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Original Article

Anaesthesia Section

Clinical Efficacy of Ambu AuraGain™ and i-gel® in Patients Undergoing Elective Gynaecological Laparoscopic Surgeries Under General Anaesthesia: A Randomised Clinical Study

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ABSTRACT

Introduction: Second-generation supraglottic airway devices that provide high seal pressures are found to be suitable for patients undergoing laparoscopic surgery, as they have a separate port for gastric tube insertion, effectively separating the airway and the oesophagus. The present study compares the usage of two such second-generation supraglottic devices-AuraGain™ and i-gel® in patients undergoing gynaecological laparoscopic surgeries.

Aim: To compare the Oropharyngeal Leak Pressure (OLP) and airway pressures achieved by the i-gel® and Ambu AuraGain™ after insertion in the supine position and during laparoscopic carbon dioxide peritoneum in the Trendelenburg position.

Materials and Methods: This randomised clinical, single-blinded study conducted at the Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra pradesh, India involved 100 female patients undergoing elective gynaecological laparoscopic surgeries under general anaesthesia with controlled ventilation. The primary objective was to compare the clinical performance of Ambu AuraGain™ (Group-A) and i-gel® (Group-I) concerning their oropharyngeal seal pressures and airway pressures in gynaecological laparoscopic surgeries. The secondary outcomes measured included the time taken for insertion, ease of insertion of the device, effects on postinsertion haemodynamic parameters like heart rate, blood pressure, oxygen saturation, ease of gastric tube insertion, and fibreoptic bronchoscopic grading of the visualised glottic structures after device placement, as well as postoperative side effects like blood staining upon removal of the device and sore throat. Data were analysed using Student's t-test and chi-square test.

Results: The mean age in Group-A was 39.62±4.085 years, and in Group-I, it was 39.48±2.468 years. The mean peak inspiratory pressures after device insertion were 14.34 mmHg in Group-A and 16.66 mmHg in Group-I. Haemodynamic parameters postinsertion were similar in both groups {Group-A: Mean Heart Rate (HR) 87.22 bpm, Mean Arterial Pressure (MAP) 89.72 mmHg, Oxygen Saturation (SpO_2) 99.58%; Group-I: Mean HR 87.50 bpm, MAP 89.72 mmHg, SpO_2 99.72%). Fibreoptic bronchoscopic grading in Group-A was 0/0/9/41, and in Group-I, it was 0/0/11/39. Blood staining upon removal was noted in four patients (8%) in Group-A and in 3 patients (6%) in Group-I. Sore throat in the postoperative period was noted in 14% of patients in Group-A and 8% in Group-I.

Conclusion: Ambu AuraGain™ was found to provide a better seal and higher OLP compared to the i-gel® in gynaecological laparoscopic surgeries and therefore provide safer and more effective ventilation for patients undergoing such surgeries. I-gel® was found to be easier and quicker to insert than the AuraGain™.

Keywords: Laproscopy, Laryngeal mask, Supraglottic devices, Trendelenburg position

INTRODUCTION

Patients undergoing gynaecological laparoscopic procedures are at a higher risk of aspiration because of the increase in intra-abdominal pressure and the head-down position [1]. The use of second-generation supraglottic airway devices with a gastric emptying tube in such surgeries is becoming popularity. They are easy to insert and provide sufficient seal pressure in the Trendelenburg position; hence, they can be considered as an alternative to endotracheal tubes [2].

The i-gel® (Intersurgical Ltd., UK), a second-generation supraglottic airway device developed by Dr. Nasir in 2007, provides an effective seal because of its latex-free medical-grade thermoplastic elastomer (styrene ethylene butadiene styrene), which is soft and gel-like, designed to anatomically fit the perilaryngeal and hypolaryngeal structures without an inflatable cuff. The device stem features a gastric port for drainage, a bite guard to enhance patency, and a wide buccal cavity stabiliser to prevent dislodgement of the device position. Many studies have established its safety and efficiency in laparoscopic surgeries [3,4] and in the Trendelenburg position [5].

