Original Article

Comparison of conventional with Parker flex-tip tracheal tube for intubation through air-Q intubating laryngeal airway

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Abstract

Background and Aims: The problem of difficult and failed intubation led to increased development of equipment for airway management. A number of supraglottic airways have now been developed to facilitate the passage of tracheal tubes. Conventional PVC tracheal tubes are recommended for intubation through the air-Q ILA. No study has compared different PVC tubes for blind intubation through air-Q ILA. Thus, we undertook this prospective, randomised, single blind study to compare two PVC tracheal tubes with different designs viz. conventional PVC tracheal tube (TT) and Parker flex-tip TT with regards to success rate, ease of intubation and total time required for successful intubation through air-Q ILA.

Material and Methods: One hundred patients of either sex, aged 18–60 years, belonging to American Society of Anesthesiologists (ASA) physical status class I and II scheduled for elective surgery under general anesthesia requiring endotracheal intubation were included in the study. Blind intubation using conventional PVC TT and Parker flex-tip tube was done in group A (n = 50) and group B (n = 50), respectively.

Results: The first attempt success rate in Parker flex-tip TT was significantly more as compared to conventional PVC TT (P = 0.002). Success rate of intubation was significantly more in Parker flex-tip TT as compared to conventional PVC TT (P = 0.004). The intubation was significantly easy in Parker flex-tip tube as compared to conventional PVC TT (P = 0.002). Total time of intubation was less in Parker flex-tip tube as compared to PVC TT (P = 0.043).

Conclusion: Unique design of the Parker Flex-tip TT resulted in increase in success rate, first attempt success rate and ease of intubation in group B in present study.

Keywords: Air-Q ILA, Parker flex-tip tube, PVC tracheal tube, tracheal intubation

Introduction

Airway management is a prime responsibility of the anesthesiologist. Tracheal intubation is considered as gold standard for airway management. The problem of difficult and failed intubation led to increased development of equipment for airway management. Supraglottic airway devices have changed the scenario from 'unable to intubate and ventilate' to 'unable to intubate but able to ventilate'.[1] However, there are situations in which supraglottic device is neither desirable nor sufficient and where tracheal intubation is required.

A number of supraglottic airways have now been developed to facilitate the passage of tracheal tubes. Classic laryngeal mask airway (cLMA) has been used as a conduit for tracheal intubation but is not an ideal intubation aid because of its

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diameter and length limitations.[2] Intubating laryngeal mask airway (ILMA), also known as LMA Fastrach was developed to facilitate intubation either blindly or with fibreoptic assistance. However, it requires the use of a dedicated tracheal tube (TT), adding to the overall cost. An alternative device is air-Q intubating laryngeal airway (ILA) [Figure 1]. It was invented by Dr. Daniel Cook and introduced in clinical practice in 2004. It allows airway maintenance for patients under general anesthesia and can also be used as an intubation aid. The manufacturers recommend the use of conventional PVC (Polyvinyl chloride) tracheal tubes for intubation through the air-Q ILA thus reducing the overall cost. The air-Q ILA is manufactured of medical grade silicone and is 100% latex free. It consists of a tube with a distally located large inflatable cuff which is to be positioned in the hypopharynx, thereby providing a cuffed perilaryngeal seal. In comparison to cLMA, the air-Q ILA allows for straightforward passage of cuffed tracheal tubes.[3]

The design and diameter of the TT influences the success rate of tracheal intubation. In contrast to the conventional PVC tube, the Parker Flex-tip tube[4] [Figure 2] has a centrally placed, soft, flexible, curved, centred, distal tip with double murphy eyes and a posterior facing bevel. This design helps it to glide along irregular surfaces and mucous membranes facilitating tracheal intubation.[5]

The manufacturers recommend the use of PVC tubes for intubation through air-Q ILA.[3] Although air-Q ILA has been compared individually with other supraglottic airway devices no study has compared different PVC tubes for blind intubation through air-Q ILA. We undertook this prospective, randomised, single blind study to compare conventional PVC TT and Parker flex-tip TT with regards to success rate, ease of intubation and total time required for successful intubation through air-Q ILA.

Material and Methods

The present study was prospective, randomised and single blind. The trial was registered prior to patient enrolment at CTRI/2017/07/009183 on 31/7/2017. Following approval from local research ethics committee and written informed consent, 100 patients of either sex, aged 18–60 years, belonging to American Society of Anesthesiologists (ASA) physical status class I and II scheduled for elective surgery under general anaesthesia requiring endotracheal intubation were included in the study.

