Original Article

A comparison between ProSeal laryngeal mask airway and Air-Q Blocker in patients undergoing elective laparoscopic cholecystectomy

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Abstract

Background and Aims: ProSeal laryngeal mask airway (PLMA) is an established device for airway management, while Air-Q Blocker (AQB) is a relatively new supraglottic device. The aim of this study is to compare AQB against PLMA in adults undergoing laparoscopic cholecystectomy under general anesthesia.

Material and Methods: Eighty-eight adult patients scheduled for laparoscopic cholecystectomy under general anesthesia were randomly allocated into two groups. A drain tube (gastric tube for PLMA and blocker tube for AQB) was inserted through the drain channel of the respective device. PLMA was inserted in Group *P* ($n = 44$) and AQB was inserted in Group A ($n = 44$) to secure the airway. The primary endpoint was airway seal pressure. Secondarily, we sought to compare overall insertion success, ease of insertion, hemodynamic effects after initial placement, ease of drain tube placement, and perioperative oropharyngolaryngeal morbidity between the devices.

Results: Oropharyngeal seal pressures for AQB and PLMA were 31.5 ± 2.41 and 29.41 ± 2.14 cm H_2O, respectively ($P = 0.01$). Insertion time was longer with AQB than PLMA, 25.59 ± 5.71 and 18.66 ± 3.15 seconds, respectively ($P = 0.001$). Ease and success rate of insertion was better with PLMA compared to AQB. Failure of device insertion was seen in 2 cases of Group A. Gastric distension was seen in 4 patients in Group A, requiring replacement with endotracheal tube in two patients. Ventilation was successful in all 44 patients with PLMA. Both the devices were comparable in providing a patent airway and adequate oxygenation during controlled ventilation. There was an increased trend of airway trauma and complications in the AQB group.

Conclusion: Both PLMA and AQB show similar efficacy in maintaining ventilation and oxygenation, during laparoscopic surgery. However, proper positioning and functioning of the blocker tube of AQB is a limiting factor, and needs further evaluation.

Keywords: Air-Q Blocker, laparoscopic cholecystectomy, oropharyngeal seal pressure, ProSeal laryngeal mask airway

Introduction

In recent years, a number of supraglottic airway devices (SAD) have been introduced in clinical practice offering a simple and effective alternative to endotracheal intubation in patients undergoing laparoscopic procedures with high success and safety.[1]

The ProSeal laryngeal mask airway (PLMA) (Laryngeal Mask Company, Henley-on-Thames, UK) besides having all the inherent qualities of Classic laryngeal mask airway offers several advantages over it.[2] It has an additional drain tube running parallel to the airway tube that prevents inadvertent gastric inflation and permits access to the gastrointestinal tract through the drainage tube (gastric tube), thereby attributing to increased safety when used with positive pressure ventilation.[3-5]

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Over the last two decades, Daniel J. Cook researched and developed the Air-Q intubating laryngeal airway that has gained wide acceptance. The Air-Q Blocker (AQB) is a novel LMA of Air-Q series which is useful in emergency medical services. It has all the distinct "rescue" airway requirements including advantages for intubation and managing the esophagus. The newer device AQB (Cookgas LLC; Mercury Medical, Clearwater, FL) is a supraglottic device designed as a primary ventilation airway which in addition has a conduit for endotracheal intubation and has the ability to place the drainage tube (esophageal blocker tube/gastric tube) via a specific integrated blocker channel. This blocker tube goes approximately 5–6 cm beyond the cuff of the AQB into the pharynx and has its own cuff that after inflation blocks the upper esophagus. This device has been used in various situations for rescue ventilation and also aids in suctioning and venting the esophagus.[6,7]

At present there is only one study comparing PLMA and AQB.[8] Our primary goal was to compare the airway seal pressures (as a surrogate for efficacy of lung ventilation) of AQB and PLMA in adults undergoing laparoscopic cholecystectomy under general anesthesia. Secondarily, we sought to compare overall insertion success, ease of insertion, hemodynamic effects after initial placement, ease of drain tube placement, and perioperative oropharyngolaryngeal morbidity between the two devices.

