

# Comparing the Effectiveness of Ambu<sup>®</sup> AuraGain<sup>™</sup> Laryngeal Mask Airway with LMA<sup>®</sup> ProSeal<sup>™</sup> in Patients undergoing Laparoscopic Surgeries- A Randomised Clinical Trial

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## ABSTRACT

**Introduction:** Second generation Supraglottic Airway Devices (SADs) contain a gastric drain tube which separates the respiratory and the alimentary tract. This provides a better oropharyngeal seal and reduces the risk of pulmonary aspiration of refluxed gastric contents compared to the first generation SADs.

**Aim:** To compare Ambu<sup>®</sup> AuraGain<sup>™</sup> (AAU) laryngeal mask airway with LMA<sup>®</sup> ProSeal<sup>™</sup> (PLMA) in terms of Oropharyngeal Leak Pressure (OLP) in laparoscopic surgeries.

**Materials and Methods:** This randomised clinical study was conducted from December 2017-September 2019, at Shri Dharmasthala Manjunatheshwara College of Medical Sciences and Hospital, Dharwad, India in 80 patients, aged 18-65 years, of American Society of Anaesthesiologists (ASA) physical status I and II undergoing laparoscopic surgeries. Patients were randomly assigned to one of the two groups: group PLMA and group AAU. After induction of anaesthesia, SADs were inserted by an experienced anaesthesiologist. OLP, pharyngeal mucosal pressure, peak airway pressure and secondary outcome parameters (the number of attempts, time required, ease, and haemodynamic response associated with insertion of LMA) were

recorded at set time points. Data was analysed using Statistical Packages for Social Sciences (SPSS) version 22.

**Results:** All patients in both the groups were comparable in terms of demographic data and baseline vital parameters. The Oropharyngeal Leak Pressure of group AAU was comparable to group PLMA at all measured time-points. The two groups were comparable in terms of pharyngeal mucosal pressure immediately after insertion of LMA, but group AAU had lesser pharyngeal mucosal pressure compared to group PLMA immediately after pneumoperitoneum, at 30 and 60 minutes. Mean peak airway pressures were lower in group AAU than group PLMA immediately after insertion of LMA (15.53±1.50 versus 17.06±2.56 cmH<sub>2</sub>O, p=0.004) and immediately after creation of pneumoperitoneum (23.03±2.96 versus 26.58±10.12 cmH<sub>2</sub>O, p=0.04). Both the groups were comparable in terms of number of attempts, time taken, haemodynamic response associated with LMA insertion and with passage of gastric tube except that PLMA was easier to insert in the first attempt compared to AAU (26/40 versus 13/40, Grade 1 ease of insertion).

**Conclusion:** Ambu<sup>®</sup> AuraGain<sup>™</sup> could be a useful alternative to LMA<sup>®</sup> ProSeal<sup>™</sup> in patients undergoing laparoscopic surgeries.

**Keywords:** Airway pressure, Oropharyngeal leak pressure, Pharyngeal mucosal pressure, Supraglottic airway devices

## INTRODUCTION

Laparoscopic surgeries have gained popularity over conventional abdominal surgeries due to various advantages like smaller incision, lower risk of postoperative complications and early discharge. However, intraoperatively the effect of pneumoperitoneum and subsequent alteration in the respiratory volumes and pressures are the major concerns in laparoscopic surgery [1]. Laparoscopic surgeries are usually done under general anaesthesia with the airway secured using an endotracheal tube. Rigid laryngoscopy associated haemodynamic responses, damage to the oropharyngeal structures during intubation, and invasiveness are some disadvantages associated with endotracheal intubation precluding the global utility of the endotracheal tube [2]. Hence there is a need for better alternatives such as Supraglottic Airway Devices (SADs) [3]. The second generation SADs incorporate a gastric drain tube in their construction to separate the respiratory and alimentary tract offering better oropharyngeal seal and improved protection against regurgitation and pulmonary aspiration in comparison to first generation SADs [4].

