Original Article

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Anaesthesia Section

Evaluation of Safety and Efficacy of AMBU® AuraOnce™ Laryngeal Mask Airway in Supine and Trendelenburg Position in Patients undergoing Perianal Surgeries: A Prospective Observational Study

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ABSTRACT

Introduction: Oropharyngeal Leak Pressure (OLP) is a crucial marker for assessing the safety and efficacy of airway devices. Positional changes during surgeries may influence airway dynamics and require objective assessment.

Aim: To compare the changes in OLP using the AMBU® AuraOnce™ Laryngeal Mask Airway (LMA) in patients undergoing perianal surgeries in supine and Trendelenburg positions.

Materials and Methods: This prospective observational study was conducted among 35 adult patients undergoing elective perianal surgeries between March 2023 and February 2024, Department of Anaesthesiology, Indraprastha Apollo Hospital, New Delhi, India. The OLP, intracuff pressure, $ETCO_2$, heart rate, mean arterial pressure, and SpO_2 were measured during surgeries under general anaesthesia with AMBU® AuraOnce™ LMA, which required both supine and Trendelenburg positions. Data were analysed using a paired t-test for continuous variables and Chi-square for categorical variables, with p-value <0.05 considered statistically significant.

Results: The mean age and Body Mass Index (BMI) were 47.14±12.87 years and 27.37±4.5 kg/m^2. A total of 21 male and 14 female patients were assessed. The mean OLPs of patients in the supine and Trendelenburg positions after LMA insertion were 20.17±1.32 cmH_2O and 20.40±1.12 cmH_2O, respectively; however, the mean OLP difference in both positions was not statistically significant (p-value >0.05). The mean arterial pressure, End-Tidal Carbon Dioxide ($ETCO_2$), and Peripheral oxygen saturation (SpO_2) in supine and Trendelenburg positions were 87.7±16.36 mmHg and 90.23±7.28 mmHg, 31.66±3.18 mmHg and 31.63±3.45 mmHg, 99.6±0.60% and 98.97±0.70%, respectively.

Conclusion: The AMBU® AuraOnce™ LMA can maintain a stable OLP, ventilation parameters, and haemodynamic profile, when the patient requires a change in position from supine to Trendelenburg position during perianal surgeries.

Keywords: Airway management, Haemodynamics, Oropharyngeal leak pressure, Ventilation

INTRODUCTION

The LMA device has been a standard component in elective surgeries for children and adults since Archie Brain described it three decades ago. The AMBU® AuraOnce™ is a single-piece, first-generation LMA featuring a 90° preformed curve design with a cuff engineered to offer effective seal pressure [1]. It maintains a low mucosal pressure, allowing the airway tube to adapt to individual anatomical variations and various head positions [2,3]. The OLP is the pressure within the airway tract at which gas starts leaking around the back of the LMA cuff. It is a crucial marker of the safety and efficacy of the airway device. A higher oropharyngeal seal pressure indicates a better seal between the supraglottic airway and the supraglottic mucosa. This high pressure provides enhanced protection against gastric aspiration and allows for more significant levels of positive pressure ventilation [4].

Patients' position during surgeries can considerably influence the performance of LMAs. The head-low or Trendelenburg position, commonly employed in perianal or gynaecological surgeries for optimal exposure, may increase intrathoracic pressure. This may be due to cephalad displacement of the diaphragm, thus affecting the seal and position of LMAs. Although saddle anaesthesia was a popular choice for such types of procedures, the need for lithotomy or Trendelenburg positioning often reduces patient tolerance under regional anaesthesia. Thus, general anaesthesia with LMAs is preferred for airway control and stable operating conditions [5,6].

Studies have reported inconsistent results regarding differences in OLP among different types of LMAs, such as AMBU® AuraOnce™, AuraGain and Supreme, in ambulatory surgeries [3-9]. Certain studies have even observed differences in OLP when LMAs are used in positions such as supine, lateral decubitus, or Trendelenburg during surgeries [10,11]. However, Saracoglu KT et al., in their study have suggested that the OLP does not change significantly in different positions [12].

