Section: Anesthesiology and Critical Care

Original Research Article

A COMPARATIVE EVALUATION BETWEEN LMA PROSEAL AND AMBU AURA40 FOR AIRWAY MANAGEMENT IN OVERWEIGHT PATIENTS UNDERGOING SURGICAL PROCEDURES

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Abstract

Background: Obesity is a known risk factor associated with many complications in anesthesia, including a difficult airway. The LMA-ProSeal™ is a second-generation supraglottic airway device with a modified cuff and drainage tube, designed for better sealing with both the respiratory and gastrointestinal tracts. The Ambu Aura40™ is a reusable laryngeal mask airway with a fixed curve that accurately replicates the natural human anatomy of the upper airway. We aimed to compare and test LMA ProSeal and Ambu Aura40 in terms of the time of insertion, ease of insertion, number of attempts, and complications in overweight patients undergoing surgery. **Materials and Methods:** Sixty patients of either sex between 18-60 years of age of ASA I and II with BMI ranging from 25 to 29.9 scheduled for surgical procedures were enrolled in the study. They were randomly divided into two groups of 30 each. Insertion time was calculated from the time of introduction of the device into the mouth till confirmation by capnographic tracing. Ease of insertion, number of attempts, and complications were also recorded to compare both the LMAs. **Result:** All sixty patients were successfully managed with either LMA ProSeal or Ambu Aura40. The mean (SD) of Insertion Time (s) in Group AA40 was 23.07 (5.90) and in Group PLMA was 30.50 (5.79) (p = 0.0001). Grade 1 ease of insertion was present in 63.3 % of the cases in the AA40 group and 66.7% in the PLMA group. Only one attempt was required to insert LMA in 26 out of 30 (86.7%) patients in the Ambu Aura40 group and 24 out of 30 (80.0%) patients in the ProSeal LMA group. Incidences of complications in both groups are statistically comparable but a higher number of cases with sore throat and blood on the device in patients managed with ProSeal LMA is clinically relevant. **Conclusion:** We conclude that AA40 is better than PLMA in terms of insertion time. There was no significant difference between the various groups in terms of the distribution of ease of insertion and the number of attempts. Both LMA AA40 and PLMA can be a good alternative for rapid airway management scenarios and daycare surgeries in overweight patients.

INTRODUCTION

As the incidence and prevalence of obesity increase around the world, anesthesiologists will be exposed to a variety of overweight and obese patients presenting for surgical and diagnostic procedures. In 1948, the World Health Organisation first recognized obesity as a disease. By definition, obesity is the accumulation of excess fat regionally, globally or both, which increases risk to health.[1]

BMI is a simple index of weight-to-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in meters (kg/m2). According to WHO, patients can be categorized as per their BMI, i.e, below 18.5 is underweight, 18.5–24.9 is normal weight, 25-29.9 is

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pre-obesity or overweight, 30.0–34.9 is obesity class 1, 35-39.9 is obesity class 2, >40 is obesity class 3. Obesity is a known risk factor associated with many complications in anesthesia, including a difficult airway.

The LMA-ProSealTM is a second-generation supraglottic airway device. ProSealTM LMA is a double mask, forming two end-to-end junctions: one with the respiratory tract and the other with the gastrointestinal tract [2]. It has been devised to improve controlled ventilation, airway protection and misplacement during movement [3]. The Ambu Aura40™ is a reusable laryngeal mask airway with a fixed curve that accurately replicates the natural human anatomy of the upper airway. It is made up of silicone. It has an oval inflatable cuff at the patient end. It is directly molded to the shaft to form a single unit for extra safety and easy insertion without causing injury to the airway.

Our study compared the performance of LMA Ambu Aura40 and LMA ProSeal in terms of insertion time, ease of insertion, hemodynamic parameters (mean arterial blood pressure and heart rate) and complications (sore throat and blood on the device).

MATERIALS AND METHODS

The data for this study has been taken from a larger, randomized, observational, prospective study conducted at Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Uttar Pradesh, India. The study protocol was approved by the Board of Studies, Department of Anaesthesiology and Institutional Ethical Committee JNMCH, Aligarh Muslim University (IEC-344/FM/IEC). Written informed consent was obtained from all the participants. Patients aged 18-60 years and weight between 50-70 kg of both genders with all Mallampatti Grades and with an American Society of Anesthesiologists physical status I–II and with a BMI between 25-29.9 scheduled for surgery at our institution were assessed for eligibility. Patients with mouth opening <2.5cm or with known difficult airways, those with potentially full stomach or hiatus hernia, those with cervical spine fracture or instability or history of allergy to latex, and those with the inability or unwillingness to provide informed consent were excluded.