LMA<sup>®</sup> ProSeal<sup>™</sup> (PLMA) (Intavent Orthofix, Maidenhead, UK) has a basic structure similar to the classic laryngeal mask airway. In addition,

it was designed with modifications to separate the respiratory and gastrointestinal tract by incorporating a gastric drain tube, thus offering improved protection against aspiration of gastric contents. The design also incorporates a second, dorsal cuff to improve airway seal, improve safety and efficacy of controlled ventilation [5]. Ambu<sup>®</sup> AuraGain<sup>™</sup> (AAU) launched in 2014, is a newer single use second generation SAD. It has a preformed tube designed to follow the anatomy of the human airway, and the soft rounded curve allows easy insertion and a low friction surface of the drain tube allows for easy gastric tube placement [6]. A study compared Ambu<sup>®</sup> AuraGain<sup>™</sup> with LMA<sup>®</sup> ProSeal<sup>™</sup> in patients undergoing laparoscopic surgeries [7], especially the OLP, but it did not perform repeated measurements throughout the procedure, which is unique to the present study.

The aim of the study was to compare Ambu<sup>®</sup> AuraGain<sup>™</sup> with LMA<sup>®</sup> ProSeal<sup>™</sup> in patients undergoing laparoscopic surgery. The primary objective was to compare the SADs in terms of OLP. Secondary objectives were comparison of Ambu<sup>®</sup> AuraGain<sup>™</sup> with LMA ProSeal<sup>™</sup> in terms of pharyngeal mucosal pressure, ease, number of attempts, time taken for insertion, and haemodynamic response to insertion of the SAD and ease of passage of gastric tube.

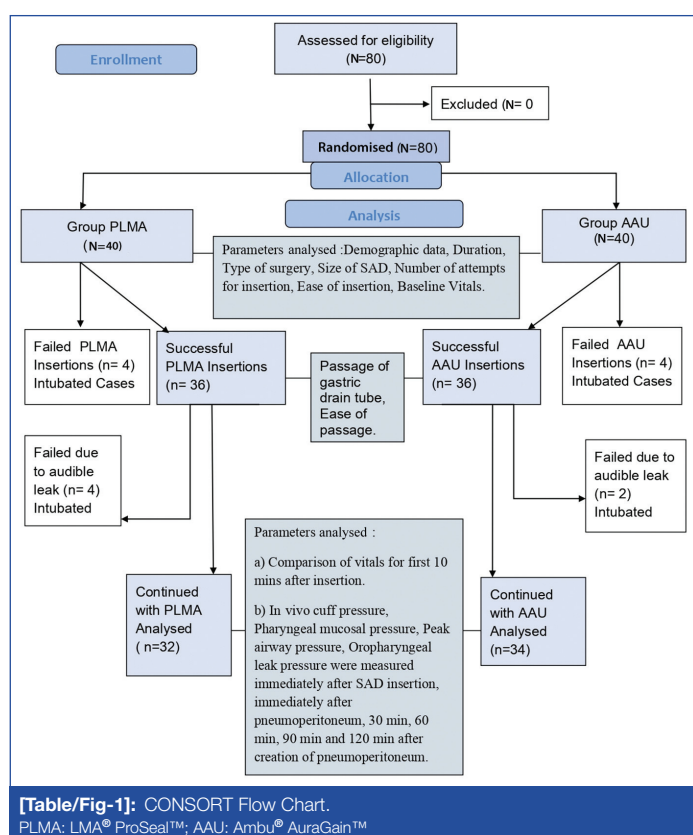
## MATERIALS AND METHODS

This randomised clinical trial was conducted, from December 2017-September 2019, at Shri Dharmasthala Manjunatheshwara College of Medical Sciences and Hospital, Dharwad, India in the main OT Complex. After approval from the Institutional Ethical Committee (SDMIEC: 0356: 2017), the trial was registered at Clinical Trial Registry of India (CTRI/2018/03/012836).

**Inclusion criteria:** Eighty patients of ASA physical status I and II, in the age group of 18-65 years, undergoing laparoscopic surgery were included in the study with a written informed consent.

**Exclusion criteria:** Patient refusal, inadequate fasting, Gastro Esophageal Reflux Disease (GERD) and restricted mouth opening were excluded from the study.