Although the advantages of ventilation during surgery with the AMBU® LMA device over other LMA devices are well-documented in the literature [1,6], data regarding devices that offer better OLP at different positions are lacking [12]. Since there are no similar studies in the literature, present study hypothesised that AMBU® AuraOnce™ LMA would have no difference in OLP when measured in the supine position compared with the Trendelenburg position. Therefore, this study aimed to measure the OLP with AMBU® AuraOnce™ LMA in two different positions, i.e., supine and Trendelenburg positions, to determine whether there is any difference in OLP between these positions or if it is safe to use this device in these positions. The primary objective of this research was to measure the difference in OLP between Trendelenburg and supine positions. The secondary objectives were to assess changes in intracuff pressure, the volume of air required to achieve an intracuff pressure of 60 cmH_2O, and the incidence of airway-related complications including sore throat, dysphagia, dysphonia, blood-stained cuff, laryngospasm, and Postoperative Nausea and Vomiting (PONV).

MATERIALS AND METHODS

A prospective observational study was conducted at Indraprastha Apollo Hospital, New Delhi, India, between March 2023 and February 2024 (12 months) after receiving clearance from the Institutional Ethics Committee (IEC) (IAH-BMR-005/01-23). All the procedures that are performed during this study were in accordance with the ethical standards of IEC and with the 1975 Helsinki Declaration, as revised in 2013.

Inclusion criteria: All adult patients of either gender who were >18 years of age, American Society of Anaesthesiologists (ASA) physical status 1 and 2 and BMI ≤40 kg/m² scheduled to undergo elective perianal surgeries, using both supine and Trendelenburg positions were included in the study.

Exclusion criteria: Patients with neck or upper airway pathology, those who were edentulous, pregnant women, those with gastroesophageal reflux disease and those with cervical spine pathology were excluded from the study.

Sample size: The required sample size was estimated using the formula for paired means:

$$n = \frac{(Z\,(1-\alpha/2)+Z\,(1-\beta)^2\cdot\sigma\,^2_d)}{\delta^2},$$

where Z_(1-α/2)=1.96 for a two-sided α of 0.05, Z_(1-β)=0.842 for a power of 80%, σ_dis the standard deviation of the paired differences, and δ represents the minimum clinically important difference (1 cmH_2O). A difference of 1 cmH_2O in OLP between the two positions was considered clinically meaningful based on prior literature [12-14]. The effect-size assumption for this study was derived from the magnitude of positional change and variability in OLP reported by Saracoglu KT et al., who reported mean OLP of 27.45±5.37 cmH_2O in the supine position and 26.04±4.92 cmH_2O in the lateral decubitus position, indicating a positional difference of approximately 1-2 cmH_2O with a standard deviation of about 5 cmH_2O [12]. These corresponded to a moderate standardised effect size of Cohen's d ≈ 0.5. Using this assumption, the calculated sample size was 34, and to ensure adequate power and allow for potential dropouts, 35 patients were finally enrolled after assessing 42 patients initially.

Study Procedure

All selected patients were informed about the details of the procedure, its benefits and possible consequences in the postoperative period while obtaining informed consent. The patients received general anaesthesia in the supine position, and their airways were secured with an AMBU® AuraOnce™ LMA per standard of care, as explained below. ASA guidelines were followed for fasting instructions. Electrocardiogram, non invasive blood pressure monitors and pulse oximeters were connected in the operating room. Preinduction baseline cardiorespiratory parameters, including heart rate, blood pressure, respiratory rate and oxygen saturation, were recorded. Pre-medication was done with fentanyl 1-2 µg/kg body weight and ondansetron 4 mg. Anaesthesia was induced with titrated doses of propofol (1.5-2.5 mg/kg body weight), followed by neuromuscular blockade with atracurium (0.5 mg/kg body weight). LMA was inserted after confirming jaw relaxation. Before insertion, the dorsal surface of the device was lubricated with water-based jelly. An appropriately sized LMA was used according to the patient's weight, and the device was inserted in the sniffing position. Anaesthesia was maintained with oxygen, sevoflurane (1%-2%) and nitrous oxide. Using a hand-held cuff manometer, air was filled in the cuff of the LMA to achieve an intracuff pressure of 60 cmH_2O. The volume of air required to reach the aforementioned intracuff pressure was noted. OLP was then determined by closing the adjustable pressure limiting valve of the circle system to 40 cmH_2O. Total flows were set at 3 L/min, and the increase in the airway pressure was observed on the monitor (pressure-time graph). OLP was noted once the plateau pressure was achieved.