The patients were randomly allocated into two study groups- Group PLMA and Group AA40. Randomization was done using a computer-based random number generator and the allocation was concealed in sealed envelopes, which were opened only after obtaining the patient's consent. Airway was secured with Ambu Aura40TM in patients of Group AA40 (n=30) and ProSealTM LMA in patients of Group PLMA (n=30). The patients were blinded, but blinding the attending anesthesiologist was not possible as the two supraglottic devices are conspicuously different.

All patients underwent pre-anesthetic checkups and were kept nil per orally (NPO) for 8 hours. Vital parameters heart rate and oxygen saturation, end-tidal CO2, lead II ECG and non-invasive blood pressure were recorded on a multi-channel monitor.

The anesthetic technique comprised a uniform premedication with midazolam 0.03mg/kg, ondansetron 0.1mg/kg, and fentanyl 1.5mcg/kg body weight. Anesthesia was induced uniformly with 2mg/kg of propofol intravenously. After adequate muscle relaxation with Inj. Succinylcholine 1.5 mg/kg, insertion of LMA was done.

Insertion time was calculated from the time of introduction of the supraglottic device into the mouth till confirmation by capnographic tracing. A maximum of three attempts with a device was allowed. In case of non-insertion after three attempts, the patient was intubated using standard laryngoscopy with an endotracheal tube, and surgery was completed. This case was documented as a failure of insertion. Ease of insertion was graded as Grade 1 (no resistance to insertion in the pharynx), Grade 2 (mild resistance to insertion), Grade 3 (moderate to severe resistance to insertion), and Grade 4 (Failed insertion).

After successful insertion, a closed system was attached to the LMA and anesthesia was maintained with 60% nitrous oxide in oxygen, vecuronium, and isoflurane as per requirement. At the end of the surgery, residual neuromuscular blockade was reversed with Inj. Neostigmine (40ug/kg) and Inj. Glycopyrrolate (10ug/kg). Removal of the device was done after adequate reversal of neuromuscular blockade.

In the postoperative period, supraglottic devices were assessed for the presence of blood stains indicating laryngeal morbidity. Post-operatively, sore throat was assessed by an independent observer blinded to the type of LMA inserted. The presence of an unpleasant sensation in the throat (which was not previously present) within 24 hours was recorded as evidence of a sore throat.

Statistical analysis was done with the use of Statistical Package for Social Sciences (S.P.S.S) software, version 20.0, International Business Machine (I.B.M) manufacturer, Chicago, USA. The results are presented in the form of numerical values, mean, standard deviation, and percentages as appropriate. The α level for all analyses was set at 0.05 and $p<0.05$ was considered statistically significant. Non-parametric data like gender and mallampati grade were analyzed using Pearson's chi-square test. Parametric data like age and weight were analyzed using the unpaired t-test. Data for the time taken for insertion was analyzed using unpaired t-test. Data for the number of attempts and ease of insertion were analyzed using Pearson's chi-square test. Data for hemodynamic changes were analyzed using unpaired t-test between the two groups and paired t-test within the group. Data for post-operative complications like blood on the supraglottic device

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and sore throat 24 hours postoperatively were analyzed using Pearson's chi-square test.