Patients having restricted mouth opening (<2.5 cm), respiratory or pharyngeal pathology, BMI ≥35 kg.m^{-2}, gastroesophageal reflux disease, upper gastrointestinal surgery or pathology and surgery in position other than supine were not included in 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 and systemic examination. Routine investigations like haemoglobin (Hb), bleeding time (BT), clotting time (CT) and urine examination were carried out in all the patients. Other investigations were carried out as per requirement.

The purpose and protocol of the study was explained to the patients. Patients were kept fasting for 6 hours prior to 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 hours before surgery. In the operating room, all routine monitoring including heart rate, ECG, non-invasive blood pressure (NIBP), end tidal carbon

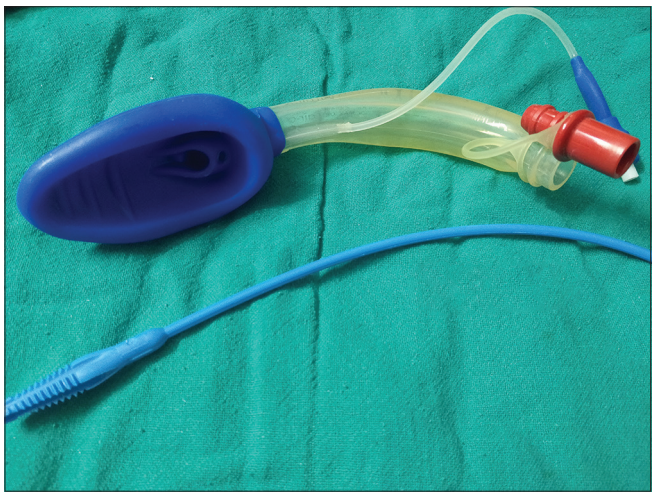

Figure 1: Air Q Intubating laryngeal airway

Figure 2: Polyvinyl chloride tracheal tube. Parker flex tip tracheal tube

dioxide ($EtCO_2$) and pulse oximetry (SpO_2) was established and baseline readings were recorded.

Patients were randomly allocated to one of the two groups using a computer-generated sequence of random numbers as follows:

Group A (n = 50): Blind intubation through air-Q ILA using conventional TT.

Group B (n = 50): Blind intubation through air-Q ILA using Parker flex-tip TT.

A standard anesthesia protocol was followed. Peripheral venous access was secured with 18-gauge cannula. After pre-oxygenation with 100% oxygen for 3 minutes, anaesthesia was induced with glycopyrrolate 0.005 $mg.kg^{-1}$, fentanyl 2 $\mu g.kg^{-1}$ and propofol 2 $mg.kg^{-1}$. Additional increments of propofol were given if required till loss of consciousness and loss of response to verbal commands was achieved. Ability to mask ventilate the patient was judged before giving neuromuscular blocking agent. Muscle relaxation was achieved with intravenous atracurium 0.5 $mg.kg^{-1}$. Patients were ventilated for 3 min via facemask and anaesthesia breathing system using 2% sevoflurane and 100% O_2. An appropriate-sized air-Q ILA was selected as per manufacturer's recommendation according to weight. Prior to placement, the cuff was deflated until dimples appear at the back of the air-Q ILA. The external surface and the cavity ridges were lubricated using water-based gel. Patients were laid in supine position with head in neutral position. Patient's mouth was opened with mandible held upwards and forward. The frontal portion of the air-Q ILA was placed between the base of tongue and the palate. The device was introduced into the pharynx by applying gentle inward and downward pressure until a fixed resistance to forward movement was felt. The cuff was inflated according to manufacturer's recommendation. Confirmation of correct placement of the device was done by capnography, chest auscultation and adequate chest rise with no audible leak. In theevent of complete or partial airway obstruction or air leak, the device was repositioned, or removed and reinserted. A maximum of three attempts were allowed, following which an alternative method to secure patient's airway was used and the patient excluded from the study. After successful placement of the device, a fiberscope was inserted and its tip positioned at the end of the air tube. Grading of glottic aperture was done using the scoring system adapted by Kapila *et al*.[6]

