A study to evaluate and compare intubating laryngeal mask airway and air-Q intubating laryngeal airway for intubation using Parker Flex Tip tube

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ABSTRACT

Background and Aims: Though manufacturer recommendations suggest use of specific endotracheal tube (ETT) with intubating laryngeal mask airway (ILMA) and air-Q intubating laryngeal airway (ILA), Parker Flex Tip tube introduced by J D Parker has certain advantages and is also cost-effective. This study was conducted to compare ILMA and air-Q ILA for intubation using Parker Flex Tip tube. Methods: Patients of either gender, aged 18–60 years, scheduled for elective surgery requiring endotracheal intubation were included in this study. In group A (n = 55), blind intubation was done through ILMA using Parker Flex Tip tube and in group B (n = 55), blind intubation was done through air-Q ILA using Parker Flex Tip tube. Success rate, number of attempts, ease and a total time of intubation were recorded. Results: Intubation was successful in 54 patients (98.2%) in group A and in 46 patients (85.2%) in group B (P = 0.026). Intubation was significantly easy with ILMA (P = 0.048). Manoeuvres for intubation were used in 10.9% patients in group A while it was used in 27.8% patients in group B. Significantly, more manoeuvres were required with air-Q ILA for intubation (P = 0.026). Number of attempts for ETT placement (P = 0.092), insertion time of ETT (T_{τ}) (P = 0.472) and total time taken for successful intubation (P = 0.526) were comparable in both the groups. Conclusion: The intubating laryngeal mask airway was superior to the air-Q intubating laryngeal airway for blind intubation using Parker Flex Tip tube.

Key words: Air-Q intubating laryngeal airway, intubating laryngeal mask airway, intubation, Parker Flex Tip tube

INTRODUCTION

management for Airway is а crucial skill Significant anaesthesiologists. morbidity and mortality in anaesthesia have been shown to result from inadequate knowledge and experience in airway management. Hence, good practice and familiarity with a variety of airway techniques and devices are essential for anaesthesiologist. In the last few years, a number of supraglottic airway devices (SADs) have been introduced in clinical practice. These devices are of great importance for patients with difficult tracheal intubation or where intubation is impossible.^[1]

The intubating laryngeal mask airway (ILMATM) was designed specifically to facilitate tracheal intubation. A relatively new supraglottic airway device, air-Q ILA (product of Cookgas[®] company) is an alternative to ILMA to facilitate endotracheal intubation. The advantages of air-Q over ILMA are that the breathing tube of the device is shorter, wider and due to removable connector, a standard endotracheal tube (ETT) can also be easily placed.^[2]

A dedicated wire reinforced silicone ETT is advocated for intubation through the ILMA. However, the low

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volume and high-pressure cuff of this tube make it less suitable for prolonged use. Also, it is very expensive and not so easily available. Parker Flex Tip tracheal tube (product of Parker Medical Company) has a curved, centred, flexible and tapered distal tip that is designed to facilitate easy, rapid and non-traumatic intubation. It is having double murphy eyes with an anterior curvature and a posterior opening bevel. It is designed so that the posterior bevel will decrease the incidence of the tube catching at the anterior or the lateral laryngeal structures during tracheal intubation.^[3] Manufacturers recommend the use of polyvinyl chloride (PVC) tubes for intubation through air-Q ILA. Various studies have been conducted using ILMA and air-Q as a conduit for endotracheal intubation.[2-5]

There is only one study in literature in which Parker Flex Tip tube was used for intubation through ILMA. The study was conducted by Kanazi et al. who compared silicone wire-reinforced tube with the Parker Flex Tip tube and conventional PVC tube for tracheal intubation through ILMA. These authors noted that minimal manipulation improved the success rate of intubation with the Parker Flex Tip tube through the ILMA and hence providing a possible alternative to the silicone wire-reinforced tube.^[3] This prompted us to undertake this prospective randomised study comparing ILMA and air-Q ILA for intubation using Parker Flex Tip tube. Parker Flex Tip tube can be a cheap alternative to recommended silicone wire-reinforced tube for ILMA. But there is no study in the literature regarding usage of Parker Flex Tip tube through air-Q for which conventional PVC tube is recommended. The primary objective was to compare ILMA and air-Q ILA for intubation using Parker Flex Tip tube with regards to the overall success rate. Secondary objectives were a number of attempts for tube placement, insertion time for the tracheal tube, manoeuvres required during insertion of ETT, ease of placement of tracheal tube and total time are taken for successful intubation. We hypothesised that air-Q ILA would have an overall success rate for intubation similar to that of ILMA using Parker Flex Tip tube.

