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Air Q Blocker LMA in Patients Undergoing Laparoscopic Cholecystectomy - A Pilot Study

Dr. Nandita Mehta[1], Dr. Apeksha Gupta[2], Dr. Rohit Gupta[3]

Acharya Shri Chander College of Medical Sciences and Hospital, Bye Pass Road, Sidhra, Jammu, Jammu and Kashmir, 180017.

Running Title: Air Q Blocker: Safety Profile

Abstract: ***Background: To evaluate the performance characteristics of Air Q Blocker laryngeal mask airway in patients undergoing laparoscopic cholecystectomy laying importance on the oropharyngeal leak pressure of the device as an indicator of the safety and efficacy of its seal. Material and Methods : After obtaining clearance from the local ethical committee, this pilot study was conducted on 40 adult , ASA I-II grade patients posted for elective laparoscopic cholecystectomy under general anaesthesia. Anaesthesia technique was standardized for all patients. Air Q Blocker of appropriate size was inserted and its position was confirmed. Intraabdominal pressures and flow rates were kept at 12 mm Hg and 2.5 L/min maximum respectively. The primary outcome measured was oropharyngeal leak pressure and its margin of safety. Secondary outcomes included the time for insertion, attempts of insertion, ease of nasogastric tube placement, haemodynamic parameters, ventilation characteristics and postoperative complications. Result: The success rate of first attempt insertion was 95 %. Mean time for insertion was 13.70 $\pm$3.05 seconds. Success of 1st attempt Gastric Tube Insertion was (95 %). Mean oropharyngeal leak pressure was 33.76 cm H2O. Mean level of margin of safety was 11.14 cm H2O.. 10 % of patients had a sore throat and 5% of patients had mild airway trauma. Ventilation was adequate in all patients, minimal haemodynamic variation and there was no incidence of postoperative complications. Conclusion: A properly positioned Air Q Blocker proved to be a suitable and safe device for airway management in fasting, adult patients undergoing elective laparoscopic surgeries. Despite of high airway pressures, it provided effective pulmonary ventilation without gastric distention, regurgitation, and aspiration.***

Keywords: Laryngeal mask airway; Laparoscopic cholecystectomy; Oropharyngeal leak pressure; Ventilation

1. Introduction

Emergence of minimally invasive surgery is described equally revolutionary to this century as development of anaesthesia was to the last century. Shift of the realm of surgery from open to laparoscopic surgeries has been of tremendous benefit both to the surgeon and the patient. Certain problems associated with these procedures are carbon dioxide insufflation, raised intraabdominal pressures and potential risk of regurgitation and pulmonary aspiration. Therefore in such procedures, airway management continues to be of paramount importance to the anaesthesiologists.

Till date, endotracheal intubation was considered as the gold standard for providing a safe glottic seal [1].But there are some disadvantages associated with tracheal intubation, which involves rigid laryngoscopy, in terms of concomitant haemodynamic responses and damage to the oropharyngeal structures at insertion. This precludes the global utility of the tracheal tube and requires a better alternative. Over a period of time, many new airway devices have been brought up for the anaesthsiologist's rescue.

Laryngeal mask airways were introduced to the world of anaesthesiology by Dr Archie Brain in 1981[2].Since then these devices have undergone a wide range of modifications both in their structure and functional characteristics[3][4]. Various devices have an inbuilt drainage channel which allow for easy venting of gastric contents (LMAproseal, LMA supreme, I gel)[5][6][7]. This has widened the armamentarium of an anaesthesiologist when dealing with a patients airway. Various generations of laryngeal mask airways are widely being used in clinical practice[8] .

A novel supraglottic deice Air Q Blocker(Cookgas® LLC, Mercury Medical, Clearwater, FL, USA) developed by Dr. Daniel Cook and introduced in 2004, is widely being used as a primary airway device or as an adjunct to tracheal intubation. It has an elliptical, inflatable, cuffed mask which is designed to be positioned in the hypopharynx and a slightly curved airway tube with a detachable connector. The shape of the cuff prevents the epiglottis from obstructing the lumen of the device and no aperture bars are present, allowing the unobstructed passage of an endotracheal tube through the Air Q Blocker LMA [9][10][11].