An appropriate-sized, assigned TT was then passed through the shaft of air-Q ILA and gently advanced into the trachea without applying undue force. The cuff of the TT was inflated and connected to the breathing circuit. Correct tube placement was confirmed by capnography and chest rise. The TT was inserted to an adequate depth which was confirmed by the presence of equal, bilateral breath sounds. After that the TT connector was removed and the air-Q ILA taken out using the removal stylet to keep TT in place. Then the TT connector was replaced and tube connected to the breathing circuit. Tracheal position was again confirmed by capnography and bilateral equal breath sounds and tube was secured in place. A total of three attempts were allowed for intubation. Appropriate adjustment manoeuvres such as head extension and cricoid pressure were attempted in sequence to facilitate intubation during subsequent attempts, failing which fibreoptic guided tracheal intubation through air-Q ILA was done.

The following data was recorded:

1. Number of attempts for air-Q ILA insertion:
   An attempt was defined as correct placement of device assessed by adequate chest rise with no audible leak, chest auscultation and capnography.
2. Insertion time of air-Q ILA (T1):
   It was taken as the time from picking up the device till appearance of a capnograph waveform. The insertion time was the sum of all the attempts taken.
3. Oropharyngeal leak pressure:
   Defined as the airway pressure at which a leak was audible after switching off the ventilator at a fixed gas flow of 3.l min^{-1} with the expiratory valve completely closed.
4. Fibreoptic grading:
   1 = vocal cords fully visible
   2 = vocal cords partially visible or arytenoid cartilages visible
   3 = epiglottis visible
   4 = others (ILA cuff, pharynx etc.)
5. Number of attempts for TT placement:
   An attempt was counted if a definite resistance was felt during thetube insertion or if esophageal intubation occurred. A maximum of 3 attempts were allowed.
6. Manoeuvres required:
   Head extension was used for the second attempt. For the third attempt, head extension with cricoid pressure was used.
7. Ease of TT placement:
   Ease of placement was graded as:
   Easy: Placement of TT in single attempt
   Difficult: More than one attempt required to place the tube
   Failure: Inability to secure the airway with TT
8. Insertion time of TT (T2):
   It was taken as time from the moment of picking up of tracheal tube till confirmation of correct placement. The insertion time was the sum of all attempts.

9. Time taken for removal of air-Q (T3):
   It was taken as time from successful placement of TT through air-Q to confirmation of TT placement after removal of device from oral cavity.
10. Total time taken for successful intubation:
    It was taken as time from picking up the air-Q ILA till removal of device from oral cavity after correct placement of TT and was the sum of T1, T2 and T3.
11. Haemodynamic changes
    Systolic BP, diastolic BP, heart rate and SpO_2 were noted. The parameters were recorded after induction, after device insertion, after intubation, at 1 min interval after tracheal intubation for 5 consecutive minutes. Thereafter, they were recorded every 5 min till 15 min.
12. Blood on air-Q ILA after removal and complications such as sore throat and hoarseness of voice were noted in both the groups.

Statistical analysis

A study by Kanazi *et al*. 2008 showed blind intubation success rate of 86% with Parker flex-tip TT against 57% with conventional PVC tube using ILMA as an intubating device.[5] Assuming these as reference values, the minimum required sample size at 5% level of significance and 80% power was obtained as at least 34 patients in each group. Hence, we conducted the study taking 50 patients in each group. The quantitative variables in both groups were expressed as mean ± SD and compared using unpaired *t*-test between groups. The qualitative variables were expressed as frequencies/percentages and compared using Chi-square test. A P value < 0.05 was considered statistically significant.

