Original Article

A randomized comparative study of three supraglottic airway devices for controlled ventilation in anesthetized patients

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Abstract

Background and Aims: The LMA® ProSeal™, LMA® Supreme™ and Ambu® AuraGain™ are second-generation supraglottic airway devices (SADs) with integrated gastric access. In this study, we compared the clinical performance of these three devices in adults for controlled ventilation in anesthetized paralysed patients.

Material and Methods: Two hundred and seventy adults, American Society of Anesthesiologists (ASA) Physical Status I-III, undergoing elective surgical procedures, were randomized into three groups with 90 patients in each: Group 1: LMA® ProSeal™, Group 2: LMA® Supreme™ and Group 3: Ambu® AuraGain™. All the three devices were evaluated for oropharyngeal seal pressure (OSP) and other parameters: ease and the number of attempts at device placement, fibreoptic laryngeal view and intraoperative and postoperative complications.

Results: In the present study, the mean OSP was 38.9 ± 3.050 cm H_2O in the LMA ProSeal™ group, 37.41 ± 4.097 cm H_2O in LMA® Supreme™ group and 37.32 ± 3.740 cm H_2O in Ambu® AuraGain™ group. The difference was found to be statistically significant ($P = 0.006$). The three groups were comparable for the ease of device insertion, number of attempts at device placement, fibreoptic laryngeal view, intraoperative and postoperative complications.

Conclusion: In this study, we found that the LMA® ProSeal™ provided the highest OSP in comparison to the other two devices, even though this difference is not clinically relevant. The use of Ambu® AuraGain™ was associated with difficult and lowest first-time insertion success rate ($P < 0.001$) along with an increased incidence of airway trauma as compared to the other two SADs.

Keywords: Ambu AuraGain, LMA ProSeal, LMA supreme oropharyngeal seal pressure, supraglottic airway devices

Introduction

The widening scope of the use of supraglottic airway devices (SADs) in prehospital care, remote locations, operation theatres and emergency medicine has led to a fundamental change in the airway management during anesthesia from a face mask *vs*. tracheal tube to a face mask *vs*. SAD *vs*. tracheal tube model.[1,2] The Fourth National Audit Project of the Royal College of Anesthetists and Difficult Airway Society (NAP4) showed that in Britain, 80% of the SADs used for airway management were first-generation devices and recommended changing over to second-generation devices for better patient outcomes.[3]

Introduced clinically in 2014, the Ambu® AuraGain™ (AMBU A/S, Ballerup Denmark) is a polyvinyl chloride, MRI compatible, single-use SAD with a preformed curved

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shaft with a double lumen, and a comparatively wider airway tube to facilitate the passage of a larger endotracheal tube.[4] The LMA® Supreme™ (LMA® Supreme, Teleflex, Athlone, Ireland) introduced in 2007, is a single-use, latex free, inflatable polyvinyl chloride airway device with an anatomically shaped airway tube expediting easy insertion, integrating advantages of LMA® ProSeal™ and LMA-Fastrach.[5]

The LMA® ProSeal™ is considered to be a prototype of second-generation SADs, especially indicated when positive pressure ventilation is indicated.[6] Our study compared the Ambu® AuraGain™ with LMA® Supreme™ and LMA® ProSeal™ [Figure 1] for controlled ventilation in anesthetised paralyzed patients undergoing elective surgery of less than two hours duration. The primary aim of our study was to compare the OSP of these three devices. The secondary objectives were to evaluate the first-time insertion success rate, ease of insertion, number of attempts, ease and number of attempts at insertion of the gastric tube, fibreoptic confirmation of the anatomical position of the SAD used, and other adverse effects.

Material and Methods

Institutional ethics committee approval (EC/02/15/784) was obtained and the trial was registered with the Clinical Trials Registry - India CTRI No (2020/02/023588) for this prospective randomized control trial in a tertiary care centre, the Sir Ganga Ram Hospital, India. Informed written consent was taken from two hundred and seventy patients aged 18 years or more, American Society of Anesthesiologists (ASA) physical status I-III, scheduled for elective surgical procedures with expected duration of surgery limited to two hours.