The Air Q Blocker airway when compared to other laryngeal mask airways of the 2nd generation, has a more secure functional bite block incorporated into the breathing tube which is designed to maintain better breathing tube patency while protecting the upper palate and front teeth from unwanted trauma . A soft, flexible guide tube is located on the right side of the breathing tube. This guide tube allows access to the posterior pharynx and upper esophagus by supporting and directing suction catheters, nasal gastric tubes up to size 18.0 Fr., and the newly designed Air Q Blocker Tubes which are designed to suction, vent and block the upper esophagus[12].

Air Q Blocker is being used safely for the past few years but no clinical study has been published on the use of this device in patients undergoing laparoscopic cholecystectomy. The aim of this pilot study was to evaluate the device in terms of the margin of safety of its oropharyngeal leak pressure ,placement in the airway, characteristics of ventilation, ease of gastric tube placement and identifying any adverse effects.

2. Material and Methods

After obtaining clearance from the college ethical committee, this study was conducted in the department of anaesthesiology and intensive care, ASCOMS, Sidhra, Jammu.

We enrolled 40 ASA I-II patients in the study. These included patients ofeither sex, age 18-65, MPG I-II and BMI <30 kg/m2 undergoing elective laparoscopic cholecystectomy. Patients with respiratory or pharyngeal pathology, allergy to drugs used in the study, morbidly obese with BMI >35 kg/m^2, with previous GI tract surgery, history of GERD, intestinal obstruction, delayed gastric emptying were excluded from the study.

A detailed history, thorough physical and systemic examination including airway assessment and routine/relevant investigations were recorded day prior to the surgery. Informed, written consent was taken and the patients were prepared by overnight fasting and premedication with tab alprazolam 0.25 mg & tab pantoprazole, night prior to the surgery. On the day of surgery, IV line was secured with an appropriately sized cannula. All patients received Injondansetron 0.1 mg/kg and inj ranitidine 50 mg I/V approximately 30 min before induction.

All baseline parameters including heart rate , blood pressure (systolic, diastolic and mean), oxygen saturation and end tidal carbon dioxide were recorded. Continuous ECG monitoring was done. After preoxygenation for 3 minutes, patients were induced with fentanyl 1 µ/kg and propofol 2 mg/kg I/V according to ideal body weight. Neuromuscular blockade for insertion of airway device was achieved with injrocuronium 0.7 mg/kg I/V. Ventilation was carried out using manual mask ventilation conducting oxygen and isoflurane till the conditions were suitable for insertion.

According to the manufacturer's recommendation, an Air Q size 3.5 was inserted in patients weighing 50 to 70 kg and a size 4.5 in patients weighing over 70 kg[13] .

Ease of LMA insertion was graded using FOUR POINT SCORING system.
3– insertion at first attempt without tactile resistance
2– insertion at first attempt with tactile resistance
1– insertion successful at second or third attempt
0– insertion failed at 3 attempts

Insertion time was measured from the moment of placing the device in the patient's mouth to the first square shaped capnographic waveform. Failed insertion was followed by three further attempts. Successful placement was confirmed by capnography and bilateral chest wall movement during manual ventilation. Proper positioning was confirmed by adequate chest expansion with gentle ventilation, absence of any leak sounds from the device and capnography readings of six successive waves, easy passage of gastric tube into stomach via drain tube and absence of gurgling sound on auscultation of epigastrium.

Failed laryngeal mask insertion was defined when there were greater than 3 unsuccessful attempts, air leaks, malposition of device and ineffective ventilation.

A well lubricated gastric tube of 16 F size was introduced through the integrated drainage channel. Number of insertion attempts of gastric tube were noted. The success rate of its insertion was recorded and ease of insertion was graded as :
1 – easy insertion
2 – difficult insertion
3 – impossible to insert

The LMA was secured to the face with adhesive tape and roll bandage.

During surgery, the intra abdominal pressure was maintained at 12 mm Hg and flow rate was kept at 2.5 L/min and cases where either pressure or flow rate had to be increased, were excluded from the study.

