ORIGINAL ARTICLE

Comparison between LMA-Classic™ and AMBU® AuraOnce™ Laryngeal Mask Airway in Patients Undergoing Elective General Anaesthesia with Positive Pressure Ventilation

A B Suzanna*, C Y Liu*, S W Syed Rozaidi**, J S M Ooi*****

*Department of Anaesthesiology and Intensive Care, Hospital Sungai Buloh, Selangor, **Prince Court Medical Centre, Kuala Lumpur, ***Department of Anaesthesiology and Intensive Care, Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur

SUMMARY

Background: The LMA-Classic™ laryngeal mask airway (Classic™ LMA) is an autoclavable and reusable laryngeal mask airway with strong evidence supporting its efficacy and safety. Due to the concern of infection risk particularly of prion disease, various single-use laryngeal mask devices were developed. The Ambu® AuraOnce™ LMA (Ambu® LMA) is a single use disposable laryngeal mask airway with special design that conforms better to the anatomy of the airway.

Objectives: The Ambu® LMA was compared to the LMA-Classic™ Classic™ LMA in respect to ease of insertion, adequacy of seal intraoperatively and postoperative complications in patients undergoing elective general anaesthesia with positive pressure ventilation.

Methods: One hundred and eighteen ASA I and II patients undergoing elective general anaesthesia were randomly allocated into receiving either the Ambu® LMA or the Classic™ LMA. The time taken and number of attempts taken to insert the laryngeal mask was recorded. Intra-operative adequacy of seal was assessed via the amount of nitrous oxide leak using a nitrous oxide analyser. Readings were charted at 0, 20, 40 and 60 minutes of operation. Complications postoperatively (blood stains on the device and occurrence of sore throat) were also recorded.

Results: The success of first attempt insertion was comparable between the two groups (Classic™ LMA 87% versus Ambu® LMA 83%). However the time of insertion was significantly shorter in the Ambu® LMA group (p=0.008). Nitrous oxide level was comparable between the two groups up to 20 minutes of operation. At 40 and 60 minutes, the Ambu® LMA showed a significant lower nitrous oxide leak compared to the Classic™ LMA. Postoperatively, incidence of blood stains was comparable between the two groups, however the incidence of sore throat was lower in the Ambu® LMA group (p=0.025).

Conclusions: This study demonstrated that the Ambu® LMA was comparable to the Classic™ LMA in terms of the ease of insertion, but provided better seal during positive pressure ventilation with less postoperative sore throat.

KEY WORDS:
Ambu® LMA, Classic™ LMA, Ease of insertion, Seal, Postoperative complication

INTRODUCTION

Laryngeal mask airway is a type of supraglottic airway device that provides an alternative to endotracheal intubation and standard mask anaesthesia in general anaesthesia. Laryngeal mask airway is inserted into the hypopharynx to form a seal around the larynx to allow spontaneous or positive pressure ventilation without the need for intubating the larynx.

The LMA-Classic™ laryngeal mask airway (Classic™ LMA) was introduced into clinical practice in 1988 by Dr Archie Brain. Classic™ LMA is an autoclavable and reusable laryngeal mask airway which consists of an airway tube connected to an inflatable mask with a silicone rim[1]. In the literature, there are over 2,500 papers supporting Classic™ LMA usage2. Following the success and popularity of Classic™ LMA, many different variants of this device have been designed and marketed.

In the late 1990s, when concerns over infection risk particularly of prion disease[3] were high, various single-use laryngeal mask devices were developed. The Ambu® AuraOnce™ LMA (Ambu® LMA) is a single use disposable laryngeal mask airway designed with a rigid curve in the main tube which replicates the human anatomical airway to better conform to the oropharyngeal anatomy[1]. The mask has an extra soft 0.4 mm cuff manufactured from polyvinyl chloride (PVC) and is claimed to provide a more readily seal that conforms better to the shape of the airway[4], hence causing less internal pressure.

Ambu® LMA has been tested in the European population[4,5]. In this study, it was tested among our Asian population in UKMMC with the purpose of comparing its ease of insertion, adequacy of the seal and postoperative complications.

