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ORIGINAL RESEARCH PERIOPERATIVE MEDICINE

Perfusion index, intraocular pressure, and hemodynamic responses on insertion of endotracheal tube, Air-Q® and Ambu® Aura-I™ in ophthalmic surgeries: a randomized controlled trial

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Abstract

Background: Different supraglottic devices have been used with general anesthesia to avoid the disadvantages of endotracheal intubation (ET), especially the pressor response. We assessed the safety and efficacy of the air-Q® (AQ) and Ambu® Aura-i™ (AI) devices compared to ET during ophthalmic operations under general anesthesia.

Methodology: This randomized clinical trial enrolled 96 adult patients undergoing elective ophthalmic surgeries who were allocated into three groups: the AQ, AI, and ET, according to the airway device used. The perfusion index, blood pressure, heart rate, and intraocular pressure (IOP) were measured before and after the airway device was inserted. The primary outcome was the change in perfusion index, whereas the secondary outcomes included the ease of insertion and changes in the hemodynamic parameters and IOP.

Results: Following the insertion of airway devices, the perfusion index decreased significantly in the ET group compared to the AQ and AI groups ($P < 0.001$). Significant increases in the heart rate, blood pressure, and IOP were observed in the ET group relative to the other groups ($P < 0.001$). The IOP following insertion of AI was significantly lower than AQ in the first two minutes post-insertion ($P < 0.001$). The AI device was significantly easier to be inserted than the AQ device ($P < 0.001$).

Conclusion: Both AI and AQ were reliable and effective in avoiding pressor stress response and increased IOP during general anesthesia, which are desirable targets during operative procedures, especially ophthalmic surgeries. The AI was superior to AQ in terms of IOP fluctuations and the ease of insertion.

Abbreviations: AI: Ambu Aura-i; AQ: air-Q; DBP: diastolic blood pressure; ET: endotracheal intubation; HR: heart rate; IOP: intraocular pressure; LMA: laryngeal mask airway; OLP: oropharyngeal airway pressure; SBP: systolic blood pressure; SD: standard deviation; SAD: supraglottic airway device

Key words: Hemodynamic Monitoring; Intraocular Pressure; Intubation, Intratracheal; Supraglottic Airway Device

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1. Introduction

The search for an effective alternative to endotracheal intubation for maintaining a patent airway during general anesthesia has led to the invention of supraglottic airway devices (SADs). The first of the SADs was the laryngeal mask airway (LMA), which was introduced into clinical use in 1988.[1]

The success of LMA triggered the design of several new variations of the device.[2] Second generation SADs include the air-Q® laryngeal mask airway and the Ambu® Aura-i™. They were introduced as simple, effective alternatives to endotracheal intubation aiming to avoid laryngoscopy-induced local and systemic adverse events.[3,4]

In 2005, the air-Q laryngeal mask airway was first developed and introduced by Daniel J. Cook. The device was designed to allow easy insertion and good seal, to help protection of the airway, and to provide a conduit for tracheal intubation during general anesthesia. It is available as disposable or reusable, and in seven sizes (from 0.5 to 4.5).[5,6]

The Ambu Aura-i is a relatively new, anatomically contoured, single-use SAD. When properly inserted, the distal tip of the cuff rests in opposition to the upper esophageal sphincter. It is characterized by a high seal pressure and easy insertion because it is more curved compared to the classic laryngeal mask airway, which provides better alignment with the natural curvature of the upper airway. It can be used as a conduit for an endotracheal tube in cases when the patient cannot be intubated or ventilated. The device is meant for single use and is available in eight different sizes according to the body weight.[7,8]

The use of SADs has recently increased and gained wide popularity. These are easily inserted, better tolerated by patients, and provide more stable hemodynamic status and intraocular pressure (IOP). In addition, these devices are minimally invasive and, therefore, less sore throat and trauma.[9,10]

