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Original Article

Anaesthesia Section

Comparative Evaluation of Placement of Auragain, ProSeal and Protector Laryngeal Mask Airways using Fiberoptic Bronchoscopy: A Randomised Clinical Study

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ABSTRACT

Introduction: Supraglottic Airway Devices (SAD) can be used instead of endotracheal intubation in both regular and complicated airway situations. Auragain, ProSeal and Protector Laryngeal Mask Airways (LMA) are second generation LMAs. They have a separate provision for gastric drainage. Auragain LMA is a recent second-generation Supra Glottic Airway device (SGA) with a preformed curved shaft and a double lumen having wider airway path to aid endotracheal intubation. ProSeal LMA also has a double cuff for better sealing to prevent gastric insufflation and aspiration. Protector LMA has two large-volume gastric drainage channels and an integrated cuff pressure indicator called the cuff pilot which enables application of higher respiratory pressure.

Aim: To compare the adequacy of placement of Auragain, ProSeal and protector LMAs by vocal cord visualisation using fiberoptic bronchoscopy.

Materials and Methods: A randomised clinical study was conducted in the Department of Anaesthesiology, SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India, from October 2021 to October 2022 among 120 patients. They were allocated by computer-generated random numbers into three groups namely Auragain, ProSeal and Protector LMA group. The adequacy of placement of LMA through Fiberoptic Bronchoscopy (FOB) using Brimacombe and berry scoring, Oropharyngeal Leak Pressure (OLP), time of insertion of LMA, number of attempts for insertion, ease of insertion of LMA, Ryle's tube insertion success rate and postoperative complications were recorded immediately, after an hour and at 24 hour, respectively. Statistical analysis was performed using International Business Machines-Statistical Package for the Social Sciences (IBM-SPSS) software version 21.0.

Results: The mean±Standard Deviation (SD) of age in Auragain group, ProSeal and Protector LMA groups were 41.35±12.96 years, 36.58±12.62 years and 36.65±12.50 years, respectively. The demographic data, procedures and duration of anaesthesia were comparable between the three groups. The mean insertion time (in seconds) was lower in the Auragain LMA group (16.80±3.66) when compared to protector LMA (20.20±6.93) and ProSeal LMA (21.68±4.44) with statistically significant difference (p-value <0.0001). The OLP (in cm H_2O) was more with ProSeal LMA (34.43±5.26) than Protector LMA (32.60±3.45) and Auragain LMA (28.55±1.85) with statistically significant difference (p-value <0.0001). The fiberoptic view was better with ProSeal LMA and statistically significant with grade 4 (p-value <0.0001) and grade 3 (p-value=0.007). The three devices were comparable in terms of ease and success of insertion of LMA, ease of placement of gastric tube and postoperative symptoms.

Conclusion: It can be concluded that the ProSeal LMA offers better airway access and safety, despite being slightly difficult to insert compared to Ambu Auragain or Protector LMA.

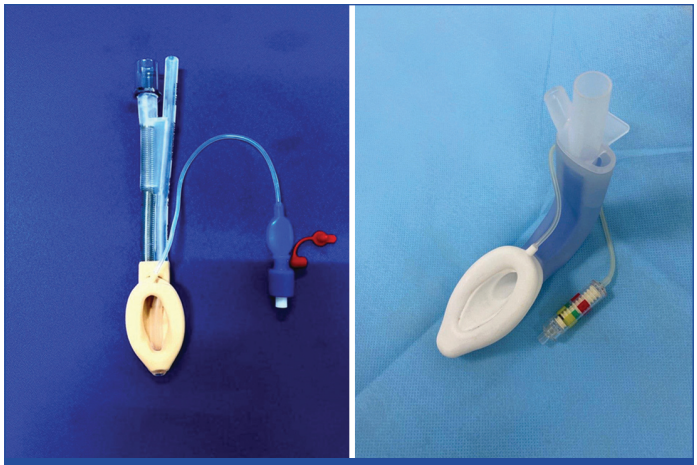
Keywords: Anaesthetic gases, Oropharyngeal leak pressure, Supraglottic airway

INTRODUCTION

The Supraglottic Airway Devices (SAD) are a cluster of tools that act as a conduit for oxygenation, ventilation, and administration of anaesthetic gases. SAD forms an indispensable part of the difficult airway ladder, standing between the endotracheal tube and face mask [1]. The LMA is the first SAD available for anaesthesia practice, since 1989 [2]. The SGAs devices are unique as they have gastric drainage built-in and offer better sealing pressure therefore, the chance of gastric insufflation is less [3]. Various difficulties faced during tracheal intubation have been overcome with the help of SADs which include laryngoscopic response which leads to extreme haemodynamic changes, oropharyngeal structural damage, and postoperative airway discomfort and morbidity [4].

