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Research Article

Comparative study between LMA-Proseal™ and Air-Q® Blocker for ventilation in adult eye trauma patients

Maha M.I. Youssef *, **Mona Lofty, Yahya Hammad, Ezzat Elmenshawy**

Department of Anesthesia, Intensive care, and Pain Management, Kasr Al Ainy Hospital, Cairo University, Egypt

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KEYWORDS

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Abstract *Background:* The disposable Air-Q® Blocker Masked Laryngeal Airway (MLA) is a new supraglottic device used for intubation, rescue ventilation, and for esophageal suctioning. Laryngeal Mask Airway-Proseal™ is a well known supraglottic device in clinical practice. The aim of the study was to compare Air-Q® Blocker against LMA-Proseal™ as supraglottic devices for ventilation.

Methods: Sixty adult healthy patients scheduled for eye trauma surgeries under general anesthesia were randomly allocated into 2 groups; Group A ($n = 30$), where Air-Q® Blocker is used, Group P ($n = 30$), where LMA-Proseal™ is used. The success rate and time of their insertion were measured. Laryngeal view grading was assessed by fiberoptic bronchoscope. Ease of gastric tube placement and any post-operative complications (airway edema, sore throat or hoarseness) were also measured. Stress response of device insertion was measured using the vital sign measurements.

Results: Success of insertion at 1st attempt was (90%) in Group A and (83.3%) in Group P. Insertion time was 18.37 ± 3.77 s in Group (A), while 23.43 ± 3.54 s in Group P, ($p < 0.001$). Airway seal pressure was comparable in both groups. Full view of vocal cords amounted to (76.7%) in Group A, and (56.7%) in Group P respectively. 1st Attempt Gastric Tube Insertion was (93.3%) in Group A, and (83.3%) in Group P. comparison of previous data in both groups showed no statistical significant differences between them. The incidence of postoperative complications and post insertion hemodynamic stress response was statistically nonsignificant when compared between the 2 groups.

* Corresponding author. Address: Department of Anesthesia, Kasr Al Ainy Hospital, Cairo University, Egypt. Tel.: +20 1220002205.
E-mail addresses: maha11youssef@live.com, maha11youssef@yahoo.com (M.M.I. Youssef).

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Conclusion: The Air-Q® Blocker demonstrated to be remarkably good as a ventilatory device, with adequate airway seal pressure, and improved facilitation of gastric tube insertion compared to LMA-Proseal™. Minimal pressor response was achieved after insertion with no statistical significance.

1. Introduction

Difficult airway is a nightmare to every anesthetist. Over the last decade, several supraglottic airway devices appeared in the clinical field as an alternative to the more invasive endotracheal intubation [1]. However, many anesthetists found themselves unaccustomed with the newly invented devices [2].

The Laryngeal Mask Airway-Proseal™ (LMA-Proseal™ Teleflex Incorporated), has a soft cuff modified to provide better sealing, as well as a drainage tube allowing gastric tube insertion. These features attribute in increasing the safety of the LMA-Proseal™ when used with positive pressure ventilation [3]. The maximum airway seal pressure varies between the patients, but the airway seal pressure of LMA-Proseal™ is approximately 10 cm H_2O higher than the LMA Classic (up to 30 cm H_2O) [3].

The newer device Air-Q® Blocker Masked Laryngeal Airway (MLA) (Cookgas LLC, Mercury Medical, Clear water, FL) is a supraglottic device designed as a primary ventilation airway as well as a conduit for endotracheal intubation. It is also adapted with a specific integrated blocker channel for placement of a gastric tube [4]. Air-Q® Blocker's distinctive characteristics namely ease of insertion, consistent adjustment of laryngeal view, as well as its ability to steadily ventilate the patient render it ideal for emergency situations including rescue ventilation, intubation, and rescue suctioning and venting the esophagus [4].