The perfusion index (PI) is the proportion of pulsatile blood flow at a certain location (as the fingers or toes) to non-pulsatile blood in peripheral tissue. It is computed by dividing the pulsatile signal (during arterial inflow) by the non-pulsatile signal (during arterial outflow), both of which are generated from the amount of infrared (940 nm) light absorbed. It is a simple and accurate method of detecting changes in digital blood flow and is a noninvasive measure of peripheral perfusion. It can predict hemodynamic response to the anesthetic drugs, procedures, and intraoperative stimuli.[11,12]

Because of their safety, ease of insertion, and good patient tolerance, the use of air-Q and Ambu Aura-i devices is growing; however, research on the effect of their insertion on the cardiovascular system and IOP is still scarce. We hypothesized that the effects of implanting the Ambu Aura-I on IOP and all hemodynamic parameters would be noticeably less severe than those of implanting the Air-Q or using an endotracheal tube. Therefore, we assessed the safety and efficacy of the air-Q and Ambu Aura-i devices compared to endotracheal intubation during ophthalmic surgeries under general anesthesia.

2. Methodology

The protocol of the current study was approved by the Research Ethics Committee, Faculty of Medicine, Cairo University, Egypt (N-83-2017). An informed written consent was obtained from each patient before the operation. Confidentiality of the patients' data was maintained by keeping anonymous records and datasheets after assigning a specific code for each patient. The trial was registered at the Pan African Clinical Trial Registry (PACTR202202567201966).

This single-blinded, parallel-group (1:1:1), randomized, clinical trial was conducted at Kasr Al Ainy Hospitals, Cairo University, Cairo, Egypt from April 2018 to December 2020.

Power analysis was performed using the ANOVA Omnibus test for independent samples. According to Atef et al.[11] the mean perfusion indices one minute after device placement were 1.47 ± 0.76 and 1.90 ± 0.32 in the endotracheal tube and supraglottic devices, respectively. Using the power of 0.8 and an alpha error of 0.05, a minimum sample size of 30 patients was calculated for each group. A total of 96 patients were included to account for probable dropouts.

We enrolled adult male and female patients, aged 18 to 60 y, ASA-I or II, undergoing elective ophthalmic surgeries under general anesthesia. We excluded patients with glaucoma, cardiovascular or pulmonary diseases, restriction of neck extension or mouth opening, pharyngeal pathology, or obstruction of the airway at or below the level of the larynx. We also excluded patients with a body mass index above 35 kg/m^2 and those with an airway score of 4 or higher.

Randomization and allocation concealment were achieved by using 3 sets of 32 identical, sealed, opaque, sequentially-numbered envelopes. Each envelope

Table 1: Comparative demographic data and ASA physical status

Parameter		Group ET	Group AQ	Group AI	P value
Age (y), mean ± SD)		58.06 ± 1.92)	57.97 ± 1.80)	58.41 ± 1.64)	0.591
Sex [n (%)]	Male	17 (53.10)	18 (56.25)	15 (46.90)	0.747
	Female	15 (46.90)	14 (43.75)	17 (53.10)	
ASA [n (%)]	I	16 (50)	19 (59.40)	15 (46.90)	0.581
	II	16 (50)	13 (40.60)	17 (53.10)	

SD: standard deviation; ASA: American Society of Anesthesiologists

contained an allocation paper marked as 'Treatment A' (n = 32), 'Treatment B' (n = 32), or 'Treatment C' (n = 32).

A member of the research team (neither involved in sequence generation nor allocation concealment) assessed participants for eligibility and assigned eligible patients to one of the three trial arms (air-Q, Ambu Aura-i, or endotracheal intubation). Participants and the data analyst were blinded to treatment allocation.

Airway assessment was performed at the preoperative visit using El-Ganzouri Airway Score[13] to determine the expected difficulty of intubation. Patients with an airway score of 4 or higher were excluded from the trial. Before surgery, all patients were fasted for 8 h. No pre-medication was allowed. Before induction of anesthesia, the patients were positioned supine with the head on a soft doughnut (4 cm high), neck flexed, and head extended. An ECG, non-invasive blood pressure, SpO_2, and capnography were monitored. A GE TuffSat pulse oximeter (Datex-Ohmeda Instrumentarium Corp., USA) was used to track the PI. An ophthalmologist employed a Schiotz tonometer (Gulden Ophthalmics, Elkins Park, Pennsylvania, USA) to measure the IOP.

