air-Q sp Trial – Supplemental Information

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air-Q sp Evaluation.

Purpose:

The air-Q Self-Pressurizing (air-Q sp) is a laryngeal airway that is inserted blindly, sits above the vocal cords and does not require inflation of a cuff with air. The purpose of this study is to evaluate the safety and effectiveness of the air-Q sp when used by paramedics in the prehospital setting. We hypothesize that the air-Q sp will be easier and quicker to insert than an endotracheal tube, provide more adequate ventilation and aspiration protection than a bag-valve-mask, and be safer (risk of aspiration, reduction of carotid blood flow) than laryngeal tubes such as the King Airway. The outcome measures will be compared to the existing airway management devices currently in use.

Primary Outcome Measures:

* Device insertion success rate. Measured after no more than 2 attempts.
* Adequacy of ventilation. Measured by chest rise, capnography, and audible air leak.

Secondary Outcome Measures:

* Device placement time. Measured from opening airway to first ventilation.
* Resistance to dislodgement. Adequacy of securing strap.
* Incidence of vomiting.
* Adequacy of airway protection. Measured as amount of gastric contents in bowl of device.
* Sudden cardiac arrest survival to hospital discharge and neurological status at time of hospital discharge.
* Type and rate of complications. (failure to ventilate, dislodgement, airway trauma – evaluated by paramedics, hospital staff and medical examiner).
* Usefulness in ED/OR/ICU for transition to ETI. Utility for ETI in ED.
* Overall clinical usefulness. (Reported by paramedic on a 1-5 Likert Scale and by ED staff as free-text comments.

Data:

In addition to standard required documentation for all patient encounters, the following information will be entered for all uses of the air-Q sp.

* Airway device(s) attempted (more than one may apply):
  + Bag valve mask
  + Endotracheal tube
* Indication for use:
  + Unable to BMV
  + Alternative to BMV
  + ETI Rescue device
* Number of attempts (1, 2) If unable, comments.
* Adequate seal (good chest rise with no audible air leak, chest rise with small audible leak, large audible air leak with inadequate chest rise, comment)
* Initial and final pulse oximetry
* Initial and final ETCO2
* Ease of use (on 1-5 Likert scale with 1 being very easy and 5 being impossible)
* Complications (bleeding, other). Comments.
* Vomiting? If so, where? (tube/bowl, oropharynx, both). If tube, easy to clear? If no, comment.
* Adequacy of securing strap (ease of use, head strap remains in place, device remains in place)
* ED Comments (by whom):
* Comments (clinical usefulness, technique, experience, suggestions):
* Medical Examiner Comments (position, trauma, aspiration)