METHODS

This was a prospective randomised single-blind study. Total of 110 patients of either sex aged 18–60 years belonging to American Society of Anaesthesiologists (ASA) physical status I or II scheduled for elective surgery under general anaesthesia with endotracheal intubation were included in the study. Duration of the study was from Jan 2018 to Dec 2018. The ethical clearance was taken from the institutional ethical committee and the trial was registered (CTRI/2018/11/016466). Written informed consent from all participants was obtained for participation in the study, and the study was conducted in accordance with the principles of Declaration of Helsinki. Patients with respiratory or pharyngeal pathology, mouth opening <2.5 cm, body mass index \geq 35 kg/m², pregnancy and anticipated difficult airway were excluded from the study.

All the patients were examined during the preoperative visit a day prior to surgery and subjected to a detailed clinical history and complete general physical as well as systemic examination. Routine investigations such as haemoglobin, bleeding time, clotting time and urine examination were carried out in all the patients as per institute protocol. Other investigations were carried out as per requirement.

The purpose and protocol of the study were explained to the patients. Patients were kept fasting for 6 h prior to the scheduled time of surgery. They were premedicated with tablet alprazolam 0.25 mg and tablet ranitidine 150 mg night before and in the morning 2 h before surgery. In the operating room, all standard monitoring including heart rate, ECG, non-invasive blood pressure (NIBP) and pulse oximetry (SpO₂) were established and baseline readings were recorded. Patients were randomly allocated to one of the two groups using a computer-generated sequence of random numbers. In group A (n = 55), blind intubation through ILMA was done using Parker Flex Tip tube and in group B (n = 55), blind intubation through air-Q ILA was done using Parker Flex Tip tube.

Standardised anaesthesia protocol was followed and all the intubations were done by a fixed performer. A peripheral intravenous line was secured with an 18 gauge cannula. Preoxygenation for 3 min was done with 100% oxygen. Induction of anaesthesia was done with intravenous doses of glycopyrrolate 0.005 mg/kg, fentanyl 2 μ g/kg and propofol 2 mg/kg. An additional increment of propofol intravenous (IV) was given until loss of response to verbal command was achieved. After achieving adequacy of ventilation neuromuscular blockade was achieved with vecuronium 0.1 mg/kg IV. Patients were ventilated for 3 min via facemask and anaesthesia breathing system with 2% sevoflurane in 100% oxygen. An appropriate size ILMA or air-Q ILA

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was selected as per manufacturer's recommendation according to the weight of the patient. Airway device was checked before use as recommended and lubricated with water-based gel. In neutral position airway devices were introduced using the standard technique for insertion. The correct placement of the device was confirmed by chest auscultation, adequate chest rise with manual positive pressure ventilation and capnography. In event of complete or partial airway obstruction or air leak, the device was repositioned, removed and reinserted. A maximum of three attempts were taken failing which an alternative method to secure the patient's airway was used and the patient was excluded from the analysis. Fibreoptic grading of the glottic aperture was done after the successful placement of the device.^[6] After that, fibrescope was removed and an appropriate sized Parker Flex Tip tube was passed through the shaft of airway devices in both the groups. Gentle advancement of the tube was done in trachea without undue force. The cuff was inflated and the circuit was connected. Correct tube placement was confirmed by adequate chest rise with manual positive pressure ventilation, capnography and chest auscultation. If unsuccessful, for 2nd attempt, in case of ILMA gentle rotation of the handle in and out and side-to-side movement was done and then the handle was lifted anteriorly.^[2] For the third attempt, in addition, to manoeuvre for second attempt 180° counter clockwise rotation of tube was done. In the case of air-Q ILA, for second attempt head extension was used and head extension with cricoid pressure was used for the third attempt.^[7] After that, the airway device was taken out keeping ETT in place. A total of three attempts were allowed. In case of failure, endotracheal intubation was done by using direct laryngoscopy.