**Sample size calculation:** Primary outcome of this study was OLP. The mean OLP was considered to be 27.17 cmH<sub>2</sub>O in the group PLMA, and 28.77 cmH<sub>2</sub>O in group AAU [7]. At an  $\alpha$  level of 0.05 and power of 80%, the calculated sample size was 38 patients in each group. A total of 80 patients were recruited, with 40 patients in each group. The flowchart is presented in [Table/Fig-1].



### Study Procedure

After a thorough preanaesthetic evaluation a day before the scheduled date of surgery, all patients were advised to follow the standard ASA fasting guidelines and were administered with oral ranitidine 150 mg and oral alprazolam 0.5 mg the night before and on the morning of surgery. In the Preoperative Room, Baseline Vital Parameters Heart Rate (HR), Non Invasive Blood Pressure (NIBP) and Oxygen Saturation (SpO<sub>2</sub>) were recorded. Using the sealed envelope method, the patients were randomly allocated into two groups, group PLMA-LMA® ProSeal™ group and group AAU-Ambu® AuraGain™ group and these envelopes were opened just before shifting the patient to the Operation Theatre (OT). Size of the SAD was selected based on the body weight of the patient as per the manufacturer's recommendation [8,9]. After shifting the patient to the OT, standard monitors were attached and HR, NIBP and SpO<sub>2</sub> readings recorded. Intravenous (i.v.) cannula of appropriate size was secured and IV fluid, ringer's lactate or normal saline, was administered as per the holliday segar formula throughout the intraoperative period [10]. After preoxygenation with 100%

oxygen for 3 minutes, IV fentanyl 2 µg/kg of Body Weight (kgBW) was administered. After 2 minutes, anaesthesia was induced with IV propofol 2 mg/kgBW. After check ventilation, muscle relaxant vecuronium 0.1 mg/kgBW was administered IV. Before inserting the SAD, the cuff of the SAD (LMA® ProSeal™ or Ambu® AuraGain™) was inflated with the maximum permissible air recommended by the manufacturer [8,9] and the cuff pressure was noted as P<sub>ex vivo</sub> with a cuff pressure manometer. The SAD was fully deflated and lubricated with a water soluble gel. Patients were ventilated for three minutes with face mask, after which the device was inserted by an experienced anaesthesiologist (experience of more than 250 SAD insertions in clinical practice). The patient was placed in "sniffing" position and in group PLMA: LMA® ProSeal™ of appropriate size was introduced by introducer tool technique [8] and in group AAU, Ambu® AuraGain™ laryngeal mask airway of appropriate size was inserted. After insertion, the device was inflated with maximum permissible volume of air and connected to the ventilator circuit and appearance of end tidal capnogram, absence of leak, adequate chest rise and adequate tidal volume delivery confirmed a successful device insertion. The in vivo cuff pressure P<sub>in vivo</sub> was noted and the pharyngeal mucosal pressure was calculated as  $P = P_{in vivo} - P_{ex vivo}$ . Ventilation parameters were volume controlled ventilation with set tidal volume 8-10 mL/kgBW with a Positive End Expiratory Pressure (PEEP) of 5 cmH<sub>2</sub>O, respiratory rate and Inspiration: Expiration ratio (I:E ratio) were adjusted from time to time to maintain an end tidal carbon dioxide of 35-45 mmHg.