MATERIALS AND METHODS

After obtaining approval from the Medical Research & Ethics Committee of Universiti Kebangsaan Malaysia Medical

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Corresponding Author: Joanna Ooi Su Min, Universiti Kebangsaan Malaysia Medical Centre, Anaesthesiology & Intensive Care, Jalan Yaacob Latif, Bandar Tun Razak, Cheras, Kuala Lumpur, Wilayah Persekutuan, Malaysia Email: joanna@ppukm.ukm.my

Table I: Patients' demographic data. Values are expressed as mean ± SD, numbers (n) and percentage in parenthesis

	Classic™ LMA (n=60)	Ambu® LMA (n=58)
Age (years)	35.3 ± 12.6	32.0 ± 11.1
Sex:		
Male	21 (35%)	21 (36%)
Female	39 (65%)	37 (64%)
BMI (kg/m^2)	23.7 ± 4.7	23.8 ± 4.5
Operation duration		
20 - <40 minutes	16 (27%)	11 (19%)
40 - <60 minutes	24 (40%)	23 (40%)
≥ 60 minutes	20 (33%)	24 (41%)

Table II: The time taken and number of attempts. Values are expressed as median, number (n) and percentage in parenthesis

	Classic™ LMA (n= 60)	Ambu® LMA (n= 58)	p value
Time taken (seconds)	40 (range 25 – 105)	35 (range 25 – 64)	0.008*
Number of attempts			
1	52 (87%)	48 (83%)	
2	7 (11%)	10 (17%)	0.437#
3	1 (2%)	0 (0%)	
	0.437#		

*computed using Mann-Whitney U test
#computed using Pearson Chi-Square test

Table III: Measured nitrous oxide levels (ppm) at various intervals. Values are measured as median (range)

	Nitrous Oxide level (ppm)		p value*
Time (minutes)	Classic™ LMA	Ambu® LMA	
0	28 (6 – 52)	29 (10 – 58)	0.521
20	41 (10 – 64)	36 (20 – 62)	0.214
40	51 (16 – 74)	41 (28 – 74)	0.047
60	54 (22 – 94)	47 (31 – 80)	0.048

*computed using Mann-Whitney U test

Table IV: Postoperative complications. Values are expressed as numbers (n) and percentages in parenthesis.

Complications	Classic™ LMA (n=60)	Ambu® LMA (n=58)	p value*
Blood stain	13 (22%)	8 (14%)	0.264
Sore throat	20 (33.9)	9 (15.5)	0.025
Sub analysis sore throat vs. operation duration			
• 20 - <40 min	4/16	0/11	
• 40 – <60 min	10/44	5/23	
• ≥ 60 min	6/20	4/24	
p value*	0.509	0.509	

*computed using Pearson Chi-Square/Fisher's exact test

Centre (UKMMC) and written informed consent, 120 adult ASA I and II patients undergoing general anaesthesia for elective minor surgical procedures where laryngeal mask was considered appropriate were recruited and randomly allocated to Classic™ LMA and Ambu® LMA groups. Patients with body mass index of more than 40 kg/m^2, with known or potential difficult airway and high risk of aspiration were excluded.

All patients were fasted according to hospital guidelines and appropriate size of laryngeal mask airway was selected based on manufacturers' instructions. The devices were tested for leaks, lubricated on the posterior surface with water soluble lubricant and deflated before insertion.

After establishing standard monitoring, patients were preoxygenated with 100% oxygen via face mask for three minutes, followed by intravenous fentanyl 2 µg/kg and propofol 2.5 – 3 mg/kg administered through a functioning intravenous line. The depth of anaesthesia was assessed using cerebral state monitor (CSM value of 40-50) and relaxation of the jaw after one minute. Aliquots of 10-20 mg of propofol were given as needed if the patients were still not relaxed. No muscle paralysis was given.

This was followed by insertion of either Classic™ LMA or Ambu® LMA by a single operator who was experienced in using both devices. The time taken to insert the laryngeal masks was from the time face mask was removed until the point when the airway devices were inflated and secured. The

number of attempts was recorded. The airway devices were inserted following standard manufacturer instructions. Only up to three attempts were allowed. A successful attempt was defined as no gag, no spasm, no cough, inaudible sound and good bilateral chest expansion with a typical square carbon dioxide curve on the capnograph. A failed attempt was defined as removal of the device after third attempt and patients required other methods of securing the airway.

Ventilation was maintained on pressure control with pressure support mode via Dräger Primus anaesthetic machine. The ventilator settings were adjusted to achieve a tidal volume of 6 – 8 ml/kg, FiO2 of 0.5, respiratory rate of 10-12 breaths/min, PEEP of 5 cm$H_2$0 and total gas flow of 2 L/min (oxygen and nitrous oxide 1 L/min each). Anaesthesia was maintained with sevoflurane, with minimum alveolar concentration at 1.0 and above. Nitrous oxide sampling was recorded using an independent nitrous oxide analyzer (Edin-Guardian Plus Nitrous Oxide Gas Monitor). The sampling line was placed 20 cm vertically above the patient's mouth and levels were measured at 0, 20, 40, 60 minutes during the operation. Nitrous oxide level at 0 minutes was taken before the gas was started. Any increase in the nitrous oxide level from then on was regarded as a leak from the laryngeal devices. Peak airway pressure was maintained below 25cm H_2O.