RESULTS

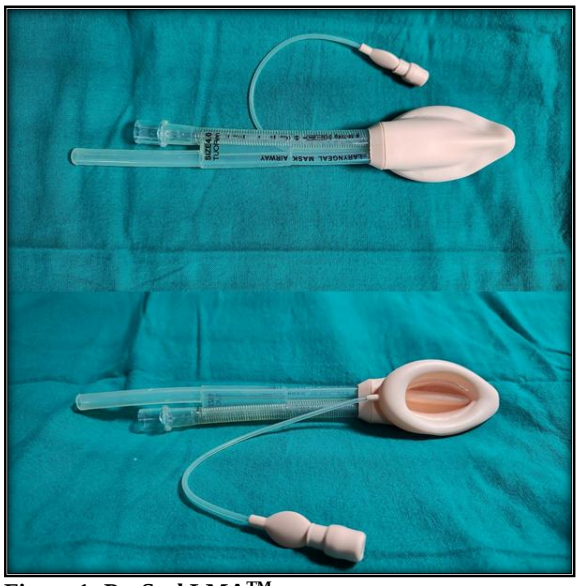

Figure 1: ProSeal LMA™

Figure 2: Ambu Aura40™

A total of sixty patients who enrolled were analyzed for the primary outcome of our study. Since there were no exclusions or losses, all participants completed the study [Figure 3]. The demographic profile of all three groups was comparable with respect to age, gender, weight, Mallampati grades and BMI as shown in [Table 1]. The mean (SD) of Insertion Time (s) in Group AA40 was 23.07(5.90) and in Group PLMA was 30.50 (5.79). There was a significant difference between the 2 groups in terms of Insertion Time (s) (p = 0.0001), with the mean Insertion Time (s) being more in the Group PLMA.

As we can see from [Table 2], there was no significant difference between the various groups in terms of the Ease of Insertion (p= 0.950). Grade 1 ease of insertion was present in 63.3 % of the cases in the AA40 group and 66.7% in the PLMA group. Grade 2 ease of insertion was experienced in 23.3% of patients in the AA40 group and 20.00% of patients in the PLMA group. In both groups, only 4 out of 30 patients experienced Grade 3 ease of insertion. There was no case of failed insertion (grade 4) in any groups. A larger proportion of patients in both groups had Grade 1 ease of insertion.

From [Table 2] it can be observed that only one attempt was required to insert LMA in 26 out of 30 (86.7%) patients in the Ambu Aura40 group and 24 out of 30 (80.0%) patients in the ProSeal LMA group. Two attempts were required in 3 out of 30 patients in the AA40 group and 5 out of 30 patients in the PLMA group. Only one patient in each group required 3 attempts to secure the airway. There were no cases of failed insertion in either of the groups. There was no significant difference between the two groups in terms of the distribution of Attempts (p >0.748).

We can observe from Table 4 that 4 out of 30 (13.3%) patients in the AA40 group and 7 out of 30 (23.3%) patients in the PLMA group complained of sore throat in the postoperative period. (p>0.317). From [Table 4] we can see that blood on the device after removal was present in 2 out of 30 (6.7%) cases in the AA40 group and 6 out of 30 patients (20.0%) cases in the PLMA group. (p> 0.129).

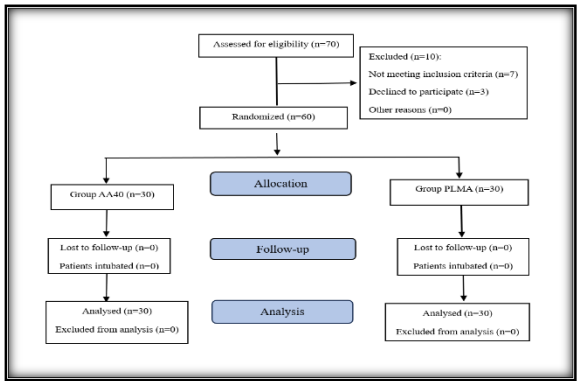

Figure 3: CONSORT flowchart

Table 1: Patient characteristics

Variables	Group AA40 (n=30)	Group PLMA (n=30)
Age (years)	33.40 ± 9.73	32.67 ± 10.47
Gender (male/female)	13/17	12/18
Weight (kg)	78.23 ± 6.71	77.07 ± 7.27
BMI (kg/m2)	27.21±1.56	27.60±1.57
MP Classification (1/2/3/4)	1/8/15/6	1/6/16/7

Table 2: Airway management details

Variables	Group AA40 (n=30)	Group PLMA (n=30)	P
Time for insertion (s)	23.07 ± 5.90	30.50 ± 5.79	0.0001

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Ease of Insertion (Grade 1/2/3/4)	19/7/4/0	20/6/4/0	0.950
Number of Attempts (1/2/3)	26/3/1	24/5/1	0.748

Table 3: Postoperative Complications

Complications	Group AA40	Group PLMA	P value
Sore throat (yes/no)	4/26	7/24	0.317
Blood on device (yes/no)	2/28	6/25	0.129

DISCUSSION

Supraglottic airway devices have been conventionally used for short surgical procedures under general anesthesia with good results. Various studies have reported encouraging results in ease of insertion, safety profile, post-operative recovery of patients, complication risk, and cost analyses.[4-6] LMAs have revolutionized anesthetic management due to their popular use in daycare surgeries and difficult airway scenarios with the advantage of being economical and ergonomic.[7-9] It is an effective method to avoid pressor response associated with laryngoscopy in patients undergoing surgery under general anesthesia.[10] The complications and risk factors during insertion of LMAs and ventilation of the patient are underreported.[11,12]