The LMA-Proseal™ may secure the airway, and provide drainage of the stomach. On the other hand, a limitation of the LMA-Proseal™ is the presence of a thick bulky cuff when inflated (larger and longer than that of LMA-classic) as well as the small size tubes which can be used if intubation is needed [3]. The Air-Q® Blocker possesses special features that can overcome the limitations posed by LMA-Proseal™ [4]. In trauma patients, difficult ventilation and intubation might be encountered due to facial edema. Full stomach creates an added problem. This fact makes endotracheal intubation the golden rule in order to protect the airway against aspiration. However, the stress of endotracheal intubation in eye trauma patients may lead to expulsive hemorrhage.

In case endotracheal intubation is needed in these patients, Air-Q® Blocker enables placement of standard normal size endotracheal tubes for age (up to 8.5 mm ID), since it is available in 3 sizes (2.5, 3.5, 4.5). On the other hand the LMA Proseal™ allows placement of maximum size endotracheal tubes of 6 mm ID [3].

We hypothesize that the Air-Q® Blocker MLA is a safe superior supraglottic airway device which is ideal for rescue ventilation and intubation. Furthermore, its insertion is easier than the LMA-Proseal™, thus enabling a rapid learning curve. The integrated blocker channel is used for passage of a Ryle tube to help stomach venting. Thus Air-Q® Blocker can be considered as an ideal tool to protect the airway in emergency situations, especially when difficult intubation is encountered.

The aim of the study was to compare the use of Laryngeal Mask Airway Proseal™ and Air-Q® Blocker as supraglottic devices for ventilation, by measuring the success rate, time of insertion for each device. Laryngeal view grades were recorded by fiberoptic bronchoscope. The sealing pressure of each device was measured after insertion using the seal pressure test. Vital signs pre and post insertion, ease of gastric tube placement and post-operative complications (sore throat or hoarseness, and blood streaked mucous) will be also measured.

2. Methodology

This study was conducted at Kasr Al-Ainy teaching hospital from May 2012 to November 2012, after approval of the local ethical committee and written patients' consent. Sixty adult healthy ASA I-II patients, (both genders), aged 18–65 years, body weight between 60 and 90 kg who were scheduled for eye trauma surgery under general anesthesia were enrolled in the study. Those patients were allowed to fast for 6–8 h before surgery.

Patients were randomly divided by computer designed lists and then concealed in closed envelopes into 2 equal groups:

Group A ($n = 30$), in which disposable Air-Q® Blocker (size 3.5) is used for ventilation.
Group P ($n = 30$), in which Laryngeal Mask Airway- Proseal™ (size 3) was used for ventilation.

Patients having respiratory or pharyngeal pathology, patients allergic to any drugs used in the study, morbidly obese patients with body mass index >40 kg/m^3, patients known to have gastro-esophageal reflux disease (GERD), hiatus hernia or previous upper gastrointestinal tract surgery as well as patients having airway score $\geqslant 4$ according to El-Ganzouri Airway Scoring were excluded from the study.

2.1. Peri-operative management

Proper airway assessment of the patients was done according to El-Ganzouri Airway Scoring System [5]. All patients received an intravenous anti-emetic, ondansetron 4 mg and an antacid, ranitidine 50 mg 1 h before the operation. Basic monitoring was established before induction of anesthesia; (pulse oximeter, electrocardiogram and non-invasive blood pressure). The patients were premedicated with intravenous atropine 0.01 mg/kg and received sedating dose of midazolam 0.02 mg/kg. Induction of anesthesia was achieved by approximate doses according to ideal body weight with fentanyl 1 μg/kg, propofol 2 mg/kg, atracurium 0.5 mg/kg and lidocaine 1 mg/kg before device insertion. Ventilation was carried out using manual mask ventilation conducting oxygen and Sevoflurane with MAC 2. After complete neuromuscular blockade which was evidenced by absence of response to Train of Four

(TOF) stimulus (TOF ratio is 0), the randomly assigned supraglottic device for each group was inserted and reconnected to the ventilator circuit. The LMA-Proseal™ was inserted using the digit method [3], and the disposable Air-Q® Blocker was inserted according to manufacturer's recommendations [4]. Insertion time of the study device was recorded for each device which started from removal of the ventilation mask, until appearance of capnography waves. Proper positioning was confirmed by inspection of chest inflation bilaterally, auscultation of the chest bilaterally, auscultation of the neck for abnormal respiratory sounds, absence of any leak sounds from the device and capnography readings of six successive waves. If, after two attempts, the device was not properly inserted, endotracheal intubation was done using fiberoptic bronchoscope which was ready to use in its cart nearby the patient, and those patients were excluded from the study.

