Request for Approval of a Trial Study

This document follows Form #EMSA-0391

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Local EMS Agencies: Santa Barbara County EMS, Ventura County EMS, Los Angeles County (Pasadena Fire)

Santa Barbara:
Total number of ambulances in County: 41
Total other ALS response vehicles: 15
List of ALS agencies: American Medical Response, Carpinteria-Summerland Fire Department, Montecito Fire Department, Santa Barbara County Fire Department
Anticipated locations of training: Santa Maria, Buellton, Santa Barbara
Total number of paramedics that would need training: 167

Ventura:
Total number of ambulances in County: 33
Total other ALS response vehicles: 27 (this includes 1 air squad)
List of ALS agencies: AMR, Gold Coast, Lifeline, Ventura County Fire, Ventura City Fire, Ventura County Sheriff's SAR, Fillmore Fire Dept.
Anticipated locations of training: Moorpark, Camarillo, Oxnard, Ventura, Fillmore, Thousand Oaks, Ojai
Total number of paramedics that would need training: 252

Pasadena Fire Department:
Total number of ambulances: 5 ALS
Total other ALS response vehicles: 10
Total number of paramedics that would need training: 90

Proposed procedure: Insertion of the Air-Q supraglottic airway for airway management

Description of the procedure: Insertion of the Air-Q supraglottic airway for airway management

Description of medical conditions for which procedure will be utilized:
1. Cardiac Arrest
2. Respiratory Failure with decreased level of consciousness
3. Altered mental status requiring airway intervention

Alternatives: BVM ventilation, Endotracheal intubation

Estimated frequency of use:
Santa Barbara County EMS: 20 cardiac arrests per month
Ventura County EMS: 50 cardiac arrests per month

Pasadena Fire Department: 8 cardiac arrests per month

We anticipate that the majority of Air-Q use with be in cardiac arrest while use will be allowed in other patients where airway management is required. Since the Air-Q will likely not be used in all cardiac arrests, we would estimate a total of ~40 uses per month.

Recommended policies:

The Air-Q can be used as an alternative to either bag valve mask ventilation, endotracheal intubation or other supraglottic airways (King-LT or Combitube). When used in place of bag valve mask ventilation the Air-Q has a significant advantage that once placed, it is easy to maintain an airway seal and provide positive pressure ventilation with a single provider. When used in place of endotracheal intubation the Air-Q has the advantage of ease of placement, rapid placement and rare occurrences of misplacement. Previous experience has shown that placement of the Air-Q requires minimal training to achieve a high success rate. Theoretical benefits of the Air-Q over other supraglottic airways (King-LT or Combitube) include lower risk of airway trauma, lower risk of carotid occlusion due to balloon pressure and faster placement due to no need to inflate a balloon.

Medical control: Off line medical control according to protocols in each LEMSA. Online medical control as dictated by LEMSA protocol and as needed.

12-3-14

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.

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.

air-Q sp Trial – Supplemental Information

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December 2, 2014

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)

Air Q evidence summary

The Air Q is a type of supraglottic airway device very similar to a laryngeal mask airway. As this is a new device, little research exists on use of the Air Q in the out of hospital environment or during cardiac arrest. There are multiple studies of other supraglottic airways that show an improved time to ventilation and improved rate of successful ventilation. As ventilation has been de-emphasized in the most recent cardiac resuscitation guidelines it is not clear whether these improvements in intermediate outcomes will translate to any improvement in patient oriented outcomes.

The only study measuring the effect of a supraglottic airway device on mortality was a study of the esophageal gastric airway (EGA) which is substantially different from the AirQ. This study [Goldenberg IF, Campion BC, Siebold CM, McBride JW, Long LA. Esophageal gastric tube airway vs endotracheal tube in prehospital cardiopulmonary arrest. Chest1986 Jul;90(1):90-6.] found no difference in survival between patients receiving the EGA vs. endotracheal intubation. A Cochrane review of SGA use in cardiac arrest found only the Goldenberg study. [Lecky F, Bryden D, Little R, Tong N, Moulton C. Emergency intubation for acutely ill and injured patients. Cochrane Database Syst Rev2008(2):CD001429.]

Research specifically studying the AirQ is limited.
Bakker EJ, Valkenburg M, Galvin EM. Pilot study of the air-Q intubating laryngeal airway in clinical use. Anaesth Intensive Care. 2010 Mar;38(2):346-8

Study of the AirQ in 59 ASA I and II patients undergoing elective surgery. Air-Q successfully placed by anesthetist in 100%. Endotracheal intubation attempted through the Air-Q in 19 patients and successful in 58%.

Joffe AM, Lieu EC, Galgon RE, Viernes D, Treggiari MM. The second-generation air-Q intubating laryngeal mask for airway maintenance during anaesthesia in adults: a report of the first 70 uses. Anaesth Intensive Care. 2011 Jan;39(1):40-5.

Air-Q placed successfully by anesthetists in 70/70 elective surgery cases. Fiberoptic intubation performed successfully in 12/13.

Galgon RE, Schroeder K, Joffe AM. The self-pressurising air-Q® Intubating Laryngeal Airway for airway maintenance during anaesthesia in adults: a report of the first 100 uses. Anaesth Intensive Care. 2012 Nov;40(6):1023-7.

Air-QSP placed successfully by anesthetists in 100/100 elective surgery cases. Fiberoptic intubation performed successfully in 28/29.