The insertion time for Ambu Aura40™ was lesser than the ProSeal™ LMA and the difference was statistically significant ($p < 0.0001$). Gonzalez et al., 2019 studied the performance of Ambu Aura40™ in paediatric patients and found that the time for insertion was less than 20 seconds in 134 out of 135 patients (99.3%).[13] Mehta et al., 2019 published a similar study comparing the efficiency of Ambu AuraGain (Group A) and Supreme Laryngeal Mask Airway (group S). The time of insertion of the device in group A was 15.53 seconds as compared to 22.60 seconds in group S. The p-value (< 0.0001) was statistically highly significant.[14] However, Wong et al., 2018 also reported that the mean insertion time was longer in the AuraGain (13+4 seconds) than in the Supreme group (11+3 seconds) (P< 0.001).[15]

A larger proportion of patients in both groups had Grade 1 ease of insertion. Singh K et al., 2017 reported grade 1 ease of insertion (easy) in 22 out of 30 cases in group PLMA, and 18 out of 30 cases in group AAU. There was no statistical significance (p= 0.273).[16] In contrast to our experience, Shariffuddin et al., in 2017 reported that the AuraGain was deemed subjectively harder to insert, with only 24 out of 50 (48%) versus 37 out of 50 (74%) of AuraGain insertions being scored 1 = easy (on a 5-point scale), P=0.013.[17]

From [Table 2] it can be observed that only one attempt was required to insert LMA in 26 out of 30 (86.7%) patients in the Ambu Aura40 group and 24 out of 30 (80.0%) patients in the ProSeal LMA group. Two attempts were required in 3 out of 30 patients in the AA40 group and 5 out of 30 patients in the PLMA group. Only one patient in each group required 3 attempts to secure the airway. There were no cases of failed insertion in either of the groups. There was no significant difference between the two groups in terms of the distribution of Attempts (p >0.748). Similar to our study Jamgond et al., 2015 Ambu Aura40 could be positioned successfully in a single attempt in 90% of the patients (27 out of the 30), whereas it's only 80% in both the LMA Classic and the I-gel groups without a statistical significance (P = 0.518).[18] Padmanabhan et al., 2018 reported that the Ambu Aura40 could be positioned successfully within a single attempt in 90% (27 out of 30) of the patients in whom the device was used whereas successful placement in the first attempt could be achieved only in 80% of the subjects in both the LMA classic and I-gel groups. This result was not significant statistically but they considered it clinically relevant.[19]

Incidences of complications in both groups are statistically comparable but a higher number of cases with sore throat and blood on the device in patients managed with ProSeal LMA is clinically relevant. These complications in the PLMA group can be probably due to trauma caused by the use of a metallic introducer and the inherent bulky design of ProSeal. Chauhan et al., 2013 observed that a higher incidence of macroscopic blood staining of the supraglottic device, sore throat, and dysphagia was observed in the PLMA group as compared to the I-gel group (P = 0.045). 7 out of 40 patients (17.5%) in the PLMA group complained of sore throat after 1 hour and in 8 out of 40 (20%) cases blood on the device was present.[20] Jamgond et al., 2015 stated that traumatic device insertion as evidenced by blood on the device was noted in 1 out of 30 patients each in the LMA Classic and Ambu Aura40 groups but this was not found to be statistically significant. 3 out of 30 patients (10%) in the LMA Classic group, complained of sore throat in the postoperative period which was statistically significant (P = 0.045). No cases of sore throat were reported in group I-Gel and Ambu Aura40™.[18]

CONCLUSION

We conclude that Ambu Aura40 is better than ProSeal LMA in terms of insertion time. There was no significant difference between the various groups in terms of the distribution of ease of insertion and the number of attempts. Both Ambu Aura40 and ProSeal LMA can be a good alternative for rapid airway management scenarios and daycare surgeries in overweight patients.