Material and Methods

This study was conducted in the Department of Anesthesiology and Intensive Care, Government Medical College, Jammu after the approval of the Hospital Ethical Committee. Eighty-eight patients of either sex ranging from 18 to 70 years of age, of American Society of Anesthesiologists Grade I and II, scheduled for elective laparoscopic surgery were included in this study. After written informed consent, patients were randomly assigned by toss of a coin to receive either an AQB or PLMA (Group A, AQB; Group P PLMA). Patients with symptomatic or untreated gastroesophageal reflux disease, obvious malformations of the airway or having limited mouth opening (less than 2.3 cm), morbid obesity, prior esophagectomy, hiatus hernia, vomiting within 24 hours of surgery, known oropharyngeal pathology making a proper SAD fit unlikely, or any condition for which the primary anesthesia team deemed intubation with a tracheal tube to be necessary were excluded.

Only first three anesthesiologists (RG, RM, and MJ) participated in insertion of the airway devices. All the participants read the manufacturers' instruction manuals and had previous experience of minimum 20 insertions with each device before the start of this prospective study.

In prerecovery, intravenous access was secured and ringer lactate infusion was started. The patient was transported to the operating room. Standard monitors including electrocardiograph, noninvasive blood pressure, and pulse oximeter were placed. All baseline parameters were recorded. Anesthesia was induced with intravenous propofol 2–2.5 mg/kg till the loss of verbal contact with the patient. Neuromuscular blockade was achieved with succinylcholine 1.5 mg/kg. Manual facemask ventilation was performed for 1 minute after which randomly assigned supraglottic airway for each group was inserted. The size of the airway device was chosen according to the manufacturer's instructions depending on the weight of the patient.[6,9]

Before placement, the devices were tested for leaks and lubricated on the tip and posterior surface with water-soluble vegetable gel. Appropriate size AQB was selected according to the patient's weight. The blocker tube was inserted after proper lubrication through the length of the blocker channel before insertion of the AQB. The device was then placed in the patient's mouth behind the tongue and the index finger of the operator's left hand was used to guide the tip of the cuff around the base of the tongue. Simultaneously, a caudad force was applied with the operator's right hand on the airway tube and the device was rotated inwardly and forward into position. If initial resistance to advancement was met, a jaw lift with the operator's left hand was performed, while the device was rotated inwardly and forward into position with the right hand. When advancement met a firm stop, the cuff was inflated with air (~15 ml for size 3.5 and ~ 20 ml for size 4.5) in accordance with the manufacturer's labeled recommendations and volume adjusted with a handheld manometer to achieve an intracuff pressure of 60 cm H_2O (Rusch Endotest, Cuff Pressure Gauge, Teleflex incorporated, Wayne, Pennsylvania,USA). After insertion of the AQB the blocker tube was further negotiated into the esophagus. The blocker tube cuff was inflated and its position was checked by getting a bouncy feel on withdrawing the blocker tube as recommended by the manufacturer.[6]

In Group P, the cuff of ProSeal LMA was thoroughly deflated using the cuff deflating tool and water soluble lubricant was applied on the dorsal surface of the ProSeal LMA. The device was preloaded with a 16 Fr gastric tube protruding approximately 3–5 cm beyond the cuff of the LMA. It was inserted with the patient's head in the sniffing position.[9] The cuff was inflated with air and the intracuff pressure was adjusted to 60 cm H_2O using a handheld cuff pressure manometer (Rusch Endotest; Cuff Pressure Gauge).[9]

Correct placement of the device was judged by adequate chest expansion and bilateral chest excursion on manual ventilation as well as auscultation over the lungs and absence of gurgling sound on auscultation of the epigastrium. Once confirmed, the device was fixed by taping it over the maxilla. End tidal carbon dioxide($ETCO_2$) sensor was connected and placement further confirmed by observing square wave capnography and $ETCO_2$ between 35 and 45 cm H_2O. Anesthesia was maintained with 33% O_2 and isoflurane in air (to achieve Minimum alveolar concentration of 1). An effective airway was defined as Oxygen saturation (SpO_2) ≥95%, $ETCO_2$ 35–45 mmHg, and minimal air leak. In case of an ineffective airway, intervention such as jaw lift, adjusting the head and neck position and changing the depth of device insertion was performed.

