

Paramedic Committee
Meeting Minutes
December 13, 2010

PRESENT

EMS Chief Martin Fuller for Chief McNutt
Rich Ellett
Chief Rick Helminski
Lt. Glenn Newman
Wayne Hartford
Jeff Nissen
Rod Standiford
Craig Koperski
Allison Armstrong
Matt Viertlbeck
Byrce Blair
Nicole Knight
Dr. David Miramontes

REPRESENTING

Whitehouse Fire – Policy Board Member
Maumee Fire – LS 7
Springfield Fire
Toledo Fire EMS Bureau
Toledo Fire
Oregon Fire – LS8
Sylvania Twp. – LS6
Sylvania Twp. – LS6
Toledo Fire
Toledo Fire – LS1
Toledo Fire – LS1
Toledo Fire – LS1
Toledo Fire/Metro Toledo Fire

STAFF

Dennis Cole
Dr. David Lindstrom
Brent Parquette

Director – Emergency Services
Medical Director
QA/QI

ABSENT

Jodi Livecchi
Tracy Stanford
Keith Mooseman
Chief Charles Flack
Mark Briggs

Toledo Fire – LS 2
Toledo Fire – LS 3
Toledo Fire – LS 4
Toledo Fire – LS 5
Whitehouse Fire – LS9
Springfield Twp. Fire – LS10
Washington Twp. Fire
Waterville Fire
Jerusalem Twp. Fire
Ottawa Hills

Call to Order

Chief Fuller called the meeting at 9:03 am.

Minute Approval

The minutes from November 1, 2010 meeting were available for review. With no corrections, Chief Helminski made a motion to approve the minutes which was seconded by Rich Ellett. Minutes were approved as written.

Training

Brent reported there was no CE in November and December. January's CE will cover toxicology review and hands-on inservice training on the new power cots. The expected delivery of the cots is sometime in January. Brent also reported we have moved forward with the purchase of the LP15's and there will be an inservice on those in February. The question was asked if there is CO monitoring in the LP15's, Brent reported yes.

QA

No report.

Old Business

Brent reported on the Auto CPR devices handout. (attached) Brent reported he went to an AHA Guidelines Instructor Conference on the 2010 AHA Guidelines for CPR a couple of weeks ago. It is noted there is not continual, constant compressions in CPR and we need to improve delivery of CPR in the field. The handout reports on the current state of CPR and two devices that deliver CPR, LUCAS and the Auto Pulse. Brent went through the handout with the comparisons of the two devices. A discussion ensued with some of the paramedics citing what they have used and not used. It was decided some of the departments have only used one of the devices and want to trial the other.

New Business

Brent reported a representative from Stryker was here last Friday, November 10th to show the power cot. The question was raised as to the position of the holder for the O² bottle in that we have the opportunity now to change it if we want. Brent reported currently it is at the head of the cot and asked if it would be better at the foot of the cot. Also Brent reported he is spec'ing out hooks for the head of the cot to hold the LP15s. A discussion ensued regarding the position of the O² holder and it was the conclusion it would be placed at the foot of the cot.

Allison asked if the county considered buying headsets for the life squads. Brent reported it would be difficult to monitor the different frequencies. A discussion of such ensued. Dennis reported he will look in to it next year.

Open Discussion

Nicki asked if it was decided what departments would get the new life squads that are coming in. Dennis reported he has input from Al and the garage mechanic, and there are some differences between them, but he is not sure yet. Dennis did report the second set of four life squads are due late January. Nicki also cited issues with Life Squad 1's seal between the cab and box.

Nicki also reported on the issue of the tablets on LS1 and not being able to download from the LifePak. Bob Boyd noted that the tablets have a hibernate setting when the lid closes causing the problem. They are in the process of checking all of the tablets.

A discussion of tablet issues ensued. Dennis said he wanted the paramedics to continue to call the IT help desk. Bob Boyd reported there is internet workorder software that they can report issues on. There is a form to fill out that creates a ticket for the problem and then a status ticket once the work is done.

Bob reported the new Panasonic tablets are due in at the end of December.

Dennis also discussed ETI's ePCR. Dennis reported Zoll is the best solution for the ALS ePCR for now.

