

Comparative Study of laryngeal mask airway Supreme and laryngeal mask airway Classic in paralyzed patients

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Abstract

Aim and Objectives: The present study was undertaken to compare the LMA Classic with LMA Supreme in assessing the ease of insertion, number of attempts, time for insertion, any unwanted responses, stability of device, peak airway pressure, leak volume and leak fraction and postoperative complications.

Methods: A total of 274 patients of ASA grade 1 and 2 were included in the study and divided into two groups with 137 patients in each group: the LMA Classic group (group C) and LMA Supreme group (group S). All patients were induced with propofol 2.5 mg/kg and atracurium 0.5 mg/kg after that appropriate sized supraglottic airway device was inserted. The ease of insertion, number of attempts, duration of insertion, stability of device, peak airway pressure, leak volume and leak fraction and postoperative complications were recorded.

Results: The insertion of Supreme LMA was very easy in 134 patients and was easy in 3 patients, difficult in 0 patients while the insertion of Classic LMA was very easy in 122 patients, easy in 15 patients and difficult in 0 patients. The first attempt insertion rate was more with Supreme LMA as compared to Classic LMA. The mean duration of insertion was significantly lower with Supreme LMA than with Classic LMA. The mean airway pressure was similar in both groups. Both devices were stable. Leak volume and Leak fraction was significantly higher in Classic LMA than Supreme LMA. Peri-operative complications were not significantly different between Supreme LMA and Classic LMA.

Conclusions: The LMA Supreme is superior to the LMA Classic because of its ease of insertion with lesser leak volume and leak fraction and better first attempt insertion rate.

Keywords: Laryngeal mask airway Classic, laryngeal mask airway Supreme, Insertion, Peak airway pressure, Leak volume, Leak fraction

1. Introduction

Endotracheal intubation is a rapid, simple, safe and non-surgical technique that achieves all the goals of airway management, namely maintaining airway patency, protecting the lungs from aspiration and permitting leak free ventilation. It remains the gold standard for airway management. Although endotracheal intubation has been the most widely accepted technique in anaesthetic practice, it is not without complications. Most of them arise from the need to visualize and penetrate the laryngeal opening. Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation and are associated with raised levels of plasma catecholamines which are responsible for hypertension, tachycardia, myocardial ischemia, ventricular arrhythmias and intracranial hypertension [1]. Transitory hypertension and tachycardia are probably of no consequence in healthy

individuals but, either or both may be hazardous to those with hypertension, myocardial insufficiency or cerebrovascular disease [2].

Supraglottic airway devices are now widely used for surgery requiring general anaesthesia, so as to avoid the complications associated with the endotracheal intubation. The laryngeal mask airway (LMA) is one of the most important airway devices, designed by Dr Archie Brain (UK) in 1981 and which was developed after the endotracheal tube. Since then, supraglottic airway devices have been used successfully and safely in anesthetic practice with various models, and have under-gone rapid development [3,4]. The LMA Classic (LMA North America, Inc., San Diego, California, USA), the first designed LMA model, was developed progressively. Their advantages over tracheal intubation include avoidance of visualization of laryngeal

opening and intubation, use of muscle relaxants and decreased risk of post operative sore throat. The primary limitation of the Laryngeal Mask Airway is that it does not reliably protect the lungs from regurgitated stomach contents, although it may act as barrier at the level of upper oesophageal sphincter if correctly positioned [5]. LMA supreme was introduced in late 2007. It represents the most advanced laryngeal airway yet developed by Archie Brain. It is a single use device. It has an anatomic curve that facilitates easy insertion, a drain tube to allow gastric aspiration, a built-in bite block and fixation tab to help secure the airway.

Many studies have been done to compare Classic LMA with Proseal LMA but very few studies have been done to compare the Classic LMA and Supreme LMA. Hence in present prospective study, we compared the two supraglottic airway devices Classic LMA and Supreme LMA based on their ease of insertion, number of attempts to establish a patent airway, time taken to do so, any unwanted responses, leak volume and leak fraction, airway pressures after securing the airway, intra-procedure stability of the device and incidence of post-operative bleeding and sore throat.