Relaxation was maintained with atracurium 0.5 mg/kg. The patient was put on volume control ventilation with a tidal volume of 6 ml/kg, inspiratory:expiratory ratio of 1:2, and respiratory rate of 12–15/minute to achieve $ETCO_2$ of 35–45 cm H_2O. The number of insertion attempts was recorded and the ease of insertion for both airways was assessed during the first attempt. Ease of device insertion was graded using a five-point scoring system (4 = insertion at first attempt without tactile resistance, 3 = insertion at first attempt with little tactile resistance, 2 = insertion at first attempt with significant tactile resistance, 1 = insertion successful at second/third attempt, 0 = insertion failed at three attempts). The insertion time of the device was recorded and the etiology of failed insertion was documented. The insertion time was noted from removal of the face mask to attachment of the breathing system to the supraglottic device (after inflation of the cuff) and delivery of the first tidal volume.

Failed device insertion was defined by any of the following criteria: 3 unsuccessful attempts or failed passage into the pharynx or malposition (massive air leak), ineffective ventilation, or evidence of airway obstruction. In the event of failure to establish an effective airway after three attempts, intubation with the endotracheal tube was performed and that case was excluded from the study.

Oropharyngeal leak pressure was measured after confirmation of insertion of the supraglottic device (i.e., before pneumoperitoneum, immediately after pneumoperitoneum, and 20 minutes after pneumoperitoneum.) During pneumoperitoneum, the surgeons were instructed to keep the insufflation pressure of the abdomen between 10 and 12 mmHg. Once anesthesia and ventilation had stabilized, the oropharyngeal leak pressure was determined at intracuff pressure of 60 cm H_2O. Ventilation was transiently stopped and adjustable pressure-limiting valve was closed with fresh gas flow of 3 l/minute (for safety, the airway pressure was not allowed to exceed 40 cm H_2O). This was the airway pressure generated when an audible leak over the mouth was detected.[10]

Hemodynamic changes, that is, heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were noted after airway device insertion; 1, 2, 5, and 10 minutes after pneumoperitoneum; and every 10 minutes thereafter till the removal of the airway device. Ventilator parameters (inspired and expired tidal volumes, peak airway pressure, and plateau pressure), $ETCO_2$, and SPO_2 were recorded after insertion, at 1, 2, 5, 10, and every 10 minutes thereafter till the removal of the airway device.

Gastric insufflation was assessed by auscultation over the epigastrium during manual lung inflation by anesthesiologist and recorded by the operating surgeon on an ordinal scale of 0–10 (0 = empty stomach and 10 = distension of stomach that interfered with surgery) at initial insertion of the laparoscope and immediately before its removal at the end of the surgical procedure.[5,6] Complications like laryngospasm, bronchospasm, hypoxia (SpO_2 ≤90%), and regurgitation were also recorded.

Ondansetron injection 4 mg was administered toward the end of the procedure. Neuromuscular blockade was antagonized by neostigmine injection 50 μg/kg and glycopyrrolate injection 10 μg/kg. Hundred percent oxygen was given before emergence. Before removal of the device, the stomach was emptied. The device was removed along with the drain tube when the patient was awake and was able to open the mouth on verbal commands.

Tolerance during removal of the airway was assessed using a scale (Good: comfortable patients; Moderate: minor sign of intolerance such as coughing, retching, and hiccups or biting of the airway; Poor: major sign of intolerance such as vomiting or vagal reaction rendering it necessary to remove the device immediately).

