Comparison between Classic™ LMA and AMBU® Auraonce™ LMA in Patients Undergoing General Anaesthesia for Short Surgical Procedures

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Research Article

ABSTRACT

Background: Both Classical and AMBU® Auraonce™ LMA act as an alternate to endotracheal intubation and standard mask anaesthesia in general anaesthesia. Newer devices are being developed to increase the ease of the insertion and reduce the complications.

Methodology: This study was undertaken to compare the ease of insertion, intracuff pressure and oropharyngeal leak pressure between the Classic™ LMA and AMBU® Auraonce™ LMA with 50 patients in each group.

Results: In Group A the time for insertion ranged from 5 s to 40 s and in Group C it ranged from 8 s to 70 s. In Group A in 43 patients the LMA was inserted in first attempt and in 7 patients the LMA was inserted in second attempt while in Group C the LMA was inserted in first attempt in 36 patients, in second attempt in 11 patients, in three attempts in 3 patients. The oropharyngeal leak pressure in Group A ranged from 18 to 28 mm Hg and in Group C the oropharyngeal leak pressure ranged from 12 to 19 mm Hg. The mean cuff pressure in Classical LMA rose from 59.96 cm H\textsubscript{2}O to 86.73 cm H\textsubscript{2}O, whereas in AMBU LMA raised from 55.06 cm H\textsubscript{2}O to 80.92 cm H\textsubscript{2}O.

Conclusion: Time needed and number of attempts for AMBU LMA insertion was significantly less than classical LMA. Oropharyngeal leak pressure was significantly higher in AMBU LMA group which shows that AMBU LMA has less oropharyngeal leak. The intracuff pressure changed significantly in classical LMA compared to AMBU LMA, with more complications.

Keywords: Classic™ LMA, AMBU® Auraonce™ LMA, Intracuff pressure, Oropharyngeal leak pressure

INTRODUCTION

Recently many devices have been introduced for intubation and maintenance of airway in an unconscious patient and for general anaesthesia. An alternate airway device to endotracheal intubation and standard mask anaesthesia in general anaesthesia is Laryngeal mask airway (LMA) [1-3]. LMA, when inserted at the inlet of the larynx at hypo pharynx without intubating it forms a airtight seal which allows spontaneous or positive pressure ventilation [1-3].

Classic™ LMA is an autoclavable, reusable LMA, which consists of an airway tube connected to an inflatable mask with silicon rim which has high chances of transmission of infection like prion disease [3-5]. The AMBU® AuraOnce™ LMA is a single use disposable LMA with a rigid curve in the main tube which replicates the human anatomical airway to better confirm to the oropharyngeal anatomy with extra soft 0.4 mm PVC cuff with lesser internal pressure [6]. Hence the present clinical study was undertaken to compare the ease of insertion between classical and AuraOnce™ LMA, changes in intra cuff pressure and oropharyngeal leak pressure.
METHODOLOGY

A study was undertaken at our medical college hospital during the study period of 36 months January 2013 to January 2016 after clearance from institutional review board clearance and informed consent from the patients.

100 patients aged 18 to 65 years who were ASA Grade I and Grade II posted for short duration surgeries like Breast biopsy, excision of fibro adenoma breast, Wound debridement, Burns dressing, cervical node biopsy, Dilatation & curettage, Free split skin graft, Hysteroscopy, DJ stent removal were included.

Patients with difficult airway, obese and ASA grade 3, 4 were excluded from the study.

The study population was randomly divided into two groups with 50 patients in each group by simple randomization using random number table. Group C (n=50) were inserted classical LMA while Group A (n=50) were inserted AMBU® AuraOnce™.

All patients were premedicated with oral diazepam 10 mg and pantoprazole 40 mg on the day of the surgery before shifting to the theatre. On the arrival of the patient in the operation theatre all standard monitors were connected and premedicated with fentanyl 2 µg/kg body weight. After giving preservative free Lignocaine 1 to 1.5 mg/kg body weight to decrease the pain on propofol injection, all patients were induced with propofol 2 to 4 mg/kg body weight given over 30 s and after loss of eye lash reflex and loss of jaw tone either classical LMA or AMBU® AuraOnce™ LMA was inserted by an anaesthetist who has inserted at least 50 classical LMA and 20 AMBU® AuraOnce™ LMA. The LMA was prepared by applying lignocaine gel on the dorsum of the cuff and was inserted by standard technique described by Archie Brain with time of insertion noted by stop clock. The total time of insertion was defined by the moment the device was picked up to the first end tidal side-stream CO₂ trace. After insertion, LMA was fixed by taping it to the chin and inflated with appropriate amount of air.