Exclusion criteria were: inadequate mouth opening (<3.5 cm), respiratory tract infection, anticipated difficult airway, cervical spine injury or risk factors for gastric aspiration (symptomatic hiatus hernia, severe gastroesophageal reflux, acute abdomen, pregnancy), body mass index (BMI) more than 40 kg/m^2, patients requiring tracheal intubation and those for emergency surgery.

Figure 1: Lateral view of the three SADs. a) LMA® ProSeal™b) LMA® Supreme™ and c) Ambu® AuraGain™®

The patients were randomized to one of the three airway groups with 90 patients in each group: Group 1: LMA® ProSeal™, Group 2: LMA® Supreme ™ and Group 3: Ambu® AuraGain™ using a computer-generated random number table and the allocation sequence was concealed by sealed envelopes which were opened after obtaining the consent of the patients. All patients were managed by anesthesiologists who had the experience of more than 100 uses with the SADs. All patients received tablet Alprazolam 0.25 mg, the night before and on the morning of surgery two hours before the procedure. The prescribed medications for concomitant diseases were continued as advised.

After obtaining venous access in the operation theatre, the patients were premedicated with intravenous Ranitidine 50 mg, Metoclopramide 10 mg, Glycopyrrolate 0.2 mg, and Midazolam 1 mg by the primary anesthesiologist. Standard monitoring including pulse oximetry, electrocardiography, non-invasive blood pressure, and capnography were applied. Patient was then positioned supine with the head placed on a silicone ring 7 cm in height. After preoxygenation for three minutes, anesthesia was induced using fentanyl 1 mcg/kg, Propofol 1 mg/kg and an appropriate dose of neuromuscular blockade. The choice of the neuromuscular blocking drug was based on the clinical judgment and was determined by the anesthesiologist conducting the case. After bag and mask ventilation, the chosen SAD as per the allocated group of appropriate size according to the manufacturer's guidelines was then placed after ensuring adequate jaw relaxation, using standard insertion technique. A total number of three attempts were allowed for device placement. In the event of a failed insertion, the case was excluded from the study and the patient was managed using an alternate device. The correct placement of the device was confirmed by monitoring end-tidal CO_2. Anesthesia was maintained with sevoflurane, nitrous oxide in 50% oxygen and boluses of the appropriate neuromuscular blocking agent.

The device insertion was graded as easy when it was successful at first attempt without any additional maneuvers (assisted mouth opening by laryngoscope or an assistant, mask rotation or finger manipulation). It was graded as difficult if more than one attempt was required or there was any need for additional maneuvers. A failed attempt was defined as the removal of the device from the mouth. The number of insertion attempts was recorded. The gastric tube was inserted through the drain

tube and the number of attempts for insertion of gastric tube was recorded.

After obtaining an effective airway, the OSP was determined at a fixed gas flow of 3 liters per min by closing the expiratory valve of the CO_2-circle system and recording the airway pressure at which equilibrium was reached (maximum pressure allowed 40 cm H_2O). The presence of a gas leak at seal pressure was detected as an audible sound escaping from the mouth.[6]

The gel displacement test was carried out by placing a bolus of 0.5-1 ml of lubricant water-soluble jelly in the proximal orifice of the drain tube to seal it. The airway pressure at which this bolus ejected was noted. A pressure less than 20 cm of H_2O, implied malposition and required another attempt at insertion. The successful passage of a lubricated nasogastric tube through the drain tube ruled out the posterior folding of the mask. Epigastric auscultation/gastric aspiration confirmed the correct position of the tube. Ease or difficulty of placement was noted. The intra cuff pressure was maintained at 60 cm of H_2O by using a VBM cuff pressure manometer (VBM Medizintechnik GmbH, Germany).

A flexible fiberscope was passed through the airway tube and the view of the laryngeal structures was graded as per the following scoring system:

Grade 4: only vocal cords seen;
Grade 3: vocal cords plus posterior epiglottis seen;
Grade 2: vocal cords plus anterior epiglottis (AE) seen; and
Grade 1: vocal cords not seen at all.[7]

At the end of the surgery, the neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. The patient's mouth was carefully inspected for any trauma to tongue, lips and teeth after removing the airway device, which was also examined for presence of any blood or bile and the findings were noted. Subsequently, the patient was shifted to the post anesthesia recovery unit. Oxygen was administered by mask and pain relief was provided by fentanyl boluses and nonsteroidal anti-inflammatory drugs (NSAIDS). The patient was then inquired about the presence of sore throat, dysphagia, and dysphonia in the PACU and 24 hours later in the ward.