2. Materials and Methods

After obtaining institutional ethical committee approval and patient's written informed consent, this prospective randomized control double blind study was conducted in 274 adult (nor motensive) patients of either sex, aged between 18-60 years, ASA and Mallampatti grade 1 and 2. Patients were scheduled for various elective surgeries under general anaesthesia with controlled ventilation using Classic LMA and Supreme LMA. Surgeries having duration less than 60 minutes were included in the study. Patients having Age <18 years and >60 years, ASA and Mallampatti grade 3 and above, patients with emergency surgeries, head and neck surgeries, patients with restricted mouth opening (<1.5 cm), increased risk of aspiration, abnormal or distorted anatomy of pharynx, obese patients with BMI >28Kg/m², patients with decreased compliance of the lungs and obstruction of the airway beyond the larynx were excluded from the study. A detailed pre-anaesthetic evaluation including history and a thorough general and systemic examination and all relevant investigations were done for all the patients. Patients were kept NBM for 6 hours prior to the surgery. Tablet pantocid 40 mg was given as anti-aspiration prophylaxis at bedtime and on the morning of surgery. Tablet alprazolam 0.25 mg was given at bedtime as anti-anxiety prophylaxis. The patients were divided into two groups based on the supraglottic airway device to be used, group C for Classic and group S for Supreme LMA. Randomization was done in the operation theatre prior to starting the case with computer generated nonsequential number.

In the operation theatre standard monitoring devices ECG, Pulse Oximeter and non-invasive blood pressure were applied to the patient and baseline parameters were recorded.

An intravenous line was secured with a 20G cannula and I.V drip was started. All patients were premedicated with glycopyrolate 4 mcg/kg + fentanyl 2mcg/kg + midazolam 0.03 mg/kg 5 minutes prior to induction of anaesthesia, followed by pre-oxygenation with 100% oxygen for 3 minutes. Then anaesthesia was induced with injection propofol in a dose of 2.5 mg/kg till loss of responsiveness, after checking for ventilation injection atracurium 0.5 mg/kg given and after 3 mins, 'morning sniffing' position was given to the patient. Size 3 Supreme LMA for 30-50 kg, size 4 from 50-70 kg and size 5 from 70-100 kg and Size 3 classic LMA for 30-50 kg, size 4 from 50-70 kg and size 5 from 70-100 kg were inserted.

The grading for ease of insertion was recorded as, very easy=3 (when assistant help was not required), easy=2 (when jaw thrust was needed by assistant), difficult=1 (when jaw thrust and deep rotation or second attempt was used for proper device insertion). A failure was defined when 3 attempts to insert the device had failed. The number of attempts to insert the device was noted. After insertion of device and inflation of cuff (as per standard recommendations) circuit was connected to the 15 mm connector of the device. Capnometer was attached. On ventilation bilateral chest expansion and a square capnograph trace were confirmed for confirming a patent airway. The time from picking up of the device (LMA) to the confirmation of bilateral chest expansion and 3 square capnograph tracing obtained was recorded as the time for establishing a patent airway. Any unwanted response like coughing, gagging was recorded. The stability of the device was noted after insertion and fixation of device in head extension, flexion, lateral rotation and chin lift. Any dislodgement of the device was evaluated based on change in capnograph or sudden decrease in expired tidal volume. Instability in particular position was noted. If a device was unstable in more than one positions than it was graded unstable. The patient was then put on mechanical ventilation with a tidal volume of 7ml/kg and anaesthesia was maintained with 50-50% oxygen and nitrous oxide and sevoflurane. Five minutes after establishing a patent airway, the expired tidal volume was noted along with the airway pressure. The leak volume was then calculated as difference between inspired and expired tidal volume and leak fraction as division of leak volume by inspired tidal volume.

At the end of procedure patient was reversed with injection neostigmine 0.05 mg/kg and glycopyrolate 0.008 mg/kg. After the patient was fully awake and responding to verbal commands the device was removed in the operation theatre itself and any blood on the device was noted. Oral cavity was inspected for any oozing or visible trauma. One hour post procedure in the recovery room, the patient was asked for any sorethroat, hoarseness of voice, dysphagia, and numbness in the tongue or oral cavity.

2.1 Statistical analysis

Data analysis was done with the help of SPSS Software version 15 and Sigma plot version 12. Quantitative data was presented as Mean±SD, Median and IQR. Study groups were compared by performing Unpaired T test or Mann-Whitney test as per results of Normality test. Qualitative data was presented as Frequency and Percentage, association among study group was assessed with the help of Chi-Square test and Fisher Exact test for 2×2 tables. P value less than 0.05 was taken as significant level.

3. Observations and Results

Demographic profiles of the patients and mean duration of surgical procedures were comparable in both the groups and difference was statistically not significant (p >0.05),(Table 1).