Following removal of the supraglottic device, any traces of visible gastric fluid or blood staining on the airway device were noted. The mouth, lips, and tongue were inspected for any evidence of trauma. Patients were asked about postoperative complications like sore throat (constant pain independent of swallowing), dysphagia (difficulty or pain on swallowing), dysphonia (inability to speak), and hoarseness of voice at 30 minutes, 1 hour, and 24 hours after removal of the device.

Our study was powered for superiority of the ProSeal over the AQB for the primary outcome which was oropharyngeal seal

pressure. Pilot data collected by us prior to this study for the AQB showed a mean (standard deviation [SD]) seal pressure of 24.8 (6) cm H_2O, while the ProSeal is reported to be 30 (8) cm H_2O.[11] Considering a difference of 5.2 cm H_2O to be the smallest clinically relevant difference in airway seal pressure, we calculated a standardized difference (difference divided by SD) of 0.65 (5.2/8). Using the nomogram of Altman (reference) for a two-sample comparison of a continuous variable, relating standardized difference, power, and significance level, a total population size of 76 (38 patients per group) was determined for our study to ensure 80% power with a two-sided alpha of 0.05 to detect a 20% difference in airway seal pressures between the AQB and PLMA.[12] After adjustment for noncompliance of 3%, a sample size of 88 was taken.

Data management and analysis were performed using appropriate statistical analysis. Ordinal data were presented as means ± SDs. 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 two-way analysis of variance with repeated measures on one factor was done. The Chi-squared test or the Fisher's exact test for small sample size was used to compare between the groups with respect to categorical data. *P* values <0.05 were considered significant.

Results

A total of 98 patients were screened. Six patients declined participation and four patients did not meet exclusion criteria and were excluded [Figure 1]. There were no statistical differences between the two groups regarding the demographic data [Table 1]. Mean oropharyngeal seal pressures in Group A were significantly higher than Group *P* (31.5 ± 2.41 and 29.41 ± 2.14 cm H_2O, respectively) (*P* = 0.01). PLMA showed a higher success rate of insertion for the first time (93.18%) than the AQB (81.82%) (*P* < 0.01). Success rate was 100% in PLMA in 3 attempts, while it was 95.46% in AQB (*P* < 0.05). The mean device insertion time was 25.59 ± 5.71 seconds in Group A, while it was 18.66 ± 3.51 seconds in Group P (*P* < 0.001). Ease of insertion was significantly better in Group *P* in contrast to Group A [Table 2].

The success rate of drain tube (gastric tube for PLMA/blocker tube for AQB) insertion in both groups was significantly

Table 1: Patient baseline demographic characteristics

Demographics	Group A (*n*=44)	Group P (*n*=44)	*P*
Age (years)	41.89±11.59	38.07±9.95	0.101
Sex M/F	9/35	11/'33	0.442
Height (cm)	151.27±5.44	153.57±6.58	0.083
body weight (kg)	54.45±3.38	56.16±4.86	0.074
Body weight index	23.92±2.76	23.90±2.53	0.973
ASA status I/II/III	31/13	33/11	0.48
Duration of surgery	47±14	49±17	0.38

Values are mean±standard deviation. ASA=American Society of Anesthesiologists physical status