Ambu AuraGain™ (AMBU Ballerup, Denmark) is a single-use second-generation supraglottic airway device introduced in June 2015, made of polyvinyl chloride. It is phthalate-free, anatomically curved to follow the human airway, with an integrated gastric access port featuring a low-friction inner surface for easier tube placement. It includes an integrated bite block, a wider airway tube which provides an intubation conduit for the standard endotracheal tube if tracheal intubation is necessary intraoperatively. The inflatable cuff provides high seal pressure. A pilot balloon indicates device size and serves as a tactile cuff pressure indicator. Navigation marks guide the flexible scope [6].

To the best of the authors knowledge, after an extensive literature search, the present is the first study to compare Ambu AuraGain™ with the i-gel® for gynaecological laparoscopic surgeries. The present study aimed to compare the clinical performance of the

second-generation Ambu AuraGain™ with the second-generation i-gel® in gynaecological laparoscopic surgeries.

MATERIALS AND METHODS

This was a randomised clinical, single-blinded study involving 100 female patients. The study took place at the Department of Anaesthesiology, Narayana Medical College and Hospital, Nellore, Andhra Pradesh, India, between April 2022 and July 2022. Institutional Ethics Committee approval was obtained (IEC/NMC/15/02/2022_11), and the trial was registered with the Clinical Trials Registry of India (CTRI/2022/03/041043). Written informed consent was taken from all patients included in the study.

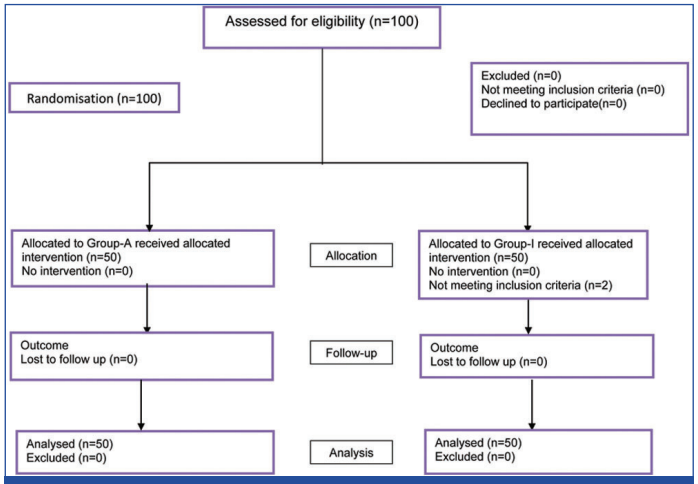
Inclusion criteria: The authors included 100 female patients of American Society of Anaesthesiologists (ASA) grade I and II, aged between 18 and 70 years, weighing between 30-70 kg, posted for elective gynaecological laparoscopic surgeries (laparoscopic tubectomy, cystectomy, hysterectomy) under general anaesthesia in the study after thorough history taking and clinical examination.

Exclusion criteria: All patients of ASA III and IV, BMI >30 g/m^2, age <18 years, hiatus hernia, gastroesophageal reflux, patients with a difficult airway (based on a history of difficult airway, inter-incisor distance <20 mm, cervical spine pathology, modified Mallampati class 4, or thyromental distance <65 mm), respiratory tract pathology, preoperative sore throat, or a planned operation time >4 hours, chronic lung disease, and pathology of the neck or upper respiratory tract were excluded.

Sample size calculation: The primary outcome measure was Oral Lichen Planus (OLP). For acquiring 80% power with a 5% type I error, the research needed to include a minimum of 76 patients (i.e., 38 in each group), as this would allow it to achieve a level of minimum clinical significance as in a similar study [6]. In the current study, the authors included a total of 100 patients (50 in each group), and the data were collected, tabulated in Excel sheets, and analysed.