Anaesthesia was maintained using isoflurane with oxygen and nitrous oxide at FiO<sub>2</sub> of 0.4 and a total flow of 1 L/min and minimum alveolar concentration of 1.2. The following parameters were recorded: number of insertion attempts; time taken for insertion from the time the SAD was held till the appearance of capnogram; ease of insertion of SAD: assessed using a scale of 1-4, 1=no resistance, 2=moderate resistance, 3=high resistance, 4=inability to place [11]. Haemodynamic parameters: heart rate and blood pressure were recorded every minute for 10 minutes after insertion of the SAD. After confirmation of adequacy of ventilation, peak airway pressures and P<sub>in vivo</sub> were noted. If there was no leak and ventilation was adequate, the cuff pressure was set to 60 cmH<sub>2</sub>O and OLP was noted by closing the expiratory valve of the breathing circuit at a gas flow of 3 L/min, until the seal pressure or a maximum pressure of 40 cmH<sub>2</sub>O was reached. Peak airway pressures, P<sub>in vivo</sub> and OLP were noted immediately after creation of pneumoperitoneum and at every 30 minute interval up to 2 hours. A lubricated oro gastric tube of appropriate size was introduced via the drain tube of the device. Ease of insertion of gastric tube through the gastric channel was noted on a 3 point scale: 1-3, 1=passed easily, 2=passed with difficulty, 3=impossible to pass [11]. In case of failure of insertion of the SAD after 3 attempts or presence of an audible leak with inadequate ventilation, patients were intubated and recorded as failed insertion. All the above parameters were recorded by an independent observer. All the measurements were performed safely, without any complications.

### STATISTICAL ANALYSIS

IBM Statistical Packages for Social Sciences (SPSS) Version 22 for windows was used for analysing the data. Categorical data was represented as frequency and percentage whereas, Chi-square test was applied to know the association between the variables. Mean and standard deviation values were calculated for continuous variables. Comparison of mean values between the groups were done using student's unpaired t-test. The p-value <0.05 was considered statistically significant.

### RESULTS

The two groups were comparable in terms of demographic characteristics except for a statistically significant difference in the weight distribution among the two groups [Table/Fig-2].

Variables	Group PLMA <sup>†</sup> N=40	Group AAU <sup>‡</sup> N=40	Statistical test	p-value
Age in mean±SD <sup>§</sup> (years)	39.40±14.17	37.73±12.11	Unpaired t-test	0.572
Gender Male/Female n (%)	10/30 (25/75)	9/31 (22.5/77.5)	Chi-square test	0.793
ASA physical status I/II, n (%)	30/10 (75/25)	29/11 (72.5/27.5)	Chi-square test	0.799
Weight in mean±SD (Kilogram)	57.48±7.46	53.63±8.81	Unpaired t-test	0.03*

**[Table/Fig-2]:** Demographic characteristics.

\*p-value <0.005 is considered as statistically significant

<sup>†</sup>PLMA: LMA® ProSeal™; <sup>‡</sup>AAU: Ambu® AuraGain™; <sup>§</sup>SD: Standard deviation; ASA: American society of anaesthesiologists

The two groups were comparable in terms of distribution of type of surgeries [Table/Fig-3]. Unpaired t-test was used for the duration of surgery (Mean±SD of group PLMA 67.75±44.49 min and of group AAU 74.13±31.36 min, p-value=0.460).

Surgery	Group PLMA* n (%)	Group AAU† n (%)
Diagnostic hysterolaparoscopy	6 (15.0)	4 (10.0)
Laparoscopic appendicectomy	7 (17.5)	5 (12.5)
Laparoscopic cholecystectomy	20 (50.0)	13 (33.0)
Laparoscopic cystectomy	2 (5.0)	4 (10.0)
Laparoscopic hernia repair	4 (10.0)	4 (10.0)
Laparoscopic myomectomy	1 (2.5)	3 (7.5)
Laparoscopic ovarian cystectomy	0	3 (7.5)
Laparoscopic salpingectomy	0	1 (2.5)
Laparoscopic hysterectomy	0	1 (2.5)
Diagnostic laparoscopy	0	2 (5.0)
Total	40 (100)	40 (100)

**[Table/Fig-3]:** Distribution of type of surgeries among the two groups.

\*PLMA: LMA® ProSeal™; †AAU: Ambu® AuraGain™

The two groups did not differ significantly in terms of size of the SAD used, number of attempts for insertion and the time for insertion. However, PLMA was found to be easier to insert in the first attempt compared to AAU [Table/Fig-4]. In 4 cases each in both the groups, there was failure to insert the LMA in the third attempt and endotracheal intubation was done.

