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Comparison of the Working Performance of Ambu Auragain and LMA Proseal in the Patients Posted for Elective Surgeries Under General Anaesthesia: A Randomized Control Trial

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ABSTRACT
This study aimed to compare the working performance and insertion characteristics of two supra-glottic airway devices, the Ambu AuraGain and the ProSeal LMA, during general anesthesia in patients undergoing elective surgeries. Forty patients with ASA physical status I-III, aged 18 to 60 years, scheduled for elective surgery under general anesthesia, were enrolled after obtaining written informed consent. Patients were divided into two groups of 20 each. Group A underwent airway management with the Ambu AuraGain, while Group P received airway management with the ProSeal LMA. Insertion characteristics (including insertion time, number of attempts, device manipulations and failed insertions) and working performance (measured by oropharyngeal leak pressure, EtCO2 and mean expired tidal volume) were recorded at induction. Perioperative data on ease of orogastric tube insertion, hemodynamics (heart rate and mean arterial blood pressure) and complications were also documented.Oropharyngeal leak pressure was significantly higher in Group A compared to Group P ($P < 0.05$). No statistically significant differences were observed in demographic data, insertion characteristics (such as insertion time, number of attempts, device manipulation and failed attempts), EtCO2, mean expired tidal volume, ease of orogastric tube insertion, hemodynamics, or postoperative complications between the two groups. Our findings indicate that the Ambu AuraGain demonstrates superior working performance, as it provides higher oropharyngeal leak pressure compared to the ProSeal LMA, in patients undergoing elective surgeries under general anesthesia.

INTRODUCTION

General anesthesia, a cornerstone of modern medicine, necessitates the maintenance of a safe and unobstructed airway[1]. Over the past century, advancements in airway management have evolved from MacEwen's pioneering endotracheal intubation in 1880 to the contemporary utilization of sophisticated supra glottic airway devices[2]. Tracheal intubation remains the gold standard for ensuring airway patency during general anesthesia[3]. However, this technique, reliant on direct laryngoscopy, demands skill and training[4]. Despite its efficacy, direct laryngoscopy and endotracheal intubation pose several risks, including increased plasma catecholamine levels leading to cardiovascular complications, intracranial pressure elevation and potential damage to oral structures and vocal cords[4]. The introduction of Archie Brain's LMA-classic in 1988 revolutionized anesthesia practice[5], paving the way for a multitude of supra glottic airway devices. These devices offer advantages such as ease of insertion, improved hemodynamic stability, reduced anesthetic requirements and fewer postoperative airway complications[6]. Nonetheless, they are not without drawbacks, including the risk of airway trauma, gastric aspiration and device displacement[7,8].

To address these concerns, newer generations of supra glottic devices have been developed, offering improved safety and efficacy. Cook proposed a classification system categorizing devices into first and second generations, while Miller introduced a system based on sealing mechanisms[9,10]. First-generation devices are commonly used in elective surgeries and as rescue options in difficult airway scenarios[11]. Second-generation devices incorporate features to mitigate aspiration risk and find utility in various surgical contexts[12]. Oropharyngeal leak pressure (OLP) serves as a critical parameter for evaluating supra glottic airway efficacy and safety[13]. Higher OLP values indicate better sealing, facilitating positive pressure ventilation and reducing gastric aspiration risk[13]. However, achieving high OLPs without compromising mucosal perfusion is essential[15]. The Proseal LMA, a prototype of second-generation devices, features a drainage channel for orogastric tube insertion, aiding in aspiration prevention[5]. Its design enables ventilation at higher pressures, enhancing efficacy in positive pressure ventilation scenarios[5]. However, excessive cuff pressure may lead to mucosal damage, necessitating careful monitoring[5]. The Ambu Auragain laryngeal mask airway, a newer second-generation device, boasts anatomical curvature for optimal airway alignment and promises high OLP[16]. Additionally, it offers integrated gastric access, a bite block and a wider airway tube, enhancing its utility as an intubation conduit[16]. In clinical practice, the choice between supra glottic devices and endotracheal intubation depends on various factors, including the nature of surgery, patient characteristics and anesthesia provider preference. While endotracheal intubation remains indispensable in certain scenarios, supra glottic devices offer a valuable alternative, particularly in elective procedures and difficult airway management.

