Comparison of the Air-Q intubating laryngeal airway with the Proseal laryngeal mask airway in elective surgeries: A randomized controlled study

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Article Info
Received: 21st January, 2019
Accepted: 20th June, 2019
Published Online: 22nd August, 2019
Keywords: Air-Q ILA, P-LMA, Controlled ventilation, Elective surgeries.

Abstract
Introduction: P-LMA has proved its superior ability to be used reliably with or without positive pressure ventilation. The new Air-Q ILA is relatively a new supraglottic device, easy to insert because of pre-shaped curve.

Materials and Methods: 80 patients undergoing short elective surgeries under general anaesthesia were randomly allocated to group A (Air Q) or group P (PLMA). General anaesthesia was given with standard dose of Propofol and supraglottic airway devices were inserted according to groups. Lungs were ventilated with control mode of mechanical ventilation. Parameters observed were effective airway time, ease and attempt of device insertion, airway seal pressure, ventilatory parameters, fibreoptic evaluation of vocal cords, vitals and perioperative complications. Statistical analysis was done with Medcalc software using ‘Z’ test and Chi square test.

Results: The mean airway seal pressure of Air-Q was lower (23.95±1.709 cm of H₂O) as compared to P-LMA (25.53±2.07 cm of H₂O) which was statistically highly significant (p=0.0004). The fibreoptic evaluation of vocal cords revealed grade I/II/III view in 37/2/1 cases of Air-Q and in 1/30/9 cases of P-LMA (p=0.0001).

Conclusion: The newer supraglottic device Air-Q is easy to insert and has an acceptable airway sealing pressure, hence can be used for controlled ventilation for short duration surgeries.

Introduction
Managing airway is one of the most important skills to master in the anesthesia profession. Supraglottic airway devices (SAD) are being routinely used in airway management, filling a niche between the face mask and tracheal tube in terms of both anatomical position and degree of invasiveness. Proseal laryngeal mask airway (LMA), introduced in 1999 is being widely used for airway management in general anaesthesia with controlled as well as spontaneous ventilation. It is designed to conform to the contours of the hypo pharynx, with its lumen facing the laryngeal opening.

In 2004, Dr. Daniel Cook, developed a new supraglottic airway device, Air-Q™ intubating laryngeal airway (ILA) which not only offers route for good ventilation but also a safe conduit for tracheal intubation. Its design includes a large and oval shaped airway tube, a short airway tube length and a tethered, removable standard 15-mm circuit adapter with the integrated bite block which makes its insertion easier. On cuff inflation, the built-up mask heel and the ridges move against the posterior pharynx and improve the anterior mask seal which isolate the oesophagus and reduce the incidence of aspiration. Currently, literature regarding Air Q™ ILA being used for ventilation is limited. Previous study demonstrated easy insertion of Air Q™ than the Proseal LMA with comparable airway pressure of both the devices. Therefore, a prospective randomized controlled study was undertaken with the primary outcome to compare the time to establish effective airway using Air-Q™ ILA and Proseal LMA. The secondary outcomes were ease and attempt of insertion, airway seal pressure, fibreoptic evaluation of vocal cords, ventilatory parameters and complications.

Materials and Methods
This clinically oriented, prospective, randomised, controlled trial was carried out from December 2015 to December 2016, after taking approval from scientific and ethical research committee (Clinical trial registration no. CTRI/2017/03/008056). Sample size calculation was done from the previous literature. Using ‘n-Master 2.0’ software, for confidence interval 95%, α error - 0.05, β error - 0.02 and 80% statistical power, a sample size of 78 required, which was rounded off to 80.

Henceforth, 80 adult patients of 18-60 years of either sex, weighing 40-80 kg with body mass index (BMI) ≤ 25, belonging to American society of anaesthesia (ASA) status I and II and Mallampatti grade I and II, scheduled for elective short surgical procedures (≤ 2hours) selected for the study. A detailed medical history and physical examination including the airway assessment and basic laboratory investigations were carried out.

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http://doi.org/10.18231/f.ijca.2019.067
Patients not willing for participation, having obesity (BMI ≥ 30), upper respiratory tract infection, gastroesophageal reflux disease, oropharyngeal pathology and pregnancy were excluded from the study. They were explained in detail about the purpose, procedure of the study and device with possible side effects. The patients were randomly assigned by sealed envelope to one of two groups. In group A (n=40), Air-Q® ILA and in group P (n=40), Proseal LMA was used for ventilation. A written informed consent was taken from all and kept fasted according to standard protocol. On arrival to operation theatre, multiparam monitor was attached, and baseline vital parameters were recorded. All patients were premedicated with injection tramadol 2mg/kg and injection dexmedetomidine 0.5µg/kg intravenously, 10 minutes before induction.

We have used Air-Q® size 3.5 for females and 4.5 for males as recommended by the literature. While, manufacturer recommends to use Air-Q® size 3.5 for patients weighing 50-70 kg and 4.5 for weighing > 70 kg. Proseal LMA size 3 was used for females and size 4 was used for males as per manufacturer and literature recommendation.