Table- 1: Showing demographic data and duration of surgery between two groups

Variable	Group C	Group S	P Value
Age (years)	43.59±9.99	43.33±9.32	0.143
Body mass index (kg/m ²)	22.06 ± 2.60	21.74 ± 3.25	0.406
Sex (Male/Female)	75/62	84/53	0.271
Duration of surgery (Min)	45 ± 6.97	50 ± 5.50	0.379

Table 2 show the results obtained in current study. The insertion of Supreme LMA was very easy (3) in 134 patients and was easy (2) in 3 patients and difficult in 0 patients while insertion of Classic LMA was very easy (3) in 122 patients, easy (2) in 15 patients and difficult in 0 patients, (p<0.05). 86.1% (118) insertion in group C was in the first attempt and only 13.8% (19) patient required second attempt whereas 98.5% (135) insertion in group S was in the first attempt and only 1.4% (2) patient required second attempt for insertion and difference was found to be statistically highly significant (p=0.000). The mean duration of insertion of Classic LMA in group C and Supreme LMA in group S were 29.79 ± 9.88 and 26.66 ± 5.55 seconds respectively and was statistically significant, (p=0.001). Unwanted response such as coughing and gagging were noted in 4 patients in group C and 2 patients in group S, (p >0.05). In group C the device was stable in 95.6% patients and was not stable in 4.4% of patients while in group S the device was stable in 98.5% patients and was not stable in 1.5% of patients, (p >0.05). The median of peak airway pressure was similar in both groups i.e. 18 cm of H₂O. The mean oropharyngeal leak volume with Classic LMA in group C was 4.69 ± 16.124 ml and with Supreme LMA in group S patient was 0.72 ± 4.158 ml and was highly significant (p=0.000). The mean oropharyngeal leak fraction with Classic LMA in group C was 0.01 ± 0.04 and with Supreme LMA in group S patient was 0.00 ± 0.01 and was highly significant (p=0.000).

Table 2: Showing the results obtained in the present study

Variable	Group C	Group S
Ease of insertion(3/2/1)	(122/15/0)	(134/3/0)
Number of attempts(1/2/3)	(118/19/0)	(135/2/0)
mean duration of insertion	29.79 ± 9.88	26.66 ± 5.55
Unwanted responses	4	2
Stability of device	131	135
Mean airway pressure(cm of H ₂ O)	18.36	18.34
Mean Oropharyngeal leak volume (ml)	4.69 ± 16.124	0.72 ± 4.158
Mean Oropharyngeal leak fraction	0.01 ± 0.04	0.00 ± 0.01

Two cases in the Classic LMA group had blood stain on the device on removal while only 1 case had blood stain on the device in Supreme LMA group. Only 2 patients in group S had developed sore throat postoperatively compared to 7 patients in group C. 2 patient in the group C and no patient in group S developed postoperative dysphagia. None of the patient in both the groups developed postoperatively lip and dental injuries, laryngospasm and numbness of tongue or oropharynx. The incidence of postoperative complications was found to be statistically not significant.

4. Discussion

One of the primary objectives of our study was to compare the ease of insertion between the two devices. The grading of insertion was done similar to the study conducted by Siddiqui *et al* [6]. The insertion of Classic LMA in group C was graded very easy (score-3) in 122 patients and was easy (score-2) in 15 patients. The insertion of Supreme LMA in group S was graded very easy (score-3) in 134 patients and easy (score-2) in 3 patients. The ease of insertion was statistically significant between the two groups. Our findings were comparing with the study of Chew *et al* [7], Trevisanuto D *et al* [8] and Jankiraman *et al* [9]. The first attempt insertion rate was more with Supreme LMA (98.5%) as compared to Classic LMA (86.1%). Second attempt insertion rate for LMA Classic was 13.9% and 1.5% in LMA Supreme group. Results of our study were correlated with different studies [10-14]. In current study all three overall failed insertion and six of the nine failed first attempt insertion occurred during the insertion of Supreme LMA, suggested that the order of insertion and inadequate depth of anaesthesia may have contributed to likelihood of failure however there was no physiological response to insertion during any of the failed attempts. Supreme LMA having anatomic curve of airway tube, a thin wedge shaped leading edge and patented lateral grooves on the airway tube facilitates easy insertion and prevents kinking and thus leading to decrease number of insertion attempts in Supreme LMA as compared to Classic LMA.

The time of insertion was considered according to the study conducted by Chew *et al* [7] the time from picking up the device to obtaining the end tidal CO₂ trace. In our study, the insertion time for both LMA was similar i.e. 26.24 seconds for Classic LMA and 26.19 seconds for LMA Supreme. These findings compare with various studies [7, 10,15-17].