Correct insertion of the LMA was defined by resistance to further downward motion, chest wall movement, presence of end tidal side-stream CO₂ waveform, and movement of the reservoir bag during spontaneous ventilation. Failure to insertion was defined as more than 3 attempts for insertion. Anaesthesia was maintained with 33% O₂, 66% N₂O and 1-2% isoflurane. Intraoperative monitoring included saturation, pulse rate, electrocardiogram, end tidal carbon dioxide, temperature monitoring cuff pressure monitoring and oropharyngeal leak pressure. All the parameters were measured every 10 min.

The intracuff pressure was measured using a three-way stopcock and calibrated aneroid manometer. The oropharyngeal leak pressure was determined by manometric stability test with a fresh gas flow of 3 L/min against a closed pressure limiting valve of the anaesthetic circuit. The airway pressure was recorded when equilibrium was attained. The patients were connected to the closed circuit were allowed to breath spontaneously.

The following characters were compared between the two groups:

a) Ease of insertion measured by number of attempts taken to insert and time taken to insert.

b) Change of intracuff pressure with the duration of anaesthesia.

c) Measurement of oropharyngeal leak pressure. Isoflurane was withdrawn at the end of surgery, nitrous oxide was cut off and the patients were allowed to breath 100% oxygen. The cuff was deflated and LMA was removed under the deeper planes of anaesthesia.

Guedels airway was inserted and the Hudson’s mask was connected with 4 to 5 L of oxygen. Respiration was assessed by seeing the chest movement, saturation and by auscultation. The patients were observed in the operation theatre for 5 min and shifted to the recovery room. The patients were observed in the ICU for three hours and were supplemented with O₂.

Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta. Using this software range, frequencies, percentages, means, standard deviations, chi square and ‘p’ values were calculated. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate’s chi square test for qualitative variables. A ‘p’ value less than 0.05 was taken to denote significant relationship.

RESULTS

In our study the patients coming for the short surgical procedures to the hospital satisfying the inclusion criteria were included in the study. The study sample consists of 100 patients, 50 patients were included in each group.

In Group A the time for insertion ranged from 5 s to 40 s (Mean of 9.64 s, SD 6.89). In Group C the insertion time ranged from 8 s to 70 s (Mean of 23.36 s, SD 15.1).
The p value is 0.0001 which is statistically highly significant. The insertion time was high in Group C compared to Group A. Thus the time required to insert Classical LMA was higher compared to AMBU® AuraOnce™ LMA (Figure 1).

In Group A in 43 patients the LMA was inserted in first attempt and in 7 patients the LMA was inserted in second attempt (Mean 1.14, SD 0.35). In Group C the LMA was inserted in first attempt in 36 patients, in second attempt in 11 patients, in three attempts in 3 patients with a mean of 1.39 and SD of 0.61. The p value is 0.0002 which is statistically significant (Figure 2). Thus the first time insertion success rate with AMBU LMA is high compared to classical LMA. Number of attempts needed to insert AMBU LMA was less compared to Classical LMA.

The oropharyngeal leak pressure in Group A ranged from 18 to 28 mm Hg (Mean of 21.7 and SD of 2.15) and in Group C the oropharyngeal leak pressure ranged from 12 to 19 mm Hg (Mean of 14.6, SD 1.68) and the p value of 0.0001 which is statistically significant (Figure 3). The oropharyngeal leak pressure in AMBU LMA was significantly higher than Classical LMA. Thus the AMBU LMA forms a better seal than Classical LMA and hence less oropharyngeal leak is seen with AMBU LMA.

In our study the cuff pressure was increasing steadily in both the groups. The mean cuff pressure in Classical LMA rose from 59.96 cm H2O to 86.73 cm H2O, whereas in AMBU LMA the intracuff pressure raised from 55.06 cm H2O to 80.92
cm H₂O with a p value of 0.0001 which is statically significant (Figure 4). Thus the intracuff pressure raised significantly in group C compared to group A.

DISCUSSION

Top priority in anaesthetic management is given to airway management and endotracheal intubation remains gold standard for this purpose which requires basic training and skills like mask holding, oxygenation, laryngoscopy etc. on the part of the anaesthesiologist [7,8]. With the increase in day care cases, minimal invasiveness and decreased operative time, LMA with their ease of insertion, proven safety has broadened its scope in modern general anaesthesia [9-11]. Hence the present study was undertaken for short surgical procedures with two different types of supraglottic airway devices.