Variables	Group PLMA <sup>†</sup>	Group AAU <sup>‡</sup>	Statistical test	p-value
Size of SAD used (3/4) (N=40 in each group)	13/27 (32.5%/67.5%)	17/23 (42.5%/57.5%)	Chi-square test	0.356
Ease of insertion of SAD (Grade 1/2/3/4) (N=40 in each group)	First attempt	26/7/1/6	Chi-square test	0.010*
	Second attempt	2/0/4/4		
Number of attempts (1/2) (N=40 in each group)	34/6 (85%/15%)	31/9 (77.5%/22.5%)	Chi-square test	0.397
Time for insertion Mean±SD <sup>§</sup> (in seconds) (N=40 in each group)	First attempt	26.71±6.48	Unpaired t-test	0.428
	Second attempt	25.00±4.24		
Size of Oro gastric tube passed (14 Fr/16 Fr) (only successful SAD insertions included; n=36 in each group)	0/36 (0/100%)	14/22 (38.8%/61.2%)	Chi-square test	0.0001
Ease of passage of oro-gastric tube (Grade 1/2/3) (only successful SAD insertions included; n=36 in each group)	30/6/0 (83.3%/16.7%/0%)	30/6/0 (83.3%/16.7%/0%)	Chi-square test	0.305

**[Table/Fig-4]:** Airway management parameters.

\*Statistically significant; <sup>†</sup>PLMA: LMA® ProSeal™; <sup>‡</sup>AAU: Ambu® AuraGain™; <sup>§</sup>SD: Standard deviation

In group PLMA, PLMA allowed the passage of 16 Fr gastric drain tube in both sizes 3 and 4. In group AAU, size 4 AAU allowed the passage of 16 Fr gastric drain tube and size 3 allowed 14 Fr gastric drain tube. On comparison of the groups, Chi-square test demonstrated a significant difference (p-value=0.0001). Both the groups were comparable in terms of ease of passage of orogastric drain [Table/Fig-4].

The two groups were comparable in terms of heart rate response and systolic blood pressures in the first 10 minutes after SAD insertion [Table/Fig-5,6]. Unpaired t-test showed statistically significant Diastolic Blood Pressure (DBP) fluctuations in group AAU compared to group PLMA at 4, 5, 8 and 9 minute after SAD insertion but none of the values were more than baseline DBP [Table/Fig-7].

Time points	Group PLMA* n=32	Group AAU† n=34	Unpaired t-test
	Heart rate (beats per min) Mean±SD <sup>‡</sup>		p-value
Baseline	80.7±10.5	78.48±11.52	0.378
1 min	81.06±13.58	76.24±10.75	0.115
2 min	81.12±13.89	76.61±10.44	0.14
3 min	79.64±12.48	76.64±10.92	0.303
4 min	79.12±13.36	76.58±10.83	0.398
5 min	78.61±12.02	76.88±12.27	0.566
6 min	78.03±11.74	76.67±11.33	0.633
7 min	78.03±12.14	76.21±11.27	0.531
8 min	78.91±11.94	75.76±10.82	0.265
9 min	78.76±12.07	76.42±10.89	0.413
10 min	78.64±11.25	75.82±10.75	0.302

**[Table/Fig-5]:** Comparison of heart rate variations between the two groups for first 10 min of SAD insertion.

\*PLMA: LMA® ProSeal™; †AAU: Ambu® AuraGain™; ‡SD: Standard deviation; Cases with continued SAD ventilation included for analysis of these parameters

Time points	Group PLMA*, n=32	Group AAU†, n=34	Unpaired t-test
	Systolic blood pressure (mmHg) Mean±SD <sup>‡</sup>		p-value
Baseline	128.78±15.20	123.98±11.83	0.119
1 min	110.82±18.35	112.72±17.59	0.672
2 min	108.76±18.83	109.21±15.33	0.915
3 min	108.21±16.36	106.39±13.52	0.624
4 min	107.64±16.93	106.73±15.76	0.822
5 min	107.39±17.52	102.06±15.21	0.359
6 min	103.64±24.01	106.27±14.83	0.593
7 min	106.45±18.06	106.82±13.84	0.927
8 min	105.82±17.86	107.12±14.48	0.746
9 min	106.61±17.76	106.88±13.99	0.945
10 min	101.55±24.22	107.82±13.75	0.200

**[Table/Fig-6]:** Comparison of systolic blood pressure variations between the two groups for first 10 min of SAD insertion.