Study Procedure

Patients were randomised into two groups [Table/Fig-1]: 'Group-A (Ambu AuraGain™)' or Group-I (i-gel®) using a closed envelope method. Investigators opened sealed opaque envelopes that concealed group allocation. Patients were blinded to their group allocation. The size of the airway device was chosen following the manufacturers' recommendations. Patients were positioned supine on the operating table, with the head resting on a gel head ring. Standard monitoring was instituted before the induction of anaesthesia, i.e., pulse oximetry, electrocardiograph, and non invasive blood pressure. Preoxygenation was carried out with high-flow oxygen for three minutes before induction of anaesthesia with intravenous (i.v.) fentanyl 1-2 µg/kg and propofol 2-3 mg/kg. Cisatracurium 0.1-0.2 mg/kg i.v. was given. The patient was ventilated for three minutes, and Ambu AuraGain™ and i-gel® were inserted. The insertion of the supraglottic airway device was done by an experienced anaesthesiologist of 10 years. The airway device was well-lubricated with a water-based lubricant and inserted by a standard method. If encountered difficulty after the 1st insertion attempt, alternate maneuvers were employed, like gentle pushing or pulling of the device, chin lift, jaw thrust, head extension, or neck flexion, and after two failed attempts, the patient would be intubated and excluded from the study. Ease of insertion is graded as: 1) easy; 2) somewhat difficult (when deep rotation and jaw thrust); and 3) difficult. (A second attempt was used for proper device insertion). The appearance of the first square waveform on the capnograph indicates satisfactory device placement for effective ventilation; otherwise, the supraglottic airway was taken out and re-inserted. The time taken for insertion was noted from the moment the airway device entered the mouth until the first upstroke on the End-tidal Carbon Dioxide ($ETCO_2$) waveform. The cuff in Ambu AuraGain™ was inflated, and intra-cuff pressure was set at 60 cm H_2O using a handheld aneroid cuff pressure monitor, and the OLP was determined by closing the expiratory valve of the circle system at a fixed gas flow of three litres per minute and noting the airway pressure (maximum allowed was 40 cm H_2O). The pressure at which the audible sound of gas escaping was heard using a stethoscope, which was placed laterally to the thyroid cartilage, was noted as OLP [7]. It was recorded soon after insertion and after one hour of gas insufflation in the Trendelenburg position.



[Table/Fig-1]: Consolidated Standard of Reporting Trials (CONSORT) flow diagram.

Preinsertion hemodynamics and postinsertion hemodynamics after device placement were noted, and peak inspiratory pressures after insertion were noted. A gastric tube was inserted depending on the size of the device used after adequate lubrication with a water-based solution through the gastric port in Ambu AuraGain™ and i-gel®. The ease of insertion of the gastric tube was graded as grade 1-easy or grade 2-difficult. Anaesthesia was maintained with O_2, air, and sevoflurane 1-2%. Controlled ventilation with a tidal volume of 6-8 mL/kg/minute was done. A fibreoptic bronchoscope was used to view the anatomical position of the airway device in the larynx. The image from the tip was captured at the end of the airway device. The Brimacombe score grading [8] was done where Grade-1: no laryngeal structure seen, Grade-2: vocal cords anterior structure is visible, Grade-3: vocal cord and posterior structure are visible, and Grade-4: only vocal cords are seen. After one hour in the Trendelenburg position, OLPs and peak inspiratory pressures were noted. In the present study, pneumoperitoneum and abdominal insufflation pressures were maintained below 15 mmHg at all times by the surgeons. The patient was reversed at the end of the surgery with Inj. myopyrollate (neostigmine 0.5 mg + glycopyrollate 0.4 mg). They were followed-up for 12 hours. Any side effects like sore throat, cough, hoarseness, dysphonia, and other complaints were noted.