The airway seal pressure was assessed for each device, with fresh gas flow adjusted at 3 L/min, by closing the expiratory valve of the circle system, and observing of the rise of the ventilator's airway pressure. A "puffing" sound was heard near the patient's mouth (release of pressure) indicating the airway seal pressure. The vital signs were recorded; just prior to device insertion (T1); after connection to capnography (T2), to assess the pressor response during device insertion.

The fiberoptic bronchoscope was used to assess the laryngeal view grade (LVG) using Brimacomb and Berry scale [6,7] (Fig. 1).

Once patients were reconnected to the ventilator circuit, a gastric tube was introduced through the integrated drainage channel present in both devices. To standardize the technique, the same brand gastric tube was used for both devices. The success rate of its insertion was recorded. After venting the stomach the blocker was introduced and inflated to achieve proper sealing. The surgery was allowed to proceed after ensuring proper positioning and sealing of the device. At the end of surgery, adequate reversal of residual neuromuscular blockade was achieved – when TOF ratio reached 0.9. The device was then removed and was checked for any blood streaked mucous as a sign of airway trauma. Post-operative sore throat or hoarseness of voice was assessed at 0, 2 and 4 h. Any regurgitation or pulmonary aspiration was also recorded.

2.2. Statistical analysis

Assuming $\alpha = 0.05$ (two-tailed), $\beta = 0.1$, a total sample size of 60 patients, equally allocated into two equal groups (30 per group), were required to detect an assumed effect size d of 0.85 or more in the mean time required for device insertion between the two study groups with a power of 90%. Estimation of sample size was performed using computer program G*Power 3 (Franz Faul, Universität Kiel, Germany); independent samples t test was used. Data management and analysis were performed using Statistical Package for Social Sciences (SPSS) vs. 19. Ordinal data were presented as means ± standard deviations (SD). Categorical data were presented as number and (percentages %). Comparisons between the two groups for normally distributed variables were done using the Student's t-test; the Mann–Whitney test, a nonparametric test equivalent to the t-test, was used in categorical variables. To compare between the groups and the change with time, a 2 way analysis of variance with repeated measures on one factor was done. The chi-square test or the Fisher's exact test for small sample size was used to compare between the groups with respect to categorical data. All p-values are two-sided. P-values < 0.05 were considered significant.

3. Results

This study was conducted on 60 patients scheduled for eye trauma surgery under general anesthesia with muscle relaxants. Patients were randomly assigned into 2 equal groups;

