

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 (primary 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 with favorable neurologic function 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.