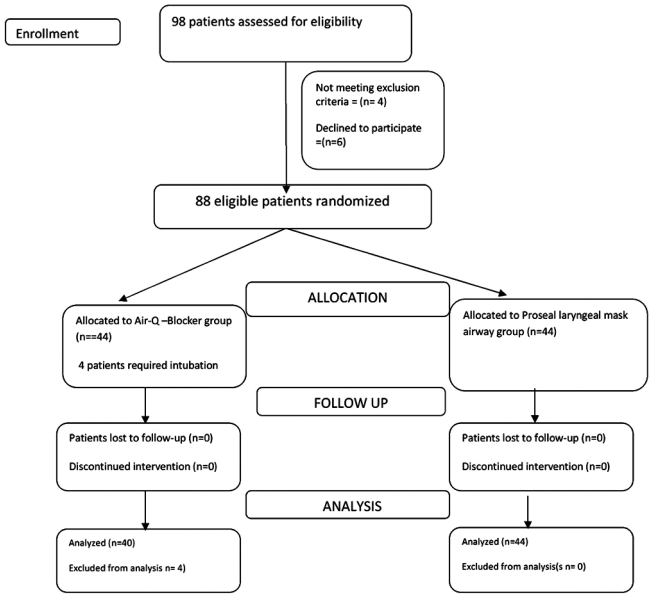

Figure 1: CONSORT flow diagram

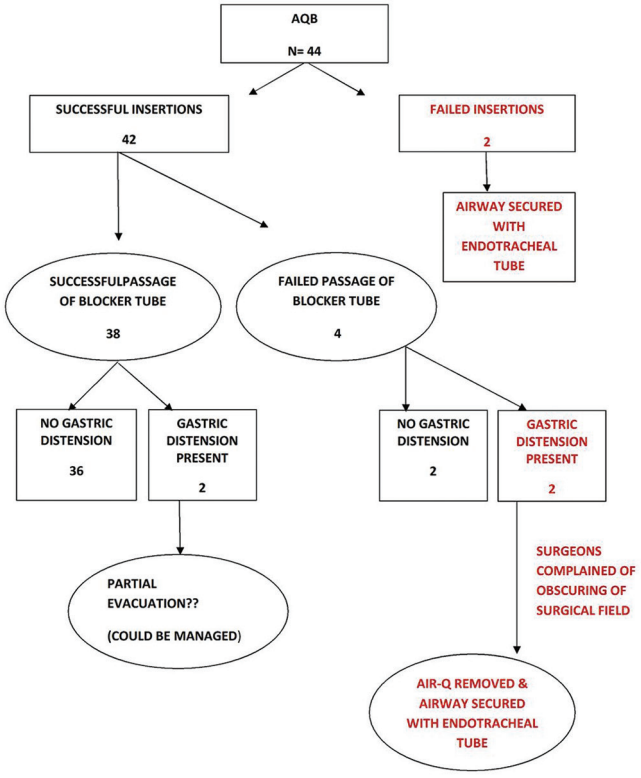

Figure 2: Flowchart showing the success and failure of Air-Q Blocker insertion

Table 2: Airway characteristics of supraglottic devices

Parameter/variable	Group A (44)	Group P (44)	*P*
Time for insertion (s)	25.59±5.71	18.66±3.15	<0.001*
Number of insertion attempts 1/2/3	36/6/2	41/3	0.0112*
Ease of insertion 4/3/2/1/0	24/15/3/0/2	38/6/0/0/0	0.001*
Successful passage of drain tube Yes/no	38/4	44/0	0.001*
Successful stomach evaluation Yes/no	38/4	44/0	0.001*
Endotracheal tube insertion YES/NO	40/4	44/0	0.001*
Oropharyngeal seal pressure (mmHg)	31.58±2.41	29.41±2.14	0.001*
Tolerance during removal good/moderate/poor	36/4/0	43/1/0	0.021*
Inspection findings on device removal			
Blood staining Y/N	4/36	2/42	0.144
Gastric fluid Y/N	0/40	0/44	0.155
Trauma Y/N	3/37	0/44	0.143

*Values are mean±standard deviation. *P<0.05=statistically significant*

different. The surgeons were questioned about the success of stomach evacuation on inserting the drain tube. In Group A, esophageal blocker tube could be passed in 38 patients and could not be passed in 4 patients. In two of these four patients, the surgeon complained about the distension in the stomach and the stomach could not be evacuated, and in these patients the device was replaced with endotracheal intubation. In other 2 patients, the stomach distention was acceptable. In Group *P* (PLMA), the gastric tube (16 Fr) could be passed in all 44 patients successfully and the stomach was successfully evacuated in all the patients [Figure 2].