STATISTICAL ANALYSIS

Statistical Package for Social Sciences (SPSS) version 25.0 (SPSS for Windows 15.0, Inc., Chicago, IL, USA) was used for all statistical analyses. For continuous data, descriptive statistics such as the mean and standard deviation were calculated. For discrete/categorical data, percentages were generated, and the Chi-square

test was carried out to test significance. An overall p-value of <0.05 was considered statistically significant.

RESULTS

The data concerning demographic profile parameters like age, BMI, Mallampati Score, ASA physical status grade, and duration of surgery were analysed between the two groups and were found to be similar [Table/Fig-2]. The preinsertion and postinsertion haemodynamics parameters [Table/Fig-3] like heart rate, mean arterial pressure, and saturation parameters three minutes after insertion were comparable between the two groups. The mean time for insertion in Group-I was 15.96 seconds, which was less compared to Group-A where the mean insertion time was 22.48 seconds. Ease of insertion [Table/Fig-4] was graded as easier in Group-I (40/10/0) compared to Group-A (19/31/0). The ease of insertion of the gastric tube through the gastric port was graded and found to be easier in Group-A (41/9) compared to Group-I (23/27). This difference was statistically significant. Fibreoptic bronchoscopy [Table/Fig-4] was done to view the position of the airway device in the larynx. The Brimacombe grading for Group-A was (0/0/9/41) and for Group-I was (0/0/11/39).

Variables	Group-A (n=50)	Group-I (n=50)	p-value
Age (in years)	39.62±4.085	39.48±2.468	0.836
Body mass index (kg/m^2)	21.36±1.411	21.52±1.328	0.561
Mallampati score (i/ii/iii)	14/30/6	16/27/7	0.841
ASA grade (1/2)	12/38	17/33	0.677
Duration of surgery (in minutes)	103.22±9.958	100.72±8.990	0.191

[Table/Fig-2]: Comparison of demographic profile, ASA physical status grading, mallampatti score, surgery duration.
Mean and standard deviation were calculated for age and BMI and duration of surgery.
unpaired t-test used for age and BMI, for ASA and Mallampati, Chi-square test was used

Preinsertion	AuraGain™ (Mean±SD)	i-gel® (Mean±SD)	p-value
Pre HR (beats per minute)	85.22±2.802	85.14±2.304	0.876
Pre MAP (mm of hg)	87.76±1.255	87.76±1.923	1.000
Pre SpO_2 (%)	99.46±0.706	99.16±0.997	0.086
Post HR (beats per minute)	87.22±3.272	87.50±2.023	0.608
Post MAP (mm of hg)	89.72±2.212	89.72±1.896	1.000
Post SpO_2 (%)	99.580±0.642	99.72±0.701	0.300

[Table/Fig-3]: Comparison of preinsertion and postinsertion parameters.
Unpaired t-test used for heart rate, SpO_2 and mean arterial pressure variation

Device insertion parameters	Group-A (n=50)	Group-I (n=50)	p-value
Time for insertion in seconds	22.48±1.619	15.96±1.261	0.0001
Ease of insertion (1/2/3)	19/31/0	40/10/0	0.0001
Number of attempts (1/2/3)	31/18/1	42/8/0	0.006
Ease of insertion of gastric tube (1/2)	41/9	23/27	0.001
Fiberoptic grading (1/2/3/4)	(0/0/9/41)	(0/0/11/39)	0.194

[Table/Fig-4]: Comparison of device placement parameters.
Unpaired t-test was used as test of significance in time for insertion parameter.
Chi-square test was used for finding out statistical significance in all other parameters in this table

The OLP [Table/Fig-5] was measured immediately after the insertion of the airway device when the patient was in the supine position. The mean OLP was higher in Group-A (32.82) compared to Group-I (27.42). One hour after insertion, the OLP remained higher in Group-A (35.44) than in Group-I (30.32). Peak inspiratory pressures [Table/Fig-5] were noted after device insertion and found to be lower in Group-A (14.34) than in Group-I (16.66). After one hour in the Trendelenburg position, peak inspiratory pressures were 24.34 for Group-A and 26.18 for Group-I. In Group-A, 4 (8%) patients showed bloodstains on removal, and 7 (14%) patients experienced sore throat. In Group-I, 3 (6%) patients showed bloodstains on removal, and 4 (8%) patients experienced sore throat [Table/Fig-6].