When the patient was shifted to the Trendelenburg position (with a tilt of 20°-30°) during the surgery, the process of checking the OLP was repeated after a washout period of at least five minutes. At the end of the operation, residual neuromuscular blockade was reversed by administering neostigmine (0.05 mg/kg) and glycopyrrolate (0.01 mg/kg). After the return of spontaneous respiration, LMA was removed and the patient was shifted to the post-anaesthetic care unit. The presence or absence of blood on the dorsal surface of the LMA, sore throat, dysphagia, dysphonia and PONV were noted in the recovery room postoperatively.

STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 28.0. The continuous variables were presented as mean±standard deviation and the median (interquartile range) for normally and non normally distributed data, respectively. The categorical variables were presented as absolute numbers and percentages. The paired t-test was used to compare normally distributed continuous variables, whereas the Wilcoxon signed-rank test was used for those variables that were not normally distributed. Categorical variables were analysed using the Chi-square test. For all statistical tests, p-value <0.05 was considered statistically significant.

RESULTS

A total of 35 patients were included in the study, and various parameters were assessed in both the supine and Trendelenburg positions. There were 21 men and 14 women, with a mean age of 47.14±12.8 years. The demographic data are listed in [Table/Fig-1].

Variables	Value
Age (years) (mean±SD)	47.14±12.87
Height (cm) (mean±SD)	160±12.56
Weight (Kg) (mean±SD)	70.69±13.18
BMI (Kg/m²)*	27.37±4.5
Gender (M/F)	21/14
ASA grades (I/II)†	14/21
Mallampati classification (I/II/III)	8/17/10

[Table/Fig-1]: Demographic data of the study population.
Values are presented as mean±SD or number of patients. *BMI: Body mass index; †ASA: American society of anaesthesiologists

In this study, three different sizes of LMA were used; 13 patients required size 3, 21 required size 4 and 1 required size 5. The mean air volumes to maintain an intracuff pressure of 60 cmH_2O in LMA sizes 3, 4 and 5 were 8.85±1.6 mL, 9.48±0.9 mL and 18±0 mL, respectively (combined mean air volume 9.49±1.8 mL). However, no change in the volume of air was required when the patient's decubitus was changed during the surgery. A few minor complications were seen, as shown in [Table/Fig-2]. A comparative analysis of different variables between the supine and Trendelenburg positions is shown in [Table/Fig-3].

Complications	Frequency
Blood-stained cuff	2
Sore throat	2
Dysphagia	0
Dysphonia	0
Laryngospasm	0
Postoperative Nausea and Vomiting (PONV)	3

[Table/Fig-2]: Table showing various complications during the study.

Variables	Supine position	Trendelenburg position	p-value	Test statistics
Oropharyngeal Leak Pressure (OLP) (cmH_2O)	20.17±1.32	20.40±1.12	0.309	t(34)=-1.03

Mean arterial pressure (mmHg)	87.7±16.36	90.23±7.28	0.335	t(34)=-0.98
Heart rate (per min)	77.86±8.53	78.8±8.10	0.031	t(34)=-2.26
$ETCO_2$ (mmHg)*	31.66±3.18	31.63±3.45	0.931	t(34)=-0.09
SpO_2 %†	99.6±0.60	98.97±0.70	<0.001	t(34)=4.35

[Table/Fig-3]: Comparative analysis between supine and Trendelenburg position.
Values are presented as mean±SD. Test statistics shown are t values (paired t-test, df=34)
*$ETCO_2$: End-tidal carbon dioxide. †SpO_2: Peripheral oxygen saturation.