Heart rate measurements were comparable in both the groups and the differences were not statistically significant. The difference in systolic blood pressure, diastolic blood pressure, and mean arterial pressure was also comparable in both the groups except during the first 5 minutes immediately after insertion of AQB when there was greater rise in blood pressures in contrast to Group P [Figure 3].

Ventilator parameters including SpO_2, inspiratory tidal volume, expiratory tidal volume, peak airway pressure, plateau airway pressure, and end-tidal CO_2 values were recorded at different time intervals after device insertion till the removal of the device and were found to be comparable between two groups.

Device tolerance during removal was significantly better in Group P. In Group P (PLMA), 43 patients had Good and 1 had Moderate device tolerance. In Group A, 36 patients and 4 patients had Good and Moderate device tolerance, respectively.

On inspection of the device after removal, blood stain on the device was found in 2 patients in Group P and 4 patients in Group A ($P > 0.05$). No patient had the presence of gastric fluid on the device. Lips/tongue/mouth trauma was noted in 3 patients in Group A and none in Group P [Table 2]. No significant difference in postoperative throat symptoms/complications was seen between two groups except for a higher incidence of sore throat in Group A at initial assessment at 30 minutes [Table 2].

Discussion

Many second-generation SADs now outperform the first-generation LMAs in all these domains being as easy or easier to insert, with higher oropharyngeal seal pressures and with design features that are intended to reduce the risk of aspiration.[13] The use of SAD under conditions of elevated intra-abdominal pressure requires an excellent airway seal to divide respiratory and alimentary tract in a reliable manner, due to the potential risk of regurgitation and pharyngeal morbidity. The second-generation supraglottic devices have been proved to be safe in such procedures. Laparoscopic surgery provides the most severe test for efficacy of SAD during positive pressure ventilation and various supraglottic devices have been found to be effective as ventilatory device for laparoscopic cholecystectomy.[4,5,14]

To date, only a single study has compared the AQB with PLMA. Youssef *et al.* showed that both devices were safe and effective airway adjuncts in mechanically ventilated anaesthetized adult patients in ophthalmological surgeries. They found that the AQB demonstrated to be remarkably good as a ventilatory