Preoxygenation was done for 3 minutes through face mask and closed circuit with O₂ flow 6 litres/min using the anesthesia work station (Fabius plus or Astiva). Induction of general anesthesia was performed with injection propofol 2 mg/kg and injection succinylcholine 1.5 mg/kg intravenously; the device was inserted after adequate jaw relaxation and fixed after confirmation of proper placement. Before placement, the devices were tested for leaks and lubricated on the tip and posterior surface with water-soluble surgical gel. The Air-Q® was inserted as per the manufacturer and literature recommendation. The Proseal LMA was inserted using the digital technique. The cuff of Air-Q® was inflated with 15-20cc of air and that of Proseal LMA with 25-30cc of air according to the size. All the devices were inserted by an anaesthesiologist having an experience of minimum 25 insertions of Proseal LMA and Air-Q®.

Proper placement of device was confirmed by absence of audible air leak with ventilation and square wave capnography. The effective airway time was considered from the time interval from picking up the device to obtaining the first end tidal carbon dioxide trace. Number of attempts taken to insert the device was recorded. Ease of insertion of the device was graded as 1. No resistance to insertion, 2. Resistance to insertion and 3. Difficult to insert.

Lungs were ventilated with volume control mode of mechanical ventilation with the ventilatory settings included I:E ratio- 1:2, tidal volume 8-10ml/kg, respiratory rate-12/min and fresh gas flow 3 liter/min. Anesthesia was maintained using O₂+N₂O (50:50) with sevoflurane and intravenous vecuronium bromide.

The airway seal pressure was measured by leak test. After 5 minutes of established airway, expiratory valve of breathing system was closed and at a fixed fresh gas flow of O₂ at 3l/min the airway pressure at equilibrium or when there was audible air leak from the throat was noted. The maximum pressure allowed was 40cm of H₂O. The fiber optic evaluation for the position of the glottis in relation to airway device was carried out and the grading was done.

Grade I: only vocal cords seen
Grade II: vocal cords and posterior surface of the epiglottis seen.
Grade III: the vocal cords and the anterior lip of the epiglottis are seen.
Grade IV: the anterior surface of the epiglottis is seen therefore encroaching on the view of vocal cords obstructing <50% of view.
Grade V: the epiglottis is completely obstructing the device opening, no view is seen.

Maximum two attempts were allowed to secure the airway. If airway was not secured even on two attempts, device was removed, and airway was secured with appropriate size endotracheal tube and the case was excluded from the study.

Vitals (heart rate, electrocardiogram, systolic blood pressure, diastolic blood pressure, SpO₂, EtCO₂) and ventilatory parameters (peak airway pressure and difference between inspiratory and expiratory tidal volume) were monitored at different time intervals throughout the procedure.

At the completion of surgery and after returning of spontaneous respiration, reversal agent was given and after fulfilling the criteria for extubation, device was deflated, removed and checked for presence of blood stain or any secretion. Perioperative complications like hypoxia (SpO₂<95%), blood stain on the device, sore throat, nausea/vomiting were noted.

Statistical analysis was done using Medcalc software. The parameters on continuous scale including the primary one, ‘effective airway time’ and others like age, height, weight, airway seal pressure and ventilatory parameters were presented as mean±SD and analysed using ‘Z’ test (standard error of difference between two means). Chi-square test was applied for categorical parameters like gender, ASA grading, ease and attempts of device insertion as well as complications. The results were considered significant if p value was <0.05.

Observations and Results

All 80 patients were analysed. There was no drop out. (Chart 1) Demographically, both the groups were comparable. (Table 1)

Insertion time to achieve effective airway for Air-Q® ILA and Proseal LMA was similar. (p=0.056) The mean airway seal pressure in group A was lower (23.95±1.709 cm of H₂O) as compared to group P (25.53±2.07 cm of H₂O) which was statistically significant (p=0.0004). (Table 2)

In group A, in 35/40 (87.5%) patients and in group P, in 34/40 (85%) patients the device was easily inserted. First attempt insertion was possible in 35/40 (87.5%) patients in group A and 37/40 (92.5%) patients in group P. Thus, ease and attempts of insertion of Air-Q® ILA and Proseal LMA were comparable in both groups. (Table 2)
No significant difference found between the two groups with respect to ventilatory parameters. (Graphs 1 and 2)

The fibreoptic evaluation of vocal cords revealed grade I/II/III view in 37/2/1 cases of Air-Q and in 1/30/9 cases of P-LMA, suggested a better fibreoptic view of glottis in group A compared to group P. The difference was statistically significant (p=0.0001). (Table 2)

After removal of airway device, blood staining was seen in 3/40 (7.5%) patients in both the groups. There was no incidence of nausea/vomiting in either group. Sore throat was seen in 4/40(10%) patients in group A and 1/40 (2.5%) in group P which was statistically not significant (p=0.356).