The unwanted responses like coughing, gagging during insertion were lesser in the Supreme LMA group than the Classic LMA group though not statistically significant. In the Supreme LMA group 1.5% patients had unwanted responses, while in case of Classic LMA 2.9% patients had such responses ($p=0.409$). This unwanted response was overcome by deepening the level of anaesthesia with bolus dose of propofol. Unwanted responses are most commonly due to inadequate depth of anaesthesia. Also could be indirectly related to the cuff volume and hence the pressure exerted by the cuff on the pharyngeal mucosal surface [18]. The incidence of unwanted responses was compare with study of Brimacombe *et al* [18], Gopinathan *et al* [19] and Taheri *et al* [20]. We found that Supreme LMA was more stable compared to Classic LMA though it was not statistically significant. There were 2 devices, which were unstable in the Supreme LMA group while 6 devices were unstable in the Classic LMA group. This could be because of design of the Supreme LMA. It has a built in bite block, fixation tab to help secure the airway and oval airway cross section which contributes to its stability.

The mean of peak airway pressure for Supreme LMA was 18.34 cm of H₂O while that for Classic LMA was 18.36 cm of H₂O and difference was not statistically significant. This finding was compare with different studies [10,21,22]. The herniation of the LMA cuff could contribute to the higher peak pressures in LMA. This was correspondence with the study of Marc Wronbel *et al* [23]. This study assumed that fatigue of material due to repeated sterilization could be mostly likely cause of herniation. As Supreme LMA is a single use device there are less chances of herniation as compared to Classic LMA.

When the LMA was designed as a supraglottic airway device its use initially was limited to spontaneous ventilation [24]. But later it was used for positive pressure ventilation. In our study the tidal volume was set at 7ml/kg. The expired tidal volume was noted and the leak volume determined. The leak fraction was calculated by dividing the leak volume by the inspired tidal volume. We have standardized the tidal volume while in some studies the airway pressure has been standardized. The mean leak volume for Supreme LMA was 0.72 ml and for Classic LMA was 4.69 ml and mean leak fraction for Supreme LMA was 0.00 and for Classic LMA group was 0.01, difference was statistically significant. LMA Supreme has a high volume and low pressure cuff which generates higher seal pressure and

decrease leak volume and leak fraction as compare to LMA Classic.

In our study, the patients were inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery. None of the patient from both group had an incidence of lip and dental injury during LMA insertion or in postoperative period. Also none of the patient from both group developed numbness of tongue or the oropharynx post-operative period. One case in Supreme LMA group had blood stain on the device on removal while there were 2 cases of blood staining in Classic LMA group, $p>0.05$. Our results compare with different studies [25-27]. Theoretically, when the cuff pressure is higher than the pharyngeal mucosal capillary perfusion pressure of the LMA-inserted patients, mucosal blood flow reduces and direct tissue trauma occurs. In the histopathologic studies performed on dogs by Martin *et al* [25], the authors reported that high LMA cuff pressure caused minor changes to the laryngopharyngeal mucosa. These minor laryngopharyngeal injuries may explain the patients' complaints of sore throat, hoarseness and dysphagia. We asked the patient for any sorethroat or hoarseness of voice one hour post procedure in the recovery room. Only two patients (1.5%) in LMA Supreme group and seven patients (5.1%) in LMA Classic group developed sore throat in postoperative period, this was not statistically significant. Zero patient in LMA Supreme group and two (1.5%) patients in LMA Classic group developed dysphagia and P values were not statistically significant. Our findings compare with previous studies [7, 21, 28-32]. In our study not a single patient from both group developed laryngospasm. One of the causes of laryngospasm is light plane of anaesthesia. These findings compare with studies of Chew *et al* [7] and Timmermann *et al* [13].

There are some limitations of the study which include- 1. Firstly we studied only low risk patients (ASA 1 and ASA 2) who had normal airways and were mostly not obese. 2. We did not compare performance with likely competitors of the Supreme LMA such as Proseal LMA. 3. Drawback of our study is that, for calculation of leak fraction, we have standardized the tidal volume as 7ml/kg and recorded the corresponding airway pressures. Some of the comparative studies have standardized the airway pressures to check for the leak fraction. 4. The study was conducted in paralyzed patients; hence our findings may be less applicable to spontaneously breathing patients. 5. Both devices were inserted by a single experienced user. Therefore results may not be applicable to inexperienced user. Further studies are needed to assess ease of insertion and first time insertion success rate by novice users, as supraglottic airways are incorporated in the difficult airway management protocol.

5. Conclusion

Classic LMA and Supreme LMA can be used safely and effectively during general anaesthesia with positive pressure ventilation in selected patients. Supreme LMA insertion was faster and easier than Classic LMA. The Supreme LMA provides a lesser leak volume and leak fraction as compared to Classic LMA. Even first attempt insertion rate of Supreme LMA better than Classic LMA. Post-operative Complications were not significantly different between Classic LMA and Supreme LMA.

From the observations of the present study, it may be concluded that the LMA Supreme is superior to the LMA Classic.

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