Oropharyngeal Leak Pressure (OLP)/ Airway pressure	AuraGain™ (Mean±SD)	I-gel® (Mean±SD)	p-value
Oropharyngeal Leak Pressure (OLP) immediately after insertion (cm of H_2O)	32.82/1.804	27.42/1.739	0.0001
Oropharyngeal Leak Pressure (OLP) after one hour in Trendelenburg	35.44/1.459	30.32/1.789	0.0001
Peak inspiratory pressure immediately after insertion (cm of H_2O	14.34/1.135	16.66/1.194	0.0001
Peak inspiratory pressure 1 hour after (cm of H_2O) Pneumoperitoneum	24.34/1.287	26.18/1.033	0.0001

[Table/Fig-5]: Comparison of OLP and airway pressures in supine and Trendelenburg position.
Unpaired t-test

Complications	AuraGain™ n (%)	I-gel® n (%)
No side-effect	39 (78%)	43 (86%)
Blood stain on removal	4 (8%)	3 (6%)
Sore throat	7 (14%)	4 (8%)
Total	50 (100%)	50 (100%)

[Table/Fig-6]: Comparison of complications after device removal.

DISCUSSION

The main finding of the present study was that AuraGain™ has a higher OLP in the supine position (soon after insertion) and during pneumoperitoneum in the Trendelenburg position compared to i-gel®, and lesser mean inspiratory.

An airway sealing pressure or 'leak' test is commonly performed with Supraglottic airway devices to quantify the efficacy of the seal with the airway. This value is important as it indicates the feasibility of positive pressure ventilation and the degree of airway protection from Supra-cuff soiling. It is also used to quantify the efficacy of airway sealing in supraglottic airway devices [7]. The primary objective of the present study was to compare the OLP between the two groups. The mean OLP of Group-A was found to be 32.82 mm of H_2O, and it increased to 35.44 mm of H_2O after one hour with pneumoperitoneum and the Trendelenburg position. These results were similar to the study conducted by Lopez AM et al., [9], who compared the OLP of Ambu AuraGain™ with LMA Supreme™ in patients undergoing gynaecological laparoscopy. In their study, the OLP of AuraGain™ was found to be 34 cm of H_2O, which is similar to the results in the present study. The high leak pressure of the Ambu AuraGain™ group is probably due to its wide proximal aperture that fits better for a good seal. The thinner, softer cuff of Ambu AuraGain™ provides a better seal on laryngeal structures [10]. Also, in gynaecological laparoscopic surgeries, the partial body weight, cephalic visceral, and diaphragm pressure caused by the pneumoperitoneum and Trendelenburg position may result in a tighter seal compared with the supine position [5]. It may be possible that the airway undergoes a configuration change in the head-down position with carboperitoneum, yielding a slightly higher sealing pressure with the airway device [11].

In the study done by Lai CJ et al., where they evaluated the i-gel® in the Trendelenburg position, in the presence of pneumoperitoneum, they could not see any clinical signs associated with aspiration in the i-gel® group [5]. They attributed this to the presence of the gastric channel in the device, which enables the release of pressure induced by abdominal insufflation and the head-down position during the perioperative period. The significance of the higher oropharyngeal seal pressure lies in the fact that it correlates to the efficacy of ventilation during carboperitoneum. During laparoscopy, the airway pressures

increase due to gas insufflation of the abdomen and also due to the Trendelenburg position. If the airway pressures exceed the OLP, it may lead to pericuff leakage of air, which could result in inadequate ventilation and may potentially lead to gastric distension. This could possibly increase the risk of regurgitation, so the slightly higher OLPs offered by the AuraGain™ confer a better safety margin for patients undergoing laparoscopic surgeries in the Trendelenburg position [12].