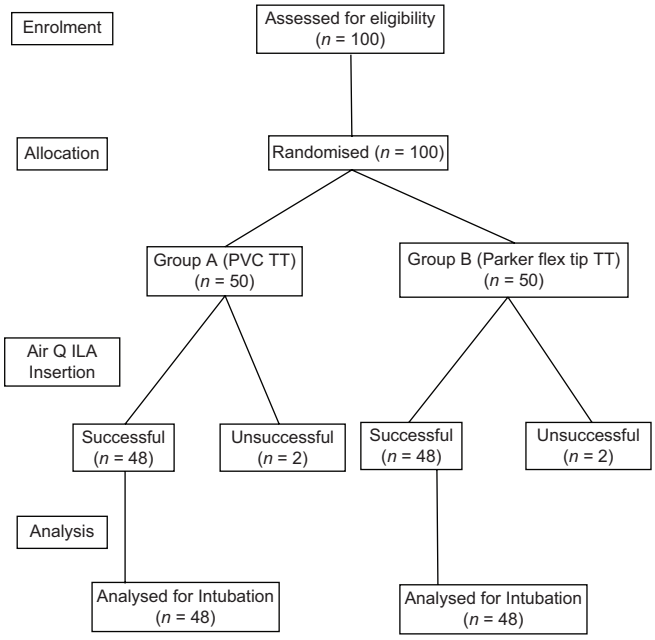

Figure 3: CONSORT diagram

Statistical Package for Social sciences (SPSS) version 15.0 was used for statistical analysis.

Results

A Consort Diagram has been shown in Figure 3. The groups were comparable with respect to age, weight and sex distribution. The mean age of patients in group A was 39 ± 13 years and in group B was 41 ± 14 years (P = 0.378). There were 8 males and 42 females in group A while group B consisted of 16 males and 34 females (P = 0.061). The mean weight of patients in group A was 62 ± 11 kg and in group B was 63 ± 10 kg (P = 0.953).

The two groups were comparable with respect to the number of attempts for air Q ILA insertion (P = 0.512), insertion time of air Q ILA (P = 0.087), oropharyngeal seal pressure (P = 0.626) and fibreoptic grading (P = 0.774). Air Q ILA could not be inserted and resulted in failure in 4 cases (2 patients in each group). Hence 96 patients were analysed statistically for intubation (48 patients in each group).

The first attempt success rate with Parker flex-tip TT was significantly more compared to conventional PVC TT (P = 0.002) [Table 1]. Success rate of intubation was significantly more with Parker flex-tip TT compared to conventional PVC TT (P = 0.004) [Table 2]. Intubation was significantly easier with Parker flex-tip tube compared to conventional PVC TT (P = 0.002) [Table 3]. Time taken for TT insertion through air-Q ILA was less with Parker flex-tip tube compared to PVC TT (P = 0.014) [Table 4]. The two groups were comparable with respect to the removal time of air Q ILA (P = 0.773). Total time of intubation was less with Parker flex-tip tube compared to PVC TT (P = 0.043) [Table 5]. HR, SBP and DBP were statistically comparable at different time intervals.

Table 1: Number of Attempts for Intubation

No. of attempts	Group A (PVC TT)	Group B (Parker flex-tip TT)	*P*	Test
1	29 (60.4%)	44 (91.7%)	0.002	Chi-square
2	2 (4.2%)	2 (4.2%)		
3	5 (10.4%)	0 (0.0%)		
Failure	12 (25.0%)	2 (4.2%)		

Table 2: Success rate of intubation

Success of intubation	Group A (PVC TT)	Group B (Parker flex-tip TT)	*P*	Test
Successful	36 (75.00%)	46 (95.8%)	0.004	Chi square
Failure	12 (25.00%)	02 (4.2%)		

Blood on air-Q ILA after removal was statistically comparable ($P = 0.645$) [Table 6]. Intubation was successful in 36 patients out of 48 patients in group A and in 46 patients out of 48 patients in group B. Hence 36 patients were included in group A and 46 patients in group B for comparison of sore throat [Table 6]. No case of hoarseness of voice was reported.

Discussion

The total time required for successful intubation in the present study was significantly less in Parker Flex-tip TT group compared to conventional PVC TT group. This may be attributed to favourable design (anteriorly curved tip and posterior bevel) of Parker Flex-tip TT. This design of the Parker Flex-tip TT resulted in increase in success rate, first attempt success rate and ease of intubation.

The success rate of intubation in the present study was 75% in PVC TT which is similar to studies conducted by Bakker *et al.*, El-Ganzouri *et al.*, Attarde *et al.*, Sethi *et al.* and Karim *et al.*[7-11] Malhotra *et al.* however, found a success rate of 96.6% with reinforced tracheal tubes.[12]

Table 3: Ease of intubation through air-Q ILA

Ease of intubation	Group A (PVC TT)	Group B (Parker flex-tip TT)	*P*	Test
Easy	29 (60.4%)	44 (91.7%)	0.002	Chi square
Difficult	7 (14.6%)	02 (4.2%)		
Failure	12 (25.0%)	02 (4.2%)		