Jeff Nissen reported on an issue regarding a long turnover of a patient to the nursing staff at Bay Park, citing he had to wait ten minutes before a nurse took over. Dr. Lindstrom said he would look into it.

Rich Ellett asked if it was considered having pediatric patients taken to a Children's hospitals. Dr. Lindstrom reported there has been discussion in the past. Dr. Lindstrom reported acute care hospitals are capable of taking care of pediatric patients and none of the Children's hospitals have made an issue of it. Also, they are not open twenty-four hours a day. Rich cited some of the physicians at St. Luke's asked to be bypassed and Rich said it is more frequent. Dr. Lindstrom asked Rich for names and he would approach Dr. Crawford.

Rod Standiford reported there is an increase in the number of patients Flower takes, Rod said they take everything now.

Captain Romstadt reported LS5 having to take a patient from Regency Hospital for a transport of a hypotensive patient to Flower Hospital. He cited the life squads are busy and that this was unnecessary for a life squad to transport. Dr. Lindstrom reported he will look into it. Dr. Lindstrom reported these places normally have private companies they use. Dr. Lindstrom said we are obligated to respond to a call. Dr. Miramontes reported these acute care hospitals have really sick patients and are hooked up to a lot of equipment and medications and they also have physicians on duty there even at night.

Next Meeting and Adjournment

With no further business, the meeting was adjourned at 10:10 a.m. The next meeting will be held Monday, **January 10th** at 9:00 a.m.

Cardiopulmonary Resuscitation

2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care: Executive Summary Statements

- Emergency medical services (EMS) systems and healthcare providers should identify and strengthen “weak links” in the Chain of Survival.
 - *Reaffirmation in the importance of a stronger emphasis on compressions of adequate rate and depth, allowing complete chest recoil after each compression, minimizing interruptions in compressions and avoiding excessive ventilation.*
- Emergency medical providers should develop a culture of measuring and ensuring high-quality CPR

The Current State of CPR

1. CPR quality is usually poor and has been equated with “trying to drive at night with your headlights off.”
2. CPR is often unmonitored and performed with inconsistent quality in both the in-hospital and out-of-hospital settings.
3. Recent data collection found improper depth of compression (72%), and chest compressions were given only 48% of the available time during resuscitation.
4. Reasons why manual CPR is difficult to perform:
 - a. **Rapidly occurring physical and mental fatigue (within one or two minutes)**
 - b. **Changes in chest wall compliance during resuscitation**
 - c. **Prioritizing other interventions**
 - d. **Performing CPR on a soft surface or while transporting patients down hallways and stairways**

These findings have spurred development of a variety of FDA-approved CPR feedback and mechanical assist devices.

Cardiopulmonary Resuscitation

2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Part 7: CPR Techniques and Devices

Mechanical Piston Devices (LUCAS):

There is insufficient evidence to support or refute the routine use of mechanical piston devices in the treatment of cardiac arrest. Mechanical piston devices may be considered for use by properly trained personnel in specific settings for the treatment of adult cardiac arrest in circumstances that make manual resuscitation difficult (Class IIb, LOE C).

- *No randomized control trials comparing the device with conventional CPR*
- *Additional case series have reported variable success with the device*
- *One feasibility study reported successful deployment during diagnostic and interventional procedures*

Load-Distributing Band CPR (Auto Pulse):

There is insufficient evidence to support or refute the routine use of the LDB in the treatment of cardiac arrest. Case series have demonstrated improved hemodynamics, ROSC, and survival to hospital discharge with use of the LDB for cardiac arrest. The LDB may be considered for use by properly trained personnel in specific settings for the treatment of adult cardiac arrest in circumstances that make manual resuscitation difficult (Class IIb, LOE B).

- *In a study using concurrent controls, the use of LDB-CPR was associated with lower odds of 30-day survival*
- *One multi-center prospective randomized controlled trial comparing LDB-CPR to manual CPR for out-of-hospital cardiac arrest demonstrated no improvement in 4-hour survival and worse neurologic outcome when the device was used. These results raised concerns about the possible harm with use of this device. (ASPIRE Trial).*

AHA Levels of Evidence

Class IIb: Benefit \geq Risk. Additional studies with broad objectives needed; additional registry data would be helpful.

- Procedure / Treatment: **May be considered**

B: Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies.