Statistical analysis

The power of the study was estimated based on a previous study comparing LMA® ProSeal™ with LMA® Supreme™ where the OSP of LMA® ProSeal™ was 30.7 ± 6.2 cm H_2O and a 10% change in OSP between the two devices was considered clinically significant.[8] Eighty five patients per group were needed with an alpha level of 0.5 and a beta level of 0.1 for our study. We, therefore, enrolled ninety patients in each group to compensate for possible losses.

Statistical analysis was performed by the SPSS program for Windows, version 17.0 (SPSS, Chicago, Illinois). Continuous variables were presented as mean ± SD, and categorical variables were expressed as absolute numbers and percentages. Data were checked for normality before statistical analysis using the Shapiro Wilk test. Normally distributed continuous variables were compared using ANOVA. Chi-Square test was used for categorical variables. If the F value was significant and variance was homogeneous, Tukey multiple comparison test was used to assess the differences between the individual groups; otherwise, Tamhane's T2 test was used. For all statistical tests, a P value of less than 0.05 was considered statistically significant.

Results

Two hundred and seventy patients were enrolled into three groups with 90 patients in each group as shown in the CONSORT flowchart [Figure 2] and completed the study. There were no significant differences in the patient characteristics and baseline airway parameters among the three groups except for differences in case of mouth opening, thyromental distance and sternomental distance, however, these differences were not clinically important [Table 1]. Patients were also comparable with regards to the haemodynamic parameters in all three groups. [Table 2]

The device was inserted successfully at first attempt in all patients in the LMA® Supreme™, 88 of 90 in LMA® ProSeal™ and 77 of 90 patients in the Ambu® AuraGain™ group and there were statistically significant differences among the three groups ($P = 0.002$). The second attempt was required in two of LMA® ProSeal™ and six patients of the Ambu® AuraGain™ group. The third attempt was needed in seven patients of Ambu® AuraGain™ group only.

Insertion was easiest in LMA Supreme™ followed by LMA® ProSeal™ and Ambu® AuraGain™ groups respectively and the difference was statistically significant ($P < 0.001$).

In the present study, the mean OSP was 38.9 ± 3.05 cm H_2O in the LMA® ProSeal™ group, 37.41 ± 4.097 cm H_2O in the LMA®Supreme™ group and 37.32 ± 3.740 cm H_2O in the Ambu®Aura Gain™ group and the difference was statistically significant ($P = 0.006$). As shown in Table 1 and Figure 3.

Gastric tube insertion was easy and placed on the first attempt in all the three groups. There were no statistically