In inference, the evolution of airway management techniques has significantly enhanced patient safety during anesthesia. From the pioneering days of endotracheal intubation to the modern era of supra glottic devices, continuous innovation continues to refine anesthesia practice, striving for optimal patient outcomes. So, we decided to compare insertion success and working performance of two second generation supraglottic airway devices-Ambu Auragain and Proseal LMA in patients undergoing elective surgery under general anaesthesia.

MATERIALS AND METHODS

Following approval from the Institutional Review Board (IRB no. 036307/2021), this prospective, randomized, single-blind study was conducted in the Department of Anaesthesiology at Govt. Medical College and Sir T Hospital Bhavnagar. A comprehensive pre-anesthetic evaluation was performed, encompassing a detailed assessment of the patient's presenting complaint, past medical history, surgical history and medication history. General physical examinations were conducted and vital signs were recorded. Based on these evaluations, patients meeting the following criteria were included: aged between 18-60 years, categorized under American Society of Anesthesiologists (ASA) grades I, II, or III and scheduled for elective surgery under general anesthesia. Exclusion criteria for this study encompassed several parameters: a mouth opening less than 2 cm, Mallampati class 4 classification, a body mass index (BMI) exceeding 30 kg/m2, presence of an upper respiratory tract infection, heightened risk of aspiration due to inadequate fasting (non-nihil by mouth status), gastroesophageal reflux disorder, hiatus hernia, or pregnancy, necessity for high airway pressure management such as in patients with chronic obstructive pulmonary disease (COPD) or asthma, cervical spine fracture or instability and a documented history of allergy to one or more drugs and latex. Additionally, written informed consent was obtained from all participants.

Patients were then randomly allocated into two groups using computer-generated random number sequences: Group P received the ProSeal LMA supra glottic airway device, while Group A received the Ambu AuraGain supra glottic airway device. On the day of surgery, patients, after confirmation of fasting status and verification of identity, were transferred to the pre-anesthetic care room, where an 18 G intravenous

catheter was inserted into the nondominant hand. Baseline parameters, including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and pulse oximetry-measured oxygen saturation (SpO2), were recorded using a multipara monitor. Subsequently, all patients received premedication consisting of intravenous glycopyrrolate at a dose of 0.004 mg/kg, ondansetron at 0.08 mg/kg, fentanyl at 2 mcg/kg and midazolam at 0.02 mg/kg intravenously, administered 20 minutes before the commencement of surgery. Following the transfer of patients to the operation theater room, vital signs were continuously monitored using a multi-parameter monitoring system. Baseline measurements of vital signs were recorded immediately before anesthesia induction and served as reference values for the study. Patients were provided with 100% oxygenation for 5 minutes via a face mask connected to a Bain's circuit to optimize oxygenation. Anesthesia induction was initiated by administering intravenous propofol at a dose of 2-2.5 mg/kg slowly until loss of eyelash reflex, jaw relaxation, absence of movements and apnea were achieved. Subsequently, ventilation was initiated using the Bain's circuit and intravenous succinylcholine was administered at a dose of 2 mg/kg to facilitate muscle relaxation. Patients were closely observed for the appearance and disappearance of fasciculations, indicating successful muscle relaxation. Following the disappearance of fasciculations, the assigned supra glottic airway (SGA) device, either Ambu AuraGain or ProSeal LMA, was inserted according to the patient's group assignment. The size of the SGA device was selected based on manufacturer recommendations. Correct placement of the device was confirmed by observing bilateral chest movement. Anesthesia maintenance was achieved using a combination of oxygen, nitrous oxide, sevoflurane, intermittent doses of intravenous vecuronium and intermittent positive pressure ventilation (IPPV). Post-insertion of the SGA device, patients were closely monitored for the insertion characteristics and operational performance of the device.

Insertion characteristics were meticulously recorded, encompassing the insertion time, measured from the moment of picking up the devices until manual ventilation was successfully established via the supra glottic airway (SGA). The number of attempts made for insertion was noted and if ventilation was deemed inadequate, corrective maneuvers such as neck flexion or extension, chin lift, or gentle adjustment of device depth were implemented. If ventilation remained inadequate despite manipulation, it was considered a failed attempt, prompting removal and reinsertion of the device. The initial insertion attempt was conducted by the principal investigator (PI) under the supervision of the co-investigator (Co-I), with subsequent attempts executed by the Co-I in the event of PI failure. A maximum of three failed insertions were permitted before categorizing the insertion as unsuccessful.