C: Very limited populations evaluated. Only consensus opinion of experts, case studies, or standard of care





Parameter	 <p>LUCAS 2 (Jolife) Adjunct to manual CPR in cases of clinical death as defined by a lack of spontaneous breathing and pulse ADULT PATIENTS</p>	 <p>Auto Pulse (Zoll) Adjunct to manual CPR in cases of clinical death as defined by a lack of spontaneous breathing and pulse ADULT PATIENTS, 18 YEARS OF AGE OR OLDER</p>
Indication for Use	<p>YES (No disclaimer against use in Trauma)</p>	<p>NO</p>
Use in Trauma?	<p>(No disclaimer against use in Trauma)</p>	<p>NO</p>
Compression Type	<p>Bellows / Piston Mechanism</p>	<p>Load-Distributing Band (LDB)</p>
Patient Parameters	<p>Adult patients who fit into the device: Sternum height of 6.7" to 11.9" Maximum chest width of 17.7" Not restricted by patient weight</p>	<p>Patient chest circumference 29.9" to 51.2" Patient chest width 9.8" to 15" Maximum patient weight - 300 lbs.</p>
Compression Depth	<p>1.5 to 2.0 inches</p>	<p>20% reduction in anterior-posterior chest depth.</p>
Compression Frequency	<p>100 ± 5 compressions per minute</p>	<p>80 ± 5 compressions per minute</p>
Duty Cycle	<p>50 ± 5%</p>	<p>50 ± 5%</p>
Compression Modes	<p>30:2 (30 compressions followed by 3 sec. pause) Continuous compressions</p>	<p>30:2 or 15:2 compressions (followed by 3 sec. pause) Continuous compressions</p>
Physical Specifications	<p>Assembled: 22.4 x 20.5 x 9.4 inches Carry Bag: 25.6 x 13 x 9.8 inches Weight (with battery): 17.2 lbs</p>	<p>32.5 x 17.6 x 3.0 inches Weight (with battery): 25.6 lbs</p>
Power Options	<p>Rechargeable Battery AC power supply Car power cable</p>	<p>Rechargeable Battery</p>

Parameter	 LUCAS 2 (jolife)	 Auto Pulse (Zoll)
Audible / Visible Warnings	YES	YES
Battery	Rechargeable Lithium Ion Polymer (LiPo) 1.3 lbs	Rechargeable Nickel-Metal Hydride (NiMH) 5.1 lbs
Battery Runtime	45 minutes (typical)	30 minutes (typical)
Battery Charge Time	Less than 4 hours at room temperature	Less than 4 1/4 hours at room temperature
Battery Replacement Requirements	Recommendation to replace the battery every 3 years or after 200 uses (of more than 10 minutes use each time)	100 full charge / discharge cycles. Note: the battery will not operate after 100 full charge / discharge cycles
Battery Cost	\$595	\$575
Replacement Item Cost / Per use	Suction Cup: \$40.00	Load-Distributing Band: \$125-\$150
Approximate Unit Cost	~\$15,000	~\$15,000

Comparison of Standard Cardiopulmonary Resuscitation (S-CPR) Alone Versus Active Compression Decompression Cardiopulmonary Resuscitation (ACD-CPR) Plus an Inspiratory Impedance Threshold Device (ITD) on Survival from Out-of-Hospital Cardiac Arrest
[ResQTrial]

Purpose

To evaluate the safety and effectiveness of ACD-CPR plus augmentation of negative intrathoracic pressure using an inspiratory impedance threshold device (ITD) in patients with non-traumatic out-of-hospital cardiac arrest

Key Finding

ACD-CPR with augmentation of negative intrathoracic pressure using an ITD improves survival to hospital discharge with favorable neurologic function. The survival benefit persisted to one year following cardiac arrest.

