intubated and excluded from the study. Anaesthesia was maintained with a mixture of oxygen and nitrous oxide (50% / 50%) at a flow rate of 2 L/min and 1-2% sevoflurane to maintain a MAC of 1. The haemodynamic parameters [heart rate (HR), systolic (SBP), diastolic (DBP) and mean arterial pressure (MAP)] were recorded at pre-induction and at 2 minute intervals for the first 10 minutes after insertion of the supraglottic devices.

At the end of the operation, the airway device was removed when spontaneous tidal volume reached a minimum of 8 ml/kg and the patient responded to verbal command. Upon removal, the airway device was inspected for traces of blood on its surface. Thirty minutes after arrival in the recovery bay, patients were interviewed by independent observers to determine whether they had a sore throat. A visual analog scale (VAS) from 0-10 was used to rate the severity of the sore throat [score of 1-3 (mild); 4-5 (moderate) and > 5 (severe sore throat)].

Sample size in this study was chosen based on similar studies done earlier (3, 7). The α value was determined at 0.05 and power of study at 80%. Using the power and sample size calculator, PS2, a sample size of 26 in each arm was obtained. Allowing for a 20% drop out rate, the total sample size determined was 62.

Table 2: Ease of insertion of both devices, values expressed in number (percentage).

	LMA™ (n=31)	SLIPA™ (n=31)	<i>p</i> value
Easy	27 (87.1)	25 (80.6)	0.49
Moderate	4 (12.9)	6 (19.4)	0.16
Difficult	0	0	
Impossible	0	0	
Success rate	100%	100%	

Data analysis was done using SPSS 13 for WINDOWS (LEAD Technologies, Inc. USA). Student’s t-test was used to analyse demographic data such as age, weight, height, body mass index (BMI), gender and ASA group. Qualitative data such as ease of insertion, heart rate, blood pressure, presence of blood on the airway device and sore throat was analysed by the Chi-square test. Analysis of variance (ANOVA) was used to compare blood pressure, oxygen saturation and heart rates between both groups. Statistical significance was considered with a *p* value of < 0.05.

Results

A total of 62 patients who underwent elective minor surgery under general anaesthesia were studied and randomly assigned into 2 groups. Thirty one patients received the LMA™ while another thirty one received

SLIPA™ as an airway device during general anaesthesia. Both groups were comparable in terms of demographic data as illustrated in Table I.

There was no significant statistical difference experienced between the two devices in terms of ease of insertion as shown in Table II.

Throughout the study period, no significant differences were detected between pre-induction and post-induction haemodynamic changes (heart rate, systolic, diastolic and mean arterial pressure) in both groups as shown in Figure 1, Figure 2, Figure 3 and Figure 4. .

Traces of blood were noted on the surface of the device in 6.5% (n=2) versus 9.7% (n=3) in the LMA™ and the SLIPA™ groups, respectively. Sore throat was complained in 19.4% (n=6) of the LMA™ group versus 12.9% (n=4) in the SLIPA™ group. Only mild sore throat (VAS 1-3) was reported in all patients that complained of this adverse effect. However, these incidences of adverse effects were found not to be statistical significant in both groups.

Discussion

In our study, placement of the device was easy in 27 patients (87.1%) in the LMA™ group and in 25 patients (80.6%) in the SLIPA™ group. All second attempts on placement of the device were successful in both groups. First insertion success rates have been reported to range between 73.3% - 98% in inserting the SLIPA™ versus 90% - 100% for the LMA™ among experienced anesthetists in previous studies (3, 4, 10, 13). Meanwhile, a study conducted on medical students with no experience on SLIPA™ or LMA™ demonstrated that the first insertion success rate was 83% and 67% with an overall success rate 94% and 89% for SLIPA™ and the SoftSeal Laryngeal Mask, respectively (14). The variation in the results may be due to the relative experience of the anesthesiologist who inserted the airway and the appropriate size of the SLIPA™ chosen. For a successful insertion, correct size selection is important because SLIPA™ comes in a fixed preformed shape and six adult sizes (47-57). SLIPA™ size was selected in previous studies by matching the patient's thyroid cartilage with the transverse diameter of the device (3, 7, 8, 10). In this study, we followed the size selection guideline which involved gender and height as recommended by the SLIPA™ manufacturer. However the range of size selection can be too wide and often found to be overlapping. Selecting the right size on the first attempt can be difficult. The development of guidelines for SLIPA™ size selection