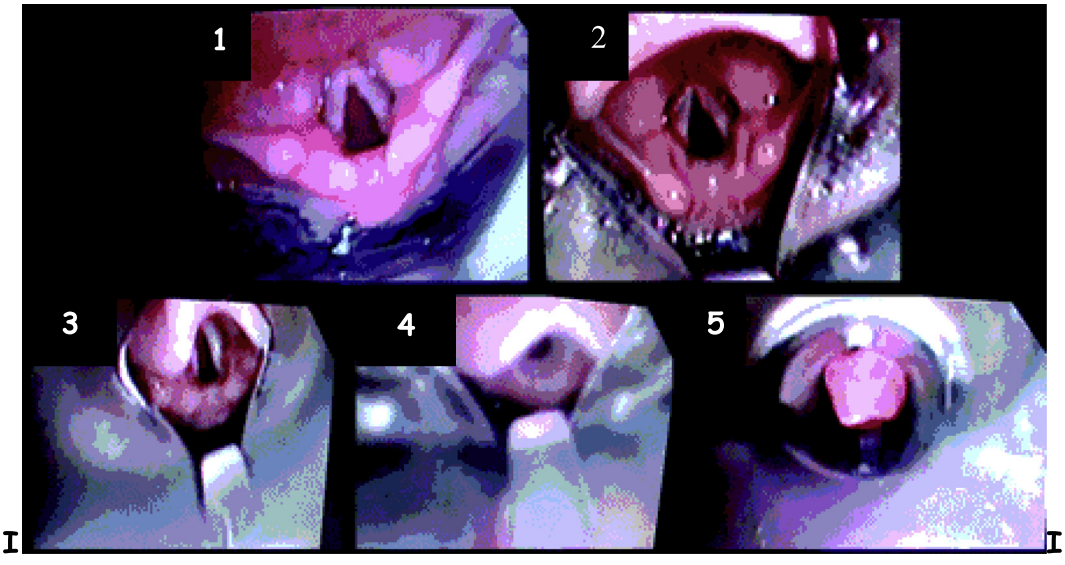

Figure 1 Laryngeal View Grades (LVG). LVG1: Only the vocal cords seen; LVG2: The vocal cords and posterior surface of the epiglottis seen; LVG3: The vocal cords and the anterior tip of the epiglottis seen; LVG 4: The anterior surface of the epiglottis is seen therefore encroaching on the view of vocal cords obstructing < 50% of view; LVG 5: The epiglottis is completely obstructing the device opening, no view was seen.

Table 1 Demographic characteristics.

	Group A (n = 30)	Group P (n = 30)
Age (years)	33.4 ± 10.13	33.2 ± 10.60
Gender		
Male (%)	17 (56.7%)	20 (66.7%)
Female (%)	13 (43.3%)	10 (33.3%)
Body weight (kg)	75.1 ± 7.12	73.7 ± 4.71
Duration of surgery (min)	65.8 ± 8.43	63.1 ± 7.12

Ordinal Data are presented as Mean ± SD, while categorical data were presented as number (%). $p < 0.05$ is considered significant.

Group A (n = 30), in which Air-Q® Blocker was used for ventilation. Group P (n = 30) in which Laryngeal Mask Airway Proseal™ was used for ventilation.

As regards the demographic data, there were no statistical differences between the two groups regarding the demographic data (Table 1).

Although the disposable Air-Q® Blocker showed a higher success rate of insertion from the first time (90%) than the LMA Proseal™ (83.3%), the results were not statistically significant (Table 2).

The mean device insertion time was 18.4 ± 3.77 s in Group A, while it was 23.4 ± 3.54 s in Group P. This finding was statistically highly significant (P value < 0.001), (Table 2).

As regards the mean airway seal pressure was comparable in both groups with no statistical significant difference (Table 2).

Concerning the laryngeal view grades (LVG), assessed by fiberoptic bronchoscope, full view of vocal cords (LVG1) was seen in 76.7% of patients in Group A, while it was seen in 56.7% of patients in Group P. These findings were not significant, Fig. 2; (Table 2).

We assessed the success rate of gastric tube insertion in both groups. It was successfully inserted from the first time in the Group A in 93.3% of cases, while in Group P; it was successfully inserted from the first time in 83.3% of cases, showing no statistical significance (Table 2).

Hemodynamic data were recorded just before device insertion (T1); after device insertion and appearance of capnography waves (T2) to monitor the occurrence of any hemodynamic stress response due to device insertion. There was no statistical significant difference between both groups and even within same group recordings, denoting minimal insignificant pressor response changes (Table 3).

With regard to postoperative complications, after removal of the device, Blood-streaked mucous was found in 3 (10%) cases in Group A, and in 4 (13.3%) in Group P. In the recovery room, sore throat occurred in one (3.3%) case in Group A, and in 4 (13.3%) cases in Group P with no statistical significant differences between groups. We did not face any case of regurgitation of gastric contents or pulmonary aspiration during the study (Table 2).

4. Discussion

Supraglottic airway devices have been introduced in the clinical field for simple, safe, and effective management of difficult airway. The Air-Q® Blocker, a supraglottic device, is designed for ventilation, intubation and proper drainage of the stomach through the integrated channel. After excessive, repeated and thorough search in the literature, we did not find any published studies concerning the disposable Air-Q® Blocker and it should be mentioned that this is the first published study on this device.

For the above mentioned reasons we were obliged to compare the Air-Q® Blocker with the Air-Q® classic.