Number of attempts for airway device insertion, insertion time of airway device (T_D) , ease of placement of device, fibreoptic grading, number of attempts for tube placement, insertion time for tracheal tube (T_T) , manoeuvres required during insertion of ETT, ease of placement of tracheal tube, time taken for removal of airway devices (T_R) , total time taken for successful intubation and complications were recorded.

An attempt was defined as correct placement of device assessed by adequate chest rise with no audible leak, chest auscultation and capnography. Insertion time of airway device (T_D) was taken as the time from picking up the device until the appearance of the capnograph waveform. A maximum of three attempts were allowed for device insertion. The insertion time was the sum of all the attempts taken. Ease of placement of device was graded as easy if the device was placed in a single attempt, difficult if more than one attempt was required to place the device (2-3) and >3 attempts were taken as a failure. Fibreoptic grading was assessed as 1) vocal cords fully visible, 2) vocal cords partially visible or arytenoid cartilages visible, 3) epiglottis visible and 4) no laryngeal structures visible.

For intubation, an attempt was considered if definite resistance was felt while tube insertion or oesophagal intubation occurs. A maximum of three attempts were considered for intubation. If in maximum three attempts, intubation was successful, it was taken as a success. In three attempts, if intubation was not successful, it was considered as a failure of intubation. Insertion time for the tracheal tube (T_{T}) was taken from the moment of picking up the tracheal tube until confirmation of correct placement by capnography. If no capnograph was detected, the tracheal tube was removed and reinserted using manoeuvre. The time of the second and third attempts was similarly recorded. Insertion time was a sum of all attempts excluding time interval between attempts. Ease of placement of tracheal tube was graded as easy if the placement of ETT was successful in a single attempt, difficult if more than one attempt was required to place the tube (2-3)and failure for >3 attempts. Time taken for removal of airway devices (T_{R}) was taken as the time from the successful placement of ETT through the device to confirmation of ETT placement after removal of the device from the oral cavity. The total time taken for successful intubation was taken as time from picking up the airway device till the removal of device from the oral cavity after correct placement of TT and was the sum of various times that is $T_{D+}T_{T} + T_{R}$.

Grossly visible blood on airway device as evidence of trauma was noted after the removal of the airway device. Complications such as sore throat, hoarseness of voice and dysphagia were recorded after 1 h of shifting of the patient to post-anaesthesia care unit in both the groups by the data collector.

Karim *et al.* reported an overall success rate of 99% with ILMA and 77% with air-Q ILA.^[2] Our estimated sample size was based on study efficacy in terms of the success rate between the two groups. For the sample size calculation, we defined a relevant clinical difference of 19% in success rate as an outcome between two groups.

We chose an 80% baseline ratio of success rate in group B based on the reference study and our hospital experience. Thus, the sample size of 53 patients per group provided a 90% power for detecting a significant difference between two groups at an alpha level of 0.05. However, we included 55 patients per group to counteract any dropouts in the study.

Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables were presented as mean \pm SD and categorical variables were presented as absolute numbers and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student's *t*-test. Nominal categorical data between the groups were compared using the Chi-squared test. *P* value <0.05 was considered statistically significant.

RESULTS

A total of 110 patients were scrutinised, randomised and allocated. Insertion of airway device was successful in all the patients in group A. So, 55 patients were analysed for intubation in group A. Air-Q ILA could not be inserted and resulted in failure in one case. Hence, 54 patients were analysed statistically for intubation in group B [Figure 1]. The two groups were comparable with respect to age, weight and sex distribution. The mean age of patients in group A was 41.62 ± 12.76 years and in group B it was 40.56 ± 12.60 years (P = 0.664). There were 37 females and 18 males both in group A and group B (P = 1.000). The mean weight of patients in group A was 60.07 ± 8.53 kg and in group B was 60.20 ± 9.99 kg (P = 0.943).

The two groups were comparable with respect to the number of attempts (P = 0.568), ease for airway device insertion (P = 0.568), fibreoptic grading and removal time of airway device [21.06 ± 7.19 sec in group A vs 22.00 ± 6.95 sec in group B (P = 0.508)]. However, mean time required for device insertion was 20.07 ± 7.75 sec in group A while in group B it was 25.56 ± 14.80 sec (P value = 0.018).

