Title
Comparison of air QR insertion techniques in pediatric patients with fiberoptic bronchoscopic assessment

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Running title

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Comparison of air Q\textsuperscript{R} insertion techniques in pediatric patients with fiberoptic bronchoscopic assessment

Running title: Air-Q insertion techniques in pediatrics
Abstract

**Background:** Air-Q® Laryngeal mask airway [LMA] is a second-generation supraglottic airway device [SAD] that provides adequate airway control in children despite the unfavourable anatomy of the paediatric airway. There are studies assessing it as a conduit for tracheal intubation and comparing the efficacy of the device with other SADs. Till date there are no studies comparing the laryngeal view through air-Q using two insertion techniques i.e., Midline and Rotational technique. Therefore, we planned to compare the fiberoptic bronchoscopic [FOB] assessment of air-Q position using these two insertion techniques.

**Methods:** In this randomised controlled trial, 80 pediatric patients of American Society of Anesthesiologists [ASA] physical status I /II of either sex, in the age group of 5 to 12 years, weighing 10 to 30 kilograms [kg] who were scheduled for elective surgery in supine position under general anaesthesia were included. The appropriate size of the air-Q based on the weight of the patient was inserted using the technique allocated to the patient.

**Results:** FOB Grade 1 [ideal position] was seen in 29/40 [72.5%] of children in the Rotational technique and 19/40 [47.5%] children in Classic midline technique [P value 0.04]. Time taken to successfully insert the air Q was significantly less with the rotational technique [7.2 ± 1.5 sec] when compared with the classic midline technique [10.2 ± 2.1 sec] [P value <0.001]. Complications were similar in both the groups.

**Conclusions:** The rotational technique of insertion of air-Q is associated with better fiberoptic bronchoscopic view and is faster when compared to the Classic Midline technique of insertion of air-Q in paediatric patients.
Keywords: Laryngeal mask airway; Supraglottic airway; Insertion techniques; Air-Q; Laryngeal view; Complications.
Introduction

Air-Q® Laryngeal mask airway [Cook gas LLC, St. Louis MU, USA] [Fig. 1] is a second generation supraglottic airway device [SAD] developed by Daniel J. Cook. It is specifically engineered for use as both a primary airway device and as a conduit for tracheal intubation in anticipated or unanticipated difficult airway in children as well as in adults.1

Other advantages being it is user friendly, availability in sizes small enough to be used in the paediatric age group and providing adequate airway control in both mechanically ventilated and spontaneously breathing children despite unfavourable paediatric airway anatomy.1,2

The anatomical differences of airway make the proper placement of SAD difficult in paediatric patients.3 It is paramount to assess the techniques to improve positioning of air-Q as improper position can cause laryngeal obstruction and inadequate seal. The fiberoptic bronchoscope helps in assessing the position of air-Q.

Since the introduction of air-Q, there are numerous studies assessing it as a conduit for tracheal intubation in adults4,5 and children6,7,8 and comparing the efficacy of the device with other SADs9,10. Previous studies1,6,11 documented that fiberoptic laryngeal view through air-Q by midline insertion technique is better when compared to other SADs in children. Jagganathan et al7 in a study stated that based on their clinical experience on 100 patients, rotational technique is best to insert air-Q.

The classic and rotational techniques have been compared for the insertion of Classic LMA3, Softseal LMA12, Proseal LMA13. Till date there are no studies comparing the laryngeal view through air-Q using two insertion techniques i.e., Midline and Rotational technique.

Therefore, we planned to compare the fiberoptic assessment of air-Q position using these two insertion techniques i.e., Midline technique and Rotational technique as our primary objective.
Based on a study conducted by Jagannathan et al\textsuperscript{7}, we hypothesized that fiberoptic assessment of air-Q position after insertion using Rotational technique will be better compared with the Midline technique in paediatric age group.