As to device insertion, in the present study the Air-Q® Blocker was inserted from the first time in 90% of cases and from the second time in 10% of cases. In consistence to our study, Galgon et al. [6] compared the Air-Q® classic to LMA-Proseal™ and found that the Air-Q® classic was inserted easily from the first time in 87% of cases when compared to LMA Proseal™. Several published studies have confirmed our results [8–12]. In the present study, the LMA-Proseal™ was inserted from the first time in 83.3% of cases and from the second time in 16.7% of cases. This was coherent with a study done by Jun et al. [12] studying the relation between the success rate of device insertion, the head position and the difficulty of intubation. The success rate of LMA-Proseal™ insertion from the first attempt was 85% and the total success

Table 2 Studied data between groups.

		Group A (n = 30)	Group P (n = 30)
Device insertion attempts N (%)	1st	27 (90%)	25 (83.3%)
	2nd	3 (10%)	5 (16.7%)
Mean time for device insertion (s)		18.4 ± 3.77**	23.4 ± 3.54**
Airway seal press. (cm H_2O)		22.4 ± 1.27	23.3 ± 3.86
Laryngeal View Grade by FOB(LVG)	1	23 (76.7%)	17 (56.7%)
	2	6 (20%)	10 (33.3%)
	3	1 (3.3%)	3 (10%)
Gastric tube insertion attempts n (%)	1st	28 (93.3%)	25 (83.3%)
	2nd	2 (6.7%)	5 (16.7%)
Blood streaked mucous n (%)		3 (10%)	4 (13.3%)
Sore throat n (%)		1 (3.3%)	4 (13.3%)

Ordinal data are presented as Mean ± SD. Nominal data are expressed as Frequency (%).
** $p < 0.005$ is considered highly significant.

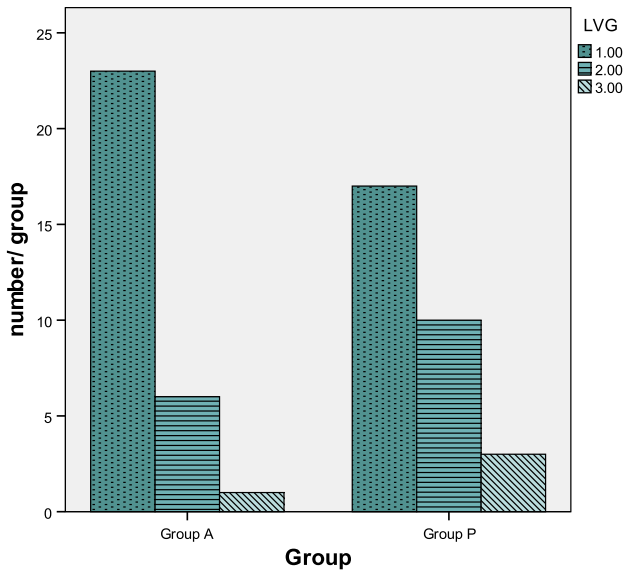

Figure 2 Laryngeal View Grades by Fiberoptic bronchoscope.

rate after three attempts was 94–100% with no statistical significance. In a study by Figueredo et al. [13] on the LMA-Proseal™ and the laryngeal tubes, the LMA-Proseal™ was inserted from the first-attempt in 77% of cases showing statistical significant difference when compared the other group ($p < 0.05$). However better results were shown in our study (83.3%) but with no statistical significant difference. Zand et al. [14] found that the LMA-Proseal™ was inserted from the first-time in 88% of cases and from the second time in 12% of cases. In another study done by Eschertzhuber et al. [15], comparing the LMA-Supreme to LMA-Proseal™, the success rate of insertion of LMA Proseal™ from the first time was 92%.