At the end of the surgery, the airway devices were removed when the patients regained spontaneous respiration and were able to maintain the airway. The laryngeal masks were inspected for blood stains and patients were asked on the occurrence of sore throat before being discharged back to general wards.

Parametric data were analyzed using unpaired T-test while Mann-Whitney U test or Pearson Chi-Square test was used to analyze the non parametric data. A p value of less than 0.05 was considered to be statistically significant.

RESULTS

Out of the 120 patients randomized, two patients from Classic™ LMA group were excluded because of faulty nitrous oxide analyzer readings and contamination of nitrous oxide from circuit disconnection. The remaining 118 patients had successful laryngeal mask airway insertion and ventilation without requiring endotracheal intubation. The demographic data and operation duration from Classic™ LMA group (n=60) and Ambu® LMA group (n=58) were comparable with no statistical difference.

The data on ease of insertion of airway devices are shown in Table II. The time taken for the Ambu® LMA insertion was significantly shorter when compared to Classic™ LMA. Both groups of laryngeal mask airway had high successful first attempt and were comparable to each other.

Nitrous oxide levels were measured at 0, 20, 40, and 60 minutes of operation. At 0 and 20 minutes, there were no differences in nitrous oxide levels measured, but there were significant differences at 40 and 60 minutes as shown in Table III.

There were no significant differences of blood stains on either device. Ambu® LMA group had significant lower occurrence of sore throat between the two groups and sub analysis showed that the occurrence of sore throat was not related to the duration of the operation. These complications are shown in Table IV as below.

DISCUSSION

In this study, we compared Ambu® LMA to Classic™ LMA which has over 2,500 papers and 270 million uses supporting its efficacy and safety[2]. Our study showed that Ambu® LMA was as effective as Classic™ LMA in maintaining the airway for positive pressure ventilation with all the patients being successfully ventilated without any difficulty. The ease of insertion seen from successful first attempts was also comparable between the groups (Classic™ LMA 87% vs. Ambu® LMA 83%). Similar results have been reported by Redfern *et al*[6], Sudhir *et al*[4] and Shariffuddin & Wang[7]. In our study, the time taken for Ambu® LMA insertion was significantly shorter when compared to Classic™ LMA. Micelli *et al*[8] and Francksen *et al*[5] also reported significant shorter insertion time of Ambu® LMA when compared to other variants of laryngeal mask airway. The shorter time needed to insert Ambu® LMA could be due to the rigid curve of its main tube which facilitated insertion as compared to the softer main tube of Classic™ LMA.

Many studies have assessed the quality of the seal of laryngeal masks either by using a fibreoptic scope to view its anatomical placement or by applying an incremental inspiratory pressure until a leak was detected. We however chose to use a nitrous oxide analyzer to detect any leakage as the two methods mentioned above would not represent our routine practice. We assumed that with the absence of an audible leak, presence of a typical square wave pattern of capnograph and a good tidal volume were indicative of an effective seal. Furthermore, studies have shown that there was no correlation between the positions and the performance of the supraglottic devices[7]. A lower nitrous oxide level at 40 and 60 minutes indicated that Ambu® LMA was superior to Classic™ LMA in providing effective seal in positive pressure ventilation. This is in accordance to a study done by Shariffuddin and Wang[7] where they found that Ambu® LMA had a significant higher oropharyngeal leak pressure as compared to Classic™ LMA. As to the reason for the initial insignificant nitrous oxide levels detected during the first 20 minutes, we theorized that the leakage from Classic™ LMA must be of very minute in nature that significant levels were only detected after 40 minutes.

In this study, we assessed postoperative pharyngeal trauma by presence of blood stains on the laryngeal masks and the occurrence of sore throat. The presence of blood stains on both devices was comparable and not significant. This was also shown in most other previous studies[9-13]. The occurrences of postoperative sore throat were significantly lower in the Ambu® LMA group. Sub analysis has also shown that the incidence of sore throat was not related to the duration of the operation. This was most likely attributed to the softer material cuff (PVC) and lower cuff pressure asserted by the Ambu® LMA[4]. Maino et al postulated that the lower cuff pressure shown by Ambu® LMA was due to its polyvinylchloride material which was less susceptible to hyperinflation caused by nitrous oxide diffusion[14].