Endotracheal tube insertion though being a basic skill among anaesthesiologists has a lesser success rates among paramedics in field emergencies. Wrong intubation in difficult circumstances in field emergencies may cause brain damage or death of patient. LMAs have revolutionized airway management since the invention of the LMA Classic™ by Dr Archie Brain which makes up the lacunae between the face mask and the endotracheal tube in terms of both anatomical position and degree of invasiveness.

LMAs play as an alternative to mask ventilation and tracheal intubation where they serve as primary airway devices. LMA can save situations like “cannot ventilate and cannot intubate” and as secondary airway device as a rescue device and in cardio-pulmonary resuscitation [11]. European guidelines for resuscitation accepted the relatively safe and easy use of LMAs by medical professionals with limited airway management experience [12,13]. Supraglottic airway devices have been included in the difficult airway algorithm.

After LMA Classic, several LMA have been introduced which differ in shape, stiffness, cuff properties and constituent material. The Auraonce AMBU LMA, AMBU Aura40™ LMA and the I-gel™, intubating LMA, LMA C Trach and proseal LMA. The LMA Classic™ is reusable silicone LMA, consists of a curved tube (shaft) connected to an elliptical spoon shaped mask at a 30 degree angle. There are two flexible vertical bars at the entry of the tube into the mask to prevent obstruction of the tube by the epiglottis with the mask surrounded by an inflatable cuff. Inflation tube and self-sealing pilot balloon are attached to the proximal wider end of the mask.

The intubating LMA-Fastrach (ILMA) is a type of an intubating system that requires the minimum alteration of the head and neck and thus can be used in cases with suspected cervical injury. ILMA is a rigid, anatomically curved airway tube made of stainless steel with a standard 15 mm connector that accommodate an 8.0 ETT and short enough to ensure passage of the ETT beyond the vocal cords. ILMA has a rigid handle attached to the tube facilitates one handed insertion, removal, and adjustment of the device’s position so that the aperture directly opposes the larynx. It has a single flap, the epiglottic elevating bar available in three sizes 3, 4 and 5 [14,15].

I-gel™ is designed for single use has an anatomically designed, non-inflatable mask, which is soft, gel likes transparent, made of a thermoplastic elastomer, it adapts to the airway after insertion. It is available in different colour coding.

Few decades earlier with risks of prion diseases being considered high, single use disposable LMA called AMBU AuraOnce™ LMA were popular. It’s a single use disposable LMA which has rigid curve in the main tube that replicates the human anatomical airway. Its mask has an extra soft 0.4 mm cuff made from PVC and it provides ready seal that confirms better to the airway shape, hence causing less airway pressure. The AMBU Aura40™ is made of silicon which consists of inflatable cuff at the patient end which is moulded to the shaft to form single unit and can be reused 40 times. The tip of the cuff is reinforced to resist folding over during insertion and plugs the upper oesophageal sphincter [16].
Baidya et al. in a meta-analysis compared AMBU AuraOnce LMA with the LMA Classic, LMA Unique and Soft Seal [17]. The principal finding in their meta-analysis is that the AuraOnce provides an oropharyngeal leak pressure higher than with the LMA Unique and equivalent to that of the LMA Classic. However, the Soft Seal provided even better leak pressure than the AuraOnce. They also found that device insertion is significantly faster with the AuraOnce than with the LMA Unique and Soft Seal and similar to the LMA Classic. First-insertion success rates for the AuraOnce are equivalent to those of all of the other three devices. All reported complications were infrequent and they found no evidence of a difference between the AuraOnce and the other three devices except for a higher incidence of sore throat with the LMA Classic.

William Donaldson et al. in a prospective randomized trial compared the I-gel™ and the AuraOnce™ in paralyzed adult patients under conditions of controlled ventilation [18]. Results were as follows First time insertions were 85.6% (I-gel) and 82% (AuraOnce) with overall success rates 96.3% (I-gel) and 94.2% (AuraOnce) (p=0.54). Average insertion times were 11.0 s (I-gel) and 11.6 s (AuraOnce) (p=0.19). Seal pressures were 30.4 cm H₂O (I-gel) and 27.8 cm H₂O (AuraOnce) (p=0.007). Peak pressures were 15.3 cm H₂O (I-gel) and 15.6 cm H₂O (AuraOnce) (p=0.57). Traumatic insertion occurred in 5.8% of I-gel™ and 2% of AuraOnce™ insertions.

