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# A prospective randomized comparative study between the self-pressurized Air-Q with blocker and baska supraglottic airway in low risk female patients undergoing ambulatory surgery

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**Keywords:** Oropharyngeal leak pressure; Spo2; Ease of insertion.

## Abstract

**Background:** No studies compared the Air Q/SP with blocker and the Baska airway, in this study we compared both devices regarding their oropharyngeal leak pressure, insertion variables (ease and time of insertion) and complications associated with their insertion or removal.

**Methods:** A total of 62 patients were enrolled in the study. All patients received 10mg intravenous metoclopramide and atropine 0.6 mg. Induction of anesthesia achieved by fentanyl 2ug/kg, propofol 1.5-2.5mg/kg, atracurium0.5mg/kg and lidocaine 1mg/kg before device insertion. Maintenance of anesthesia achieved by isoflurane, atracurium, oxygen and air. The supraglottic device was inserted and connected to capnography. Device insertion was considered successful by observing bilateral chest wall movement and stable square-wave capnogram trace. Two failed insertion attempts were considered failed insertion of the device, and patient was withdrawn from the study. Insertion time was measured from the moment a device was picked up until confirmation of the first wave on a capnogram. Ease of insertion was assessed using a subjective grading score of 1–4 (1: No resistance; 2: mild resistance; 3: moderate resistance; and 4: inability to insert the device) by the anesthesiologist who inserted the device. Oropharyngeal leak pressure through the device will be assessed as follows: After insertion and fixation of the device, 10 min after initial assessment, and after completion of surgery. Oropharyngeal leak pressure will be determined by closing the adjustable pressure-limiting valve to 30cm H2O at the fresh gas flow rate of 3l/min and reading the airway pressure on the monitor in the anesthesia machine at which a steady state of airway pressure was established. At the conclusion of the surgery, the device will be removed, and the patient will be then moved to the Post-Anesthesia Care Unit (PACU).

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After removing the device, any blood staining on the device will be observed. During anesthesia maintenance and emergence, the following complications will be recorded, hypoxemia (SpO2 <90%), airway obstruction, cough, vomiting, and gastric insufflation. To document any postoperative complications such as sore throat, dysphagia, and dysphonia, a blinded investigator assessed all patients in the PACU. Results: A total of 62 patients fulfilling inclusion criteria were enrolled in our study, we found that oropharyngeal leaking pressure was higher in Baska (35.52 ± 4.37 cm H2O) which denotes a better sealing than air QILA SP with blocker (leaking pressure of Air-Q SP is 22.23 ± 2.96). With no difference between both devices in easiness of insertion, number of trials, time of insertion and postoperative complications.

**Conclusion:** The supraglottic airway devices Baska mask and Air-Q SP, both are suitable for positive pressure ventilation in anesthetized female patients with the use of muscle relaxant and the Baska mask provides better seal with the glottic aperture when compared to Air Q SP in this population.

## Introduction

Supraglottic Airway Devices (SAD) [1] have become valuable for both routine and difficult airway management. After the creation of the Laryngeal Mask Airway (LMA) classic in the 1980s, there has been a steady increase in the applications for use of supraglottic airways [2]. Over 15 years ago, Daniel J. Cook, M.D., developed and patented the Air-Q Masked Laryngeal Airway that has gained worldwide acceptance [3].

Its features enable direct insertion of larger tracheal tubes (up to 7.5 and 8.5-mm IDs for Air-Q sizes 3.5 and 4.5, respectively) through the airway tube [4].

The Air-Q family has introduced many improved designs, among which the Air-Q blocker intubating laryngeal airway (Air-Q ILA blocker) in 2011. It has all the previously mentioned advantages, in addition a new built-in soft guide channel that accepts regular Nasal Gastric (NG) tubes to suction or optional Blocker Tubes for accessing the posterior pharynx and managing the esophagus, clinicians can suction the pharynx or suction, vent and block the upper esophagus.