Concerning the mean time for device insertion; it was 18.37 ± 3.77 s in Group A, while it was 23.43 ± 3.54 s in Group P, showing a highly statistical significant difference. This was in accordance with the study done by El-Ganzouri et al. [8] who found that the mean time for Air-Q® classic insertion was 19.7 ± 3.8 s. This finding was supporting our results. The present study results agreed with Galgon et al. [6] who found that the insertion time was shorter with the Air-Q® classic than with the LMA Proseal™. Same results were also found in the study of Samir and Sakr [16], where the mean insertion time for Air-Q® classic was 22.6 ± 4.3 s and this finding was also in agreement with our results. However, Seet et al. [17] who worked on LMA Supreme and LMA-Proseal™ found that the mean time of device insertion was 30 s with inter quartile range of 20–38 s. In contrast to the present study, Jun et al. [12] found that the mean insertion time of the LMA Proseal™ from the first attempt was 9.2 ± 5.1 s. The variability of these results was probably related to the method of calculation of the time of insertion. In our study, the time of insertion started from removal of mask ventilation till appearance of the first capnography wave, while in Jun et al.s' [12] study insertion time was calculated from opening the patient's mouth to removal of the assessor's hand after LMA-Proseal™ insertion into the pharynx.

As regards airway seal pressure; in the current study, the mean airway seal pressure was 22.4 ± 1.27 cm H_2O in Group A, while in Group P it was 23.67 ± 1.49 cm H_2O with no statistical significant difference. In consistency to our results, El-Ganzouri et al. [8] found that the mean airway seal pressure was 24 ± 2 cm H_2O. Our results were matching with the study done by Bakker et al. [18] in which they studied the Air-Q® classic in the clinical field. They found that the mean seal pressure was 19 ± 5 cm H_2O. Similar results were shown by Joffe et al. [19] who found that the median airway seal pressure was 25 cm H_2O. In contrary to our study, higher results were presented by Galgon et al. [6]. They found that the mean ± (SD) airway seal pressures for the Air-Q® classic and Proseal™ were 30 ± (7) cm H_2O and 30 ± (6) cm H_2O, respectively ($p = 0.47$), and concluded that the Air-Q® classic performed well as a primary airway during the maintenance of general anesthesia with an airway seal pressure similar to that of the Proseal™. Their net result was similar to those presented in our study, showing comparable airway seal pressures in both devices. Seet et al. [17] found that the airway seal pressure was 25 ± 6 cm H_2O for the LMA Proseal™ which coincided with our results.

With reference to the Laryngeal view grades (LVG), in the present study LVG1 was seen in 76.7% of patients in Group A, while it was seen in 56.7% of patients in Group P. Our results were matching with El-Ganzouri et al. [8], who found that LVG 1 was seen in 73.3%, Jun et al. [12], who found that the frequency of full vocal cord visibility (LVG1) was 87.2–93.9%, Samir and Sakr [16] who found that LVG 1 (as seen through the Air-Q® classic) was seen in 60% patients, and also with Brimacombe and Keller [20] who found that full vocal cord visibility was seen in 93.3% cases. However, when Abdellatif and Ali [21] compared the laryngeal view grade using LMA Proseal™ and streamlined liner of the pharynx airway (SLIPA™), they found that LVG1 was seen in 46% of patients. In contrast, our study showed slightly better results regarding laryngeal view grade of LMA Proseal™.

Regarding gastric tube insertion; successful gastric tube insertion from the first time was found in 93.3% cases in the Group A and in 83.3% of patients in Group P, but with no statistical significant difference between both devices. Slightly better results were found in a study done by Brimacombe and Keller [20] which found that gastric tube placement in the LMA-Proseal™ was almost 100% successful, showing inser-

Table 3 Hemodynamic changes at specific intervals.

	MBP mmHg		MHR b/min ($n = 30$)		$MSPO_2$ (%)	
Time	Group A	Group P	Group A	Group P	Group A	Group P
T1	72.7 ± 7.99	71.8 ± 9.37	71.6 ± 8.34	70.2 ± 9.16	99.1 ± 0.93	99.6 ± 0.51
T2	73.7 ± 9.35	74.4 ± 8.57	74.2 ± 5.22	73.1 ± 7.51	99.3. ± 0.46	99.1 ± 0.34

Ordinal data are expressed as Mean ± SD. $p < 0.05$ is considered significant.