Study Design

- Prospective, randomized, 2-arm, open, blinded, multicenter trial
- Conducted under an Investigational Device Exemption (IDE G050062) and Federal Exception from Informed Consent (21CFR50.24)
- Eligible patients assigned to treatment with ITD + ACD-CPR (Intervention group) or standard CPR (Control group) on a 1:1 basis according to a pre-specified weekly randomization schedule
- Strong emphasis on immediate chest compressions with early placement of study devices
- Survival and neurologic outcomes assessed up to one year after cardiac arrest

Study Devices

- ResQPump™ ACD-CPR Device and ResQPOD® Impedance Threshold Device (ITD); both manufactured by Advanced Circulatory Systems, Inc., Roseville, MN

Study Endpoints

- *Primary Endpoint* - Survival to hospital discharge with favorable neurologic function, defined as a modified Rankin Scale (mRS) ≤ 3
- *Secondary Safety Endpoint*- Rate of major adverse events, including death, through hospital discharge
- *Secondary Efficacy Endpoint* – Survival and neurologic function and through one year (various neurologic assessment tools)

Enrollment Criteria

- *Initial enrollment criteria* - Adults (presumed ≥ 18 years of age) with non-traumatic out-of-hospital cardiac arrest and who were candidates for CPR
- *Final criteria (final analysis population)* - Patients who met initial criteria AND the cardiac arrest was of cardiac origin AND at least one minute of CPR was provided by EMS

Study Sites

- Seven coordinating EMS sites in US: Minneapolis, MN; St. Paul, MN; Whatcom County, WA; Oshkosh, WI; Oakland and Macomb Counties, MI; Washtenaw and Livingston Counties, MI; Indianapolis, IN
- Included 46 EMS agencies in urban, suburban, and rural areas, combined total population of 2.3 million.
- Study protocol reviewed and approved by 25 participating Hospital Review Boards

Study Population

- 2470 patients randomized, 1653 met final criteria: 813 in Control group and 840 in Intervention group.
- Similar baseline characteristics. Mean age 66.8 ± 14.5 yrs in Control group and 67.0 ± 15.2 yrs in Intervention group; 66% male (both groups). Initial recorded rhythm ventricular fibrillation/pulseless ventricular tachycardia (VF/VT) in 30% of Control and 35% of Intervention groups, respectively.

Results

- Patients in the Intervention group had a 53% relative increase in survival to hospital discharge with a mRS of ≤ 3 (primary endpoint): 75/840 (8.9%) vs. 47/813 (5.8%), $p=0.019$, OR 1.58 [CI= 1.07, 2.36].
- There were no survivors in either group if CPR was initiated > 10 min after the 911 call.
- *Patients with an initial recorded rhythm of VF/VT*: Survival to hospital discharge with MRS ≤ 3 was greater in the Intervention subgroup: 23% versus 17%, $p=0.0645$ (non-significant).
- One year after cardiac arrest, there was a $>50\%$ increase in survival in the Intervention group: 8.8% (74/840) versus 5.9% (48/813) in the Control group, $p=0.030$.
- The overall rate of major adverse events was not significantly different between groups. There were more reports of pulmonary edema in the Intervention group, coexistent with the increased survival in this group.
- Neurologic function was similar between groups at 90 days and one year after cardiac arrest. There was no increase in the number of patients with severe neurologic impairment in the Intervention group.
- Results were consistent across study sites, patient age groups, gender.

Conclusions

- ACD-CPR with augmentation of negative intrathoracic pressure using an ITD improves survival to hospital discharge with favorable neurologic function. The survival benefit persisted to one year following cardiac arrest.
- The combination of ITD + ACD-CPR has an acceptable safety profile for use in patients with cardiac arrest.
- The combination of ITD + ACD-CPR is feasible to teach and implement in variety of EMS environments.
- These results support the routine use of ITD + ACD-CPR during cardiac arrest to increase survival to hospital discharge with favorable neurologic function.

Funding

The ResQTrial was supported by a grant from the United States National Institutes of Health (R44-HL065851-03)

Sponsor

Advanced Circulatory Systems, Inc. (1905 County Road C West, Roseville, MN 55113 USA)

www.advancedcirculatory.com

Contact: Keith Lurie, MD, Chief Medical Officer; 651-403-5600

Regulatory Status of Study Devices

- The ResQPOD is commercially available in the US (-10 cmH₂O inspiratory impedance) and outside the US (-16 cmH₂O inspiratory impedance, version used in the ResQtrial).
- The ResQPump is similar to the CardioPump[®], which is CE marked and is currently marketed outside the US. Use of the ResQPump is investigational in the US.

Media Contact:
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Advanced Circulatory Systems, Inc.

