COMPARISON OF BLIND TRACHEAL INTUBATION THROUGH THE AIR-QTM BLOCKER AND THE LARY SEAL TM PRO LARYNGEAL MASK AIRWAYS IN ANESTHETIZED PARALYZED ADULT PATIENTS UNDERGOING ELECTIVE OPHTHALMIC OPERATIONS, A RANDOMIZED CONTROLLED STUDY

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Abstract

Background: Supraglottic airway devices (SADs) are important tools for airway management. Supraglottic airway devices have been introduced into brief surgical interventions because they are less invasive than intubation and safer than mask to maintain the patency of airway after induction of anesthesia. They are inserted via the oral route and can be used as conduit for endotracheal intubation. In the current study we aim to compare Air-Q TM Blocker intubating laryngeal airway versus Laryseal TM pro laryngeal mask regarding total insertion time of laryngeal mask and endotracheal tube ,as well as ease of device insertion and any added manipulation done for successful insertion, effect on hemodynamics, SPO2 and post operative complications. **Methods:** This randomized controlled trial was conducted in Kasr Al-Ainy university hospitals, after obtaining approval from Kasr Al-Ainy hospital research ethical committee, written informed consents were taken from 64 patients, all of whom completed this study. Patients were randomly allocated into 2 equal groups, 32 each, according to the inclusion and exclusion criteria. AirQ TM Blocker group (n=32): Where Air-Q TM Blocker laryngeal airway was used for ventilation & blind intubation. Laryseal TM Pro group (n=32): Where laryseal TM Pro laryngeal mask was used for ventilation & blind intubation. **Results:** In our study revealed that Total insertion time (SAD and ETT) was insignificantly different between both groups (P-value 0.816). Regarding the effect on hemodynamics, SPO2 and post-operative complications as sore throat, dysphagia, hoarseness of voice; there was no significant difference between both devices. **Conclusion:** Laryseal pro showed to be as efficient as Air Q blocker regarding the total insertion time of the device and endotracheal tube.

Key words: Air Q TM Blocker; Laryseal TM Pro; Laryngeal ; Endotracheal tube.

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INTRODUCTION:

Establishing an airway is considered as one of the most important anesthesiologists' skills, so being not able to establish an airway may cause disastrous consequences [1]. Supraglottic airway devices (SADs) are important tools for airway management. Supraglottic airway devices have been introduced into brief surgical interventions because they are less invasive than intubation and safer than mask to maintain the patency of airway after induction of anesthesia. They are inserted via the oral route and can be used as conduit for endotracheal intubation [2]. Prediction of difficult intubation is through El Ganzouri Risk Index [3].

In the current study we aim to compare Air-Q TM Blocker [4-7] intubating laryngeal airway versus Laryseal TM pro [8, 9] laryngeal mask regarding total insertion time of laryngeal mask and endotracheal tube, as well as ease of device insertion and any added manipulation done for successful insertion, effect on hemodynamics, SPO2 and post-operative complications.

METHODS:

This randomized controlled study was conducted, Kasr Al Ainy Hospital Cairo university, Cairo, Egypt. After being approved by the Research Ethics committee of Kasr Alainy, faculty of medicine, Cairo university, it was registered as a clinical trial (NCT 05624073). A written informed consent was obtained from all patients. In this study, we enrolled 64 patients (18-60 years) of both sexes with American society of Anesthesiologists (ASA) physical status I