Ever since the idea of SAD has launched, applying an optimum intra-cuff pressure that maintains enough sealing yet not injurious to the oropharyngeal mucosa concerns anesthesiologists [5]. A good seal will provide good ventilation, will guarantee the desired depth of anesthesia at lower gas flows and with lesser leaks to the esophagus, it will not cause rise in intragastric pressure thus preventing regurgitation [6]. However, when the cuff pressure is more than the mucosal perfusion pressure, it is likely to either cause postoperative pharyngo-laryngeal symptoms [7] (sore throat, dysphagia, dysphonia) or cause local mucosal trauma and nerve injuries [8].

Therefore, in 2013 another improvised design of the Air-Q family has evolved, a Self-Pressurized Air Q (AirQ SP) with blocker [9]. It has a drain tube through which a suction tube is passed like the Air-QILA blocker, And Instead of the pilot balloon and inflating cuff, the Air-Q SP with blocker incorporates a self-regulating periglottic cuff at the end of this tube [10], a communication orifice at the junction of the periglottic cuff and the airway tube. This communication between two spaces enables the cuff to dynamically regulate intra-cuff pressure depending on airway pressure. This distinguishing feature of the Air-Q SP may result in reduced risk of airway morbidities related to cuff hyperinflation [11].

In 2014 a comparative study, between LMA-Proseal and Air Q blocker was held. It showed that the Air-Q Blocker LMA 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™ [12].

## Materials and methods

This prospective Randomized comparative study was conducted in obstetrics and gynecology operating theater, Kasr Al-Ainy hospitals, Cairo University.

The study was approved by both scientific committee of anesthesia department, and Research & ethics committee of Faculty of medicine, Cairo University (Ethical approval number is N-24-2018). Written informed consents were obtained from all patients.

The study was designed to compare between Air/Q self-pressurized airway with blocker (Figure 1) and the Baska mask (Figure 2), regarding their oropharyngeal leak pressures, insertion variables (ease and time of insertion).

Female patients undergoing ambulatory surgeries between the age group of 18 and 50 years, with ASA (American Society of Anesthesiologists) classification I and II, and Ganzouri airway scores less than 4.

Patients with ASA III - V, Ganzouri airway score Airway score ≥ 4, oropharyngeal pathology, have risks of gastric aspiration, gastroesophageal reflux disease, hiatus hernia or previous upper gastrointestinal tract surgery were excluded from the study.

Proper airway assessment of the patients was done according to El-Ganzouri Airway Scoring System including: Mouth opening, thyromental distance, Mallampati score, and history of difficult intubation, to exclude patients with suspected difficult intubation. All patients received premedication in form of IV metoclopramide 10 mg and IV atropine 0.6 mg.

Monitoring was fulfilled by Five lead electrocardiogram (lead II and V simultaneously), Pulse oximetry, Noninvasive arterial blood pressure, and Capnogram.

Induction of anaesthesia was achieved by approximate doses according to ideal body weight of Fentanyl 2ug/kg, Propofol 1.5-2.5mg/kg and atracurium 0.5mg/kg and Lidocaine 1mg/kg before device insertion.

Maintenance of anaesthesia was achieved by isoflurane, atracurium, oxygen and air.

The supraglottic device was inserted and connected to the capnogram.

Insertion technique of the supraglottic device is done according to manufacturer guidelines for each device.

For the Baska mask, the device was lubricated well on both sides, head and neck were placed in neutral position, and the proximal firmer part of the device was compressed between the thumb and two fingers and advanced toward hard and soft palate, the tab was pulled slightly if needed to increase curvature of the device for better fitting, the device was advanced till resistance was felt [13].

For the Air-Q SP airway, the jaw was lifted during insertion and the head was extended, proper lubrication of both the front and back of the air-Q Blocker as if the patient's mouth is dry the air-Q Blocker ridges can get stuck on the back of the tongue during placement.

The air-Q SP was advanced at a forward angle aiming for the back of the tongue and soft palate.

Then the colored connector was pushed by index finger till feeling resistance [14].

Successful insertion of the device was confirmed by observing bilateral chest wall movement and a stable square-wave capnogram trace.

Two failed insertion attempts were considered as failure of insertion of the device, and the patients were withdrawn from the study.

Insertion time was defined as time interval between picking the device up till appearance of the first wave on the capnogram.

Ease of insertion was assessed using a subjective grading score of 1–4 (1, no resistance; 2, mild resistance; 3, moderate resistance; and 4, inability to insert the device) by the anesthesiologist who inserted the device.