Before the onset of anesthesia, the IOP, systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), and PI were measured. A 20-G cannula was inserted to provide intravenous access.

Fentanyl 1 µg/k) and thiopental 5 mg/kg were used to induce anesthesia until the eyelash reflex was lost. Atracurium was given at a dose of 0.5 mg/kg. After complete muscular relaxation, tracheal intubation or insertion of an airway device was attempted.

In the endotracheal tube group (ET group), intubation

of the trachea was tried using direct laryngoscopy and a cuffed tracheal tube (internal diameter 7 mm for women and 8 mm for men). In the air-Q group (AQ group), size 3.5 was used for women and size 4.5 for the men. The cuff was inflated to 5-10 cm^3 of air. In the Ambu Aura-i group (AI group), patients weighing 30–50 kg were fitted with a size 3 device, patients weighing 50–70 kg with a size 4, and patients weighing more than 70 kg with a size 5 device.

SADs were blindly inserted as per the manufacturer's instructions. The correct position of each device was tested. The ease of insertion of each device was graded as follows: excellent = 1 (no resistance to insertion), good = 2 (slight resistance to insertion), poor = 3 (moderate resistance to insertion), and impossible = 4 (more than 3 unsuccessful attempts or the entire insertion process takes more than 120 sec). Patients were excluded of the research if the insertion was poor or difficult, and the protocol required intubation of the trachea.

Isoflurane 1-2% in a combination of oxygen and air was used to maintain anesthesia. The lungs were mechanically ventilated to maintain an end-tidal carbon dioxide concentration of 4.0 to 4.7 kPa. The IOP, SBP, DBP, HR, and PI were measured before the airway device insertion, and then at 1, 2, 3, and 5 min.

Oropharyngeal leak pressure (OLP) was tested using clinical confirmatory tests.

The primary outcome was the change in the PI. The secondary outcomes included the ease of insertion of both SADs as well as changes in the HR SBP, DBP, and IOP. Outcomes were assessed by an experienced anesthesiologist.

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences for Windows, version 15 (SPSS, Inc, Chicago, II, United States). The Chi-square test was used to evaluate categorical variables. The mean and standard deviation of normally distributed data were calculated and evaluated using one-way and

Table 2: Pre-induction, pre-insertion, and post-insertion values of perfusion index

Parameter	Group ET	Group AQ	Group AI	P value
Pre-induction	3.18 ± 0.96	3.02 ± 0.94	3.08 ± 0.82	0.771
Pre-insertion	4.93 ± 1.12	4.45 ± 0.97	4.78 ± 0.88	0.153
Post-insertion				
• 1 min	2.03 ± 0.75	4.29 ± 0.96	4.65 ± 0.87	P1 < 0.001* P2 < 0.001* P3 = 0.308
• 2 min	2.22 ± 0.78	4.17 ± 0.95	4.51 ± 0.87	P1 < 0.001* P2 < 0.001* P3 = 0.364
• 3 min	2.48 ± 0.78	4.33 ± 0.96	4.64 ± 0.88	P1 < 0.001* P2 < 0.001* P3 = 0.487
• 5 min	2.72 ± 0.74	4.46 ± 0.98	4.78 ± 0.89	P1 < 0.001* P2 < 0.001* P3 = 0.461

*Data given as mean ± standard deviation; P1: comparison between ET group and AQ group; P2: comparison between ET group and AI group, P3: comparison between AQ group and AI group; *significant*

two-way analyses of variance with repeated measurements, as well as the post hoc Dunnett test where needed. Data that were not normally distributed (as determined by the Kolmogorov-Smirnov test) were presented as median (range) and evaluated using the Kruskal-Wallis or Freidman tests if needed.