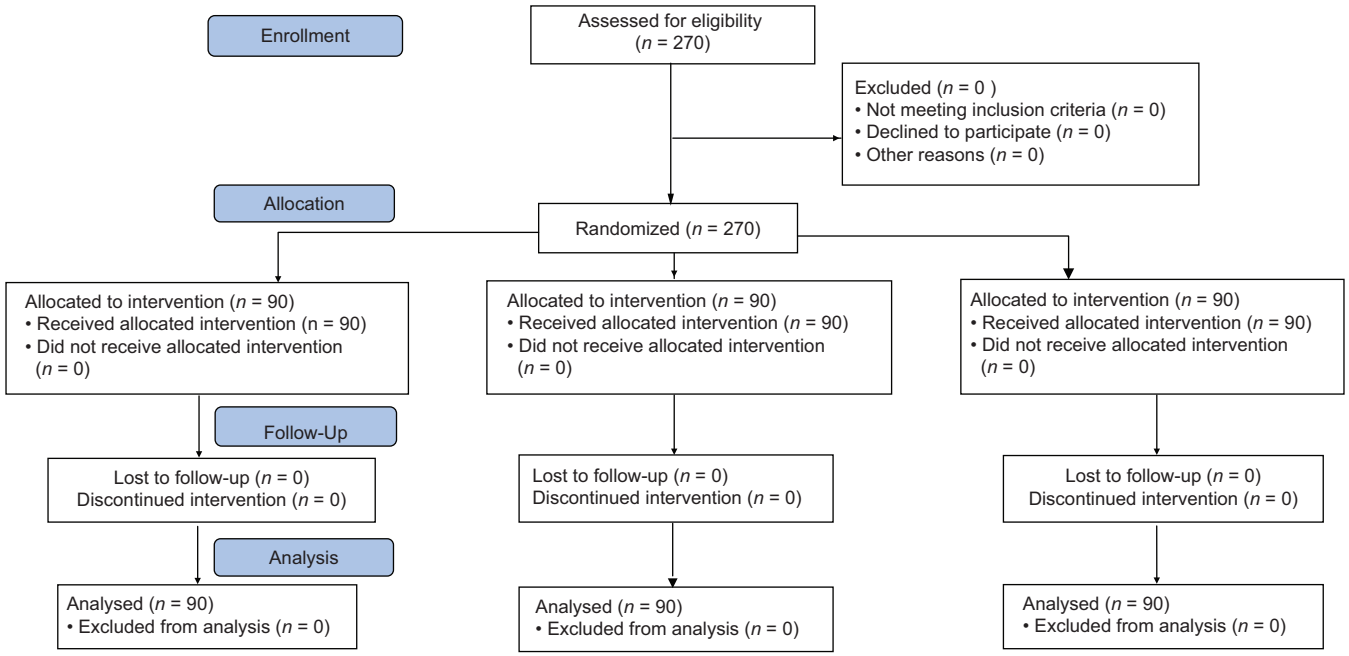

Figure 2: Consort Diagram

Table 1: Patient Characteristics, Oropharyngeal Seal Pressure and Others Parameters

	Group 1 (*n*=90)	Group 2 (*n*=90)	Group 3 (*n*=90)	*P*
Age (yrs.)	38.47±13.745	40.64±15.401	41.48±15.541	0.378
Sex (M/F)	29/61	34/56	42/48	0.134
Weight (kg)	65.6±8.439	63.81±10.855	64.80±10.690	0.488
Height (cm)	162.19±5.852	162.44±5.561	164.28±5.420	0.953
ASA Physical status				
I	61	58	57	0.809
II	28	32	33	0.709
III	1	0	0	0.367
MPG grade (1/2/3)	45/44/1	47/42/1	43/46/1	0.986
Mouth opening (cm)	5.847±0.2179	6.152±0.3663	6.264±0.4307	<0.001*
TM Distance (cm)	7.11±0.888	7.18±0.956	7.64±1.088	0.001
SM Distance (cm)	13.56±0.996	13.83±1.047	14.13±1.260	0.003
Neck movement Normal/Restricted	90/0	90/0	90/0	_
OSP (cm of H_2O)	38.9±3.050	37.41±4.097	37.32±3.740	0.006
Attempts at device insertion				
1	88	90	77	<0.001*
2	2	0	6	0.027
3	0	0	7	0.001
Ease of insertion	88	90	74	<0.001*
Attempts at gastric tube insertion 1/2/3	90/0/0	90/0/0	90/0/0	-

Values are expressed as mean±SD. A P<0.05 is taken as significant. Group 1: LMA® ProSeal™. Group 2: LMA® Supreme™. Group 3: Ambu® AuraGain™*

significant differences in the three groups. The laryngeal view on fibreoptic confirmation of anatomical position of the three devices was comparable in the three groups [Table 3]. There were no cases of the lip or dental trauma in all three groups. Blood on the mask was observed in ten patients in the LMA® ProSeal™ group, eight patients in the LMA® Supreme ™ group and 18 patients in the Ambu® AuraGain™ group. There was no statistically significant difference in the three groups ($P = 0.057$).

Sore throat was noticed in eight patients of the LMA® ProSeal™ group, 11 patients of the LMA® Supreme™ group and 13 in the Ambu® AuraGain™ group. There was no statistically significant difference in the three groups ($P = 0.478$).

Dysphonia was not observed in any patient of the LMA® ProSeal™ group but it was present in two patients each of the LMA® Supreme™ and the Ambu® AuraGain™ groups.