\*PLMA: LMA® ProSeal™; †AAU: Ambu® AuraGain™; ‡SD: Standard deviation  
Cases with continued SAD ventilation included for analysis of these parameters

Time points	Group PLMA*, n=32	Group AAU†, n=34	Unpaired t-test
	Diastolic blood pressure (mmHg) Mean±SD <sup>‡</sup>		p-value
Baseline	77.85±8.71	76.08±8.93	0.371
1 min	52.33±25.36	55.53±27.99	0.597
2 min	61.70±12.47	66.64±11.12	0.094
3 min	52.46±25.14	55.90±27.65	0.565
4 min	61.18±12.28	67.42±11.35	0.036
5 min	60.82±12.19	67.03±10.66	0.031



6 min	61.27±12.74	67.55±10.49	0.033
7 min	60.88±13.02	66.61±11.84	0.066
8 min	61.06±12.56	67.36±11.61	0.038
9 min	61.30±12.32	66.94±10.80	0.05
10 min	61.64±12.72	66.76±10.93	0.08

**[Table/Fig-7]:** Comparison of diastolic blood pressure variations between the two groups for first 10 min of SAD insertion.

\*PLMA: LMA® ProSeal™; †AAU: Ambu® AuraGain™; ‡SD: Standard deviation; Cases with continued SAD ventilation included for analysis of these parameters

Unpaired t-test was used for the mean ex vivo pressure in group PLMA was 49.35±29.10 cmH<sub>2</sub>O and in group AAU was 45.95±26.78 cmH<sub>2</sub>O (p-value=0.588). Mean peak airway pressures were significantly lower in group AAU than group PLMA immediately after SAD insertion and after creation of pneumoperitoneum, but not later on during the surgery. Mean P<sub>in vivo</sub> and mucosal pressures were significantly lower in group AAU than group PLMA immediately, 30 and 60 minutes after creation of pneumoperitoneum, but not later on. The two groups were comparable in terms of OLP at all measured time points [Table/Fig-8].

Variables	Peak airway pressure Mean±SD <sup>§</sup> (cmH <sub>2</sub> O)	In vivo cuff pressure (P <sub>in vivo</sub> ) Mean±SD (cmH <sub>2</sub> O)	Mucosal pressure Mean±SD (cmH <sub>2</sub> O)	Oro pharyngeal leak pressure Mean±SD (cmH <sub>2</sub> O)
<b>Immediately after insertion of SAD</b>				
Group PLMA	17.06±2.56	75.45±25.8	33.76±18.81	27.76±4.68
Group AAU	15.53±1.50	66.53±19.39	30.48±13.04	25.71±4.12
p-value	0.004*	0.109	0.415	0.061
<b>Immediately after creation of pneumoperitoneum</b>				
Group PLMA	26.58±10.12	86.06±21.63	45.03±12.63	29.39±4.96
Group AAU	23.03±2.96	65.35±20.03	29.76±13.44	27.29±4.74
p-value	0.04*	<0.0001*	<0.0001*	0.08
<b>30 minutes after creation of pneumoperitoneum</b>				
Group PLMA <sup>†</sup>	26.90±12.53	93.05±22.90	53.62±18.93	29.10±4.62
Group AAU <sup>†</sup>	25.92±6.51	64.00±21.70	29.92±13.22	27.12±5.00
p-value	0.731	<0.0001*	<0.0001*	0.170
<b>60 minutes after creation of pneumoperitoneum</b>				
Group PLMA	30.44±18.82	85.33±28.55	46.44±23.40	28.88±4.26
Group AAU	26.56±7.88	62.00±18.75	28.44±11.22	28.47±5.17
p-value	0.452	0.01*	0.01*	0.849
<b>90 minutes after creation of pneumoperitoneum</b>				
Group PLMA	25.00±4.36	88.00±39.40	29.33±3.09	28.00±8.00
Group AAU	24.63±3.54	67.25±11.80	27.75±7.74	28.75±6.67
p-value	0.886	0.184	0.885	0.878
<b>120 minutes after creation of pneumoperitoneum</b>				
Group PLMA	25.67±3.21	91.33±41.30	32.67±3.58	28.67±7.02
Group AAU	25.40±2.70	69.60±14.24	24.00±3.16	28.00±8.00
p-value	0.903	0.305	0.590	0.909

**[Table/Fig-8]:** Comparison of in vivo pressure, mucosal pressure, peak airway pressure and oro pharyngeal leak pressure between the groups.