3. Results

One hundred twenty-nine adult patients undergoing elective ophthalmic surgeries under general anesthesia were assessed. Ninety-six met the eligibility criteria and were randomly allocated into one of three groups: the ET group (n = 32), the AQ group (n = 32), or the AI group (n = 32). There was no loss to follow up or exclusions after randomization.

Table 1 shows no significant differences between the studied groups regarding age, sex, or ASA (P > 0.05). There was no significant difference between the three groups in the pre-induction and pre-insertion values of the PI, HR, SBP, and DBP. Despite being significantly different, the pre-induction and pre-insertion IOP values were within the normal range (9−21 mmHg). Induction of anesthesia increased the PI. Following insertion of all airway devices, the PI decreased in all groups; however, this decrease was only significant in the ET group. Also, there was no significant difference after insertion between the AQ and AI groups (P > 0.05) (Table 2).

When compared to the insertion of the Ambu Aura-i or air-Q devices, endotracheal intubation was linked with significant increases in all three hemodynamic parameters. However, no significant differences were detected between the AQ and the AI groups regarding the HR, SBP, and DBP measurements after insertion (P > 0.05) (Table 3).

Induction of anesthesia reduced the IOP in all groups when compared to pre-induction readings. Endotracheal intubation raised the IOP above the pre-insertion and pre-induction levels. The changes in IOP in the two SADs groups did not exceed the pre-insertion or pre-induction levels. The IOP following insertion of Ambu Aura-i was significantly lower than after insertion of air-Q in the first two minutes (both P values < 0.05) (Table 4).

The Ambu Aura-i device was inserted significantly (p < 0.001) easier than the air-Q device (Table 5).

4. Discussion

Different SADs have been invented as alternatives to conventional endotracheal intubation during general anesthesia to avoid the disadvantages of intubation, especially the pressor response.[9, 10]

In the present study, the PI increased following the induction of general anesthesia in all groups. Endotracheal intubation resulted in a significant

Table 3: Comparative hemodynamic parameters. pre-induction, pre-insertion, and post-insertion

Parameter	Group ET	Group AQ	Group AI	P value
Pre-induction HR	81.13 ± 8.88	81.84 ± 9.08	80.16 ± 9.75	0.765
Pre-insertion HR	74.69 ± 9.17	73.03 ± 8.46	70.16 ± 9.68	0.138
Post-insertion HR				
• 1 min	95.88 ± 8.32	73.97 ± 8.17	70.47 ± 8.90	P1 < 0.001* P2 < 0.001* P3 = 0.305
• 2 min	90.62 ± 8.33	71.94 ± 8.06	68.28 ± 9.08	P1 < 0.001* P2 < 0.001* P3 = 0.266
• 3 min	85.78 ± 8.12	71.59 ± 8.30	68.09 ± 9.11	P1 < 0.001* P2 < 0.001* P3 = 0.311
• 5 min	79.03 ± 8.90	68.25 ± 8.37	64.69 ± 9.31	P1 < 0.001* P2 < 0.001* P3 = 0.335
Pre-induction SBP	120.94 ± 9.50	123.56 ± 12.72	124.34 ± 11.39	0.452
Pre-insertion SBP	108.97 ± 8.83	112.72 ± 12.69	112.87 ± 12.10	0.301
Post-insertion SBP				
• 1 min	143.25 ± 9.01	108.34 ± 12.61	108.59 ± 11.75	P1 < 0.001* P2 < 0.001* P3 = 1.000
• 2 min	131.50 ± 9.53	103.94 ± 12.44	103.41 ± 11.49	P1 < 0.001* P2 < 0.001* P3 = 1.000
• 3 min	116.50 ± 9.51	98.53 ± 12.29	97.31 ± 11.13	P1 < 0.001* P2 < 0.001* P3 = 1.000
• 5 min	114.19 ± 9.79	91.31 ± 10.70	90.88 ± 10.43	P1 < 0.001* P2 < 0.001* P3 = 1.000
Pre-induction DBP	75.78 ± 8.14	75.34 ± 8.04	75.13 ± 8.16	0.947
Pre-insertion DBP	69.66 ± 9.55	68.06 ± 7.47	67.97 ± 7.59	0.657
Post-insertion DBP				
• 1 min	82.62 ± 8.27	68.16 ± 6.97	65.97 ± 7.56	P1 < 0.001* P2 < 0.001* P3 = 0.761
• 2 min	74.84 ± 8.06	63.72 ± 6.72	62.69 ± 7.83	P1 < 0.001* P2 < 0.001* P3 = 1.000
• 3 min	71.94 ± 7.94	58.66 ± 6.64	59.47 ± 7.63	P1 < 0.001* P2 < 0.001* P3 = 1.000
• 5 min	67.66 ± 9.52	53.84 ± 5.55	55.56 ± 6.96	P1 < 0.001* P2 < 0.001* P3 = 1.000