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REFERENCES

1. James W. WHO recognition of the global obesity epidemic. Int J Obes. 2008;32(suppl 7):S120-S126
2. Brimacombe J, Keller C. The ProSeal laryngeal mask airway. Anesthesiol Clin North Am.2002;20(4):871-891.
3. Cook TM, Lee G, Nolan JP. The ProSeal™ laryngeal mask airway: a review of the literature. Can J Anaesth.2005;52:739-760.
4. Schälte G, Stoppe C, Aktas M, Coburn M, Rex S, et al. (2011) Laypersons can successfully place supraglottic airways with 3 minutes of training. A comparison of four different devices in the manikin. Scand J Trauma Resusc Emerg Med 19: 60.
5. Jagannathan N, Sohn LE, Sawardekar A, Gordon J, Langen KE, et al. (2012) A randomised comparison of the LMA SupremeTM and LMAProSealTM in children. Anaesthesia 67: 632-639.
6. Verghese C, Brimacombe JR (1996) Survey of laryngeal mask airway usage in 11,910 patients: safety and efficacy for conventional and nonconventional usage. Anesth Analg 82: 129-133.
7. Rosenblatt WH, Ovassappiam A, Eige S (1998) Use of the laryngeal mask airway in the United States: A randomized survey of ASA members. ASA annual meeting, Orlando, USA.
8. Maltby JR, Beriault MT, Watson NC, Fick GH (2000) Gastric distension and ventilation during laparoscopic cholecystectomy: LMA-Classic vs. tracheal intubation. Can J Anaesth 47: 622-626.
9. Sharma V, Verghese C, McKenna PJ (2010) Prospective audit on the use of the LMA-Supreme for airway management of adult patients undergoing elective orthopaedic surgery in prone position. Br J Anaesth 105: 228-232.
10. Bhattacharya D, Ghosh S, Chaudhuri T, Saha S. Pressor responses following insertion of laryngeal mask airway in patients with controlled hypertension: comparison with tracheal intubation. J Indian Med Assoc.2008;106(12):787-810.
11. Goldmann K, Gerlach M, Bornträger C (2011) ProSeal™ laryngeal mask in normal weight and obese patients : oxygenation under pressure-controlled ventilation and different end-expiratory pressures. Anaesthesist 60: 908-915.
12. Zoremba M, Aust H, Eberhart L, Braunecker S, Wulf H (2009) Comparison between intubation and the laryngeal mask airway in moderately obese adults. Acta Anaesthesiol Scand 53: 436-442.
13. González del PRI, Ramos DY, García PC, González NH, Rodríguez FM, Chacón RJA et al. Efectividad de la máscara laríngea Ambu® Aura40TM para anestesia general en cirugía ortopédica pediátrica. Rev.Med.Electrón.2019;41(6):1325-1340.
14. Mehta H, Tejash H. Sharma, Jayshri Desai. An Observational Study to Compare Ambu Auragain and Supreme Laryngeal Mask Airway for Controlled Ventillation Under Anaesthesia. Indian J Anesth Analg.2019;6(2):438-442.
15. Wong DT, Ooi A, Singh KP, Dallaire A, Meliana V, Lau J et al. Comparison of oropharyngeal leak pressure between the Ambu® AuraGain™ and the LMA® Supreme™ supraglottic airways: a randomized-controlled trial. Can J Anaesth.2018;65(7):797-805.
16. Singh K, Gurha P. Comparative evaluation of Ambu AuraGain™ with ProSeal™ laryngeal mask airway in patients undergoing laparoscopic cholecystectomy. Indian J Anaesth 2017;61:469-74.
17. Shariffuddin II, Teoh WH, Tang E, Hashim N, Loh PS. Ambu® AuraGain™ versus LMA Supreme™ Second Seal™: a randomised controlled trial comparing oropharyngeal leak pressures and gastric drain functionality in spontaneously breathing patients. Anaesth Intensive Care. 2017;45(2):244-250.
18. Jamgond S, Ali L, Manjunath M. A prospective randomized study comparing the efficacy of the LMA ClassicTM, the AMBU Aura40 Laryngeal MaskTM and the I-GelTM using fiberoptic bronchoscope in spontaneously breathing anesthetized patients, IAIM. Artigo em Ingles.2015;2(7):105-115.
19. Sharath P, Supriya Kumari MC. A comparison of three supraglottic airway devices: the LMA Classic, the Ambu Aura40 laryngeal mask and the i-gel in spontaneously breathing anaesthetised patients. J. Evid. Based Med. Healthc.2018;5(12):1078-1084.
20. Chauhan G, Nayar P, Seth A, Gupta K, Panwar M, Agrawal N et al. Comparison of clinical performance of the I-gel with LMA proseal. J Anaesthesiol Clin Pharmacol.2013;29:56-60.

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