& II and Ganzori Score less than 3 who were scheduled for elective ophthalmology operation. Patient with upper respiratory tract infections, obstructive sleep apnea (OSA), full stomach (trauma, morbid obesity BMI> 40Kg/m2, pregnancy, history of gastric regurgitation and hiatus hernia), active chest (pneumonia, acute exacerbation of bronchial asthma, interstitial lung disease and COPD) or cardiac conditions (angina, MI, decompensated heart failure and arrhythmia were excluded from the study. They were allocated into 2 equal groups of 32 and were kept in closed and opaque envelopes. AirQ TM Blocker group (n=32): Where Air-Q TM Blocker laryngeal airway was used for ventilation & blind intubation. Laryseal TM Pro group (n=32): Where laryseal TM Pro laryngeal mask was used for ventilation & blind intubation. The hemodynamic parameters (heart rate, SBP, DBP, MBP) were monitored continuously and recorded at the following time points: before and after induction of anesthesia, before and after SAD insertion, , immediately after blind tracheal intubation, thereafter 5 and 10 min post-intubation. Primary outcome was total insertion time (seconds); insertion time (seconds) of the SAD is the time needed for correct SAD placement and started when SAD touched teeth to the first recorded rectangular capnogram curve with satisfactory bilateral chest expansion + insertion time of the endotracheal tube through the SAD (seconds) is the time in seconds from insertion of the endotracheal tube blindly until capnographic confirmation [5]. Secondary outcomes were Oropharyngeal leak pressure (OLP) (cmH2O): OLP is the achieved plateau pressure at which leak sound is heard around mouth when adjustable pressure-limiting valve of circle system is completely closed with a fresh gas flow at 3l. /min. while patient is apneic. To ensure safety, maximal allowable OLP should be fixed at 40 cmH2O [10-12]. Ease of SADs insertion: insertion score is a four-point scoring system (3=insertion at first attempt without any tactile resistance, 2=insertion at first attempt with tactile resistance, 1=insertion successful at second attempt, 0=insertion failed at second attempt), the number of intubation attempts of the endotracheal tube through the chosen SAD and if ETT couldn't be inserted by the second attempt, SAD was removed and ETT was inserted directly by the laryngoscope, ventilatory parameters; inspired tidal volume (ITV), expired tidal volume (ETV) & leak volume (LV) in ml, and leak fraction (LF) in % were recorded. LV=ITV-ETV. LF (%) =LV/ITV X100, peak inspiratory pressure (PIP) (cmH2O), dynamic lung compliance (Cdyn) (ml/cmH2O) , and laryngopharyngeal morbidity (LPM) parameters (sore throat, dysphagia & hoarseness) at 1&4h. postoperatively.

STATISTICS/DATA ANALYSIS:

Sample size calculation based on the primary outcome [5]. Subject characteristics were compared between groups. Continuous normally distributed variables were analyzed using Student's t-test and data will be expressed as mean (standard deviation). Categorical variables were analyzed using Chi-squared test and data reported as n & %. All statistical tests were carried out using a confidence interval of 95% (α-error =0.05) with study power 80% (β-error =0.2).p-values less than 0.05 was considered statistically significant.

RESULTS:

In this study, 91 patients were assessed for eligibility (figure 1), 18 patients did not meet the criteria and 9 patients refused to participate in the study. The remaining patients were randomly allocated into two equal groups (32 patients in each). All allocated patients were followed-up and analyzed statistically by computer software. Age, gender, BMI, ASA physical status and Ganzori Score were comparable between both groups (table 1). The insertion time (sec) of SAD was significantly shorter in LarySeal TM pro group than Air-Q TM Blocker group (P = <0.001) (table 2). Insertion time (sec) of ETT through SAD was significantly lower in Air- Q TM Blocker group than LarySeal TM pro group (P-value 0.03). However, there was no statistically significant difference in the total insertion time when both groups were compared together (P-value 0.816). The number of insertion attempts of SAD was higher in Air Q TM Blocker group than Laryseal TM pro group (P-value=0.076). That was statistically insignificant (table 3). Score of Ease insertion SAD was significantly higher in Laryseal TM pro group Range (2 - 3) than Air Q TM Blocker group Range (1-3) (P-value=0.01). The overall success rate of blind intubation was significantly higher in Air-Q TM Blocker group than LarySeal TM pro group (P-value 0.01). Oropharyngeal leak pressure was significantly higher in LarySeal TM pro group than Air-Q TM Blocker group (P-value <0.001). Leak volume was significantly lower in LarySeal TM pro group than Air-Q TM Blocker group than (P-value <0.001). Peak inspiratory pressure and Cdyn were insignificantly different between both groups (table 3). Regarding SBP, there was no statistically significant difference between both groups when the two groups were compared together (table 4). DBP was insignificantly different between both groups at all measurements (table 5). Heart rate was insignificantly different between both groups at all measurements (table 6). SpO2 level was insignificantly different between both groups at all measurements (table 7). Postoperative complications were assessed immediately post-operative (first hour) and reassessed 4 hours later (table 8). LPM were insignificantly different between both groups.