Our secondary objective was to compare the ease of insertion of air-Q with each technique in terms of number of attempts for successful insertion and duration of insertion. Haemodynamic changes during insertion, oropharyngeal leak pressure [OPLP] and occurrence of complications such as trauma, laryngospasm and hypoxemia were compared.
Materials and Methods

Study design

This randomized study was conducted in the Department of Anaesthesia and Intensive Care, Post Graduate Institute of Medical Education and Research [PGIMER], Chandigarh, from August 2015 to November 2016. It was registered in the Clinical Trial Registry of India [CTRI/2018/09/015574]. After approval of protocol by Institutional Ethics Committee [INT/IEC/2015/724] and written informed parental consent, 80 paediatric patients of American Society of Anesthesiologists [ASA] physical status I /II of either sex, in the age group of 5 years to 12 years, weighing 10 to 30 kilograms (kg) who were scheduled for elective surgery in supine position [cataract surgeries, inguinal hernia, urethroplasty] under general anaesthesia were included in the study. Surgical time for all the surgeries was less than 45 minutes and anaesthetic duration was less than 1 hour.

Children with either history of upper respiratory tract infection [cough, fever, rhinorrhea] within 3 weeks or on the day of surgery, respiratory tract pathology [oropharynx, larynx] , anticipated difficult airway, increased risk of aspiration, gastro esophageal reflux disease, non fasting status, hiatus hernia, lung diseases, cardiorespiratory or cerebrovascular disease were excluded.

Preparation of the patient

80 pediatric patients were randomly allocated into two groups, 40 patients in the Classic Midline technique group, and 40 in the Rotational technique group using a computer generated random number table. The random numbers assigned were concealed in opaque sealed envelopes.

After confirming the fasting status of patients according to Standard Nil Per Os [NPO] guidelines, standard ASA monitoring for Heart rate [HR], Saturation of peripheral oxygen [SpO2], Non invasive blood pressure [NIBP] and End tidal carbondioxide [EtCO2] was attached in the operating
room. Patient was induced with 100% oxygen and sevoflurane [6-8%] following which intravenous cannula was inserted and 2 μg/kg of fentanyl administered. With end tidal sevoflurane concentration of 2.5% before device insertion, the depth of anaesthesia was confirmed by the absence of motor response to jaw thrust.

The appropriate size of the air-Q based on the weight of the patient, was inserted using the allocated technique to the patient. In the Classic Midline technique group, the air-Q was inserted using manufacturer’s recommended technique. By stabilizing the patient’s neck and head with the non-dominant hand, the patient’s mouth was opened. The lubricated mask of the air-Q was placed at the base of the tongue with a slight forward angle and by gently applying downward and inward pressure, air-Q was placed in position. Correct placement is determined by resistance to further advancement.

In the Rotational technique group, the air-Q was inserted with its lumen facing backwards and once the resistance in posterior pharyngeal wall is felt, it is rotated through 180 degrees and then passed downwards into position.

After insertion, the cuff of the air-Q was inflated as per the recommendations [0.5 ml and 1 ml respectively for sizes 1.5 and 2 to maintain cuff pressure in the range of 20-30 cm H2O] and the breathing circuit of the anaesthesia machine was attached to the proximal end of the air-Q. Adequate bag movements and chest rise confirmed airway patency. Capnography was monitored for adequate ventilation.

If any airway obstruction and inadequate ventilation with significant leak was observed, the air-Q was reinserted using the same technique. When the second attempt failed, the other technique was used to insert the air-Q. The anesthesiologist blinded to the technique used, assessed the laryngeal view by the fiberoptic bronchoscope [FOB size 3.5mm OD; Pentax, Tokyo, Japan]. Positioning of
the tip of the fiber-optic bronchoscope at the distal outlet of the air-Q ILA was used to determine the scoring of the laryngeal view. Grade scoring was based on standard established scoring system by Jagannathan et al for FOB grading of laryngeal view through air-Q:\(^2^1\):

Grade 1: Only vocal cords seen

Grade 2: Vocal cords and posterior surface of epiglottis seen

Grade 3: Vocal cords and tip of anterior surface of epiglottis seen, < 50% of obstruction to vocal cords by epiglottis

Grade 4: Epiglottis downfolded and its anterior surface seen, > 50% of obstruction to vocal cords by epiglottis

Grade 5: Epiglottis downfolded and vocal cords cannot be seen directly

The optimal position of air-Q was considered if the FOB grades were 1 and 2. FOB grades 3 to 5 were considered as sub optimal. At the end of the surgery, under deep plane of anaesthesia, air-Q was removed. Patients were monitored for any complications like laryngospasm, hypoxemia [SpO2 below 92%] and trauma [i.e., blood on the device after removal].