Dr. Archie IJ Brain introduced the blind insertion technique of LMA which later posed some difficulties as proper placement of the LMA is necessary to avoid gastric insufflation and leakage of gas. This was overcome with the help of a visual assessment of the position of the vocal cords using a fiberoptic bronchoscope and subsequent scoring of the view using a fiberoptic scoring system [5].

The ProSeal LMA [Table/Fig-1] is an SGA that has a separate provision for gastric drainage. It also has a double cuff for better sealing for preventing gastric insufflation and aspiration [1]. Protector LMA [Table/Fig-2] was first used in 2015. It is made of medical-grade silicone with two large-volume gastric drainage channels and integrated with a cuff pressure indicator [6]. This LMA belonging to the second generation has higher respiratory pressure, allowing the possible evacuation of regurgitated material, and permits the insertion of a Ryle's tube through the integrated gastric port [6]. The Ambu Auragain LMA [Table/Fig-3] is a single-use, preformed second generation SGA with an integrated gastric port and a wider airway path to aid the introduction of a larger endotracheal tube [3]. The Auragain LMA has a preformed curved shaft and a double lumen.



[Table/Fig-1]: ProSeal LMA.
[Table/Fig-2]: Protector LMA. (Images from left to right)

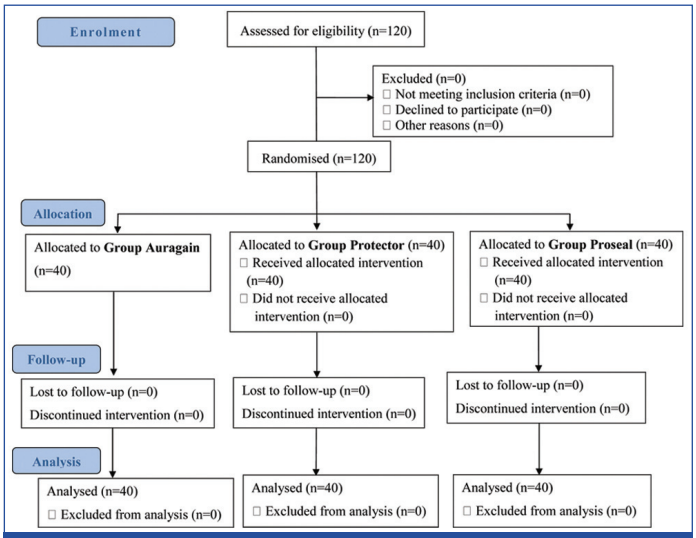
[Table/Fig-3]: Ambu Auragain LMA.

In the present study, the seal pressure was measured with the help of Oropharygeal leak pressure, and placement of LMA was confirmed and graded using fiberoptic view. This offered a great comparative analysis of the three LMAs. Sharma M et al., in their study concluded that the ProSeal LMA had better seal followed by Supreme LMA and Ambu Auragain LMA [7]. The present study was done to advance the comparison of the three different LMAs allowing better handling of difficult airway, as there were no studies previously comparing these three LMAs in particular. A main disadvantage of ProSeal LMA as noted by Agrawal N et al., in their study is that the ProSeal LMA being reusable can transmit prions despite undergoing standard washing and sterilisation techniques [8]. Apart from this disadvantage, no further drawbacks were noted in any other studies for Protector LMA and Ambu Auragain LMA. The present study endeavoured to compare ProSeal LMA, Protector LMA and Auragain LMA in patients undergoing general anaesthesia without paralysis with the LMA being inserted soon after induction.

The present study aimed to compare three SGAs based on the fiberoptic view of the vocal cords, OLP, insertion time, ease of insertion, and Ryle's tube insertion success rate along with the postoperative symptoms and morbidity. The primary measure was to compare the adequacy of placement of three different LMAs using vocal cord visualisation scoring through fiberoptic bronchoscopy [9]. The secondary objectives were to look for OLP, ease of insertion, number of insertion attempts, first attempt success rate, time taken for insertion of LMA, Ryle's tube insertion success rate and airway related complication.