Table 1: Demographic data

| Parameters          | Group-A       | Group-P       | P value |
|---------------------|---------------|---------------|---------|
| Age (years)         | 39.4±12.27    | 37.45±12.717  | 0.4873  |
| Sex M:F             | 27:13         | 26:14         | 0.8142  |
| Height (cm)         | 163.825±8.635 | 162.125±7.25  | 0.3432  |
| Weight (kg)         | 57.1±8.403    | 55.625±6.283  | 0.3767  |
| BMI kg/m²           | 22.24±2.59    | 22.36±2.94    | 0.8469  |
| Duration of surgery (minutes) | 66.37±28.397 | 64.75±26.48  | 0.7926  |
| ASA grading ASA I:II | 33:7         | 30:10         | 0.4152  |
Table 2: Airway Parameters

| Parameter                                      | Group A          | Group P          | p value |
|------------------------------------------------|------------------|------------------|---------|
| Effective airway time                          | 18.963±2.74      | 17.9±2.12        | 0.0561  |
| Mean airway seal pressure                       | 23.95±1.709      | 25.53±2.07       | 0.0004  |
| Ease of device insertion                        | 35/5/0           | 34/6/0           | 0.7470  |
| Grade I/II/III                                 |                  |                  |         |
| Attempts of device insertion                    | 35/5             | 37/3             | 0.4589  |
| First/Second                                   |                  |                  |         |
| Fiberoptic evaluation of glottic visualization  | 37/2/1/0         | 1/30/9/0         | 0.0001  |
| Grade I/II/III/IV                              |                  |                  |         |

Graph 1: Mean peak airway pressure (Cm of H2O)

Graph 2: Difference between inspiratory and expiratory tidal volume (Mililitres)

Discussion

Among all SADs, Proseal LMA is the “gold standard” second generation supraglottic airway device used for airway management during general anaesthesia.9 The Air-Q™ intubating laryngeal airway is relatively a new supraglottic airway device. Few literatures proved its efficacy when used for controlled ventilation in adults and children.3,5,7,10,11

We found comparable mean effective airway time in both the groups. R E Galgon et al inserted Proseal LMA using gum elastic bougie which might have taken longer time to insert the Proseal LMA compared to Air Q™ in their study.3 On comparing with I gel, less time was required to establish airway with Air-Q™ which could have been due to the need for continuous downward traction for I gel insertion.11
Not a single case of difficult insertion was seen in either of the group. The semi inflated anterior part of the wide cuff of Air-Q™ minimizes the folding back of the cuff’s tip during insertion and short airway tube with the integrated bite block promotes easy insertion of Air Q.  

Timmermann et al postulated a seal pressure of at least 20 cm H2O in combination with a square wave capnogram to classify an airway to be sufficient.15 The sealing pressure of Air-Q™ (23.95±1.709 cm H2O) achieved in our study was lower than the Proseal LMA (25.53±2.07 cm H2O), but was enough for adequate ventilation and higher than the critical pressure recommended in adults to prevent aspiration.16 Design features unique to the Air-Q™ that are likely to improve its airway seal pressure include: (1) an anterior curve of the airway tube that better approximates the upper airway and provides a more stable end-to-end coupling with the glottis; (2) mask ridges that improve the transverse stability of the bowl and support the lateral cuff seal; and (3) a higher posterior heel height, which improves the seal at the base of the tongue.5,12-14

Data are available to reveal the seal pressure of Air-Q™ to be comparable to second generation SADs3,6,7,17 Keller et al demonstrated that over-inflation of the c LMA resulted in a decline in airway seal pressure.18 If this holds true for the Air-Q™, then the mean airway seal pressure observed in our study may have been underestimated.

The chosen sizes of devices were appropriate as no difference was found between the two groups in any ventilatory parameters which suggest that there was no cuff leakage. No difficulty was found using both the devices for controlled ventilation. Till now, none of the studies observed the ventilatory parameters.

We found better fibreoptic view of glottis in group A compared to group P. Our finding offers evidence to support the potential ability of Air-Q™ to fulfill a role as a bridging airway that facilitates fibreoptic endotracheal intubation as suggested by previous studies.6,19,20 All patients remained hemodynamically stable throughout the perioperative period in both the groups. Blood staining was seen in 7.5% of patients in both the groups and sore throat was observed in 10% of patients in group A and 2.5% of patients in group P. They were reassured and managed with hot water gargles.

Limitation of our study was being the small sample size. Though statistical differences have been noted, the impact of these differences on the clinical level is minor. As a secondary outcome, a decreased incidence of sore throat was found, which did not allow concluding, given the reduced sample, on the traumatic character or not of the Air-Q™. 

Conclusion
We conclude that the newer supraglottic airway device Air-Q can be used for controlled ventilation for short duration surgeries as it is easy to insert and has an acceptable airway sealing pressure.

Conflict of Interest: None.

Funding: None.
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How to cite this article: Moorthy PVC, Desai D, Upadhyay MR. Comparison of the Air-Q intubating laryngeal airway with the Proseal laryngeal mask airway in elective surgeries: A randomized controlled study. Indian J Clin Anaesth 2019;6(3):349-54.