Anaesthesia was maintained with 33% oxygen , 66% nitrous oxide and 0.5-1% isoflurane (depending on patient requirements). Intraoperative muscle relaxation was achieved with incremental doses of injrocuronium 0.1 mg/kg I/V.

Close circle system was connected and patients were mechanically ventilated using volume controlled intermittent positive pressure ventilation with a tidal volume of 8 ml/kg, fresh gas flows of 3 l/min, respiratory rate of 12-14/min and inspiratory-to-expiratory time ratio of 1:2, to achieve effective oxygenation and ventilation. Peak airway pressure (cm H2O) was recorded while patients were on volume controlled ventilator mode.

Oropharyngeal leak pressure was measured by ventilating the patients manually and closing the popoff valve of the ventilator during a steady flow of 5 l/minute and gradually increasing peak airway pressure until a leak was audible or to a maximum of 40 cm H^2O. Leak pressure was measured before initiation of pneumoperitoneum, 5 min after pneumoperitoneum , 20 and 40 minutes thereafter. Margin of safety of oropharyngeal leak pressure was calculated by subtracting the peak airway pressure from the leak pressure(margin of safety = leak pressure – peak airway pressure) [14][15] .

Hemodynamic parameters (heart rate , systolic, diastolic and mean blood pressure) and ventilation parameters (oxygen saturation ≥ 95 % and end tidal carbon dioxide between 30-35 mm Hg) were noted and adjusted accordingly [16][17].

Residual effect of neuromuscular blocking agents was reversed with inj. neostigmine 50 µ/kg and inj. Glycopyrrolate 10µ/kg. The Air Q Blocker LMA was removed once patients were breathing spontaneously and obeying simple commands. Before removal of the device, stomach was emptied again and nasogastric tube removed.Complications like laryngospasm, bronchospasm, hypoxia (SpO2 ≤ 90 %) and regurgitation or aspiration were noted.

Presence of blood or bile on the device was noted and the mouth, lip and tongue were inspected for evidence of trauma in the immediate post-operative period. Patients were asked about having post-operative sore throat and were assessed for hoarseness of voice at 30 minutes, 2hrs and 24 hours after removal of the device.

At the end of the surgery, all the data so collected was compiled and analysed statistically. We used the descriptive statistical methods (mean, standard deviation, frequency distribution) in the evaluation of the data. In the repetitive measurements of multiple groups we used one way variant analysis and in the comparison of subgroups we used the newmankeuls multiple comparison test.

3. Result

A total of 40 patients were enrolled in this study. The demographics of the study group were as follows: Age (40.63 ± 10.78 years), weight (62.65 ± 14.6 kg) and BMI (24.35 ± 4.04). The study group included 22 male and 18 female subjects. As assessed during pre-operative airway examination 30 patients had Grade I and 10 had Grade II Mallampati grading.

Based on American Society of Anesthesiologists (ASA) risk grading, 31 patients belonged to ASA Grade I, and 9 patients to ASA Grade II.

Size 3.5 Air Q Blocker was introduced in 33 patients and size 4.5 was used in 7 patients.

The Air-Q was successfully inserted in all the patients (100%) [Figure 1]. The first attempt for insertion of the Air-Q was successful in 38 patients and in 2 patients, a second attempt was required. The first attempt success rate was 95 % and second attempt success rate was 5%.

Mean time for Air Q Blocker insertion was 13.70 $_{\pm}$3.05 seconds. Ventilation was found to be adequate in all patients in our study as seen by the values of oxygen saturation and mean levels of end tidal carbon dioxide at all intervals during the surgery [Table 1 & 2].

Gastric tube insertion was successful in all patients (easy in 38 patients and difficult in 2 patients). The first attempt success rate of nasogastric tube placement was 95 % and second attempt success rate was 5 %.