*Data given as mean ± standard deviation P1: comparison between ET group and AQ group; P2: comparison between ET group and AI group, P3: comparison between AQ group and AI group; *significant*

Table 4: Comparative values of intraocular pressure pre-induction, pre-insertion and post-insertion

Parameter	Group ET	Group AQ	Group AI	P value
Pre-induction IOP	14.66 ± 1.12	16.16 ± 1.35	15.47 ± 1.19	P1 < 0.001* P2 = 0.028* P3 = 0.081
Pre-insertion IOP	12.69 ± 0.93	13.38 ± 1.31	12.66 ± 0.94	P1 = 0.037* P2 = 1.000 P3 = 0.027*
Post-insertion IOP				
• 1 min	16.91 ± 1.15	13.38 ± 1.31	12.66 ± 0.94	P1 < 0.001* P2 < 0.001* P3 = 0.041*
• 2 min	16.91 ± 1.15	13.38 ± 1.31	12.66 ± 0.94	P1 < 0.001* P2 < 0.001* P3 = 0.041*
• 3 min	15.56 ± 1.05	12.91 ± 0.93	12.59 ± 0.91	P1 < 0.001* P2 < 0.001* P3 = 0.593
• 5 min	12.97 ± 1.00	12.84 ± 0.99	12.47 ± 0.67	0.074

*Data given as mean ± standard deviation; P1: comparison between ET group and AQ group; P2: comparison between ET group and AI group, P3: comparison between AQ group and AI group; *significant*

Table 5: Comparative ease of insertion of both supraglottic airway devices

Ease of insertion	Group AQ	Group AI	P value
Excellent	12 (37.50)	30 (93.75)	**< 0.001***
Good	16 (50.00)	2 (6.25)	
Poor	4 (12.50)	0 (0)	
Impossible	0 (0)	0 (0)	

*AQ: air-Q; AI: Ambu Aura-i; Data given as n (%); P *significant*

reduction of the PI compared to both supraglottic devices. However, we found no significant difference between air-Q and Ambu Aura-I groups.

Atef et al.[11] assessed the PI following the insertion of I-gel, classic LMA, and endotracheal tube. The researchers reported a significant decrease of the PI by more than 10% in all patients after insertion of the endotracheal tube and LMA, but in only 40% of patients after insertion of the I-gel, which is a second-generation SAD similar to the air-Q and Ambu aura-I devices used in our study.

Our patients had significantly higher HR, SBP, and DBP values after endotracheal tube insertion compared to those who were managed with either device, which indicates a significantly lesser pressor response with the use of either SADs. This could be explained by the absence of laryngoscopy-induced sympathoadrenal stimulation during the introduction of the SADs, which attenuates the hemodynamic responses. We detected no difference between air-Q and Ambu Aura-i groups regarding these hemodynamic parameters.