Intubation was successful in 54 cases (98.2%) in group A and 46 cases (85.2%) in group B (P = 0.026) [Table 1]. Odds ratio of failure rate for group B as compared to group A was 9.39 and its 95% CI is 1.132-77.909. Number of attempts for ETT placement (P = 0.092) and insertion time of ETT (22.80 ± 10.62 s in group A vs 21.30 ± 9.94 s in group B) [P = 0.472] were

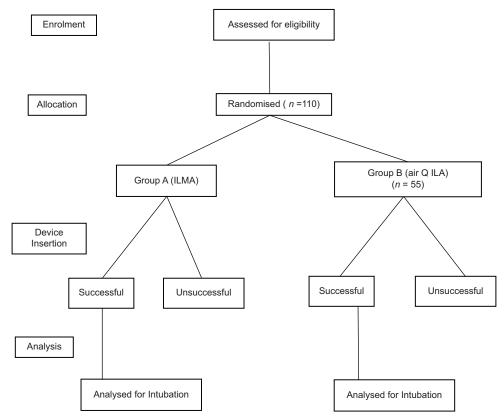


Figure 1: Consort diagram

comparable in both the groups [Table 1]. Manoeuvres for intubation were used in 10.9% patients in group A while it was used in 27.8% patients in group B (P = 0.026) [Table 2]. Intubation was significantly easy in group A (89.1%) as compared to group B (72.2%) ([P = 0.048] [Table 2]). Total time taken for successful intubation was comparable in both the groups (63.74 ± 17.82 s in group A vs 66.13 ± 19.73 s in group B) ([P = 0.526] [Table 2]).

Blood on the device was present in 11 cases (20%) in group A while it was present in 12 cases (22.2%) in group B (P = 0.776). Dysphagia was reported in one case (1.8%) in group A while it was not reported in group B (P = 1.000). No hoarseness of voice was reported in group A while it was present in two cases (3.7%) in group B (P = 0.243). The sore throat was not present in any of the cases in group A while it was present in three cases (5.6%) in group B (P value = 0.118).

DISCUSSION

The overall success rate of intubation was significantly more in the ILMA group as compared to the air-Q ILA group [Table 1]. The present study is in accordance with different studies though both these authors used manufacturer-recommended ETT through the study devices.^[2,8] The success rate after the first attempt of successful intubation via an ILMA using the silicone wire-reinforced ETT, Parker Flex Tip tube and PVC

| Table 1: Success rate of intubation | | | | |
|---------------------------------------------|-------------------------|-------------------------|-------|--|
| Intubation success | Group A (<i>n</i> =55) | Group B (<i>n</i> =54) | Р | |
| Yes | 54 (98.2%) | 46 (85.2%) | 0.026 | |
| Failure | 1 (1.8%) | 8 (14.8%) | | |
| No of attempts for successful intubation | | | | |
| 1 st attempt | 49 (89.1%) | 39 (72.2%) | 0.092 | |
| 2 nd attempt | 4 (7.3%) | 6 (11.1%) | | |
| 3 rd attempt | 1 (1.8%) | 1 (1.9%) | | |
| Insertion time of ETT | | | | |
| TT (sec) | 22.80±10.62 | 21.30±9.94 | 0.472 | |

| Table 2: Manoeuvres required | | | |
|------------------------------|-------------------------|-------------------------|-------|
| Manoeuvres | Group A (<i>n</i> =55) | Group B (<i>n</i> =54) | Р |
| Yes | 6 (10.9%) | 15 (27.8%) | 0.026 |
| No | 49 (89.1%) | 39 (72.2%) | |
| Ease of intubation | | | |
| Easy | 49 (89.1%) | 39 (72.2%) | 0.048 |
| Difficult | 5 (9.1%) | 7 (13.0%) | |
| Failure | 1 (1.8%) | 8 (14.8%) | |
| Total time taken for | | | |
| successful intubation | | | |
| Total time(s) | 63.74±17.82 | 66.13±19.73 | 0.526 |

tube were 90%, 54% and 48%, respectively in a study.^[3] These authors observed that after manipulation, the success rate did not change for silicone wire-reinforced tube whereas it increased in Parker Flex Tip tube and PVC ETT to 86% and 57% respectively.^[3]

The result of the present study is in contrast to a study in which authors observed an overall better success rate for intubation with air-Q ILA as compared to ILMA [(96.6%) vs (91.6%)].^[9] These authors used standard PVC ETT through air-Q ILA in case of failure of intubation in the first attempt which might be the reason for the increased success rate with this device.