MATERIALS AND METHODS

The present randomised clinical study was conducted in the Department of Anaesthesiology, SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India, from October 2021 to October 2022. Study was conducted after obtaining Institutional Ethical Committee (IEC) approval (2861/IEC/2021). The present trial was registered with clinicaltrials.gov (CTRI/2021/09/036570). Study included 120 patient, who were allocated by computer-generated random numbers to three groups namely: Auragain, ProSeal, and Protector LMA groups. Written informed consent was obtained from all the participants and Consolidated Standards of Reporting Trials (CONSORT) flow diagram is presented in [Table/Fig-4].



[Table/Fig-4]: CONSORT flow diagram.

Sample size calculation: The sample size was calculated based on study by Singh K and Gurha P, where it was obtained from the time of insertion and substituting their values for [10]:

$n=(Z_{\alpha/2+}Z_{1-\beta})^2 (\sigma_1^{2+}\sigma_2^2)/(\mu_1+\mu_2)^{2-}$

where,

$Z_{\alpha/2}$:1.96, $Z_{(1-\beta)}$:0.84, σ_1:1.94, σ_2:2.22, μ_1:13.57, μ_2:11.60

$Z_{\alpha/2}$:Level of significance at 5%

$Z_{(1-\beta)}$: Power of study 80%

Sample size of 40 subjects in each group was considered.

Inclusion criteria: Patients with American Society of Anesthesiologists (ASA) physical status-I and II, aged between 18-65 years, Body Mass Index (BMI) ≤29 kg/m^2 and patients who underwent elective surgeries of duration less than 90 minutes were included in the study.

Exclusion criteria: Patients with anticipated difficult airway, patients at risk of gastroesophageal regurgitation and with airway-related conditions such as trauma, trismus, or neck swelling were excluded from the study.

Study Procedure

Standard monitors like Electrocardiogram (ECG), Non Invasive Blood Pressure (NIBP) and Serum Pressure Oxygen (SpO_2) were attached to the patients, on receiving in the operating theatre and the preoperative vitals were noted. The patient was given routine premedication with injection glycopyrrolate 0.2 mg Intravenous (i.v.) injection ondansetron 4 mg i.v., and midazolam 1 mg i.v. Standard general anaesthesia was administered to the patient without neuromuscular blocking agents. The patient was adequately preoxygenated for three minutes with a facemask and was induced with fentanyl 2 mcg/kg i.v. and propofol 2 mg/kg i.v. The appropriate size was chosen according to the patient's body weight. After achieving adequate jaw relaxation, the LMA was lubricated and inserted using the standard insertion technique. The patients were unaware of the group allocation and data was collected by the principal investigator [9].

The insertion time of the selected LMA was measured from taking the LMA in hand till the appearance of a square wave capnography [9]. The number of attempts needed for the insertion of the LMA was noted. The attempt was repeated if there was no proper chest rise or if there was an audible leak after placement of the LMA. If more than two attempts were made during insertion or if the airway was secured with a tracheal tube, it was considered a failed attempt [9]. The grading for ease of insertion are as follows: 1) easy or 2) difficult [10]. The insertion was described as difficult when deep rotation or jaw thrust was made during the insertion attempt [10]. If leak was appreciated after insertion, the LMA was repositioned [10]. The OLP was measured following the insertion of LMA. The OLP was measured by setting the adjustable pressure-limiting valve to 70 cmH_2O with manual ventilation. The OLP was measured till the point where it reaches a steady state and was detected by hearing an audible leak over the mouth [9]. The placement of the LMA was visualised using fiberoptic bronchoscopy and graded using Brimacombe and Berry scoring [9]:

Grade 4 only vocal cords visible;

Grade 3 vocal cords plus posterior epiglottis visible;

Grade 2 vocal cords plus anterior epiglottis;

Grade 1 vocal cords invisible.

According to this grading, grade 4 was desired to ensure proper placement and seal of LMA. The systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, oxygen saturation, and respiratory rate were noted pre-induction, immediately after administration of induction agents, and subsequently at 5, 10, 15, 20, 25 and 30 minutes after LMA insertion [9].