The working performance of the SGAs was evaluated by measuring oropharyngeal leak pressure (OLP), conducted by closing the adjustable pressure limiting valve against a fresh gas flow of 5 L/min. The airway pressure at equilibrium, when air leak was detected in the oropharynx, was recorded, with a maximum airway pressure limit set at 40 cm of H2O. Additionally, end-tidal carbon dioxide (EtCO2) levels were measured post-insertion and the SGAs were connected to a ventilator for pressure-controlled ventilation at 17 cmH2O for five breaths to determine the mean expired tidal volume. Following device insertion, an appropriately sized orogastric tube was lubricated and inserted through the gastric channel. Correct placement of the orogastric tube was confirmed by aspiration of fluid or detection of injected air via auscultation over the epigastrium, with ease of insertion noted.

Hemodynamic parameters, including mean arterial pressure and heart rate, were recorded before and after device insertion at specified intervals during the perioperative period. Following surgery, all patients received ventilation with 100% oxygen until emergence criteria were met, after which anesthesia was reversed using neostigmine and glycopyrrolate. The SGA was then removed after thorough oropharyngeal suction and inspected for any bloodstains. Postoperatively, patients were assessed for sore throat and if present, were treated conservatively with gargle and analgesics. Primary outcome measures of the study included insertion characteristics (insertion time, number of attempts, manipulations) and working performance (OLP, EtCO2, mean expired tidal volume) of both SGAs. Secondary outcome measures comprised ease of orogastric tube insertion, hemodynamic changes and perioperative complications. Statistical analysis involved a sample size calculation to ensure adequate power, with continuous variables presented as mean (SD) and categorical variables as number (%). A type 1 error of 0.05 and power of 80% were utilized, with a ratio of sample size in treatment and control groups set at 1, an allowable difference of 1.3, SD of 0.3 and a dropout rate of 5%. Statistical tests included independent t-tests for continuous variables and chi-square tests for categorical variables, with significance set at $p<0.05$. IBM SPSS Statistics 20 was employed for data analysis.

RESULTS AND DISCUSSIONS

Patients' characteristics in terms of age, weight and height were comparable among both the groups ($P>0.05$) (Table 1). There was no statistical difference in number of attempts, manipulation after insertion and

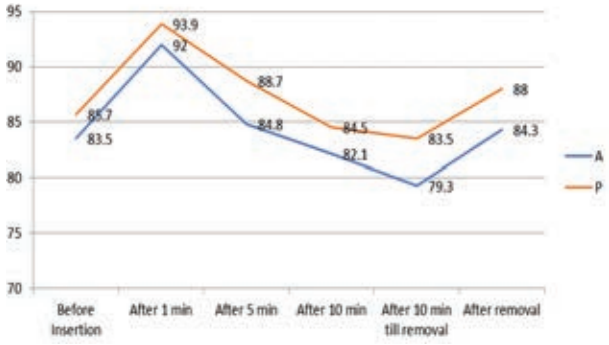

Fig. 1: Changes in heart rate

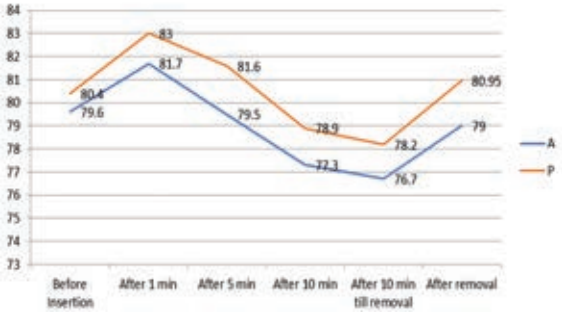

Fig. 2: Changes in mean arterial pressure

failure of insertion between group A and group P. (P>0.05) (Table 2). There was no statistical difference in mean insertion time between group A and group P. (p>0.05) (Table 3). Orogastric tube was inserted easily and successfully in more number of patients in group A than in group P but difference is not statistically significant. (P>0.05) (Table 4) There was statistically significant difference in Oropharyngeal leak pressure between group A and group P with higher oropharyngeal leak pressure in group A than in group P. This indicates the better working performance of Ambu AuraGain in comparison to ProSeal LMA. (P <0.05) (Table 5) There was no statistically significant difference in mean expired tidal volume between group A and group P. There was no statistically significant difference in ETCO2 between group A and group P. (Table 7)