**STATISTICAL ANALYSIS**

As there were no previous studies comparing the two insertion techniques of air-Q with fiberoptic bronchoscopic assessment in pediatric patients, the sample size was calculated on the basis of the results obtained by the Classic LMA study\(^{13}\) [i.e. Fiberoptic assessment of LMA position in children: a randomized crossover comparison of two techniques]. Sample size calculation was performed based on the assumption that the incidence of better FOB grades 1 and 2 will improve from 62% with the classic midline technique to 92% with the rotational technique. With an alpha
error of 0.05 and a power of 90%, 37 patients in each group would be required. To account for attrition/dropouts, a total of 80 patients were enrolled.

Discrete categorical data was represented in the form of either a number or a percentage [%]; continuous data, assumed to be normally distributed, and written as either in the form of its mean and standard deviation or in the form of its median and interquartile range, as per the requirement. The normality of quantitative data was checked by measures of the Kolmogorov-Smirnov tests of normality. Statistical analysis was performed using the Paired T Test for continuous variables, Wilcoxon Signed Rank Test for categorical data. P value < 0.05 was considered statistically significant. All the statistical tests were two-sided and performed at a significance level of $\alpha=0.05$. Analysis was conducted using IBM SPSS STATISTICS [version 22.0].
Results

Consort flow diagram of enrolled patients was as is seen in Fig 2.

The demographic data such as age, gender and weight of patients as well as sizes of air-Q were comparable in both the groups [Table 1].

FOB Grade 1 [ideal position] was seen in 29/40 [72.5%] of children in the Rotational technique and 19/40 [47.5%] children in Classic midline technique, the difference of which was statistically significant [P value 0.04]. The optimal position of air-Q i.e., FOB Grade 1 and Grade 2 was seen in 97.5% and 80% of the children in the Rotational technique and Classic Midline technique respectively, the difference of which was also statistically significant [P value 0.04] [Table II].

Time taken to successfully insert the air-Q was significantly less with the rotational technique [7.2 ± 1.5 sec] when compared with the classic midline technique [10.2 ± 2.1 sec] [P value <0.001] [Table II]. Two patients in the classic midline technique group required alternate technique to insert the air-Q. These two patients were excluded in analysis for time taken to insert the air-Q.

Successful insertion of air-Q in first attempt was seen in 32/40 [80%] patients in the classic midline technique and 38/40 [95%] patients in the rotational technique. This was comparable [P = 0.1] [Table II]. The overall success rate of insertion of air-Q [i.e., successful insertion with 2 attempts] was statistically similar with the techniques, 100% with the rotational technique and 95% with the classic midline technique [Table II].

The air-Q was easily inserted in 95% and 80% of the children with the rotational technique and classic midline technique respectively. In 15% of patients in the classic midline technique and in 5% of patients in the rotational technique, it was moderately difficult to insert the air-Q which was statistically not significant [P = 0.1] [Table II].
The mean OPLP of air-Q was 22.6 ± 1.8 cm of H2O and 23.3 ± 1.4 cm of H20 in the classic midline technique group and the rotational technique group respectively which was statistically similar in both the groups [Table II] .

Complications were similar in both the groups. Laryngospasm was seen in 2/40 [5%] patients in the classic midline technique group and none in the rotational technique group. Blood on the device was seen in 2 patients in the classic midline technique group and 1 patient in the rotational technique group [Table III] .

*Intra operative haemodynamic changes*

The HR, Mean arterial pressure [MAP] at pre induction, post insertion, post induction, 5 min after insertion, 10 min after insertion and 15 min after insertion were noted and analysed using two way repeated measured Analysis of variance [ANOVA] test within the group.

The mean HR in the classic midline technique of insertion changed from 97 ± 10 per min post induction to 100 ± 10 per min post insertion, which was statistically significant, and from 92 ± 10 per min to 93 ± 10 in the rotational technique of insertion [Table IV] . However, there was no significant difference at subsequent readings in both the groups. This increase in heart rate post insertion was significantly higher in the classic midline technique. There was no statistical difference in MAP in both the groups at all the times.
Discussion

Our study suggests that insertion of air-Q with the rotational technique shows better FOB grading compared to the classic midline technique. The time taken to insert the air-Q is significantly less with the rotational technique compared to the classic midline technique. To the best of our knowledge, this is the first study in the literature comparing the rotational technique with the classic midline technique of insertion of air-Q in children. All other authors have used either the classic midline technique or the rotational technique of insertion of air-Q in pediatric patients.