The observed hemodynamic responses are consistent with the results of earlier studies. Zhi et al.[14] compared the Ambu Aura-i to the air-Q as conduits for fiberoptic-guided tracheal intubation in children with ear deformity and found no significant differences between the two devices as regard the patients' hemodynamics. Rangaswamy et al.[8] evaluated the use of Ambu Aura-i as an independent ventilatory device and a conduit for tracheal intubation in pediatric patients, reporting the

lack of significant changes in HR and mean arterial pressure after insertion of the Ambu Aura-i. Furthermore, Abbas et al.[15] reported that in adult patients undergoing elective ophthalmic operations, the hemodynamic values exceeded the pre-insertion measurements only in the endotracheal intubation group, and they were significantly higher compared to the I-gel group. Comparably, in children undergoing strabismus surgery, the use of I-gel was associated with minimal changes in the HR and mean arterial pressure with slight fluctuations below the pre-insertion levels, while the post-insertion measurements were significantly higher in the intubation as well as the LMA groups with increases above the pre-insertion levels.[16]

In partial agreement with our results, Akhondzade and colleagues[17] found that the HR increased significantly compared to its baseline value in adult patients undergoing ophthalmic surgery with endotracheal intubation, classic LMA, and I-gel. In addition, the researchers reported that SBP and DBP both increased significantly with endotracheal intubation relative to their baseline values, whereas the mean arterial pressure was significantly lower than its baseline value in the two SADs groups.

We found a significant increase in the IOP after the introduction of the endotracheal tube. This could be attributed to the increased sympathetic autonomic nervous system activity, which causes arterial and venous vasoconstriction, elevation of the central venous pressure, and resistance to aqueous humour outflow in the trabecular meshwork. The IOP did not increase after insertion of the air-Q or Ambu Aura-i. However, during the first two minutes after insertion, the IOP was significantly lower in Group AI than Group AQ. This might be due to easier insertion, lower number of insertion attempts and less manipulation with Ambu Aura-i.

In agreement with our findings, earlier research work reported that the IOP increased significantly after tracheal intubation and less significantly after insertion of LMA, but it did not increase at all after I-gel insertion.[11] Moreover, Akhondzade et al.[17] observed that the IOP significantly increased over the pre-intubation values in the endotracheal intubation group, but not in the other two SADs groups. The IOP after insertion was significantly higher with intubation, followed by LMA, and the least values were obtained with I-gel. Abbas et al.[15] reported an increase in IOP in the endotracheal intubation group relative to the pre-insertion level, while the IOP was nearly stable in the I-gel group, which caused a significant difference between the two groups after insertion. In addition, Allahyari et al.[16] observed that the IOP tended to decrease in the I-gel group after insertion, whereas the levels increased with endotracheal intubation and LMA insertion.

Both SADs were successfully inserted and placed without case exclusion, which is in line with Rangaswamy et al. who reported successful insertion in all the patients with the first attempt.[8] Moreover, Wahba et al. reported that the total and first-attempt success rates for air-Q in pediatric patients were 94.7% and 82.7%, respectively.[18] We observed that the insertion of Ambu Aura-i was significantly easier than that of air-Q. Perhaps, air-Q requires more training and time to achieve proper positioning and higher seal pressure, whereas the Ambu Aura-i allows easy and correct placement from the first time, and it does not require much time for skill mastering.

The present study is one of the few randomized clinical trials comparing two commonly used SADs (i.e., Ambu Aura-i and air-Q) in adult patients undergoing ophthalmic operations. Nevertheless, our results were limited by the exclusion of patients who had a difficulty in airway management.

5. Conclusions

Both Ambu Aura-i and air-Q were found safe and effective in avoiding the pressor stress response and IOP elevation associated with endotracheal tube insertion, during general anesthesia, which are much desirable targets especially ophthalmic procedures. The Ambu Aura-i was superior to air-Q as regards the ease of insertion and IOP fluctuations.

6. Data availability

The numerical data generated during this research is available with the authors.

7. Conflict of interest

The authors report no conflict of interest, and no external or industry funding was involved.

8. Authors' contribution

NN: Concept, conduction of the study work, data interpretation and manuscript editing

IM: Concept, conduction of the study work and manuscript drafting

NH: Design, data analysis and manuscript editing

GO, TK: Design, data interpretation and manuscript editing

HA: Design, conduction of the study work and manuscript drafting

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