After the surgery, the LMA was removed after ensuring spontaneous respiration. The blood on LMA, if present was noted following extubation. The duration of anaesthesia was also noted. The patient was followed-up for postoperative airway morbidity and symptoms in the immediate postoperative period and upto 24 hours postoperative. Immediate postoperative airway morbidity includes blood on LMA, coughing, laryngospasm, hoarseness, trauma to the mouth, lip and tongue. The postoperative symptom includes dysphonia and sore throat was noted from the first hour upto 24 hours and data was collected for all the parameters.

STATISTICAL ANALYSIS

The data was given in the form of mean, standard deviation, frequency and percentage. Categorical variables were provided as absolute numbers and percentages, whereas continuous variables were presented as mean±SD. One-way Analysis of Variance (ANOVA) was used to compare continuous variables. The Pearson's Chi-square test was used to compare categorical variables. Using a two-tailed test, significance was determined as p-values less than 0.05. IBM-SPSS software version 21.0 (IBM-SPSS Science Inc., Chicago, IL) was used to analyse the data.

RESULTS

The age (p-value=0.161), gender (p-value=0.686), height (p-value=0.499), weight (p-value=0.444), BMI (p-value=0.758), and duration of anaesthesia (p-value=0.567) were similar in all the three groups [Table/Fig-5].

The mean insertion time (in seconds) was least with Auragain LMA group (16.80±3.66) and longest with ProSeal LMA (21.68±4.44) and the difference was statistically significant (p-value <0.0001).

The ease of insertion was best {grade 1 (easy)} with Auragain LMA in 87.5% patients, Protector LMA in 85% and ProSeal LMA in 75% patients and the procedure was tough {grade 2 (difficult)} with Auragain LMA in 12.5%, Protector LMA in 15% and ProSeal LMA in 25% [Table/Fig-6]. The ease of insertion of gastric tube was easiest (Grade 1) with ProSeal LMA in 97.5% patients, Auragain LMA in 95% and protector LMA in 90%. The Oropharyngeal Leak Pressure (OLP) was highest with ProSeal LMA (34.43±5.26) and lowest with protector LMA was 32.60±3.45 and in Auragain LMA, it was 28.55±1.85. The difference was statistically significant (p-value <0.0001) [Table/Fig-6].

Variables	Auragain LMA	ProSeal LMA	Protector LMA	p-value
Age (years) (mean±SD)	41.35±12.96	36.58±12.62	36.65±12.50	0.161
Height (metre) (mean±SD)	1.58±0.06	1.57±0.07	1.57±0.08	0.499
Weight (kg) (mean±SD)	62.70±7.32	61.43±8.31	60.41±8.37	0.444
BMI (kg/m^2) (mean±SD)	24.97±2.40	24.82±2.12	24.57±2.77	0.758
Duration of anaesthesia (mins) (mean±SD)	44.87±14.95	47.87±13.53	47.62±13.30	0.567
Gender n (%)				
Female	34 (85)	31 (77.5)	32 (80)	0.686
Male	6 (15)	9 (22.5)	8 (20)	
ASA n (%)				
I	13 (32.5)	11 (27.5)	13 (32.5)	0.855
II	27 (67.5)	29 (72.5)	27 (67.5)	
Size of LMA n (%)				
1	24 (60)	24 (60)	27 (67.5)	0.726
2	16 (40)	16 (40)	13 (32.5)	
Mallampati score n (%)				
1	4 (10)	5 (12.5)	5 (12.5)	0.453
2	30 (75)	25 (62.5)	31 (77.5)	
3	6 (15)	10 (25)	4 (10)	

[Table/Fig-5]: Demographic data of the study population.

Clinical parameters	Auragain LMA	ProSeal LMA	Protector LMA	p-value
Ease of Insertion of LMA n (%)				
Grade 1 (easy)	35 (87.5)	30 (75)	34 (85)	0.298
Grade 2 (difficult)	5 (12.5)	10 (25)	6 (15)	
FOB view using Brimacombe and Berry scoring n (%)				
Grade 4	0	20 (50)	2 (5)	<0.0001
Grade 3	20 (50)	12 (30)	26 (65)	0.007
Grade 2	16 (40)	8 (20)	10 (25)	0188
Grade 1	4 (10)	0	2 (5)	0.122
Blood on LMA n (%)				
Yes	0	1 (2.5)	5 (12.5)	0.025
No	40 (100)	39 (97.5)	35 (87.5)	
Insertion time (mean±SD)	16.80±3.66	21.68±4.44	20.20±6.93	<0.0001
Oropharyngeal leak pressure (cmH_2O) (mean±SD)	28.55±1.85	34.43±5.26	32.60±3.45	<0.0001

[Table/Fig-6]: Clinical parameters of LMA.
p-value <0.05 considered significant

The best FOB view (grade 4 view) was found with ProSeal LMA in 50% patients, Protector LMA in 5% and worst with Auragain LMA (0%) with p-value <0.0001 [Table/Fig-6]. The first attempt insertion success rate was 100% in Auragain LMA patients, 95% in ProSeal LMA and 97.5% in protector LMA. Blood on LMA was noted with Protector LMA in 12.5% patients and ProSeal LMA in 2.5% (p-value=0.025) [Table/Fig-6].