We found that the optimal position [FOB grade 1 and 2] and ideal position [FOB grade 1] of air-Q in relation to the glottis was significantly better with the rotational technique [97.5% and 72.5%] compared to the classic midline technique [47.5% and 80%] in pediatric patients. With regard to the rotational technique of insertion of air-Q, our results are comparable with that of Jagannathan et al, in which the fiberoptic view was superior with the rotational technique of insertion of air-Q in children with anticipated difficult airway.

The results obtained with the classic midline technique of insertion of air-Q in our study correlate with that of Darlong et al in which the optimal FOB grading [grade 1 and 2] was seen in 84% of children with the classic midline technique of insertion of air-Q. The findings do not correlate with studies of Whyte et al, Sinha et al, Jagannathan et al in which the optimal FOB grading was seen in 58%, 65%, and 68% of the pediatric patients respectively. This difference was apparent because these studies had a large number of children with no vocal cords visible as they have used the size 1 of air-Q along with sizes 1.5 and 2.

In our study, we found that the time taken to insert the air-Q was significantly less with the rotational technique [7.2 ± 1.5 sec] when compared with the classic midline technique [10.2 ± 2.1 sec, P value <0.001] in pediatric patients. The time taken to insert the air-Q with the classic midline
technique in our study was similar to that of Jagannathan et al\(^6\) in which it was 11.1 ± 1.5 sec. It was not similar, however, with that of Darlong et al\(^9\) and Sinha et al\(^2\) in which the time taken to insert the device was 16.3 ± 1.5 and 13.3 ± 3 sec respectively with the classic midline technique of insertion. This difference in time taken to insert the device was because of the difference in definitions of insertion time. In these studies insertion time have been defined as the time from picking up the device to obtaining the square waveform of capnography. In our study, we have defined it as the time from mouth opening to the confirmation of airway patency.

In our study, we observed that the success rate of device insertion in the first attempt and ease of insertion was 95% with the rotational technique and 80% with the classic midline technique, which was not statistically significant. Our results with the rotational technique of insertion of air-Q regarding the first attempt success rate were similar to that of Jagannathan et al\(^7\) in which it was 100%. In other studies by Sinha et al\(^2\), Darlong et al\(^9\), and Jagannathan et al\(^1\) with the classic midline technique, the first attempt success rate was in the range of 95 – 100% which do not correlate with results of the classic midline technique of our study. This might be because of the use of neuromuscular blockade, in their studies, which alters the tone in the airway musculature and improves the ease of insertion and thus the first attempt success rate of insertion in children.

We found that there was no difference in the OPLP with the technique of insertion of air-Q, which were 22.6 ± 1.8 cm of H\(_2\)O with the rotational technique and 23.3 ± 1.4 cm of H\(_2\)O with the classic midline technique group. In previous studies with the classic midline technique of insertion of air-Q by Darlong et al\(^9\) and Whyte et al\(^11\), the OPLP of air-Q correlated with our study i.e., 20.2 ± 4.6 cm of H\(_2\)O and 23 cm of H\(_2\)O respectively in neutral position in paediatric patients. In contrast to our study the OPLP of air-Q in studies by Jagannathan et al\(^1\) and Sinha et al\(^2\) was 19 ± 5.4 and 18.5 ± 1.8 cm of H\(_2\)O respectively with the classic midline technique of insertion of air-Q. This might be because of the comparison in different age groups and weight parameters.
In our study we did not find any statistically significant difference in the complications with the rotational and the classic midline technique of insertion of air-Q. Though laryngospasm and blood on the device was seen in 5% of patients with the classic midline technique and in 2.5% patients in the rotational technique, our study was not powered to calculate the small differences in complications. Our results were similar to that of previous studies by Whyte et al\textsuperscript{11} and Darlong et al\textsuperscript{9} in which the blood on the device was seen in 5% and 3.1% of pediatric patients respectively with the classic midline technique of insertion of air-Q.

The ease of insertion, first attempt success rate of insertion, OPLP and complications of air-Q were similar with both the techniques of insertion of air-Q suggesting the use of the rotational technique as an alternative technique to insert the air-Q in pediatric patients. However, because of better FOB grading and lesser time taken to insert the device with the rotational technique, it can be used as a technique of choice in children for optimal positioning of air-Q and for intubating through air Q.