\*Statistically significant; †PLMA: LMA® ProSeal™; ‡AAU: Ambu® AuraGain™; §SD: Standard deviation; cases with continued SAD ventilation included for analysis of these parameters (n=32 in group PLMA and n=34 in group AAU)

## DISCUSSION

**Oro pharyngeal leak pressure:** Due to high airway pressures created by pneumoperitoneum in laparoscopic surgery, suboptimal and failed ventilation can be encountered with the use of SADs. But, second generation SADs allow higher airway pressures due to their effective seal [7]. OLP test is commonly performed to quantify the seal of airway when SAD is used [12].

In the current study, it was observed that the OLP of group AAU was comparable to group PLMA at all measured time points [Table/Fig-8]. A

study conducted by Singh K et al., found no significant difference in the OLP between AAU and PLMA (OLP of PLMA was 7.17±16.91 cmH<sub>2</sub>O and that of AAU was 28.77±4.82 cmH<sub>2</sub>O immediately after insertion of SAD) which was comparable to the results of this study. Unlike the current study, OLP was measured only once immediately after insertion of the SAD [7].

A study conducted by Shariffuddin II et al., compared OLP of AAU and LMA® Supreme™ Second Seal™ (OLP of AAU 24.1±7.4 cmH<sub>2</sub>O versus OLP of LMA® Supreme™ Second Seal™ 23.6±6.2 cmH<sub>2</sub>O) and found no significant difference between them, similar to the current study [13]. Here, the study was conducted on spontaneously breathing patients and on all type of surgeries. LMA® Supreme™ Second Seal™ is a single use second generation SAD with features of LMA® ProSeal™ incorporated [14].

In a study by Lopez AM et al., in patients undergoing gynaecological laparoscopic surgery, AAU achieved higher OLP than LMA® Supreme™ Second Seal™ throughout the procedure (OLP of AAU 34±5 cmH<sub>2</sub>O versus OLP of LMA® Supreme™ Second Seal™ 29±5 cmH<sub>2</sub>O), in contrast to the results in the current study [15]. In a study conducted by Joshi R et al., the mean OLP of AAU was significantly higher than PLMA (OLP of AAU 23.3±4.6 cmH<sub>2</sub>O versus OLP of PLMA 20.6±4.8 cmH<sub>2</sub>O), in contrast to the present study [16]. However, this study was conducted on paediatric age group, and not during laparoscopic surgery.

**Pharyngeal mucosal pressure:** The pharyngeal mucosal pressures, resulting from the SAD cuff, depend on the relative dimensions of the pharynx and the SAD, the degree of accommodation by the pharynx and the inflation pressure required to extend the cuff sufficiently for its function as an airway. The morbidity resulting from this transmitted mucosal pressure is undetermined. It may be an important consideration when prolonged or repeated SAD usage is anticipated. In this case, the intracuff pressure can be monitored, adjusted from time to time and maintained at a value less than the pharyngeal mucosal capillary perfusion pressure and prevent mucosal ischaemia [17]. While using SAD, if transmitted pharyngeal mucosal pressure exceeds capillary perfusion pressure, there is a possibility of mucosal ischaemia [18]. There are a few studies comparing the pharyngeal mucosal pressure exerted by these two SADs under discussion. In this study, group AAU had lower pharyngeal mucosal pressure compared to PLMA group immediately, at 30 and 60 minutes after creation of pneumoperitoneum. But the mean pharyngeal mucosal pressures of the two groups were comparable immediately after insertion of SAD, at 60 and 120 minutes [Table/Fig-8].