Table 2: Haemodynamic Parameters

	Group 1 (*n*=90)	Group 2 (*n*=90)	Group 3 (*n*=90)	*P*
Heart rate (beats/min)				
Pre induction	78.30±7.804	78.90±9.290	79.33±8.888	0.899
Just after induction	81.77±8.888	82.90±8.596	82.33±8.076	0.546
5 min after induction	83.70±11.600	85.87±7.912	83.83±11.812	0.675
10 min after induction	85.43±10.105	81.17±17.440	83.90±14.048	0.501
Mean arterial Pressure (mm Hg)				
Pre induction	97.72±8.877	93.87±10.654	97.72±8.877	0.199
Just after induction	87.77±12.561	81.67±12.45	83.97±13.538	0.456
5 min after induction	85.07±11.608	81.23±11.837	82.03±13.074	0.665
10 min after induction	80.77±10.150	79.80±10.883	79.60±13.960	0.813

Values are expressed as mean±SD. A P<0.05 is taken as significant. Group 1: LMA® ProSeal™. Group 2: LMA® Supreme™. Group 3: Ambu® AuraGain™*

Table 3: Fibreoptic Grading and Adverse Effects

	Group 1 (*n*=90)	Group 2 (*n*=90)	Group 3 (*n*=90)	*P*
Fiberoptic grading				
Grade 1	Nil	Nil	Nil	-
Grade 2	2	4	4	0.66
Grade 3	12	16	12	0.625
Grade 4	76	70	74	0.503
Blood on mask	10	8	18	0.057
Sore throat	8	11	13	0.478
Dysphonia	nil	2	2	0.358
Regurgitation	3	3	5	0.696

Values are expressed as mean±SD. P<0.05 is taken as significant. Group 1: LMA® ProSeal™. Group 2: LMA® Supreme™. Group 3: Ambu® AuraGain™*

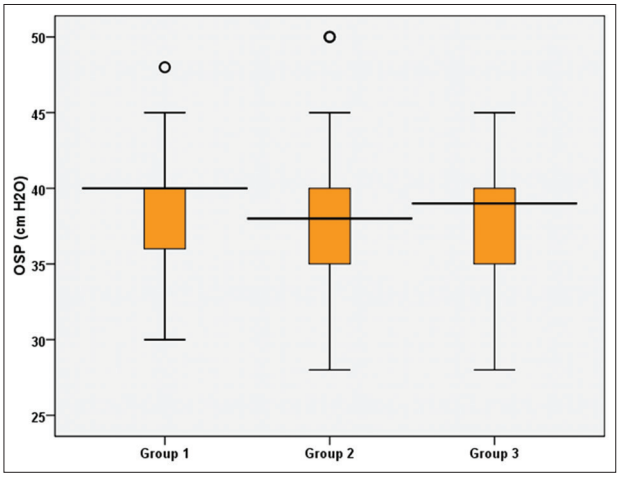

Figure 3: Box plot showing oropharyngeal seal pressure of different groups. Group 1: LMA® ProSeal™ Group 2: LMA® Supreme ™ Group 3: Ambu® AuraGain™

There was no statistically significant difference in all three groups ($P = 0.358$). No case of dysphagia was reported in any patient.

Gastric regurgitation was observed in 11 patients with 3 patients each in both LMA® ProSeal™ and LMA® Supreme™ groups as compared to 5 patients in the Ambu® AuraGain™ group. There was no statistically significant difference in all three groups ($P = 0.696$). We found no cases of pulmonary aspiration in any patient.

Discussion

In this study, we found that the LMA® ProSeal™ provided the highest OSP in comparison to the other two devices. The use of Ambu® AuraGain™ was associated with difficult and lowest first-time insertion success rate along with an increased incidence of airway trauma as compared to the other two SADs.