Oropharyngeal leak pressure was determined by closing the Adjustable Pressure-Limiting (APL) valve to 30 cmH2O at the fresh gas flow rate of 3 L/min and reading the airway pressure on the monitor in the anesthesia machine at which a steady state of airway pressure was established [15].

At the end of the surgery, the device was removed, and the patients were then transferred to the Post-Anesthesia Care Unit (PACU).

After removing the device, any blood staining on the device was observed.

During anaesthesia maintenance and emergence, complications were recorded, including hypoxemia (SpO2 <90%), airway obstruction, cough, vomiting, and gastric insufflation. To document any postoperative complications such as sore throat, dysphagia, and dysphonia, a blinded investigator has assessed all patients in the PACU.

Demographic data were collected preoperatively (name, age, weight, ASA, Ganzouri airway score, type of device, time for device insertion. The number of trials for device insertion were recorded. Oropharyngeal leak pressures after insertion and fixation of device, 10 minutes after the initial assessment, and after completion of surgery were recorded, and finally, postoperative complications were recorded (vomiting, aspiration, blood on device, bronchospasm, or desaturation).

### Sample size

Depending on a previous study [16], the mean SD of sealing pressure with the Baska mask was 28.6 ± 2.9. We assumed a difference of 10% with other groups. G power software (version 3.1.3, Germany) was used with alpha error 0.05 and power of 95% and doubling of SD, the sample size will be 26 per group to be increased to be 31 per group for possible dropouts.

### Statistical Analysis

Data was presented as mean and standard deviation for parametric variables and median and range for nonparametric variables. Frequency of complications as blood on the tip of the device, bronchospasm or regurgitation of gastric juice, were reported as number and percent between groups. Incidence of complications was analyzed using Fisher's exact test. All other group comparisons will be made using the t-test for parametric data and the chi-square test or Mann Whitney-u tests for nonparametric data as appropriate. A P-value <0.05 will be considered statistically significant.

Data entered by qualified research assistants. All data analysis and graphical demonstrations were done, using the statistical package for social sciences SPSS software.

## Results

Sixty-five patients were enrolled, 62 patients met the inclusion criteria and were included in the study. Then patients were randomly divided into two equal groups (the SP blocker group: 31 and the baska group: 31). The flow chart of the patients through the study followed the CONSORT flow diagram is presented in Figure 3.

Demographic data including age, ASA classification and Ganzouri airway score were comparable between both groups (Table 1). Both groups were compared as regard numbers of insertion trials, time of insertion and ease of insertion and there is no statistical significance difference between both groups (Table 2). As regard leak pressure, there were statistically significance differences between both groups as shown in figure 4 (p- value <0.001) The baska group showed higher leak pressure than the SP blocker group which denotes better sealing, there were no difference in readings at the same group. Only 6.5% in baska group and 3.2% in air Q SP group showed postoperative complication in the form of bloody mucus which is not statistically significant as shown in Table 3. Data are represented as mean ± SD, or percentage (%), p- value <0.05 considered to be significant.