The mean oropharyngeal leak pressure at prefixed intra abdominal pressure of 12 mm Hg was 33.76 cm H^2O [Table 3]. Mean level of margin of safety was 11.14 cm H2O [Table 4]. There was optimal oxygenation in all the cases as shown in table 1. There were no significant haemodynamic changes before and after insertion of the device and even after 1,5 and 10 minutes after initiation of the pneumoperitoneum [Table 5].

There were no episodes of laryngospasm/bronchospasm, cough and stridor. Two patients (5%) had minor airway trauma as deduced by observation of macroscopic blood on the dorsum aspect of the cuff of laryngeal mask airway after its removal and 4 patients (10%) reported having sore throat after removal of the device at the end of surgery [Figure 2]. None of the patients had dysphonia or dysphagia.

4. Discussion

Modern day anaesthetic practices aim towards minimizing the use of invasive manoeuvres and that holds more true in case of airway management. There has been a huge drift from conventional endotracheal intubation towards newer devices which has widened the scope of modern day anaesthesiology.

Supra-glottic airway devices are being used widely in many clinical scenarios in anaesthesia and are a good alternative to endotracheal intubation in some procedures. Each newer generation of these devices came with some distinguishing feature from the older ones. One of the most significant achievement was the incorporation of a gastric channel which served as a guide to the pharynx and oesophagus. This feature gained more significance with the rising trend of laparoscopic surgeries where due to the pneumo-peritoneum and position of the patient, there is a rise in the intra abdominal pressures which make regurgitation and aspiration very likely. So devices with an access to the oesophagus allow us to vent it beforehand and thus acts as a safety mechanism [18] .

The Air-Q Blocker LMA (ILA™, Cookgas® LLC, Mercury Medical, Clearwater, FL, USA) is a new supra-glottic airway device designed for airway maintenance, conduit for endotracheal intubation and proper drainage of the stomach through the integrated channelduring general anaesthesia. The major advantage of the device design is that conventional PVC endotracheal tube can be passed through the Air-Q Blocker to intubate the trachea (up to 7.5 and 8.5 mm ID through Air-Q size 3.5 and 4.5, respectively) without the use of laryngoscope. It has also been used successfully for fibreoptic guided endotracheal intubation in various age groups and surgeries [19][20] .

Many studies have been conducted on the use of Air Q Blocker in various age groups and surgeries. Search of literature does not show any study to test the effectiveness of Air Q Blocker LMA as an airway device in patients undergoing laparoscopic cholecystectomy. During laparoscopic surgeries, the anaesthesiologists being the captain of the ship, with the airway in their hands ,has to deal with the untoward risks of increased intra abdominal pressures. Here come the important role of the nasogastric drain channel and a good margin of safety as far as the oropharyngeal leak pressures are concerned.

Oropharyngeal leak pressures have been widely accepted as a reference criteria for assessing the safety of Laryngeal mask airways. This holds more importance in laparoscopic surgeries where intra abdominal pressures are raised.For delineating the safety of a device, the oropharyngeal leak pressure must always be higher than peak airway pressure during pneumoperitoneum. Margin of safety of oropharyngeaal leak pressure is defined as the value for the margin of pressure between the highest peak airway pressure and the thee maximum oropharyngeal leak pressure. Thus

this determines the safety gap of a device for use in laparoscopic cholecystectomy [21] .

We effectively used Air Q Blocker LMA for securing a safe airway in patients undergoing cholecystectomy laparoscopic cholecystectomy. The primary outcome measured was the oropharyngeal leak pressure and margin of safety of leak pressure. Mean oropharyngeal leak pressure noted was 33.76 cm H^2O.Mean level of margin of safety was 11.14 cm H^2O.

Secondary outcomes measured were the first attempt success rate of insertion, time of insertion, ease and attempts of nasogastric tube insertion, haemodynamic parameters, ventilation characteristics and post operative complications. The Air Q Blocker was inserted from the first time in 95% of cases and from the second time in 5% of cases which makes it a great airway device. In consistence to our study, Maha M.I. Youssef et al. compared the Air Q Blocker to LMA Prosealand found that the Air Q Blocker was inserted easily from the first time in 90% of cases when compared to LMA Proseal[22] . Mean insertion time of 13.70 seconds makes early airway control possible. Ventilation was adequate in all the cases and no patient required endotracheal intubation. Good quality of ventilation as assessed by oxygen saturation of the patients at various intervals intraoperatively and end tidal carbon dioxide makes it even more valuable as a bridging device in difficult airway scenarios.