Several workers have evaluated the OSP among these three devices.[8-11] Higher OSP in the LMA® ProSeal™ group when compared to the LMA® Supreme™ as found in our study, was reported by previous studies.[8-10] However, a recent study in adults undergoing laparoscopic cholecystectomy under positive pressure ventilation reported similar OSP between the LMA® ProSeal™ and Ambu® AuraGain™ groups.[11]

Our finding of observing higher OSP with LMA® Supreme™ than Ambu® AuraGain™ is in agreement with the earlier work. Lopez *et al.*,[12] compared these two devices and showed a higher mean OSP of 34 cmH_2O for the Ambu® AuraGain™ *vs.* 29 cmH_2O in the Supreme. Wong *et al.*,[13] found that the OSP of the Ambu® AuraGain™ was 4.8 cmH_2O higher than that of the LMA® Supreme™ in adults undergoing ambulatory surgery. Another study comparing the Ambu® AuraGain™ with the LMA® Supreme™ has reported no significant differences in OSP between the devices.[14]

First-time insertion success rate in our study was the highest with the LMA® Supreme™ (100%) followed by the LMA® ProSeal™ (97.8%) and Ambu® AuraGain™ (82.2%). The large cuff along with the bulky shaft of the Ambu® AuraGain™ were probably responsible for its lowest first time insertion success rate.[13] The finding concurs with previous studies reporting higher first time insertion success rate with the LMA® Supreme™ as compared to Ambu® AuraGain™ and LMA® ProSeal™ airway devices by novices as well as experienced anesthesiologists.[8,9,13,15] On the contrary, other workers have reported comparable first time insertion

success rate for the Ambu® AuraGain™ and the LMA® Supreme™.[12,14]

We found that insertion of the device was most easy with LMA® Supreme™ followed by LMA® ProSeal™ and Ambu® AuraGain™. Lopez compared the LMA® Supreme™ with, the Ambu® AuraGain™ and reported that Ambu® AuraGain™ required additional manoeuvres for placing the device securely.[12]

The optimal placement of a SAD is confirmed by clinical evaluation including expired tidal volume, tests performed to exclude malposition of the device and also by fibreoptic examination. The fibreoptic position of the three SADs was found to be comparable. The fiberscope insertion through the LMA® Supreme ™ was slightly difficult as compared to the other SADs possibly because of oblique placement of airway and drain tube in this device. On the contrary, a study by Lopez AM *et al*. concluded that the fiberscopic view of vocal cords was similar with both LMA® ProSeal™ and LMA® Supreme™, albeit easier to achieve with the LMA® ProSeal™, probably because of the shape of the device.[16]

Gastric tube insertion was easy and could be placed at first attempt in all three groups and is in agreement with previous work.[8,16] The haemodynamic parameters noted among the three devices were comparable [Table 2].

The Ambu® AuraGain™ was associated with higher incidence of airway trauma along with difficult first-time insertion manifesting as presence of blood on the mask as compared to the other study SADs. Other complications were comparable in the three groups.

All the study devices belong to the second generation SADs and have been devised for use with controlled ventilation. Each chosen SAD of the study offers certain unique features. The LMA® ProSeal™ remains the gold standard with which the other SADs are compared. The LMA® Supreme™ can be easily placed even with limited mouth opening, is disposable and has the manufacturer's claim of achieving high OSP. The third device Ambu® AuraGain™ is a new device which has been used in limited studies but never the less offers a large airway tube (useful for endotracheal tube placement) in addition to a gastric drain tube. A manikin study comparing six SADs has reported higher success rate of fibreoptic aided tracheal intubation through Ambu® AuraGain™ than other devices.[17] This device is also made up of phthalate-free material. The phthalates are known to alter the endocrine system, interfere with steroid genesis and impede with luteal function in females.[18] These agents are also known to have anti-androgenic effects.[19]

Some limitations exist in our study. The anesthesiologist could not be blinded to the chosen study device. Patients with difficult airways were excluded from the study though we did include patients up to 40 BMI. We also did not examine the role of the Ambu® AuraGain™ as a conduit for tracheal intubation.

We conclude that the highest OSP was achieved with the LMA® ProSeal™ followed by the LMA® Supreme™ and the Ambu® AuraGain™ in patients undergoing surgery with controlled ventilation. However, this statistically significant difference in OSP may not be clinically relevant. The Ambu® AuraGain™ may be an effective disposable alternative SAD to the LMA® Supreme™ and the LMA® ProSeal™. The LMA® Supreme™ was easier to place and may be helpful in patients with decreased mouth opening. Further studies are needed to confirm our findings.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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