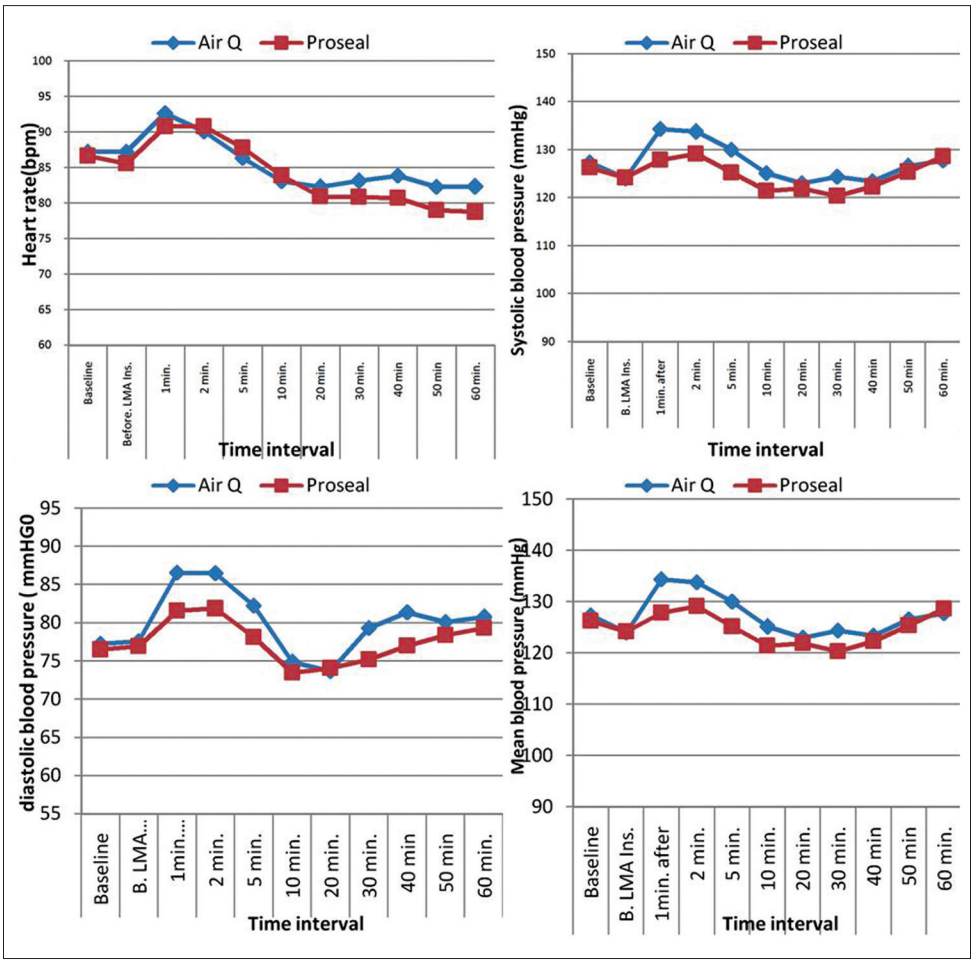

Figure 3: Hemodynamic parameters after insertion of airway device

device, with adequate airway seal pressures and fast learning curve comparable to PLMA.[8] Galgon *et al*. compared Air-Q intubating laryngeal airway (Air-Q) with PLMA and found that Air-Q device was easy to insert and the airway seal pressures of Air-Q and PLMA were similar. Overall, both the devices were equally effective for providing general anesthesia.[15]

Mean oropharyngeal seal pressure was statistically significantly higher in the AQB group than PLMA (31.5 ± 2.41 and 29.41 ± 2.14 cm H_2O, respectively) ($P = 0.01$). Our results collaborate clinically to the study conducted by Galgon *et al*. where the mean ± SD oropharyngeal seal pressures for Air-Q and PLMA were similar to that obtained in our study (30 ± 7 and 30 ± 6 cm H_2O, respectively). Youssef *et al*. while comparing AQB and PLMA found the oropharyngeal seal pressures as 22.4 ± 1.27 and 23.67 ± 1.49 cm H_2O respectively, with no statistically significant difference. However, the difference in our study may be of little clinical relevance as the pressures in the both groups were within clinically acceptable range and comparable to oropharyngeal seal pressure seen with various studies using PLMA for airway management in patients undergoing laparoscopic cholecystectomy.[5,16-19]

We required fewer insertion attempts to successfully insert PLMA than AQB. First attempt insertion success rates for PLMA were higher than AQB (93% vs. 86.3%). However, in contrast to our results, Youssef *et al*. obtained lower first attempt insertion success rates for PLMA (83.3% vs. 90%) than in AQB. This may be related to the use of digital method for PLMA by Youssef *et al*. which is an inferior method in contrast to its insertion over a gastric tube or suction catheter.[15] Galgon *et al*. have demonstrated that PLMA had higher success rate of insertion in the first attempt compared to Air-Q (98% vs. 88%); a second attempt was necessary for 6 patients (12%) in the Air-Q group.[15] This may be attributed to the higher success rate when PLMA is inserted over a gum elastic bougie or gastric tube or suction catheter through its drain tube rather than the digital insertion or introducer tool technique.[15,20-23]

The ease of insertion was better in Group P than Group A. Better ease of insertion with PLMA in our patients may again be explained by the vast data which demonstrate the superiority of bougie/gastric tube/suction catheter guided insertion of PLMA in contrast to the digital method.[20-25]

However, there is not enough data for insertion characteristics and ease of insertion of drain tube via AQB with only a single study available in literature which used gastric tube with high success rate of insertion.[8] However, the success rate of the blocker tube used in our study did not emulate that of passing the gastric tube via AQB by Youssef *et al*. This may be due to different design characteristics of the blocker tube and gastric tube with former being shorter in length with an inflatable cuff.