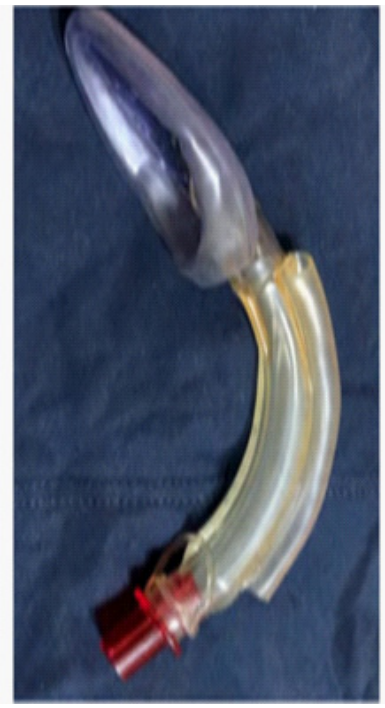

**Figure 1:** Air-q SP blocker

**Figure 2:** Baska Mask

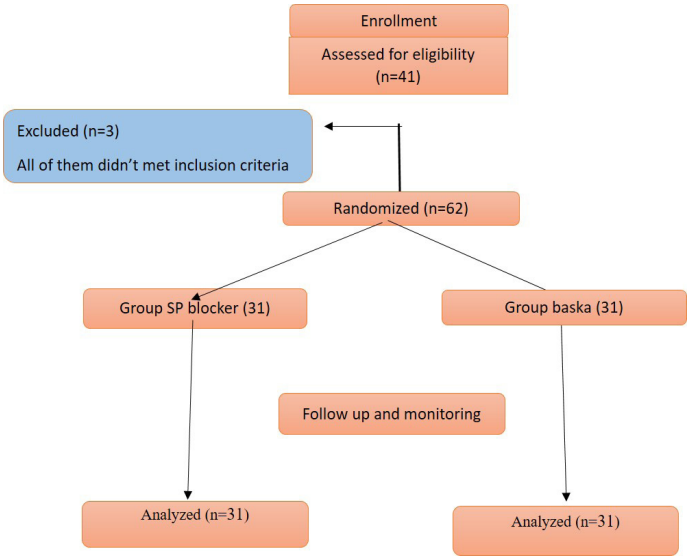


**Figure 3:** Consort flow diagram of the study.

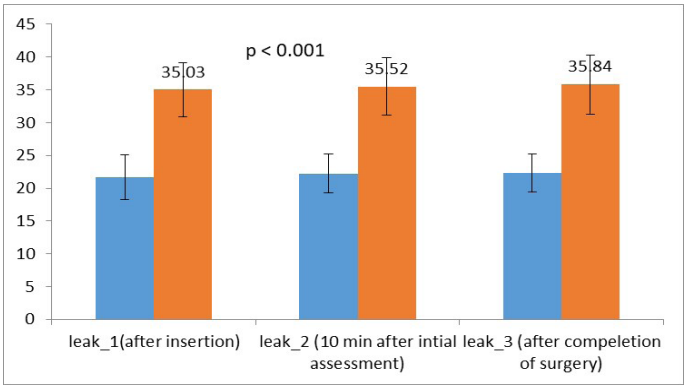


**Figure 4:** Significant difference in leak pressure between 2 groups.

**Table 1:** Demographic data.

| variables | | SP group n=31 | Baska group n=31 | p value |
|---|---|---|---|---|
| Age | | 28.97 ± 8.27 | 31.10 ± 8.20 | 0.313 |
| Weight | | 70.55 ± 8.31 | 73.16 ± 7.06 | 0.187 |
| ASA | 1 | 29 (93.5%) | 28 (90.3%) | 1 |
| | 2 | 2 (6.5%) | 3 (9.7%) | |
| Ganzouri | 0 | 13 (41.9%) | 14 (45.2%) | 0.798 |
| | 1 | 18 (58.1%) | 17 (54.8%) | |

Data are represented as mean ± SD, percentage (%). ASA: American society of anesthesiologist.

**Table 2:** Device insertion criteria.

| Variables | | SP group n=31 | Baska group n=31 | p value |
|---|---|---|---|---|
| Trials | 1 | 31(100) | 31(100) | |
| Time (sec) | | 22.3 ± 3.56 | 24.9 ± 4.54 | 0.941 |
| Ease of insertion | Easy | 28 (90.3) | 27 (87.1) | 1 |
| | Mild | 3 (9.7) | 4 (12.9) | |
| | Moderate | 0 (0) | 0 (0) | |
| | Inability | 0 (0) | 0 (0) | |

Data are represented as mean ± SD, or percentage (%).

**Table 3:** Incidence of postoperative complications in studied groups.

| Variables | | SP group n=31 | Baska group n=31 | p value |
|---|---|---|---|---|
| Post-operative complication (bleeding) | Yes | 1 (3.2) | 2(6.5) | 1 |
| | No | 30 (96.8) | 29(93.5) | |

Data are represented as percentage (%)

## Discussion

The main finding in this prospective comparative randomized clinical trial is that the Baska mask provides a better seal with the glottis aperture compared with the Air Q SP.

However, the Baska mask proved to be more difficult to insert than the Air Q SP, longer insertion times but without statistical significance in this population of low-risk females

To the best of our knowledge, this is the first study that compares Baska mask with Air Q SP regarding sealing pressure.