There are certain limitations of this study. As only healthy children with normal airway anatomy were studied, our results may not be extrapolated to the children with difficult airway. Only two sizes 1.5 and 2 of air-Q were studied. Size 0.5 was recently introduced. Further studies are needed with sizes 1 and 0.5 of air-Q. As our study was done on children on spontaneous ventilation during surgery who did not receive any muscle relaxant, these results may not be applicable to children who receive neuromuscular blockade for positive pressure ventilation.

**Conclusion**

We conclude that the rotational technique of insertion of air-Q is associated with better fiberoptic bronchoscopic view and is faster when compared to the Classic Midline technique in pediatric patients. Complications such as blood on the device and laryngospasm were similar in both the
techniques. Hence the rotational technique of insertion of air Q can be the technique of choice in children for optimal positioning of air-Q and also for intubating through air-Q.
References


Table 1. Demographic Data

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Classic Midline Technique</th>
<th>Rotational Technique</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>7.6 ± 2.3</td>
<td>7.4 ± 1.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Weight(Kg)</td>
<td>17.5 ± 3.3</td>
<td>18.3 ± 3.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Gender(M/F)</td>
<td>19/21</td>
<td>29/11</td>
<td>0.02</td>
</tr>
<tr>
<td>Air Q Sizes (1.5/2)</td>
<td>15/25</td>
<td>14/26</td>
<td>0.8</td>
</tr>
</tbody>
</table>

The values are expressed as mean ± SD or numbers and analyzed using independent t test. The values expressed in ratios were analyzed using chi square test.
### Table 2. Characteristics of the Device

<table>
<thead>
<tr>
<th></th>
<th>Classic midline technique</th>
<th>Rotational technique</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOB Grade I</td>
<td>19</td>
<td>29</td>
<td>0.045*</td>
</tr>
<tr>
<td>FOB Grade II</td>
<td>13</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>FOB Grade III</td>
<td>6</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>FOB Grade IV</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>FOB Grade V</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>FOB Grading I + II (Optimal position)</td>
<td>32</td>
<td>39</td>
<td>0.044*</td>
</tr>
<tr>
<td>Time taken to insert the device (seconds)</td>
<td>10.2 ± 2.1</td>
<td>7.2 ± 1.5</td>
<td>&lt;0.001†</td>
</tr>
<tr>
<td>Number of attempts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st attempt</td>
<td>32 (80%)</td>
<td>38 (95%)</td>
<td>0.1‡</td>
</tr>
<tr>
<td>2nd attempt</td>
<td>6 (15%)</td>
<td>2 (5%)</td>
<td></td>
</tr>
<tr>
<td>Alternate approach used</td>
<td>2 (5%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Ease of insertion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easy</td>
<td>32 (80%)</td>
<td>38 (95%)</td>
<td>0.1‡</td>
</tr>
<tr>
<td>Moderate</td>
<td>6 (15%)</td>
<td>2 (5%)</td>
<td></td>
</tr>
<tr>
<td>Difficult</td>
<td>2 (5%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>OPLP</td>
<td>22.6 ± 1.8</td>
<td>23.3 ± 1.4</td>
<td>0.7§</td>
</tr>
</tbody>
</table>

Values entered as mean ± SD or numbers (%) p<0.05 = Significant

*chi square test, † unpaired t test, ‡ Fischer exact test

FOB : Fiberoptic Bronchoscopy

OPLP : Oropharyngeal leak pressure
Table 3. Complications

<table>
<thead>
<tr>
<th></th>
<th>Classic midline technique</th>
<th>Rotational technique</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood on the device</td>
<td>2/40 (5%)</td>
<td>1/40 (2.5%)</td>
<td>0.6</td>
</tr>
<tr>
<td>Response to removal of device</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>2/40 (5%)</td>
<td>0/40</td>
<td>0.1</td>
</tr>
<tr>
<td>Desaturation</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Values expressed as numbers (%), analyzed using Fischer exact test
Legend for figures

Fig. 1. air-Q® laryngeal mask airway
Fig. 2. CONSORT flow diagram. Eighty children were randomly allocated into the classic midline technique group and rotational technique group.