In our study, we found that mean insertion time was significantly longer in Group A (25.59 ± 5.71 seconds for Group A and 18.66 ± 3.15 seconds for Group P). In contrast to our results, Youssef *et al*. found out that AQB insertion took significantly lesser time than insertion of PLMA (mean time 18.4 ± 3.77 vs. 23.4 ± 3.54 seconds). This may be explained by the use of digital method by Youssef *et al*. requiring a longer time for insertion of PLMA.[21-23] Galgon *et al*. also found a lesser time required to achieve a clinically adequate airway in whom Air-Q was inserted in contrast to those in whom PLMA was inserted (Air-Q 20 ± 14 seconds; PLMA 28 ± 11 seconds).[16] The longer time in their study to insert PLMA may be related to additional step of use of laryngoscopy prior to insertion of PLMA railroaded over the gum elastic bougie.[17] Furthermore, the different device characteristics of AQB in contrast to the Air-Q may be the contributing factor for longer time of insertion in our study in contrast to the study by Galgon *et al*.

Passage of drain tube via drain channel in the desired position was more successful in Group P with better evacuation of stomach. The prior insertion of gastric tube via whole length of the drain channel of PLMA may have made it easy to guide it into the esophagus without it going astray in the hypopharynx. However, blocker tube negotiated via AQB may go astray in the pharynx with its coiling and failure to be placed in the desired position.[26] Furthermore, the AQB is a new device with scarce data in literature regarding ideal technique of insertion and success of blocker tube placement through this device which is in sharp contrast to established practice of railroading the PLMA over the gastric tube/suction catheter/gum elastic bougie.

We found a lower incidence of blood stain on the device and sore throat at 30 minutes in patients in Group P. In contrast to our study, Youssef *et al*. and Galgon *et al*. observed that blood streaked mucous on the device and sore throat was found in more patients in the PLMA group than AQB. This may be attributed to better technique of using the gastric tube guided insertion of PLMA in our study.[20-24] The higher incidence of oropharyngeal morbidity in cases of AQB in our patients may be related to its longer time for insertion, more attempts, and less ease of insertion.

There were certain limitations to our study. First, the study involved patients with a normal airway and whether the same outcome can be extrapolated to patients with difficult airway is subject to performance of similar large-scale studies in patients with difficult airway.

Second, all the users had less experience with the AQB than with the PLMA because AQB is a relatively new device, whereas PLMA has been in use in our institution for over a last decade. LMA Classic™ (LMA North America, San Diego, CA) is recognized to have a short-term learning curve of 15 insertions.[27,28] Youssef *et al*. have demonstrated a rapid learning curve with AQB in 30 patients and hence we considered 20 to be the sufficient number to establish the learning curve for both the airway devices. However, it may have been possible that 20 insertions of AQB by each participant may have been insufficient to match the robust long-standing learning curve of PLMA established over many years in our institution. This may be responsible for longer AQB insertion time and shorter PLMA insertion times in our study in contrast to other studies comparing AQB with PLMA.

Third, blinding was not possible for the anesthesiologist inserting the device. Fourth, the airway device insertion was done under muscle relaxant effect, so the results are not necessarily the same for spontaneously breathing and less deeply anesthetized patients.

Conclusion

Both PLMA and AQB show similar efficacy in maintaining ventilation and oxygenation, during laparoscopic surgery. Although AQB provides marginally better oropharyngeal seal than PLMA, proper positioning and functioning of its blocker tube is a limiting factor, which needs further evaluation.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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