The complications in both the groups of patients were comparable. There was no statistical significance (p>0.05) (Table 8). In both groups, there was an increase in heart rate from base line after insertion of 1 min and after removal of device, but the rise was statistically not significant. (p>0.05) Fig. 2: Changes in mean arterial pressure In both groups, there was an increase in mean arterial pressure from base line after insertion and removal of device, but the rise was statistically not significant (p>0.05.

Recent airway management trends have shifted from endotracheal tubes to supraglottic airway devices [17]. These devices, starting with the Classic Laryngeal Mask Airway introduced in 1983, offer advantages including reduced invasiveness, avoidance of direct laryngoscopy, easy placement, hands-free airway maintenance, improved hemodynamic stability and decreased airway-related morbidity[18]. Introduction of airway devices with drainage systems has addressed issues such as aspiration risk[19]. Lu *et al*. demonstrated the efficacy of drainage tube-equipped supraglottic airway devices in securing airways during laparoscopic surgery[20]. First-generation devices serve as conduits, while second-generation ones feature safety designs like integrated bite blocks and gastric drainage channels, doubling as conduits for endotracheal intubation[21]. Some cuffless devices like I-gel and Baska mask may reduce laryngopharyngeal trauma risk [22,23]. First-generation devices develop air leaks at lower pressures (16-20 cmH2O), while second-generation devices withstand higher pressures (20-35 cmH2O) [24,25]. With over 2500 articles and 200 million uses, supraglottic airway devices are extensively employed [26]. Soft, compliant materials in device construction reduce aspiration risk, prompting their use in various surgeries[27], including ear, ophthalmic, laparoscopic, pediatric, cardiac and gynecological procedures.

An ideal SGA should offer high oropharyngeal leak pressure (OLP) with low pharyngeal mucosal pressure [15]. However, preventing aspiration at higher airway pressures may necessitate higher cuff pressure, potentially compromising mucosal perfusion[28], leading to greater airway morbidities. In our study, surgeries lasting less than 180 minutes were preferred due to potential deleterious effects of prolonged SGA use on mucosa or vasculature depending on cuff volume and pressure[29]. Tongue ischemia has been reported with prolonged insertion of the intubating LMA and CLMA [23,30], possibly due to a vacuum-like effect causing hematoma formation on the lateral edge of the tongue following insertion of the 3rd generation laryngeal mask airway[30].

We included patients aged 18-60 years in our study, considering factors such as chin fat dissolving and teeth loss with age, which can make bag and mask ventilation difficult and SGA insertion challenging. Most patients weighed between 50-80 kgs, with obesity potentially complicating airway management due to increased chin fat and shorter necks. Patient characteristics regarding age, weight and height were similar between groups (p value > 0.05), aligning with previous studies[14,15,31]. The first-attempt insertion success rate was comparable between groups A (85%) and P (80%) (p value > 0.05). No patients required a third attempt and there were no failed attempts in either group, consistent with prior research[15]. In both groups A and P, external manipulations were required

Table 1: Patients Characteristics

Patients' characteristics	Group-A (Ambu AuraGain) (n=20)	Group-P (ProSeal LMA)(n=20)	p-value
Age(years)	26.65 ± 8.96	31.55 ± 11.71	0.14
Weight(kg)	51.15 ± 8.12	55.55 ± 8.85	0.11
Height(cm)	162.35 ± 4.11	164.30 ± 4.67	0.16

Table 2: Insertion characteristics of the device

		Group-A (Ambu AuraGain) (n=20)		Group-P (ProSeal LMA)(n=20)		
Variable		N	%	N	%	p-value
Insertion attempts	First	17	85	16	80	0.68
	Second	3	15	4	20	
Manipulation requires after insertion to Improve ventilation	03	15	4	20	0.67	
Failed insertion	00	00	00	00		

Table 3: Mean Insertion time of the device

Time	Group-A (Ambu AuraGain) (n=20)	Group-P (ProSeal LMA) (n=20)	p-value
Duration(sec)	15.05 ± 4.03	15.75 ± 4.70	0.616