The placement of gastric tube was also successful in 95 % of the cases. 2 gastric tube insertions were graded difficult because of insufficient lubrication and after proper generous lubrication, gastric tube insertion
was achievable.

There have been numerous studies emphasising the role of Air Q intubating laryngeal mask airway as a primary device for securing the airway and for endotracheal intubation. It has been used successfully for endotracheal intubation in various age groups, patients with difficult airway and cases with high risk of aspiration [23][24] .The colour coded, removable , tethered connector for direct access to the airway tube allows intubation with any standard endotracheal tube.

Hemodynamic data(systolic, diastolic, mean blood pressure and heart rate) were recorded just before device insertion, after device insertion and 1,5 and 10 minutes after initiation of pneumoperitoneumto monitor the occurrence of any hemodynamic stress response due to device insertion or intraoperative events . There was minimal difference at any interval during the surgery. Those results were similar to the study done by Galgon et al. 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[25] .

There was no incidence of laryngospasm, bronchospasm, stridor or cough in any of the patients and we came to the inference that there was no incidence of regurgitation or aspiration. Thus, we came to the conclusion that Air Q Blocker is an effective supraglottic airway device in laparoscopic cholecystectomy owing to the presence of a wide drainage channel allowing easy passage of nasogastric tube and accepted levels of margin of safety.

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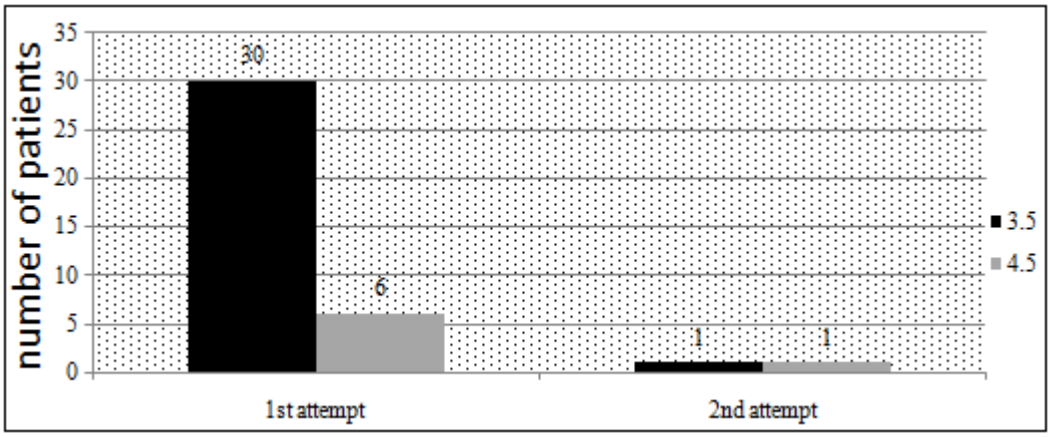

Figure 1: Number of attempts for successful insertion of the Air-Q laryngeal mask airway.