The ideal supraglottic device must Fulfill certain criteria such as high airway seal pressure with low resistance to gas flow, low incidence of pulmonary aspiration and complications.

Baska mask is a supraglottic airway device without inflatable cuff and has an oesophageal drainage inlet and side channels for aspiration of gastric content as well as an integrated bite-block.

However, it is different from other non-inflatable cuffs as the central channel continues to run through it.This leads to improvement in the seal reducing leak and making ventilation

more efficient, as the air during positive pressure ventilation inflates the cuff and seals the airway [17,18,19].

An integral bite block is present which always makes the airway patent.

Alexiev and colleagues compared the Baska mask with the single-use Classic Laryngeal Mask Airway (cLMA) in 150 females at low risk for difficult tracheal intubation as regard sealing pressure and found that the seal pressure achieved with the Baska mask was significantly greater than with the cLMA, indicating a better seal with the glottic aperture ($p < 0.001$) [20].

Abdel Aziz RA and Osman MY compared the utility of I-Gel with Baska Mask during general anaesthesia in obese patients undergoing elective ambulatory surgeries and found that Oropharyngeal Sealing Pressure (OSP) was significantly higher following Baska mask insertion (p value= 0.0008) [21], which is in line with our study.

In this study, there was few numbers of cases with minor blood staining of the baska mask compared to Air Q SP after removal at the end of the operation.

Also, there were no differences in other complication rates, such as laryngospasm, or in the severity of throat pain, dysphagia, dysphonia or hoarseness on emergence postoperatively.

The low incidence of sore throat in study can be attributed to the soft seal non-inflatable mask of Baska mask. This finding agrees with the study of Van Zundert and Gatt [16] which showed minimal blood staining and postoperative sore throat.

Alexiev et al found that insertion attempt success rate in the first trial was 73% which differs from our study where first attempt success rate was 100% regarding baska mask.

This may be due to difficulties with insertion of the Baska mask as precise positioning of the cuff orifice against the glottis is necessary to ensure optimal ventilation [20].

However, that was not reached in their study as they did not use muscle relaxation before insertion of supraglottic air way. Hence, they use more propofol increments to facilitate insertion during second and third attempts.

Abdel Aziz RA et al is in line with our study in easy insertion and high success rates (first attempt was 90%) with little limitations in patients with BMI (body mass index) >35 [21].

Baska mask were easily inserted with high success rates and this finding agrees with the results of Trivedi [22], Van Zundert [16], Bamgbade [23] and Radhika [24].

El-Refai et al, in their study comparing I-gel and Baska found that mean insertion time in seconds was significantly shorter in I-gel group compared to Baska group (13.87 vs 31.67) respectively. Mean oropharyngeal leak pressure according to El-Refai et al was significantly higher in Baska group than I-gel group (38.83 vs.26.50 cmH2O respectively) (P=0.000), which is also in line with our study showing mean leak pressure of baska group of 35.52±4.37cmH2O [13].

In the current study we found that the leaking pressure for Air-Q/SP blocker was 22.3 ± 3.3.

In consistency to our results Galgon RE, et al., who compared air-Q and air-Q SP, the leak pressure recorded for Air-Q SP was 27 ± 8. However, 60.9 % of the participants of this study were males unlike our study in which all participants were females [4].

Concerning mean time of device insertion, in the current study, the air QILA SP with blocker was 22.3 ± 3.56 (sec), this was in accordance to .M.I. Youssef et al [12] who found the insertion time of air q with blocker was 18.37 ± 3.77 (sec).

When selecting supraglottic device for adequate patient ventilation, one should consider availability, balance between its efficacy and applicability in the term of cost, whether it is invasive or not and the higher sealing pressure.

There are several limitations to this study. First, we only studied healthy adult females undergoing ambulatory surgeries, and our results may not apply to patients with some comorbidities (poor lung compliance, obese patients). Second, there is no much variability in device size used as we only studied adult females. Third, the study was not double blinded, so investigator bias, particularly regarding the user-reported ease of insertion, was possible.

## Conclusion

The supraglottic airway devices Baska mask and Air-Q SP, both are suitable for positive pressure ventilation in anesthetized female patients with the use of muscle relaxant and the Baska mask provides better seal with the glottic aperture when compared to Air Q SP in this population.

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