Similar results were seen in a study conducted by Singh K et al [7] (pharyngeal mucosal pressure of AAU size 3 was 33.00±18.22 cmH<sub>2</sub>O and that of PLMA size 3 was 64.00±14.42 cmH<sub>2</sub>O and pharyngeal mucosal pressure of AAU size 4 was 45.29±27.30 cmH<sub>2</sub>O and that of PLMA size 4 was 67.68±15.68 cmH<sub>2</sub>O). Calculated pharyngeal mucosal pressure was lower in group AAU compared to group PLMA. Pharyngeal mucosal pressure was measured in a similar method as in the current study. However, it was measured only once, after insertion of SAD before the pneumoperitoneum.

**Number of attempts and time taken for SAD insertion:** The current study found no difference between group AAU and group PLMA in terms of number of attempts taken for insertion of the SAD, with insertion being successful in the first attempt in most cases [Table/Fig-4].

The studies conducted by Singh K et al., [7] (18/30 cases in first attempt in group AAU versus 24/30 cases in first attempt in group PLMA) and Joshi R et al., [16] (45/47 cases in first attempt in group AAU versus 45/47 cases in group PLMA in the first attempt) also found similar successful insertion rates at first attempt.

In the study conducted by Singh K et al., [7], group AAU took a longer time for insertion of SAD compared to the group PLMA (13.57±94 sec

in AAU versus 11.60±2.22 sec in PLMA). The authors have attributed rigid Polyvinyl Chloride (PVC) preformed structure of AAU as the cause for prolonged time taken for insertion in comparison to flexible silicone structure of PLMA.

In contrast, time taken for insertion of AAU was significantly shorter in a study conducted by Joshi R et al., [16] (12 sec in AAU versus 20 sec in PLMA) in the paediatric age group. Due to preformed anatomical curve of the SAD, shorter time was taken for insertion of AAU.

The current study showed no difference between the groups in terms of time taken for insertion of SAD [Table/Fig-4].

**Ease of insertion:** In this study, it was found that the insertion of PLMA was easier than AAU in the first attempt [Table/Fig-4]. In contrast to this, studies conducted by Singh K et al., [7] and Joshi R et al., [16] found no significant difference between the group AAU and group PLMA in terms of ease of insertion.

There was no significant difference between the two groups in terms of haemodynamic response to insertion of SAD.

**Passage of gastric tube:** PLMA was considered superior over AAU in terms of passage of wider bore gastric tube [Table/Fig-4], in contrast to the results obtained in other studies [7,16], wherein, AAU allowed the passage of a larger bore gastric tube. However, there was no significant difference noted between the groups in terms of ease of insertion of gastric tube.

**Peak airway pressures:** It was noted that the mean peak airway pressures in group AAU were lower than group PLMA immediately after insertion of SAD and creation of pneumoperitoneum [Table/Fig-8]. Further studies are required to evaluate the differences in peak airway pressures between these SADs.

### Limitation(s)

In the present study, an indirect method was employed to measure pharyngeal mucosal pressure producing a derived value. Mucosal pressure in the pharynx can also be measured directly with a microchip sensor which may be more accurate. Postoperative complications such as sore throat, hoarseness, discomfort were not assessed. The placement of SADs was confirmed clinically (visible chest rise and capnography), and not with fiberoptic visualisation of laryngeal aperture. This study included patients undergoing all types of laparoscopic surgeries, position during the procedures was not uniform.

### CONCLUSION(S)

The current study suggests that Ambu® AuraGain™ LMA has oropharyngeal leak pressures similar to LMA® ProSeal™ with a lesser pharyngeal mucosal pressure and lower peak airway pressures. Hence, it can be concluded that Ambu® AuraGain™ could be

a useful alternative to LMA® ProSeal™ in patients undergoing laparoscopic surgeries.

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#### AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

#### PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Mar 25, 2022
- Manual Googling: May 11, 2022
- iThenticate Software: May 16, 2022 (16%)

#### ETYMOLOGY: Author Origin

Date of Submission: **Mar 17, 2022**  
Date of Peer Review: **Apr 15, 2022**  
Date of Acceptance: **May 17, 2022**  
Date of Publishing: **Jun 01, 2022**