Table 4: Orogastric tube insertion

		Group-A (Ambu AuraGain) (n=20)		Group-P (ProSeal LMA)(n=20)		
Variable		N	%	N	%	p-value
Ease of gastric tube insertion	Easy	18	90	16	80	0.37
	Difficult	2	10	4	20	

Table 5: Oropharyngeal leak pressures of the devices

Parameters	Group-A (Ambu AuraGain) (n=20)	Group-P (ProSeal LMA)(n=20)	p-value
Oropharyngeal Leak pressure (in cm H2O)	35.9 ± 7.19	29.5 ± 5.95	0.004

Table 6: Mean Expired Tidal Volume

Parameters	Group-A (Ambu AuraGain) (n=20)	Group-P (ProSeal LMA)(n=20)	p-value
Mean expired tidal volume (ml)	426.25 ± 43.34	441.0 ± 18.47	0.170

Table 7. ETCO2

Parameters	Group-A (Ambu AuraGain) (n=20)	Group-P (ProSeal LMA) (n=20)	p-value
ETCO2 (mm Hg)	34.6 ± 2.68	34.05 ± 3.02	0.546

Table 8. Postoperative complications

Parameters	Group-A (Ambu AuraGain) (n=20)	Group-P (ProSeal LMA) (n=20)	p-value
Airway trauma	01	01	0.99
Oropharyngeal pain after removal	03	03	

in 3 and 4 patients, respectively, with a slightly lower incidence in group A, though not statistically significant (p value > 0.05), consistent with previous studies[15,31] Mean insertion time in seconds was comparable between the groups (p value > 0.05), in line with prior research[14]. However, variations in insertion time have been noted in other studies, possibly due to differences in device structure[14,15,31]. First-attempt insertion of orogastric tubes was successful and similarly easy in both groups (p value > 0.05), with both devices accommodating larger bore tubes, favouring better gastric decompression, consistent with earlier findings[14,15,31].

In our study, oropharyngeal leak pressure was higher in group A (35.9 cmH2O) compared to group P (29.5 cmH2O), with a statistically significant difference (p value < 0.05). This can be attributed to the preformed shape and slightly larger cuff size of Ambu AuraGain compared to LMA ProSeal, which forms a better seal around the oropharynx[31]. Oropharyngeal leak pressure is crucial for SAD efficiency, particularly in situations like obesity, laparoscopic surgery and restrictive lung disease[14]. The preformed shape and larger bowl size of Ambu AuraGain contribute to its superior positioning and seal. Our findings are consistent with previous studies[14,21,31]. However, OLP of Ambu AuraGain varies compared to other SGAs in different clinical scenarios, with some studies reporting higher OLP compared to LMA Supreme in gynecologic laparoscopy[13], while others report similar OLP to LMA Supreme in children under general anesthesia[24] and comparable to other SGAs in various studies[1,31,32,332]. Mean expired tidal volume and ETCO2 were comparable between both groups (p > 0.05), suggesting effective positive pressure ventilation, consistent with previous studies[21]. Hemodynamic parameters (heart rate and mean arterial pressure) showed no significant differences between groups, with increases from baseline after insertion and removal (p > 0.05), likely due to stress response. These results were in consonance with the previous studies [14,21,31]. No serious complications were noted. Airway trauma, indicated by blood staining of device after removal, occurred in one patient per group, with oropharyngeal pain reported by three patients in each group (p > 0.05). Factors contributing to oropharyngeal

pain include insertion technique, device size, use of lubricants, cuff overinflation, duration of surgery and airway gases[14,15,21,30,31]. Limitations include applicability to adult patients with normal airways, single OLP measurement without observing different patient positions and lack of end-procedure OLP and intracuff pressure measurements. Further studies are recommended to compare Auragain and Proseal efficacy in the Indian population.

CONCLUSION

Our findings suggest that both the Ambu Auragain and LMA Proseal are viable options for safe and effective use in patients undergoing general anesthesia. Nevertheless, our study indicates superior operational efficacy of the Ambu Auragain, as it yields higher oropharyngeal leak pressure compared to the Proseal LMA in patients undergoing elective surgery under general anesthesia.

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