ABSTRACT

The AZ modification provides an airway management tool that can be used in a supraglottic and endotracheal manner interchangeably. We present a clinical trial where the concept of an exchange between two ventilation methods using this modification is investigated. Modification of two supraglottic airway platforms confirmed ease of placement and exchange between the two ventilation modes, allowing true staged extubation and intubation.

BACKGROUND

A novel AZ-airway concept introduced at the 2016 DAS annual meeting was well received encouraging a proof of concept study. The device allows interchangeable supraglottic (SG) and endotracheal (ET) ventilation, provides rescue supraglottic airway device (SAD), ability to convert to endotracheal tube (ETT), and safer smooth or true staged extubation from an existing ETT without use of an exchange catheter or interrupting ventilation. This allows “tracheal rest” and “staged extubation” in difficult airways or intensive care setting1-3. The unique design includes a removable (R-piece) tube replaced by an ETT, enabling ventilation in a SG or ET mode depending on ETT depth. The goals were to:

1) Implement AZ-airway concept on commercially available SAD platforms
2) Test claimed capabilities on manikin
3) Clinical trial on patients

METHODS

The study was conducted after Institutional Review Board ethics approval. Two SAD models were chosen, the Ambu AuraGain as an inflatable cuff, and the i-gel as a non-inflatable cuff platform and were altered according to a 3D printed prototype. These concepts were verified:

a) SG ventilation with R-piece,

b) R-piece to ETT change for SG ventilation,

c) Alternating ET and SG ventilation with existing ETT without interruption,

d) Removal of SAD while keeping ETT in place

e) Conversion of existing ETT to SAD

In the departmental simulation center structurally altered SADs were tested on manikins. Fiberoptic bronchoscopy and videobronchoscopy confirmed optimal positioning. Next, the concept was tested on seven consented patients with sterile manner of SAD alteration in the operating room. An anesthesiology staff, resident or nurse anesthetist did the initial insertion to test ease of insertion. Positioning was confirmed by fiberoptic bronchoscopy.

RESULTS

At the time of this report, 7 out of 10 IRB approved patients were included. The “AZ modification” was achieved by a longitudinal opening in the body of the SAD shaft transforming it to a non-cylindrical, incomplete tube. An R-piece was made using the proximal portion of a larger ETT. The table shows the patient population, primary diagnosis, the supraglottic and R-piece used, and the operator. The initial placement was mentioned as easy and no different in effort or time compared to a conventional SAD. In all cases an ETT was passed without difficulty. In one case (case 6) only supraglottic part was tested and ETT placement was not performed.

<table>
<thead>
<tr>
<th>No</th>
<th>Pt.</th>
<th>SAD</th>
<th>Rpiece</th>
<th>ETT</th>
<th>Operator</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>60 y/o 110 kg F</td>
<td>i-gel 4</td>
<td>ETT 9.0</td>
<td>7.5</td>
<td>CRNA</td>
</tr>
<tr>
<td>2</td>
<td>55 y/o 102 kg M</td>
<td>i-gel 5</td>
<td>ETT 9.5</td>
<td>7.5</td>
<td>CRNA</td>
</tr>
<tr>
<td>3</td>
<td>49 y/o 97 kg M</td>
<td>i-gel 4</td>
<td>ETT 9.5</td>
<td>7.5</td>
<td>Staff</td>
</tr>
<tr>
<td>4</td>
<td>69 y/o 77kg F</td>
<td>AuraGain 4</td>
<td>ETT 9.5</td>
<td>7.5</td>
<td>Resident</td>
</tr>
<tr>
<td>5</td>
<td>64 y/o 70kg M</td>
<td>AuraGain 4</td>
<td>ETT 9.5</td>
<td>8.5</td>
<td>Resident</td>
</tr>
<tr>
<td>6</td>
<td>70 y/o 70 kg M</td>
<td>AuraGain 4</td>
<td>ETT 8.5</td>
<td>----</td>
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<td>i-gel 4</td>
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<td>Resident</td>
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</tbody>
</table>

DISCUSSION

Currently there is no single device that can be used as both a supraglottic and infraglottic airway, interchangeably, without compromising ventilation. The concept of staged extubation as currently mentioned in some literature using an exchange catheter is a misnomer since it involves a period of unprotected airway with only the exchange catheter in place. Other scenarios of use for a device that can provide both types of ventilation include:

- Failed intubation rescue with a need for intubation
- Unclear if intubation will be necessary
- Need for Smooth Intubation
- Need for Smooth Exstubation (e.g. in neurosurgery or ENT)
- Intraoperative change from intubation to supraglottic ventilation or vice versa.
- Staged Exstubation and tracheal rest in ICU patients
- Unstable cervical spines
- Intubation by low trained personnel – field

We were interested to see if the concept could be implemented in currently commercially available SAD which included either a cuff based or gel based mask portion. The manikin results were promising encouraging a trial in live patients. Our results demonstrated that in both SAD models AZ alteration can be easily performed. The claims were tested in simulation center using both platforms of SADs successfully. The clinical trial showed same results as that of manikins for ease of insertion, functionality, possibility of interchanging SAD to ETT and staged extubation.

REFERENCES

2) Mort TC. Continuous airway access for the difficult extubation: the efficacy of the airway exchange catheter. 2007; 105(5):1357-62