



Ventura County Emergency Medical Services

Early use of the King Airway and impedance threshold device by basic and advanced life support personnel in the treatment of adult patients with out-of-hospital cardiac arrest.

**Trial Study - 18 Month Report
May 15, 2011**

Introduction:

The Ventura County EMS system has BLS and ALS first responders and ALS ambulance services. Cardiac arrest treatment protocols begin with 2-rescuer CPR with bag-mask ventilation (BMV) at a 30:2 compression:ventilation ratio and use of an AED. Paramedics continue 30:2 CPR with BMV, and include rhythm assessment, defibrillation, IV/IO medications, and advanced airway as needed.

In the 2005 American Heart Association (AHA) Guidelines for CPR and Emergency Cardiovascular Care (ECC), the impedance threshold device (ITD) was designated as Class IIa (Benefit >> Risk. It is reasonable to perform procedure/administer treatment).

- “Although increased long-term survival rates have not been documented, when the ITD is used by trained personnel as an adjunct to CPR in intubated adult cardiac arrest patients, it can improve hemodynamic parameters and ROSC (Class IIa).”

The King Airway (KA) is not specifically mentioned in the 2005 Guidelines, but two other perilaryngeal airways, the Combitube and Laryngeal Mask Airway (LMA) were also Class IIa.

- “Thus, it is acceptable for healthcare professionals to use the Combitube as an alternative to the endotracheal tube for airway management in cardiac arrest (Class IIa).”
- “It is acceptable for healthcare professionals to use the LMA as an alternative to the endotracheal tube for airway management in cardiac arrest (Class IIa).”

The objective of this trial study was to determine if a revision of EMS treatment protocols, to include early insertion of a KA and application of an ITD in adult (age \geq 18) patients with out-of-hospital cardiac arrest, would increase the likelihood of survival with favorable neurologic function (CPC 1 or 2).

Methods:

Study Design

The trial is a prospective, non-randomized, historically controlled intervention study to evaluate the effect of the introduction of the KA and ITD into EMS cardiac arrest treatment protocols. All adult cardiac patients who met clinical criteria were included. Historical controls were all cardiac arrest patients over the 18 months prior to the intervention meeting the same criteria.

The trial study was approved by the Ventura County Medical Center (VCMC) Institutional Review Board. The VCMC IRB also approved the continuation of the trial on request for renewal at one year.

Setting

Ventura County, California. Population 800,000. EMS response with BLS and ALS fire department first responders and paramedic-staffed ambulances.

Duration

Control period: March 1, 2008 through August 31, 2009

Intervention period: September 1, 2009 through February 28, 2011

Proposed extension period: March 1, 2011 through August 31, 2012

Inclusion criteria

All patients who are presumed to be 18 years of age or older and sustain a non-traumatic cardiac arrest.

Exclusion criteria

Patients less than 18 years of age, traumatic cardiac arrest and patients that had return of spontaneous circulation (ROSC) prior to KA insertion attempt.

Training

All EMTs and paramedics in Ventura County that treat EMS patients attended an in-service training that included the use of the KA and ITD. Training materials and personnel were provided by Ventura County Fire Protection District (VCFPD) and the ITD device manufacturer (Advanced Circulatory Systems, Minneapolis, MN). Train-the-trainer sessions were conducted for individual service providers. The two hour training session taught field providers the indications, contraindications, use and trouble shooting of the ITD. For BLS personnel, training included the indications, contraindications, placement, trouble shooting and use of the KA. ALS personnel had received training on use of the KA prior to the study. Also included in the training was a review of the 2005 AHA Guidelines as well as reinforcement of a team approach and how to work together when using the device.

Protocol

Treatment protocols were revised.

Prior to the trial the cardiac arrest protocol included:

BLS:

- CPR with BMV at 2 ventilations/30 compressions
- AED analysis, shock as indicated

ALS:

- Advanced airway after IV, medications, earlier if unable to ventilate

Trial protocol for the first 9 months included:

BLS/ALS:

- Chest compressions at 100/min
- Insert KA and attach ITD
- Asynchronous ventilations at 10/min
- AED analysis, shock as indicated
- If ROSC, remove ITD

Trial protocol for the second 9 months included:

BLS/ALS:

- Chest compressions at 100/min
- BMV and attach ITD
- 30:2 compression:ventilation ratio

Hospital care

The KA and ITD remained in place until the patient's care was transferred to hospital personnel. All hospital respiratory therapy and emergency department personnel were advised of the study.

Primary Outcome Measure

Survival to Hospital Discharge with CPC 1 or 2

Data Collection

The following data was collected on all patients:

- name (for hospital follow-up)
- sex
- age
- incident number
- date
- time of arrest
- etiology of arrest
- time of first CPR
- time of defibrillation (if applicable)
- bystander witnessed/EMS witnessed/not witnessed
- initial rhythm
- airway management (BVM only, KA, ETT)
- waveform capnography / initial ETCO₂ in mmHg values
- return of spontaneous circulation (ROSC) (Y,N)
- time of spontaneous circulation (ROSC)
- timing light use
- admission to hospital
- outcome
 - died in hospital
 - survived to discharge
 - cerebral performance category
 - overall performance category

Patient care reports and equipment use forms were submitted by all prehospital care providers to the EMS Division of VCFPD, in a paperwork-equipment exchange system. VCFPD secured all data received from hospitals regarding survival outcomes of study patients. All records regarding this trial have been maintained in a locked file and or secured electronic data base which can be accessed by the EMS quality managers involved in the study.