In the present study, there was no statistical difference between preinsertion and postinsertion hemodynamics between the two groups. When comparing the time taken for insertion, for i-gel® it was 15 seconds, and the mean insertion time for Ambu AuraGain™ was prolonged in comparison, found to be 22 seconds. This was similar to the study conducted by Sharma B et al., who reported the mean insertion time for i-gel® as 14.33 seconds [13]. The extra time required to inflate the cuff in the Ambu AuraGain™ group may have contributed to this difference. Wong DT et al., found that the insertion time was longer for the Ambu AuraGain™ when compared to LMA Supreme [14]. In another study done by Shariffuddin II et al., it was reported that the Ambu AuraGain™ (33.4 seconds) took longer to obtain the first waveform on the capnograph. This was accounted for by the structural dissimilarity between the two devices, as the Ambu AuraGain™ has a slightly firmer tip and a bulky posterior curvature with a larger cuff to provide higher seal pressures [15].

When comparing the number of insertion attempts, they were increased in Group-A than in Group-I, which was similar to the study by Shariffuddin II et al., where the AuraGain™ was deemed subjectively harder to insert, with only 24/50 (48%) versus 37/50 (74%) of AuraGain™ insertions being scored 1 = easy (on a 5 point scale). This also correlates to the cadaveric study [10], which found that the harder tip of Ambu AuraGain™ is difficult to bend and less flexible as it hits the posterior wall before moving towards the perilaryngeal area [15]. The bulky structure of Ambu AuraGain™ and large cuff further add to its difficulty in insertion [16] in comparison to Group-I.

Gastric tube insertion was found to be easier in Group-A compared to Group-I due to its smooth surface of the gastric port in AuraGain™, due to polyvinyl material, and also the width, which permits easy passage [17]. It was more difficult to insert a well-lubricated 12-FG gastric tube into the i-gel® due to the smaller aperture of the gastric access port, and therefore this took longer [18].

Fibreoptic bronchoscopic confirmation and grading of the view were done using Brimacombe grading [7]. Both groups had a median Brimacombe grading of 4 (cords visible) in both groups, and this was not statistically significant. This shows that it is possible to use these devices as an intubation conduit [19,20]. Although, the size 4 AuraGain™ would allow a slightly easier passage of a 7.5 mm ETT as its inner diameter is 12.7 mm compared to the size 4 i-gel® whose inner diameter is 12.3 mm [17].

The postoperative complications in Group-A included blood staining on removal seen in 4 (8%) of the patient population and sore throat present in 7 (14%). In the study by Shariffuddin II et al., the incidence of postoperative sore throat varied from 3-10% for the Ambu AuraGain™ and 0-38% for the LMA Supreme [15]. In Group-I, blood staining on removal was seen in 3 (6%) and sore throat in 4 (8%). L'Hermite J et al., compared the incidence of sore throat following the insertion of three SADs (LMA Unique, LMA Supreme, and i-gel®) and reported that the incidence of sore throat was similar among the three devices [21]. Jagannathan N et al., compared Ambu AuraGain™™ and LMA® Supreme in infants and children and no complications were observed in both groups [22].

Limitation(s)

The present study was not done on difficult airway cases and included only procedures lasting for less than two hours. Obese patients were excluded from the present study. The authors did not measure the leak pressure at the end of surgery for either device.

CONCLUSION(S)

Ambu AuraGain™ was found to be superior to the i-gel® in terms of providing slightly higher OLPs and lower airway pressures in gynaecological laparoscopic surgeries, thereby ensuring better ventilation. Its usage in such surgeries may provide a better safety margin for the patient. The AuraGain™ took slightly longer and was more difficult to insert, but this can be overcome by an experienced anaesthesiologist in an elective setting. The larger diameter of the AuraGain™ facilitated faster and smoother insertion of a gastric tube, and the larger size will permit smoother insertion.

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- 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

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