A post-hoc analysis using the Wilcoxon signed-rank test was conducted to assess the paired differences in OLP between the supine and Trendelenburg positions. The results showed no statistically significant differences (Z=-1.009, p-value=0.313), indicating that a change in position did not alter the OLP.

DISCUSSION

The OLP is commonly used to measure the efficacy of airway sealing systems in nearly all types of LMA devices [15]. Furthermore, this measure ensures successful LMA placement and protects the airway tract [13]. The AMBU® AuraOnce™ LMA is a first-generation, curved, disposable airway tube that is perfectly moulded according to the human peri-laryngeal anatomy. Compared with other first-generation airway devices, it exhibits a higher OLP and aspiration prevention rate [14,16,17].

Optimal positioning is crucial for good surgical access. Each position on the operating table carries certain risks and complications, which are modified in a patient who has been anaesthetised. These complications can be attributed to physiological changes associated with a specific position or mechanical causes. Sometimes, the most frequently adopted positions, such as supine, Trendelenburg, lithotomy, or prone positions, are manoeuvred on the table itself when the patient is under general anaesthesia. If such a patient is ventilated with a supraglottic airway device, the safety and protection of the airway during and after the positioning warrant extra attention. Many researchers have attempted to determine the OLPs of different generations of LMAs in various positions; however, a unanimous conclusion has not been reached [10,12,18-22]. Flexion of the head and neck in such patients can severely compromise the effectiveness of airway ventilation. In contrast, rotation of the head and neck does not cause any significant changes in OLP and peak inspiratory pressure [17]. Similarly, the change from supine to lateral decubitus position has minimal effect on the OLP and tidal volumes [18].

Owing to the lack of literature on the OLP of LMA in the Trendelenburg position, it was measured in this study. In the Trendelenburg or head-down position, gravity allows abdominal organs to shift towards the head end. This shift can restrict diaphragmatic movement, leading to a decrease in functional residual capacity of the lungs and reduced tidal volumes. The resultant lowering in the capacity of the thoracic cavity can alter the positioning and seal of LMA devices, potentially affecting OLP [19]. Moreover, fluid displacement may occur from the lower body to the upper airway in the Trendelenburg position, resulting in venous engorgement and pharyngeal oedema, potentially affecting the OLP of LMA [20].

Effect on OLP after positional change: When the OLP of the AMBU® AuraOnce™ LMA was measured in present study participants in the supine position and compared with that in the Trendelenburg position, statistically or clinically significant differences were not observed (p-value=0.313), indicating stable airway sealing despite positional changes. The mean OLP in the supine position was 20.17 cmH_2O and that in the Trendelenburg position was 20.40 cmH_2O. Saracoglu KT et al., studied the efficacy of LMA in supine and lateral decubitus positions in 88 participants by measuring their OLP and found comparable values, i.e., 27.45±5.37 and 26.04±4.92, respectively [12]. A case report published by Lim JA et al., also concluded that a change in position during anaesthesia from supine to lateral decubitus did not affect OLP [21]. Foo LL et al., compared the Baska mask with LMA Supreme in different positions during anaesthesia. They concluded that although OLP was higher in the former in all positions (p-value <0.001), the OLP of each device was relatively stable during and after the change in position from supine to others [22]. These consistent findings across studies reinforce that positional change alone does not significantly compromise the sealing ability of modern supraglottic airway devices.