Table 4: Time taken for TT insertion through air-Q ILA

Group	Group A (PVC TT)		Group B (Parker flex-tip TT)		*P*	Test
	Range	Mean±SD	Range	Mean±SD		
Time (sec)	8-82	20.69±14.9	8-66	13.6±8.5	0.014	Student *t*-test

Table 5: Total time of intubation

Group	Group A (PVC TT)		Group B (Parker flex-tip TT)		*P*	Test
	Range	Mean±SD	Range	Mean±SD		
Time (sec)	40-144	69.4±27.7	39-121	58.7±15.1	0.043	Student *t*-test

Table 6: Comparison of blood on air-Q ILA and sore throat

	Group A (PVC TT)	Group B (Parker flex-tip TT)	*P*	Test
Blood on device				
Present	3 (6.3%)	2 (4.2%)	0.645	Chi square
Absent	45 (93.8%)	46 (95.8%)		
Sore throat				
Present	4 (11.1%)	3 (6.5%)	0.460	Chi square
Absent	32 (88.9%)	43 (93.5%)		
Total	36 (100%)	46 (100%)		

First attempt intubation success rate using PVC TT through air-Q ILA in the present study was similar to that reported by Bakker *et al.* El-Ganzouri *et al.* Attarde *et al.* and Sethi *et al.*[7-10] With regards to ease of intubation, Malhotra *et al.* reported intubation as easy in 87.9% and moderate in 12% of patients.[12] Sethi *et al.* found that intubation through air-Q ILA was easy in 42%, moderate in 24%, difficult in 13% of patients and impossible in 20% of patients.[10] The results of the present study differ from these studies as parameters for assessing ease of intubation were different in all the studies.

The results of the present study differ from those reported in literature regarding mean time for intubation. Ebied *et al.* found higher mean time for successful intubation without using bougie (28 ± 10 sec).[13] This could be due to increased number of attempts in the study group (3 attempts in 43% subjects). Abdel-Halim *et al.* also reported a higher mean time (33 ± 7 sec) for insertion of the TT via air-Q ILA.[14] This might be due to the use of fibreoptic as a conduit for tracheal intubation. Malhotra *et al.* reported a lower insertion time than in the PVC TT group but similar to Parker flex-tip TT group.[12] The likely reason could be use of reinforced tubes.

Badawi *et al.* observed a slightly higher mean total time taken for intubation using PVC TT (78 ± 21 sec).[15] This could be attributed to the difference in technique and manoeuvres employed for insertion. Malhotra *et al.* reported a much higher mean total time taken for intubation (105 ± 36 sec).[12] This could be due to increased number of second attempts (24.1% cases). Ebied *et al.* recorded a lower total time for successful intubation (48 ± 10 sec) which may be because they did not include the time required to remove the air-Q ILA in the total time.[13]

Bakker *et al.* reported visible blood on air-Q in17% subjects.[7] This higher incidence could be due to the difference in technique and manoeuvres employed. Similarly Karim *et al.* had an incidence of 10%[11] Malhotra *et al.* reported a lower incidence of blood on airway device (2%).[12] This difference could be attributed to the use of tongue depressor to introduce air-Q ILA which aids in smooth insertion of the device.

Bakker *et al.* reported a similar incidence of sore throat in 10% subjects who were intubated with PVC TT.[7] Malhotra *et al.* reported a lower incidence of sore throat (7%).[12] However, they were similar to the Parker flex tip group in the present study. The difference could be because they used reinforced

tubes for intubation through air-Q ILA (PVC tubes were used only in second and third attempts).

We have not done cost benefit analysis. Both the tubes are made of PVC and the cost of Parker flex tip tube is comparable to conventional PVC tube of standard make.

However, there were certain limitations to present study. First, all the cases included had normal airways with no anticipated difficult intubation. The results may differ in patients with difficult airway. Second, lack of assessment of failed cases in both the groups by fibreoptic bronchoscope is a limitation as it can assess whether the failure was due to technical or anatomical cause. Blind intubation is no longer advocated and fiberscope should be used when available. Lastly, we have compared only two PVC tubes with different designs. The results may vary with reinforced tubes. We have stated that air-Q ILA can be used as a stand alone device for positive pressure ventilation with high oropharyngeal seal pressure but we cannot claim its superiority over other intubating supraglottic airway devices as we have not compared it with any other supraglottic airway device.

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Conflicts of interest
There are no conflicts of interest.

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