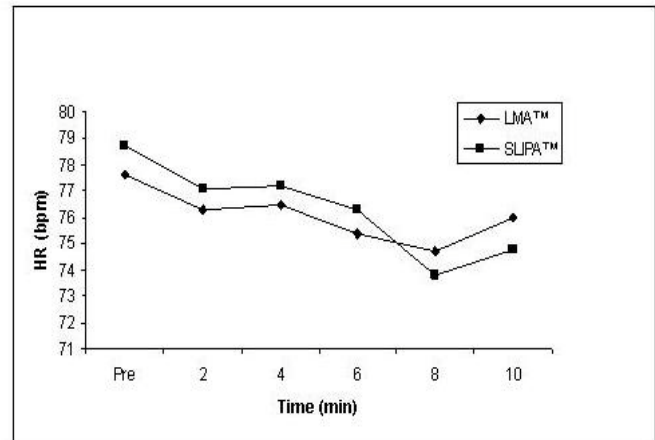


Figure 1: Changes in heart rate (HR) at different time intervals of both devices.

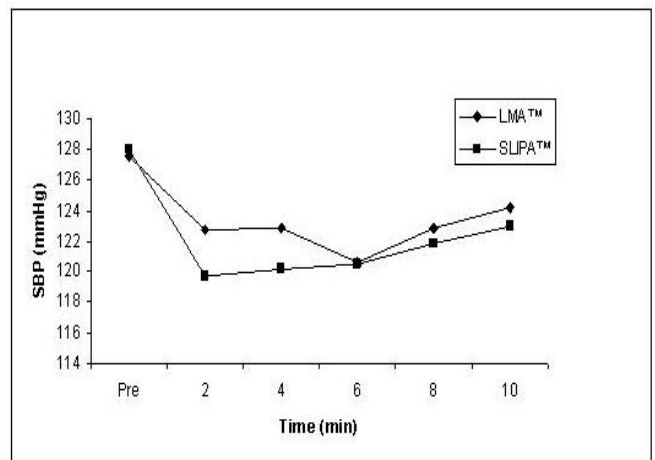


Figure 2: Systolic blood pressure (SBP) at different time intervals of both devices

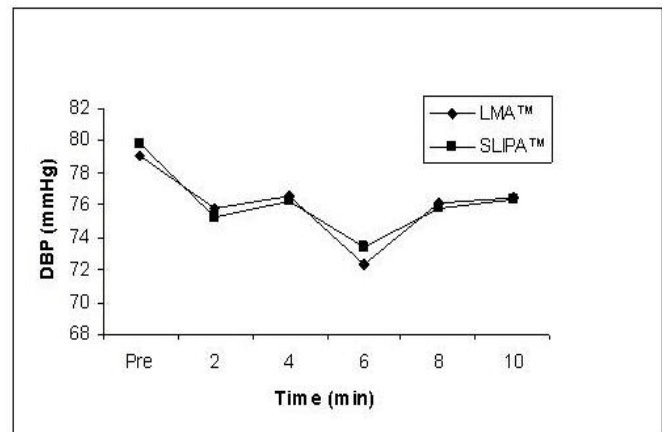


Figure 3: Diastolic blood pressure (DBP) at different time intervals of both devices.