There were few limitations to our study. Our patients were anaesthetized and given positive pressure ventilation without paralysis. Even though we monitored the depth of anaesthesia in our patients using MAC and CSM monitor, there was still a possibility of the patients moving, thus increasing the nitrous oxide detection. Secondly, the nitrous oxide level detected in the study might be a contaminant from previous patients although our operating theatres were equipped with good functioning laminar flow ventilation and scavenging system. Lastly, this was a single unblinded study and the operator could be a potential bias.

CONCLUSION

The Ambu® LMA was comparable to the Classic™ LMA in terms of the ease of insertion. Ambu® LMA had shorter insertion time and provided better seal during positive pressure ventilation with lesser postoperative sore throat.

REFERENCES

1. Sung A, Kalstein A, Radhakrishnan P, Yarmush J, Raoof S. Laryngeal Mask Airway: Use and Clinical Applications. J Bronchol 2007; 14: 181-8.
2. Cook T, Howes B. Supraglottic Airway Devices: Recent Advances. BJACEACCP 2011; 11: 56-61.
3. Cook T. The Classic Laryngeal Mask Airway: A Tried and Tested Airway. What Now? [Editorial]. Brit J Anaesth 2006; 96: 149-152.
4. Sudhir G, Redfern D, Hall JE, Wikes AR, Cann C. A Comparison of the Disposable Ambu®AuraOnceTM Laryngeal Mask with the Reusable LMA Classic Laryngeak Mask Airway. Anaesthesia 2007; 62: 719-22.
5. Francksen H, Bein B, Cavus E, Renner J, Scholz J, Steinfath M, Tonner PH, Doerges V. Comparison of LMA Unique, Ambu Laryngeal Mask and Soft Seal Laryngeal Mask During Routine Surgical Procedures. European J Anaesth 2007; 24: 134-40.
6. Redfern D, Sudhir G, Wilkes AR, Hall JE. A Cross Over Trial Comparing Ambu® Laryngeal Mask with Classic™ Laryngeal Mask Airway Under Anaesthesia. Presented at European Society of Anaesthesiologists 2006 Annual Meeting, Madrid. Abstract no. A- 1047.
7. Sharidduddin II, Wang CY. Randomised Crossover Comparison of the Ambu®AuraOnceTM Laryngeal Mask with the LMA ClassicTM Laryngeal Mask Airway in Paralysed Anaesthetised Patients. Anaesthesia 2008; 63: 82-5.
8. Miceli L, Mattelig S, Fasano N, De Lucia S, Savoia C, Della Rocca G. LMA Classic™ versus LMA Ambu® in Patients Undergoing Orthopaedic Surgery. Presented at European Society of Anesthesiologists 2006 Annual Meeting . Abstract no. A-1046.
9. Hagberg CA, Jensen FS, Genzwuerker HV, Krivosic-Horber R, Schmitz BU, Hinkelbein J, Contzen M, Menu H, Bourzoufi K. A Multicenter Study of the Ambu® Laryngeal Mask in Nonparalysed, Anesthetized Patients. Anesth Analg 2005; 101: 1862-6.
10. Gernoth C, Janderweth O, Contzen M, Hinkelbein L, Genzwuerker HV. Prospective Comparison of Ambu® Laryngeal Mask and LMA- Classic™ in Patients with Immobilized Cervical Spine. Supplement European Journal of Anaesthesiology 2005; 22 (S34): 76.
11. Genzwuerker HV, Hinkelbein J, Krivosic-Horber R, Harberg CA, Jensen FS. Performance of the New Single-use Ambu® Laryngeal Mask in Different Head Positions. Anesthesiology 2004; 101: Abstract no. A-1590.
12. Herve Y, Trans-Van D, Labadie P, Dardare E, Avargues P, Fontaine B. Clinical Evaluation of a New Disposable Airway Device: The Ambu® Laryngeal Mask. Presented at European Society of Anaesthesiologists 2005 Annual Meeting.
13. Hagberg CA, Jensen FS, Genzwurker H, Krivosic-Horber R, Schmitz BU, Menu H. Combined International Multi–Centre Phase I and II Study and Performance of the Ambu® A/S Laryngeal Mask. Presented at International Anesthesia Research Society 2005. Poster no. S211.
14. Maino P, Dullenkopf A, Bernet V, Weiss M. Nitrous Oxide Diffusion into the Cuffs of Disposable Laryngeal Mask Airways. Anaesthesia 2005; 60: 278-82.