Williams’s et al. in a randomized comparison of the AMBU Aura Once Laryngeal Mask and the LMA Unique (LMAU) in spontaneously breathing adults reported LMA insertion time of 5-40 s, first insertion success rates with AMBU was 85%, while with LMAU was 82%. Higher oropharyngeal leak pressure in the AMBU was seen compared to the LMAU which may be due to the 90° angulation of the AMBU LMA. There was a single failure within the AMBU group when there was easy insertion but inability to ventilate. In our study the first time insertion and time needed was less in AMBU group in comparison with the Classical LMA group, where the results were in comparison with the study by Williams et al. [19].

Ng et al. [13] and Shariffuddin et al. [20] have hypothesized that these failures may be due to epiglottic down folding on insertion of the AMBU. In their study they also noted the intracuff pressure was stable in both the devices as they did not use N₂O. The initial cuff pressure in Unique LMA group was higher compared with the AMBU LMA group. But there was no increase in post-operative complications. Shariffuddin et al. [20] observed that the sealing pressure in AMBU LMA was higher than classical LMA [18]. Further Williams et al. [19] observed a mean oropharyngeal leakage pressure of 6 cm H₂O which was similar to that reported by Shariffuddin et al. [20] in his study but lower when compared to that observed by Vaida et al. [21] and Francksen et al. [22]. Suzanna et al. [1] compared LMA-Classic™ and AMBU® AuraOnce™ LMA in patients undergoing elective general anaesthesia with positive pressure ventilation. In their study the time of insertion was shorter in AMBU LMA group. They also compared first attempt insertion success in both the devices. In their study the first attempt success rate was 87% in Classic™ LMA versus 83% in AMBU® LMA. In our study the cuff pressure rose steadily in both the groups but it was more in Classical LMA group compared with AMBU® AuraOnce™ LMA supporting the observation in Shariffuddin et al. [20] study.

Van Zundert et al. [23] compared cuff-pressure changes in LMA-Classic and the new Soft Seal laryngeal masks during nitrous oxide anaesthesia in spontaneous breathing patients cuff pressures increased in the LMA-Classic group from 45 to 100.3 mm Hg and from 45 to 46.8 mm Hg in the Soft Seal laryngeal mask group. They reported that the cuff pressures may be measured for reusable LMA. Francksen et al. [22] compared the disposable LMA devices, LMA Unique, AMBU LMA and Soft Seal LMA during routine surgical procedures for controlled ventilation reported that the insertion time was shortest with AMBU LMA, while the failure rate was comparable in all the three devices. There was no difference in the post-operative complications. They reported that all the three devices are clinically suitable with respect to insertion time, oxygenation, oropharyngeal leak pressure and post-operative complications [24].

We observed the oropharyngeal leak pressure was higher with with AMBU® AuraOnce™ LMA in comparison with the Classic™ LMA thus forming a tight seal w AMBU® AuraOnce™ in comparison with. Thus supporting the observations in a study by Williams et al. [19].

**CONCLUSION**

In our study we observed that the time needed for AMBU LMA insertion [5 s to 40 s (Mean of 9.64 s, SD 6.89)] was significantly less than classical LMA [8 s to 70 s (Mean of 23.36 s, SD 15.1)].

In our study we observed that the number of attempts for AMBU LMA insertion [43 patients - first attempt & 7 patients - second attempt: Mean 1.14, SD 0.35] was significantly less than classical LMA [36 patients - first attempt, 11 patients - second attempt, 3 patients - third attempt: mean of 1.39, SD of 0.61].

In our study we observed that Oropharyngeal leak pressure was significantly higher in AMBU LMA group [18 to 28 mm Hg: Mean of 21.7, SD of 2.15] than classic LMA [12 to 19 mm Hg: Mean of 14.6, SD 1.68] which shows that AMBU LMA has less oropharyngeal leak.
The intracuff pressure changed significantly in classical LMA [59.96 cm H₂O to 86.73 cm H₂O] compared to AMBU LMA [55.06 cm H₂O to 80.92 cm H₂O], thus predisposing to the development of post-operative complications like sore throat and dysphagia. AMBU LMA can be used as an alternative to oro-tracheal intubation even by the paramedical persons in an emergency situation. Since AMBU LMA is a disposable supraglottic airway device there is reduced transmission of infection.

REFERENCES