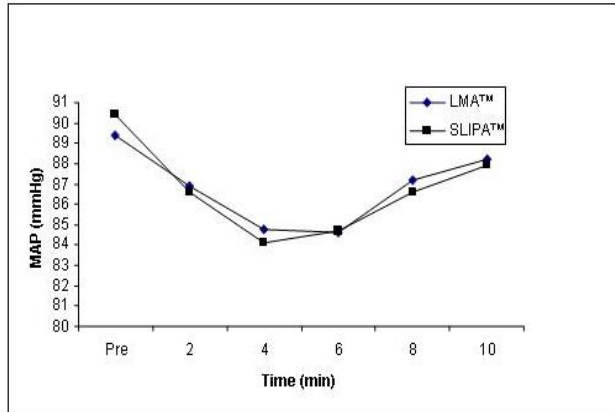


Figure 4: Mean arterial pressure (MAP) at different time intervals of both devices.

amongst the Asian population is therefore recommended.

One benefit of using a supraglottic airway device is that it does not require the use of a laryngoscope during insertion, thus avoiding direct stimulation of the larynx and trachea. During endotracheal intubation, a brief temporary increase of heart rate and blood pressure with possibility of developing arrhythmias may occur caused by stimulation to the upper airway caused by the laryngoscope blade, to the tracheal intubation itself and cuff inflation of the endotracheal tube (12). In this study, there was no significant difference between the two groups in terms of haemodynamic changes (HR, SBP, DBP and MAP) after insertion of the device. Interestingly, a study has reported that with SLIPA™ use, blood pressure and heart rate increased more compared to the LMA™ (7), but this difference was not as marked as that observed between endotracheal intubation and LMA™ insertion (12). We postulate that a reduction in insertion time and a more stable haemodynamic response may be achieved with the correct SLIPA™ size selection and insertion technique.

In this study, patients in the SLIPA™ group had a slightly higher incidence of blood stains (9.7%) compared to those in the LMA™ (6.5%) group after removal of the airway devices, however this was not statistically significant. Reinsertion of SLIPA™ was associated with blood stained devices in all 3 patients, suggesting that SLIPA™ has the potential to cause more trauma with more than one insertion attempt. Incidence of blood traces on the SLIPA device has been found to range between 20% - 40% in previous studies as compared to 11% - 22% in the LMA group (4, 10, 15). The SLIPA™ device is made of stiffer plastic material than the LMA™, which causes more direct trauma to the oral mucosa. The following

manoeuvres have been suggested to help improve on ease of insertion and to reduce trauma: assisted insertion by an assistant holding up the jaw or by creating a more suitable space in the pharynx with the use of a laryngoscope or by using a gloved left thumb with either the middle or index finger (3).

In our study, the incidence of sore throat was lower in the SLIPA™ (12.9%) group compared with the LMA™ (19.4%) group, however this was not found to be statistically significant. We did not standardise other factors such as intraoperative analgesia used for example intravenous morphine or parecoxib which may reduce the incidence of sore throat postoperatively. Sore throat assessed by the VAS score may also be very subjective. Similarly, another study (10) also reported fewer patients in the SLIPA™ group (2%) who complained of sore throat compared with those in LMA™ group (14%). This higher incidence of sore throat in the LMA™ group could be due to the inflatable cuff of the LMA™ exerting pressure on the pharynx. Even so, in most studies conducted, the use of SLIPA™ was associated with a higher incidence of sore throat which could be attributable to its stiff material which could irritate and damage the pharyngeal mucosa (4).

There were a few limitations in our study. As it was impossible to 'blind' the primary investigator who inserted the airway devices, the potential for bias exists. Maximum airway sealing pressures were not measured comparing both devices to evaluate which device provided higher airway sealing pressures. Theoretically, supraglottic airway devices with higher sealing pressures should be able to protect the airway from aspiration better than those with low sealing pressures. In this study, we did not insert a fiberoptic bronchoscope through the airway port to evaluate the glottic view to assess appropriate placement of the airway devices. Lastly, as we excluded obese patients and those with a difficult airway, the results cannot be extrapolated to this group of patients.

In conclusion, this study showed no significant differences between the use of LMA™ and SLIPA™ in terms of ease of insertion, haemodynamic changes and adverse effects (traces of blood on the airway device and sore throat) in patients undergoing minor surgical procedures.

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