Results:

Table 1

EMTs trained	484
Paramedics trained	230
EMT King Airway insertion attempts	168 total patients, 1 attempt only
EMT King Airway insertion success	111 (66%)
PM King Airway insertion attempts	227 total patients
PM King Airway insertion success	159 1st attempt, 13 2nd attempt = 172 (76%)
Complications	20: Unable to insert: Emesis in oropharynx 48: Unable to insert: No emesis 29: Unable to ventilate after insertion 21: Emesis in airway section of device

EMT King Airway insertion success rate was 66% and paramedic was 76%.
Complications are listed in Table 1.

Table 2

Dates	3/08-11/08		12/08-8/09		9/09-5/10			6/10-2/11						
N	101	%	281	%	247	%	BVM	ETT	KA	240	%	BVM	ETT	KA
VT/VF	35	35%	77	27%	62	25%				43	18%			
AS	53	52%	126	45%	127	51%				138	58%			
PEA	14	14%	78	28%	56	23%				58	24%			
ROSC	28	27.7%	101	35.9%	88	35.6%				82	34.2%			
D/C														
Alive	10	9.9%	34	12.1%	29	11.7%	7	1	21	22	9.2%	18	3	1
CPC 1/2	9	8.9%	29	10.3%	18	7.3%	7	0	11	20	8.3%	17	2	1
CPC 3/4	1	1.0%	5	1.8%	11	4.5%	0	1	10	2	0.8%	1	1	0

N = All cardiac arrests, cardiac etiology

487 patients were enrolled in the intervention period (247 in the first 9 months, 240 in the second 9 months) and results were compared to the 382 patients in the prior 18 month control period.

During the first 9-month intervention period, results for ROSC (33.8% vs. 35.6%) and overall survival (11.5% vs. 11.7%) remained essentially unchanged from the control period.

There was a trend toward a reduction in the proportion of patients with CPC 1 and 2 scores (9.9% to 7.3%) and an increase in CPC 3 and 4 (1.6% to 4.5%). These differences were not statistically significant.

The KA was discontinued after the first 9 month intervention period and the protocol changed to include 2-hand mask grip for BMV ventilation with an ITD.

In the second 9-month period the overall survival was 9.2% with a CPC 1 and 2 proportion of 8.3%.

Discussion:

In the first 9 months there was no improvement in the overall survival or proportion of patients with CPC 1 or 2 with use of the KA and ITD. The KA was removed from the BLS protocol and used by paramedics only if unable to ventilate and unable to insert an endotracheal tube.

The King Airway is a Class IIa device in the 2010 AHA Guidelines (2):

- During CPR performed by providers trained in its use, the supraglottic airway is a reasonable alternative to bag-mask ventilation (Class IIa, LOE B) and endotracheal intubation (Class IIa, LOE A).

However, this recommendation is based upon studies that reported ability to insert the device and to adequately ventilate patients (3-5). We were unable to identify a study that evaluated the effect of the device on cardiac arrest survival with favorable neurologic outcome.

A possible explanation for the observed increase in patients with hospital discharge CPC scores of 3 and 4 is the potential for reduced brain circulation from carotid artery compression by the KA oropharyngeal balloon. Carotid bulb compression with the LMA has been shown to decrease carotid blood flow in anesthetized normotensive adults (6), and this effect would be expected to be more prominent in the low-flow setting. Further investigation is needed.

The ITD is a Class IIb (Benefit \geq Risk, Procedure/treatment may be considered) device in the 2010 AHA Guidelines (2):

- “The use of the ITD may be considered by trained personnel as a CPR adjunct in adult cardiac arrest (Class IIb, LOE B).”

Preliminary results (7) from the ROC PRIMED study (8) indicate that the ITD did not improve survival. However, the trial was conducted in a number of sites with varying protocols, many of them different than in Ventura County, and the individual site results are yet not published. Two recent studies conclude that the ITD, as part of a bundle of care with standard CPR (9) and active compression-decompression CPR (10) is associated with improved cardiac arrest survival.

Limitations:

The sample size for the first 9 months of the trial was insufficient to have statistically significant results for the KA/ITD portion. The IRB approval was to evaluate whether the change in protocol resulted in an improvement in care, and, when it was clear that there was no patient benefit, it was necessary to revise the protocol.

Similarly, there are no statistically significant results for the ITD portion of the study at this time, and data collection is continuing.

Hospital care has changed during the trial that will affect the analysis. All patients with ROSC are now triaged to a STEMI Receiving Center to be evaluated for therapeutic hypothermia.

Conclusion/Recommendations:

We did not find a benefit from use of the King Airway as a routine device and will continue to use bag-mask ventilation and endotracheal intubation as indicated.

The potential benefit of the impedance threshold device is not yet known and should be further evaluated.

We recommend that the impedance threshold device portion of the trial be continued for an additional 18 months.

References:

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