Karim YM, Swanson DE. Comparison of blind tracheal intubation through the intubating laryngeal mask airway (LMA Fastrach) and the Air-Q. Anaesthesia. 2011 Mar;66(3):185-90.

Compared intubation through LMA Fastrach vs Air-Q in 154 healthy adults undergoing elective surgery. Blind intubation successful after two attempts in 75/76 (99%) with Fastrach vs 60/78 (77%) with Air-Q. Fiberoptic intubation used on third attempts to achieve intubation success in 100% with Fastrach vs 95% with Air-Q.

The following literature review includes studies of laryngeal mask type airways (NOT airq) in emergency situations or simulation.

Ben-Abraham R, Weinbroum AA. Laryngeal mask airway control versus endotracheal intubation by medical personnel wearing protective gear. Am J Emerg Med2004 Jan;22(1):24-6.

This study showed that physicians could place an LMA faster than an endotracheal tube in a mannequin model.

Bryden DC, Gwinnutt CL. Tracheal intubation via the laryngeal mask airway: a viable alternative to direct laryngoscopy for nursing staff during cardiopulmonary resuscitation. Resuscitation1998 Jan;36(1):19-22.

This study randomized nursing staff to training in endotracheal intubation vs LMA placement then tested their performance on anesthetized patients in the operating room. Success rate was higher when LMA was used (97% vs 39%).

Calkins MD, Robinson TD. Combat trauma airway management: endotracheal intubation versus laryngeal mask airway versus combitube use by Navy SEAL and Reconnaissance combat corpsmen. J Trauma1999 May;46(5):927-32.

Showed that Navy SEAL corpsman could place an LMA in a mannequin faster than a combitube or ETT.

Deakin CD, Peters R, Tomlinson P, Cassidy M. Securing the prehospital airway: a comparison of laryngeal mask insertion and endotracheal intubation by UK paramedics. Emerg Med J2005 Jan;22(1):64-7.

UK paramedics were tested in placement of LMA vs ETT in anesthetized patients. ETT success rate was 71.2% vs. 88.8% with LMA. LMA success rate was 80% in cases where ETT was unsuccessful.

Gatward JJ, Thomas MJ, Nolan JP, Cook TM. Effect of chest compressions on the time taken to insert airway devices in a manikin. Br J Anaesth2008 Mar;100(3):351-6.

Showed that SGA devices (i-gel, LMA Classic, LMA Proseal) could be placed faster during chest compressions than ETT.

Martin SE, Ochsner MG, Jarman RH, Agudelo WE, Davis FE. Use of the laryngeal mask airway in air transport when intubation fails. J Trauma1999 Aug;47(2):352-7.

LMA was placed successfully by air medical providers in 16/17 patients who had failed endotracheal intubation.

Pennant JH, Walker MB. Comparison of the endotracheal tube and laryngeal mask in airway management by paramedical personnel. Anesth Analg1992 Apr;74(4):531-4.

Study of LMA vs ETT placement by paramedics in anesthetized patents. Higher success with LMA vs ETT (94% vs 69%). LMA placement was faster than ETT (38sec vs 88sec)

Reinhart DJ, Simmons G. Comparison of placement of the laryngeal mask airway with endotracheal tube by paramedics and respiratory therapists. Ann Emerg Med1994 Aug;24(2):260-3.

Study of LMA vs ETT placement by paramedics in anesthetized patents. Higher success with LMA vs ETT (100% vs 52.6%). LMA placement was faster than ETT (39sec vs 209sec)

Samarkandi AH, Seraj MA, el Dawlatly A, Mastan M, Bakhamees HB. The role of laryngeal mask airway in cardiopulmonary resuscitation. Resuscitation1994 Oct;28(2):103-6.

Cardiac arrest patients randomized to LMA vs ETT. No difference in O2 saturations. No regurgitation in any patient.

Tentillier E, Heydenreich C, Cros AM, Schmitt V, Dindart JM, Thicoipe M. Use of the intubating laryngeal mask airway in emergency pre-hospital difficult intubation. Resuscitation2008 Apr;77(1):30-4.

Intubating LMA used by physicians out of the hospital. 50% of patients in cardiac arrest prior to airway management. I-LMA successfully placed in 45 patients, 41 of who had previously failed ETT attempts. LMA successfully placed in 96%. Successfully intubated through LMA in 91%

Timmermann A, Russo SG, Crozier TA, Eich C, Mundt B, Albrecht B, et al. Novices ventilate and intubate quicker and safer via intubating laryngeal mask than by conventional bag-mask ventilation and laryngoscopy. Anesthesiology2007 Oct;107(4):570-6.

Medical students were more successful in ventilating a mannequin with iLMA vs BVM. Higher rate of successful intubation through ILMA vs conventional DL.

Timmermann A, Russo SG, Rosenblatt WH, Eich C, Barwing J, Roessler M, et al. Intubating laryngeal mask airway for difficult out-of-hospital airway management: a prospective evaluation. Br J Anaesth2007 Aug;99(2):286-91.

Eleven patients with "difficult airway" were successfully intubated using ILMA. 37% were in cardiac arrest.

Winterhalter M, Brummerloh C, Luttje K, Panning B, Hecker H, Adams HA. [Emergency intubation with magill tube, laryngeal mask and esophageal tracheal combitube in a training-course for emergency care physicians]. Anasthesiol Intensivmed Notfallmed Schmerzther2002 Sep;37(9):532-6.

Emergency-care physicians with no experience (???) were faster to place LMA compared to combitube or ETT in a mannequin. The physicians liked the combitube the best.