In the present study, the mean time required for ILMA insertion was less as compared to air-Q ILA (20.07 \pm 7.75 sec vs 25.56 \pm 14.80 sec (*P* value = 0.018). Results of the present study are similar to different studies in terms of time taken for device insertion.^[5,10] However, these results are different from studies in which very little time was observed with air-Q ILA as compared to the ILMA group.^[9,11] Less time was taken for air-Q ILA insertion as compared to ILMA by these authors might be due to the use of tongue depressor for air-Q ILA insertion which created adequate space for the insertion of air-Q ILA leading to a lesser time.

In the present study, a number of attempts for intubation were comparable in both the groups [Table 1]. Comparable results were observed by various authors regarding the number of attempts for intubation though most of the authors used the manufacturer's recommended ETT via the study devices.^[5,9-11] ILMA was found to be better than air-Q ILA for intubation.^[8] In their study, intubation was done with reinforced silicone tube through ILMA and conventional ETT was used via air-Q ILA and difference was found to be statistically significant. These authors postulated that provision of the handle on the ILMA, together with its rigid metal body, allowed manoeuvrability when aligning its lumen with the tracheal inlet.^[8]

The result of the present study [Table 1] is similar to different studies regarding the insertion time of intubation.^[7,12] Both of these authors used manufacturer-recommended tubes for intubation. Longer time for intubation via ILMA was observed as compared to air-Q ILA in a study.^[11] This might be due to the fact that unlike the present study these authors used fibreoptic for intubation through both the groups and duration of insertion of the endotracheal tube were calculated from the time fibreoptic entered the device until the anaesthesia circuit was reconnected to the tracheal tube. Statistically longer time was observed with air-Q ILA as compared to ILMA for intubation in another study.^[5] The difference observed by these authors can be due to the usage of manufacturer-recommended ETT in their studies as compared to the use of Parker Flex Tip tube in the present study. Intubation was significantly easy in group A (89.1%) as compared to group B (72.2%) in the present study [Table 2]. These results are in agreement with the results of a study in which authors observed more ease of insertion via ILMA as compared to air-Q ILA though they used conventional PVC ETT with air-Q ILA and reinforced silicone ETT with ILMA.^[8] In contrast in another study, the same ease of intubation was observed between ILMA and air-Q ILA in which standard recommended ETT was used.^[9]

Regarding the total time taken for intubation, the result of the present study [Table 2] is similar to a study even though these authors used silicone ETT for intubation through ILMA.^[7] In contrast, more time was taken for successful intubation via ILMA as compared to air-Q ILA ($130 \pm 35 \text{ sec vs } 105 \pm 36 \text{ sec}$).^[9] Authors stated that as they used Chandy's manoeuvre while intubation through ILMA, that might have resulted in an increase in intubation time via ILMA resulting in an increase in total intubation time.

Overall, the number of patients with air-Q ILA had an increased rate of complications as compared to ILMA except for dysphagia which was seen only in one patient that too with ILMA Results are consistent with findings of various authors.^[5,7,10,12]

There are manufacturer recommendations for ILMA and air-Q ILA. Many a time, ETTs either due to its cost factor or other reasons are not available with the users. Parker Flex Tip tube introduced by J D Parker has certain advantages like it has a flexible, curved, centred, tapered distal tip that facilitates rapid, easy and non-traumatic intubation and is also cost-effective. There are a few limitations to the present study. Patients with normal airways were included in this study. Hence the results may differ in patients with difficult airways. Another limitation was the inability to blind the observer and data collector. Further, airway morbidity should have been assessed for a longer duration. In this study, the only first-hour parameter was assessed which also adds to the limitation of the study.

CONCLUSION

In the present study, the overall success rate using Parker Flex Tip tube was more with ILMA (98.2%) as compared to air-Q ILA (85.2%). It can be further suggested that Parker Flex Tip tube can be used as an alternative to silicone tube with ILMA but more multicentre studies are required over larger population to evaluate the utility of Parker Flex Tip tube with air-Q ILA.

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Conflicts of interest

There are no conflicts of interest.

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