No immediate postoperative complications like coughing, laryngospasm, hoarseness of voice, trauma to mouth, lip and tongue were noted in any group. Also, postoperative symptoms (sore throat and dysphonia) after an hour and 24 hour were not noted in any group. There was no significant difference in systolic and, diastolic blood pressure at preoperative to 30 minutes between the LMA groups. There was no significant difference in mean arterial pressure, heart rate, respiratory rate and SpO_2 at preoperative to 30 minutes between the LMA groups.

DISCUSSION

In the present randomised clinical study, three second-generation LMAs were compared in terms of fiberoptic view of the vocal cords, OLP, insertion time, ease of insertion, and Ryle's tube insertion success rate along with the postoperative symptoms and morbidity. In the current study, the time taken for insertion was lower with Ambu Auragain LMA followed by Protector LMA and ProSeal LMA [Table/Fig-7] [3,10,11,16]. Singh K and Gurha P, in their study showed that ProSeal LMA needed less time than Ambu Auragain LMA, whereas Wong DT et al., showed Supreme LMA lesser than Ambu Auragain LMA [10,11]. Joshi R et al., in their study showed Ambu Auragain lesser than ProSeal LMA [3]. The number of attempts in the current study concluded 40 in the first attempt with Ambu Auragain LMA, 39 with Protector LMA and 38 with ProSeal LMA [Table/Fig-8] [10,12-14]. Ari DE et al., in their study showed 30 in the first attempt with I-gel LMA and 29 with Protector LMA [12]. Singh K and Gurha P, showed 18 with Ambu Auragain LMA and 24 with ProSeal LMA [10]. ElGohary M et al., showed 40 attempts with Classical LMA, 60 with ProSeal LMA and 80 with I-gel LMA [13]. Bhat CB et al., showed 20 with ProSeal LMA and 21 with Classic LMA [14]. The first attempt success rate in the current study was 100% with Ambu Auragain LMA followed by Protector and ProSeal LMA, which were 97.5% and 95%, respectively [Table/Fig-9] [3,8,15,16]. Moser B et al., showed a 98% success rate with Ambu Auragain LMA and 74% with Protector LMA [15]. Seet E et al., showed a higher success rate with LMA Supreme than ProSeal LMA [16]. Joshi R et al., concluded success rates were equal with both ProSeal LMA and Ambu Auragain LMA [3]. Agrawal N et al., concluded a 100% success rate with both ProSeal LMA and Ambu Auragain LMA [8].

Type of LMA	Current study	Singh K and Gurha P [10] India 2017	Wong DT et al., [11] Canada 2018	Joshi R et al., [3] India 2020	Seet E et al., [16] Canada 2010
ProSeal LMA	21.68±4.44	11.60±2.22	-	20	30
Protector LMA	20.20±6.93	-	-	-	-
Ambu Auragain LMA	16.80±3.66	13.57±1.94	13±4	12	-
Supreme LMA	-	-	11±3	-	26

[Table/Fig-7]: Comparison of time taken for insertion (in mean±SD) (in seconds) [3,10,11,16].

Type of LMA	Current study n=120	Ari DE et al., [12] Turkey 2022 n=64	Singh K and Gurha P [10] India 2017 n=60	ElGohary M et al., [13] Egypt 2019 n=60	Bhat CB et al., [14] Kerala 2018 n=60
ProSeal LMA	38 in first attempt	-	24 in first attempt	60 in first attempt	20 in first attempt
Protector LMA	39 in first attempt	29 in first attempt	-	-	-
Ambu Auragain LMA	40 in first attempt	-	18 in first attempt	-	-
I-gel LMA	-	30 in first attempt	-	80 in first attempt	-
Classic LMA	-	-	-	40 in first attempt	21 in first attempt

[Table/Fig-8]: Comparison of number (n) of attempts [10,12-14].