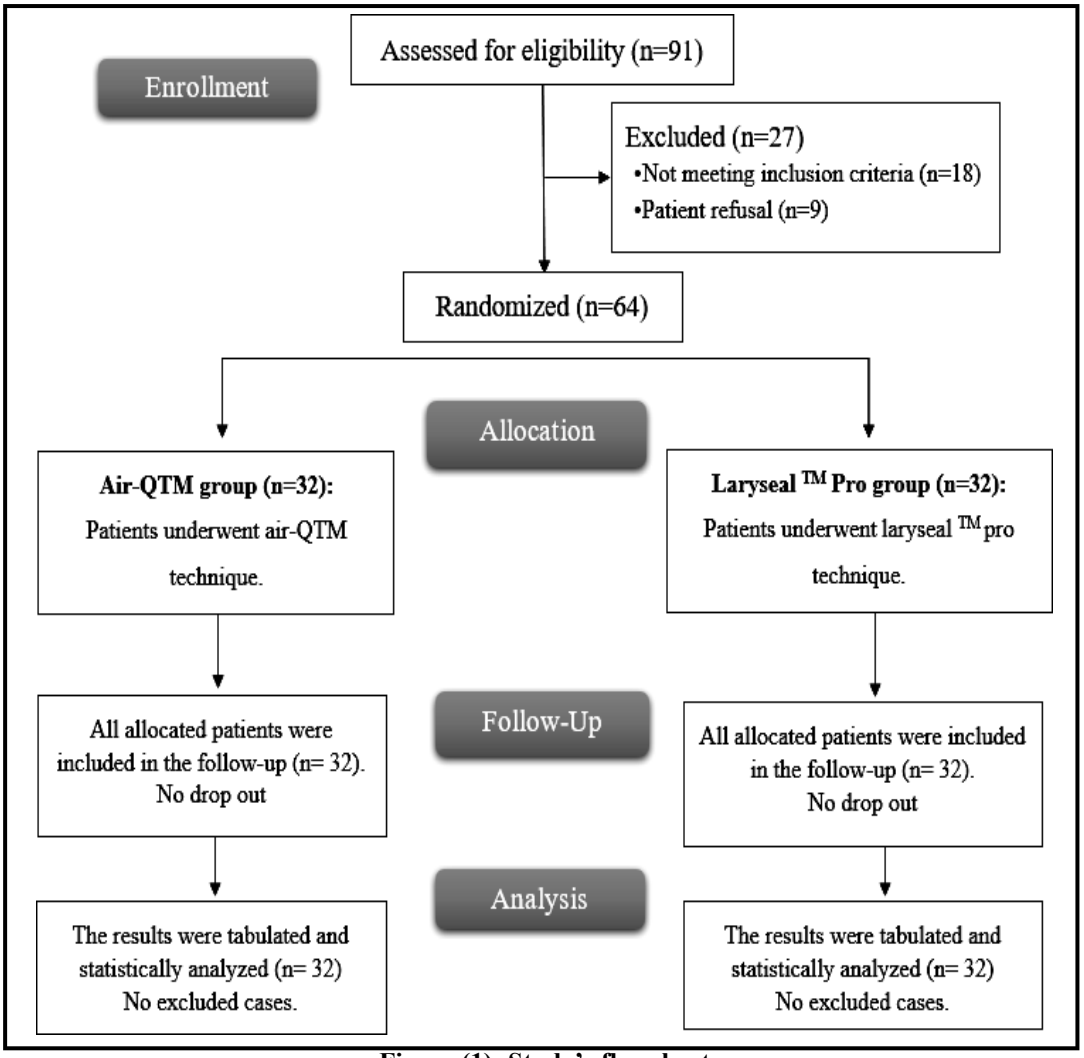

Figure (1): Study's flowchart

Table (1): Patient characteristics of the studied groups

		Air-Q TM Blocker Group (n=32)	LarySeal TM pro Group (n=32)	P value
Age (years)		44.5 ± 12.03	38.88 ± 11.79	0.064
		22 – 60	21 - 60	
Gender	**Male n (%)**	20 (62.5)	14 (43.75)	0.133
	Female n (%)	12 (37.5)	18 (56.25)	
BMI (kg/m^2)		26.38 ± 5.76	26.59 ± 4.09	0.862
		19 – 40	22 – 40	
ASA physical status	**I n(%)**	15 (46.88)	22 (68.75)	0.076
	II n (%)	17 (53.13)	10 (31.25)	
Ganzori Score	**0**	11 (34.38)	19 (59.38)	0.130
	1	17 (53.13)	11 (34.38)	
	2	4 (12.5)	2 (6.25)	

ASA: American society of anesthesiologists.

Table (2): SAD and intubation characteristics of the studied groups (PRIMARY OUTCOME).

	Air-Q TM Blockergroup (n=32)	**LarySeal TM progroup (n=32)**	**P value**
Insertion time of SAD(Sec)	48.1 ± 14.58(30 – 90)	36.2 ± 5.57(25 – 45)	**<0.001***
Insertion time of ETT through SAD (Sec)	50.8 ± 17.12(33 – 112)	61.1 ± 19.41(33 – 88)	**0.03***
Total insertion time (Sec) (Study Primary outcome)	98.7 ± 26.88(65 – 202)	97.2 ± 22.06 (65 – 133)	0.816

**Significant as P value ≤0.05, SAD: supraglottic airway device, ETT: Endotracheal tube*

Table (3): Parameters were used to assess the efficacy of the insertedSAD of the studied groups (SECONDARY OUTCOME)

		Air-Q TM Blocker group (n=32)	**LarySeal TM pro group (n=32)**	**P value**
Number of insertion attempts of SAD	**1**	29 (90.63)	32 (100)	0.076
	2	3 (9.38)	0 (0)	