tion from the first time in 59 out of 60 cases. In another study done by Eschertzhuber et al. [15], the success rate of gastric tube insertion was 91% from the first time in the LMA-Proseal™ group, which coincides closely with our results. Moreover Evans et al. [22] found that gastric tube insertion in the LMA-Proseal™ was successful from the first attempt in 97% of cases and from the second time in 1% of cases while it failed in 2% of cases. At the beginning of our study, the gastric tube was inserted from the second time in 2 (6.7%) cases in Group A and in 5 (16.7%) cases in Group P. It should be mentioned that these results were due to inadequate gastric tube lubrication, but after proper generous lubrication, gastric tube insertion was more achievable. The fact that the Air-Q® Blocker is rather a new device, made it difficult to find any published studies concerning success rate of gastric tube placement.

With regard to hemodynamic pressor response after insertion of both devices, comparison of pre and post insertion hemodynamics showed no statistical significant differences within the same group recordings. Those results were similar to the study done by Galgon et al. [6] which recorded hemodynamic and respiratory data at baseline and over the first 5 min after device placement. No significant changes over time were observed for heart rate and SpO_2. In both the Air-Q® classic and the LMA-Proseal™ groups, systolic, diastolic and mean arterial blood pressures have shown a decrease over time ($p < 0.05$). In addition, systolic, diastolic and mean blood pressure values were significantly higher in the Air-Q® classic group compared to the LMA-Proseal™ group ($p = 0.002$, $p < 0.001$ and $p < 0.001$, respectively). Our study was also consistent with a study done by Jeong et al. [23] who found that the LMA-Proseal™ is a useful alternative to the endotracheal tube with more hemodynamic stability in laparoscopic cholecystectomy; especially in hypertensive patients. Similar results were shown in a study done by Choi et al. [24] who found that the use of LMA Proseal™ produced steady hemodynamic responses before and after insertion. Furthermore, in a study done by Sharma et al. [25], they found that there were no significant hemodynamic changes at 1 and 5 min after insertion of the LMA Proseal™ in 100 patients undergoing laparoscopic surgery. In addition, Evans et al. [22], found hemodynamic stability with the insertion of LMA Proseal™ in 300 patients.

With reference to complications, in the current study blood-streaked mucous was found in 3 (10%) cases in Group A, and in 4 (13.3%) cases in Group P. Sore throat occurred in one (3.3%) case in Group A, and in 4 (13.3%) cases in Group P. Comparison of the two groups showed no statistical significant difference as regards the previous data. We did not face any cases of regurgitation of gastric contents or pulmonary aspiration in both groups. Our results were matching with a study done by Abdellatif and Ali [21] who worked on LMA Proseal™. They found that the incidence of post-operative blood stained mucous was 10.1% and the incidence of sore throat was 22%. The incidence of sore throat when using supraglottic device depended on the method of insertion, number of insertion attempts, cuff volume inflated, and depth of anesthesia. Moreover El-Ganzouri et al. [8] found in his study that 3.3% had blood stained mucous; and Galgon et al. [6] found gross blood in 19% in the Air-Q® classic group and 8% in the LMA Proseal™ group after its removal. In contrast to our study, Galgon et al. [6] found that postoperative sore throat was more common in both groups with 46% in the Air-Q® classic group and 38% in the LMA Proseal™ group. Furthermore Bakker et al.s' [18] study revealed that 10% of patients were noted to have dysphagia and 1 patient was diagnosed with bilateral lingual nerve injury but made a complete recovery in four weeks. Consequently, Joffe et al.s' [19] study showed that 1:4 (26%) patients complained of mild sore throat postoperatively before discharge.

The limited sample size and the absence of published researches on the Air-Q® Blocker MLA were the main limitations in our study. Other limitation was impossibility of blinding of the assessor in the study. We suggest further studies to be done on a wider population scale to concur our conclusions. More efforts should be done to ensure its widespread use among residents especially due to its rapidly rising learning curve.

5. Conclusion

The Air-Q® Blocker MLA demonstrated to be remarkably good as a ventilatory device, with adequate airway seal pressure, and improved facilitation of gastric tube insertion compared to LMA-Proseal™. Minimal pressor response was achieved after insertion with no statistical significance.

Conflict of interest

No conflict of interest.

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