Air Q Study protocol

Introduction

Airway management is a critical skill performed in both the hospital and out of hospital setting. The optimal methods for prehospital airway management and best airway devices are still a matter of debate despite many studies comparing airway management techniques. Endotracheal incubation, while once considered the gold standard in advanced airway management has been challenged as an optimal strategy due to difficulty in training and skill maintenance, time required for placement, risk of misplacement, and questionable benefit even when performed under ideal conditions.

The Air-Q is a supraglottic airway that can be placed easily, requires minimal training and skill maintenance and has low risk of misplacement. Although the Air-Q and similar devices (LMA, iGel, etc.) have been well studied and have an excellent safety track record for in hospital use by physicians, data on prehospital use and use by non-physicians is limited.

Purpose:

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 these existing airway management devices currently in use.

Methods

Study Design

We will conduct a prospective observational study of use of the Air-Q for prehospital airway management. Use of the Air-Q will be optional at the discretion of the treating paramedic. We will analyze all episodes of advanced airway management including bag-valve mask ventilation, Air-Q insertion, endotracheal intubation, and placement of other supraglottic airways.

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.

Setting

Ventura County EMS

Santa Barbara County EMS

Pasadena Fire Department

Duration

The duration of the study will be 12 months.

Data will be reviewed every 6 months for safety monitoring.

Start date: TBA

End date: TBA

Inclusion Criteria:

All adult patients requiring positive pressure ventilation with absent gag reflex.

Exclusion Criteria:

Patients with an intact gag reflex

Patients weighing less than 45kg

Patients less than 18 years of age

Training:

Paramedics will receive one hour of instruction on indications for placement and technique for placement of the Air-Q. Training will include hand on placement of the Air-Q in airway mannequin simulators.

Protocol:

Air-Q size 3.5 and 4.5 airways will be carried by ALS units selected for the study.

Use of the Air-Q will be at the discretion of the treating provider.

Providers will be encouraged to place the Air-Q as early as possible after need for positive pressure ventilation is established.

After successful placement of the Air-Q the provider will have the option to continue ventilation via Air-Q or to oxygenate the patient followed by conventional endotracheal intubation.

Intubation THROUGH the Air-Q will not be allowed during the duration of this study.

Data Collection:

The following data will be collected for each patient

Airway device attempted (more than one may apply):

 -Bag valve mask

 -Air-Q

 -Endotracheal tube

 -Combitube

 -King-LT

Age

Gender

Date

Sequence number / run number

Indication for use

 -Cardiac Arrest

 -respiratory failure with pulses present

 -severely depressed mental status with pulses present

 -other

Chief complaint and secondary complaints

Initial blood pressure

Blood pressure on hospital arrival / care handover

Initial pulse oximetry

pulse oximetry after placement of each device

Pulse oximetry on hospital arrival / care handover

ETCO2 after airway placement

ETCO2 on hospital arrival / care handover

Ease of use (of each device used) on 1-5 Likert scale with 1 being very easy and 5 being impossible

Number of attempts

Successfully able to ventilate with each device: Y/N

Adequacy of seal.

Complications (dislodgement, bleeding, other)

Vomiting (inside and/or outside device).

Emergency Department evaluation (adequacy of ventilation, aspiration, other)

Medical Examiner comments (placement, trauma, aspiration, other)

Adequacy of securing device.

For cardiac arrest patients:

ROSC in the field

survival to hospital admission

survival to hospital discharge

CPC score at hospital discharge

Evaluation:

Every use of the device will be evaluated. For each area (Santa Barbara County EMS, Ventura County EMS, Pasadena Fire), the air-Q will be introduced as a treatment protocol revision for all paramedics and for all patients. We will compare the experience with the air-Q to that of existing airway devices as part of our quality improvement programs using historical controls.