Ease of insertion SAD		2.3 ± 0.65(1 – 3)	2.7 ± 0.46(2 – 3)	**0.01***
Success of intubation attempts	**1st**	23 (88)	8 (38)	**<0.001***
	2nd	3 (12)	13 (62)	
Overall successful Blind intubation		26 (81.25)	21 (65.63)	0.157
Oropharyngeal leak pressure (cmH2O)		27.8 ± 3.07(25 – 35)	30.2 ± 0.88(30 – 35)	**<0.001***
Leak volume (ml)		43.2±14.66(25 – 90)	14.4 ± 4.38(10 – 22)	**<0.001***
Peak inspiratory pressure (cmH_2O)		23.6 ± 1.24(22 – 26)	22.9 ± 2.15(16 – 27)	0.181
Cdyn (ml/cmH_2O)		51.2 ± 6.05(40 – 58)	52.4 ± 4.28(43 – 57)	0.381

**Significant as P value ≤0.05, Cdyn: Dynamic lung compliance*

Table (4): Systolic blood pressure (SBP) measurements of the studiedgroups.

	Air-Q TM Blocker group (n=32)	**LarySeal TM pro group (n=32)**	**P value**
T0	138.3 ± 12.46 (110 – 165)	132.8±10.05 (118-148)	0.056
T1	141.3 ± 12.04 (115 – 167)	137.5 ± 8.93(123-151)	0.165
T2	136.3 ± 11.98 (111 – 161)	131.2 ± 9.58(115-146)	0.065

T0 = baseline readings T1 = 1 minute after induction of anaesthesia T2=Readings 5 minutes after ETT insertion blindly via SAD

Table (5): Diastolic blood pressure (DBP) of the studied groups

	Air-Q TM Blocker group(n=32)		LarySeal TM pro group (n=32)		P value
	Mean ± SD	Range	Mean ± SD	Range	
T0	81.7 ± 7.18	70 - 92	80.6 ± 5.86	70 - 91	0.506
T1	84.8 ± 6.99	73 - 95	84.4 ± 5.59	75 - 95	0.844
T2	80.3 ± 6.83	69 - 90	79.3 ± 5.83	70 - 90	0.531

T0 = baseline readings T1 = 1 minute after induction of anaesthesia T2=Readings 5 minutes after ETT insertion blindly via SAD