Type of LMA	Current study	Moser B et al., [15] Switzerland 2017	Seet E et al., [16] Canada 2010	Joshi R et al., [3] India 2020	Agrawal N et al., [8] India 2021
ProSeal LMA	95%	-	88%	95.7%	100%
Protector LMA	97.5%	74%	-	-	-
Ambu Auragain LMA	100%	98%	-	95.7%	100%
Supreme LMA	-	-	98%	-	-

[Table/Fig-9]: Comparison of first attempt success rate (%) [3,8,15,16].

The ease of insertion of LMA in this current study was better with Ambu Auragain LMA followed by Protector LMA and ProSeal LMA [Table/Fig-10] [7,8]. Sharma M et al., in their study showed that Supreme LMA was easy to insert than ProSeal LMA and Ambu Auragain LMA [7]. Agrawal N et al., in their study showed that ProSeal LMA was easy to insert than Ambu Auragain LMA [8]. The OLP in the current study showed better seal pressure with ProSeal LMA followed by Protector LMA and Ambu Auragain LMA [Table/Fig-11] [7,10,16]. Seet E et al., in their study showed a better seal with ProSeal LMA followed by Supreme LMA [16]. Whereas, Sharma M et al., in their study also showed that ProSeal LMA had a better seal than Supreme LMA and Ambu Auragain LMA [7]. Singh K and Gurha P, in their study showed a better seal with Ambu Auragain LMA than ProSeal LMA [10].

	Current study (grades)		Sharma M et al., [7] India 2021		Agrawal N et al., [8] India 2021	
Type of LMA	1	2	1	2	1	2
ProSeal LMA	30	10	88	2	46	4
Protector LMA	34	06	-	-	-	-
Ambu Auragain LMA	35	5	74	16	47	3
Supreme LMA	-	-	90.0	-	-	-

[Table/Fig-10]: Comparison of ease of insertion of LMA [7,8].

Type of LMA	Current study	Seet E et al., [16] Canada 2010	Sharma M et al., [7] India 2021	Singh K and Gurha P [10] India 2017
ProSeal LMA	34.43±5.26	25±6	38.9±3.050	27.17±16.91
Protector LMA	32.60±3.45	-	-	-
Ambu Auragain LMA	28.55±1.85	-	37.32±3.740	28.77±4.82
Supreme LMA	-	21±5	37.41±4.097	-

[Table/Fig-11]: Comparison of Oropharyngeal Leak Pressure (OLP) in mean±SD cmH_2O [7,10,16].

Ryle's tube insertion was 100% successful with the current study [Table/Fig-12] [7,9,17], similar to findings by Sharma M et al., Ozgul U et al., and Liu Y et al., showed a success rate of 96.66% and 97.56%, respectively [7,9,17]. In the current study, vocal cord visualisation scoring through fiberoptic bronchoscopy was graded better with ProSeal LMA followed by Protector LMA and Ambu Auragain LMA. Joshi R et al., concluded Ambu Auragain was better than ProSeal LMA similar to Sharma M et al., for whom ProSeal LMA had better grading than Ambu Auragain and Supreme LMA [3,7]. Shimbori H et al., in their study concluded better grading with ProSeal LMA than classic LMA [18].

Type of LMA	Current study	Ozgul U et al., [9] Turkey 2019	Liu Y et al., [17] China 2021	Sharma M et al., [7] India 2021
ProSeal LMA	100%	96.66%	-	100%
Protector LMA	100%	-	97.56%	-
Ambu Auragain LMA	100%	-	-	100%
Supreme LMA	-	-	-	100%

[Table/Fig-12]: Compariosn of Ryle's tube insertion success rate (%) [7,9,17].

Limitation(s)

The main limitation of the present study was that the ability to intubate using the three LMAs were not assessed, postoperative morbidity like sore throat or hoarseness of voice was not correlated with mucosal perfusion pressure and the present study was conducted only on adult patients. Hence, the effectiveness in the paediatric population was still not explored.

CONCLUSION(S)

Of the three SGA's, ProSeal LMA had better OLP and fiberoptic scoring indicating better placement and seating with easier Ryle's

tube insertion which overweighs Auragain's easier and lesser time for LMA insertion. Hence, the present study concludes that the ProSeal LMA offers better airway access and safety despite being slightly difficult to insert compared to Ambu Auragain or Protector LMA.

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