Effect on intracuff pressure after positional change and cuff inflation volume: This study also compared the change in intracuff pressure of the AMBU® AuraOnce™ LMA in the supine and Trendelenburg positions. The cuff was inflated to maintain a pressure of 60 cmH_2O in the supine position, which is the recommended maximum pressure for the LMA [23]. Upon repositioning the patient to the Trendelenburg position, the intracuff pressure remained unchanged. This finding was supported by a few other studies that have attempted to replicate these results with different LMA devices [23,24]. An optimal air volume is always required to maintain the airway seal during positive pressure ventilation and reduce pharyngeal complications. An increase in the intracuff pressure can cause pharyngeal mucosal ischaemia despite high OLP. An intracuff pressure of <60 cmH_2O can prevent these complications and provide an optimal OLP. A volume of air ranging from 7 mL to 9 mL is sufficient for achieving this optimal pressure [25]. The mean volume of air to maintain an intracuff pressure of 60 cmH_2O in the present study was 9.49±1.8 mL.

Effect on haemodynamic and respiratory parameters: As the patient's position changes, physiological alterations in the body can be detected by measuring various parameters, including mean arterial pressure, heart rate, $ETCO_2$, and SpO_2. These values were recorded in each patient before and after the positional change, and an attempt was made to determine the differences in them. The mean arterial pressure showed a slight increase in the Trendelenburg position (90.23 mmHg) compared with the supine position (87.7 mmHg); however, this change was not clinically significant and did not require any intervention. This finding was consistent with the physiological effects of Trendelenburg positioning, which increases venous return and preload, thereby modestly elevating arterial pressure. Comparable trends in MAP following positional change during general anaesthesia have also been reported by Saracoglu KT et al., and Lim JA et al., where such changes were transient and clinically insignificant [12,21]. In this study, mild differences in heart rate and peripheral oxygen saturation (SpO_2)were observed between the Trendelenburg and supine positions; although statistically significant, these differences were clinically insignificant. The ETCO2 levels remained well-maintained in both the positions. Furthermore, adequate oxygenation was preserved throughout the positional change, indicating effective ventilation and gas exchange with the AMBU® AuraOnce™ LMA. These trends are similar to the findings recorded by a few studies when the patients were changed from supine to other positions; however, due to the paucity of published literature evaluating individual physiological and airway parameters of the LMA across different surgical positions- particularly the Trendelenburg position- a strict parameter-wise comparison with existing studies was not feasible [18,21].

In this study, OLP was measured in two different positions sequentially, which raises a potential methodological concern regarding the period or carryover effect. These effects are due to natural changes in patients' responses over time, independent of interventions, and when the first condition influences subsequent ones [25]. To minimise these effects, a brief washout time of at least five minutes was introduced before retesting, allowing tissue compliance and airway pressures to stabilise. Furthermore, a post-hoc analysis utilising the Wilcoxon signed-rank test was conducted.

Major complications associated with LMA devices are rare. However, in the present study, two cases of blood-stained cuff, two cases of sore throat in the postoperative period and three cases of PONV were found. PONV can have a multifactorial aetiology, such as the female sex, young age, history of prior postoperative emesis, motion sickness, general anaesthesia and opioid use [1]. Therefore, the incidence of PONV in present study cannot be attributed exclusively to the use of any particular type of LMA device. Previous literature has also reported low incidence of transient airway morbidity such as cough, dysphonia, dysphagia, and occasional laryngospasm even when recommended cuff pressures were maintained [26,27]. These findings are consistent with the mild nature of airway-related complications observed in the present study.

Limitation(s)

The limitations of this study include a single-centre design, a non blinded research design and a lack of fiberoptic positional verification.

CONCLUSION(S)

This study demonstrated that AMBU® AuraOnce™ LMA maintains a stable OLP during transition from the supine to the Trendelenburg position. Intracuff pressure, tidal ventilation, and airway mechanics remained unaffected by the positional change, indicating reliable airway sealing and ventilation. The volume of air required to maintain an optimal intracuff pressure of 60 cmH_2O was consistent with recommended safe ranges. Haemodynamic and respiratory parameters showed only minimal, clinically insignificant variations, confirming physiologic stability during positional change. Airway-related complications were infrequent and mild, reinforcing the safety profile of the device. Overall, the AMBU® AuraOnce™ LMA can be considered a safe and effective supraglottic airway device for surgeries requiring Trendelenburg positioning.

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