Table (6): Heart rate measurements of the studied groups

	Air-Q TM Blocker Group (n=32)	LarySeal TM pro group (n=32)	P value
T0	84.6 ± 7.29(70 – 96)	84.3 ± 5.74(72 – 93)	0.864
T1	85.8 ± 5.38(76 – 96)	83.3 ± 6.01(70 – 91)	0.077
T2	83.7 ± 5.32(75 – 94)	81 ± 6.24(69 – 90)	0.063

T0 = baseline readings T1 = 1 minute after induction of anaesthesia T2=Readings 5 minutes after ETT insertion blindly via SAD

Table (7): SpO_2 level (%) measurements of the studied groups

	Air-Q TM Blocker group(n=32)	LarySeal TM pro group (n=32)	P value
T0	97.8 ± 0.79(97 – 99)	97.9 ± 0.69 (97 – 99)	0.503
T1	98.1 ± 0.67(97 – 99)	98.3 ± 0.57(97 – 99)	0.231
T2	97.8 ± 0.79(97 – 99)	97.8 ± 0.66(97 – 99)	1

T0 = baseline readings T1 = 1 minute after induction of anaesthesia T2=Readings 5 minutes after ETT insertion blindly via SAD

Table (8): Laryngopharyngeal morbidity of the studied groups (fourhours post-operative)

		Air-Q TM Blocker group (n=32)	LarySeal TMpro group (n=32)	P value
Post-operative complication	**Dysphagia**	2 (6.25)	2 (6.25)	1
	Sore throat	1(3)	3 (9.38)	0.238
	Hoarseness of voice	3 (9.38)	1 (3.13)	0.613

DISCUSSION:

Tracheal intubation is considered the gold standard for protecting the airway. As the supraglottic airway devices (SADs) could be inserted without laryngoscopy, so that SADs with different designs and safety issues could be used to manage easy and difficult airways in anesthesia and emergency medicine [13] with continuous patient oxygenation &ventilation, new generations of SGD can be used as a conduit of endotracheal intubation with less hemodynamic stress response and less postoperative complications [14].

In this study, we enrolled 64 patients (18-60 years) of both gender with American society of Anesthesiologists (ASA) physical status I& II who were scheduled for elective ophthalmology operation. In our study we compared Air Q TM Blocker with Laryseal TM pro Laryngeal mask regarding total insertion time [primary outcome]. To the time being to our knowledge there are no studies in the literature on laryseal TM pro laryngeal mask. Demographic characteristics e.g., gender, age and BMI which could influence the results were not statistically significant between the two groups. This enabled us to analyze the performance parameters of the two devices with

greater authority. The main finding of our study revealed that Total insertion time of (SAD and ETT) was insignificantly different between Air Q TM Blocker and Laryseal TM Pro groups (98.7 ± 26.88, 97.2 ± 22.06 respectively) (P-value 0.816). However, there was no statistically significant difference in the total insertion time when both groups were compared together (P-value 0.816).

In agreement with our study Laferrière-Langlois, Pascal, et al. [14] a randomized controlled trial compared three supraglottic airway devices used as a conduit to facilitate tracheal intubation with flexible bronchoscopy, they found that Median intubation times were similar across the three groups (Air-Q Blocker, 44 sec; AuraGain, 45 sec; i-gel, 36 sec; P = 0.08. in the Laryseal TM Pro laryngeal mask collected data were similar to AuraGain and i-gel laryngeal masks regarding the insertion time. Hand in hand with our study Gupta et al. [15] found that PLMA had a shorter insertion time than Air-Q blocker (18.7 ± 3.2 and 25.6 ± 5.7 s, respectively) due to easy gastric tube–guided insertion of PLMA . In our study Laryseal TM pro laryngeal mask has shorter insertion time than Air Q TM blocker.