NIH-FUNDED STUDY IS FIRST TO DEMONSTRATE INCREASED LONG-TERM SURVIVAL WITH FAVORABLE NEUROLOGIC FUNCTION AMONG PATIENTS RECEIVING CPR USING ACS[®] RESQPUMP[™] AND RESQPOD[®] CPR DEVICES

Chicago (November 14, 2010) -- A combination of two devices could save the lives of several thousand cardiac arrest patients each year if implemented nationwide, suggests results of a clinical trial presented at today's American Heart Association Resuscitation Science Symposium. A significantly higher percentage of patients who experienced out-of-hospital cardiac arrest survived after receiving active compression decompression cardiopulmonary resuscitation (ACD CPR) performed with the ResQPump[™] and the ResQPOD[®] impedance threshold device as compared to those receiving conventional, manual CPR performed with a pair of hands. Both devices are manufactured by Advanced Circulatory Systems, Inc. (ACSI) in Roseville, Minn.

Ralph J. Frascione, MD, associate professor of emergency medicine at the University of Minnesota and EMS medical director at Regions Hospital in St. Paul (Minn), presented the results of the study.

"Each year, approximately 300,000 Americans experience out-of-hospital cardiac arrest, and the national average for survival to hospital discharge is dismal – only about 5 percent," Frascione said. "However, in this study, patients who received CPR by rescuers using the device combination had a 53 percent higher survival to hospital discharge rate with favorable neurologic function than those who did not, and, a significant survival benefit was still present one year after the initial cardiac arrest event."

"The goal of resuscitation during cardiac arrest is long-term survival with preservation of brain function," commented Dr. Tom P. Aufderheide, principal investigator at one of the study sites. "This new, effective intervention achieves that goal and is potentially the most significant advancement in the treatment of cardiac arrest since defibrillation."

Funded by the National Institutes of Health and sponsored by Advanced Circulatory Systems, Inc., the trial compared survival rates among a control group of 813 cardiac arrest patients receiving standard CPR to an intervention group of 840 receiving ACD CPR, performed using the ResQPump, with an impedance threshold device (ITD), the ResQPOD. All other aspects of patient care, such as airway management, IV fluids, medications, defibrillation, resuscitation length, etc., were similar between the two groups. The randomized, prospective, multi-center trial was performed in seven distinct U.S. geographic locations, including 46 emergency medical services (EMS) agencies in urban, suburban, and rural areas serving a total population of 2.3 million.

"We are thrilled," said Keith G. Lurie, MD, chief medical officer of Advanced Circulatory Systems. "This was a huge undertaking, involving thousands of EMS providers and hospital personnel over a span of about five years. It is also the first prospective, randomized clinical trial to demonstrate a long-term survival benefit with favorable neurologic benefit using CPR devices."

The ResQPOD[®] is an impedance threshold device (ITD) that selectively prevents unnecessary respiratory gases from the entering the chest during the chest wall recoil phase of CPR. It is attached within the ventilation circuit between the airway device and the ventilation source. By selectively restricting airflow during CPR, the device creates a small but important negative pressure (vacuum) in the chest that has been shown in numerous human and animal clinical trials to increase blood flow back to the patient's heart during CPR.

The ResQPump™ is a hand-held active compression decompression (ACD) CPR device placed in the same position on the sternum as the hands and enabling rescuers to perform similar chest compressions as in conventional CPR. Instead of allowing the chest wall to recoil passively, however, rescuers pull up on the ResQPump's handle with its suction cup. This provides active decompression of the chest, promotes optimal chest wall recoil and creates a negative intrathoracic pressure (vacuum) that helps return blood to the heart. The handle contains a force gauge and metronome that guide compression depth, recoil and rate. The ResQPump is identical to the CardioPump®, an ACD CPR device available for sale outside the US.

About ACSI

Advanced Circulatory Systems, Inc. is a privately held manufacturer of advanced circulatory technology based in Roseville, Minn. Its mission is to restore life and improve the quality of life for patients experiencing cardiac arrest, low blood pressure and head injury by developing new technologies to non-invasively increase circulation throughout the body, improving opportunities for survival and quality of life. The company manufactures and markets the ResQPOD, a version of which is currently available for sale and in use at more than 1,200 hospitals and EMS systems throughout the U.S.; and the CardioPump, which is currently available for sale only outside the U.S.