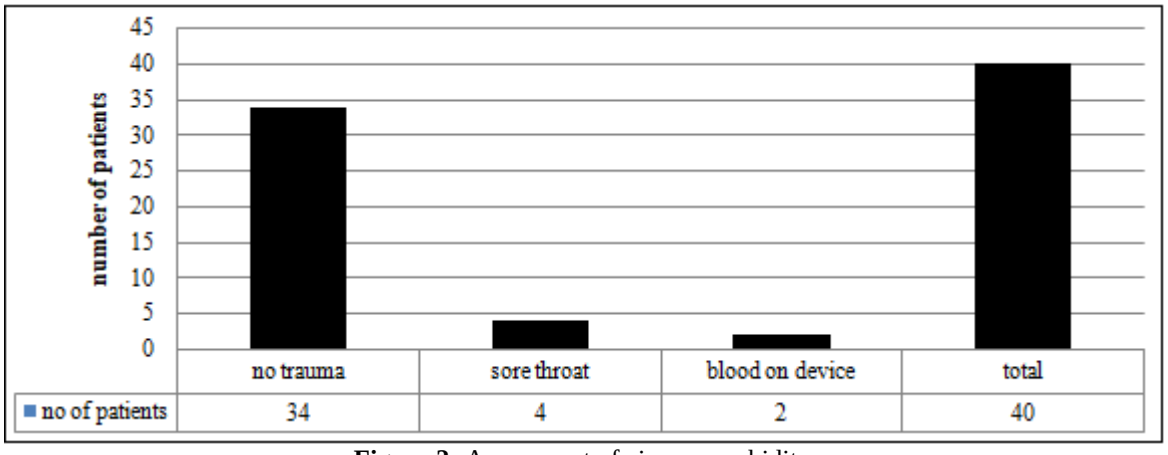

Figure 2: Assessment of airway morbidity

TABLE 1. ADEQUACY OF VENTILLATION					
PULSE OXIMETRY	AIR Q BLOCKER SIZE				TOTAL
	3.5		4.5		
	n	%	n	%	
Adequacy of ventilation					
98 %	14	42.42 %	2	28.5 %	16
99 %	19	57.57 %	5	71.4 %	24
100 %	0	0 %	0	0 %	
Total	33	100	7	100	40

TABLE 2. END TIDAL CARBON DIOXIDE		
ETCO2 (MM HG)		VALUE
BEFORE INSERTION		32.7 ± 1.93
AFTER INSERTION		33.00 ± 0.81
DURING PNEUMO-PERITONEUM	AT 1 MIN	33.00 ± 1.53
	AT 5 MIN	32.75 ± 1.10
	AT 10 MIN	32.52 ± 0.70

Table 3. MEAN OROPHARYNGEAL LEAK PRESSURE (CM H2O)			
S. NO	Time interval	MEAN OROPHARYNGEAL LEAK PRESSURE (CM H2O)	OVERALL MEAN
1	After lma insertion (before pneumoperitoneum)	32.85 cm H2O	33.76 cm H2O
2	5 minutes after pneumoperitoneum	34.O2 cm H2O	
3	20 minutes thereafter	34.43 cm H2O	
4	40 minutes thereafter	34.66 cm H20	

Table 4. MARGIN OF SAFETY OF THE OROPHARYNGEAL LEAK				
S. NO	TIME INTERVAL	MEAN OROPHARYNGEAL LEAK PRESSURE (CM H2O)	MEAN PEAK AIRWAY PRESSURE (CM H2O)	MARGIN OF SAFETY OF OROPHARYNGEAL LEAK
1	Before pneumoperitoneum	32.85 cm H2O	21.55 cm H2O	11.3 cm H2O
2	After 5 minutes of pneumoperitoneum	34.O2 cm H2O	22.43 cm H2O	11.59 cm H2O
3	20 minutes thereafter	34.43 cm H2O	23.65 cm H2O	10.78 cm H2O
4	40 minutes thereafter	34.66 cm H20	23.76 cm H2O	10.90 cm H2O

TABLE 5 . PERIOPERATIVE HAEMODYNAMIC RESPONSE					
PARAMETERS	BEFORE INSERTION	AFTER INSERTION	DURING PNEUMOPERITONEUM		
			AT 1 MIN	AT 5 MIN	AT 10 MIN
Heart rate (/min)	84.55 ± 7.94	85.12 ± 14.6	85.35 ± 6.72	86.00 ± 7.61	85.00 ± 12.2
SBP (mmHg)	122.9±10.3	115 ± 9.5	128.4 ± 16.4	123.3 ±11.2	122.7± 9.7
DBP (mmHg)	80 ± 7.7	74.6 ± 6.9	83.3 ± 11.9	76.5 ± 10.5	73.8 ± 8.6
MAP (mmHg)	94.3 ± 8.3	91.7 ± 6.0	90.3 ± 12.6	89.77 ± 10.2	91.1 ± 9.0