As regards easy score of SAD insertion was significantly higher in Laryseal TM pro group (Range 2 -3) than Air Q TM Blocker group (Range 1-3) , this was significant (P-value = 0.01). In agreement with our study Jindal, Swati et al. [6], in a comparative evaluation of Air-Q blocker and Proseal laryngeal mask airway in patients undergoing elective surgery under general anaesthesia, they found that the easy of insertion score was higher in proseal laryngeal mask than Air Q TM Blocker, the Laryseal TM pro laryngeal mask had higher easy score of insertion of SAD than Air Q TM blocker. In contrary to our study Gupta, Roshni et al. [15] compared between ProSeal laryngeal mask airway and Air-Q Blocker in patients undergoing elective laparoscopic cholecystectomy found that Air Q TM blocker was easier than the proseal (p-value <0.01). In the present study we found the laryseal TM pro group showed a higher easily insertion score than Air Q TM Blocker group.

As regards successful intubation Via SAD in our study we found that the overall success rate of intubation was 47 cases out of 60 in both groups , the Air Q Tm blocker showed higher success rate of intubation than Laryseal TM Pro group (81.25%, 65.63% respectively) however it was statistically insignificant with (p-value 0.157). Regarding the number of intubation attempts, patients who were intubated from first attempt were more in Air Q TM Blocker group than Laryseal TM pro group.(23 patients 88%, 8 patients 38% respectively). In agreement with our study Gupta, Roshni, et al. [15] found that the Successful intubation was higher in Air QTM blocker than proseal laryngeal mask (100% and 90% respectively) , In our study we found that Air Q TM blocker group better than Laryseal TM Pro group when used as a conduit for intubation. In contrast to our study, Laferrière-Langlois et al. [14] found that the success of intubation, and the number of attempts were similar between three devices. This may be explained by different sample size, age group and different devices used in this study.

Regarding oropharngeal leak pressure , in our study OPLP was higher in lary Seal TM pro group than AirQ TM Blocker group (30.2 ± 0.88 versus 27.8 ± 3.07 cmh2o) which was statistically significant (p- value 0.001). OPLP is the pressure at which puff is heard after making oropharyngeal leak test which there is a release of air from SGD making a puff. In agreement with our study, Jindal, Swati et al. [6] conducted a Comparative evaluation between Air-Q blocker and Proseal laryngeal mask airway in patients undergoing elective surgery under general anaesthesia, found that PLMA provided higher values of OLP than Air-Q blocker (31.9 ± 6.5 versus 27.5 ± 5.8 cmh2o) probably due to the larger ventral cuff of PLMA that secures the proximal pharynx and the dorsal cuff, which pushes the ventral cuff more thoroughly into the periglottic tissues. This study provides the same result regarding OPLP higher in PLMA. In contrast to our study, Gupta, Roshni et al. [15] indicated that OPLP was higher in Air Q Blocker group (31.58 ± 5.71cmh2o). In our study OPLP was 27.8 ± 3.07 cmh2o.

As regard hemodynamics (HR, ABP) & Oxygen saturation changes: In our study, there were no statistical difference in all parameters when both groups compared together. (p-value > 0.5). In agreement with our study, a study done by Jindal, Swati et al., [6] cleared that there were no significant statistical difference found in the two groups in terms of hemodynamics. In contrast to our study a study by Gupta, Roshni et al. [15] found that Heart rate measurements were comparable in both groups and The difference in systolic, diastolic and mean arterial pressure were also comparable in both the groups except during the first 5 minutes immediately after insertion of AirQ Blocker when there were greater rise in blood pressures readings in contrast to proseal group.

As regards post-operative complications: In our study, there were no statistically significant differences between the 2 group devices, Postoperative complications (dysphagia, sore throat, and hoarseness of voice) were minimal severity (score 1). In agreement with our study, Jindal, Swati et al. [6] found no statistically significant differences between the two groups. Also, Laferrière-Langlois Pascal et al. [14] found no statistically significant differences between three laryngeal masks. In contrast to our study Gupta, Roshni et al. [15] found

that lower incidence of post-operative complications at 30 minutes in patient when Air Q blocker used which less than our study (7 out of 40 VS 6 out 32) (17% VS 18.7%) patient and this explained that they detect complication only in the first thirty minutes post operative.

CONCLUSION AND RECOMMENDATIONS:

Laryseal pro showed to be as efficient as Air Q blocker regarding the total insertion time of the device and endotracheal tube. Furthermore, it was found to be superior to Air Q Blocker in ease of insertion. We recommend that more research can be done on laryseal TM pro laryngeal mask and especially in field with different airway management.

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