

## Survival from Hospital Discharge to One Year After Out-of-Hospital Cardiac Arrest: A Comparison of Standard CPR versus Active Compression Decompression CPR Plus and Impedance Threshold Device

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## Disclosure Information

- Presenter: Robert A. Swor, DO
  - No financial interests in Advanced Circulatory Systems Inc. (ACSI- manufacturer of the study devices)
- Co-authors:
  - No financial interests in ACSI
  - R. Frascone, B Mahoney, M Wayne, R Swor, T Aufderheide, R Domeier & M Olinger received grant funds to their institutions to conduct the study
  - R Holcomb received consulting fees for statistical analysis services

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## Background: ResQTrial

The randomized, prospective, multicenter ResQTrial was a NIH-funded clinical trial conducted in the United States from 2005-2010. The primary analysis focused on patients in patients with out-of-hospital cardiac of presumed cardiac etiology. \*

### Findings:

1. Active compression decompression CPR plus an impedance threshold device (ACD+ITD) (n=842) resulted in a relative 52% higher survival to hospital discharge rate vs standard (S) CPR (n=814)(P=0.019)
2. ~1/3 of the subjects randomized to treatment in that trial were excluded due to non-cardiac causes.

\*Aufderheide et al. Lancet 2011;377:301-311

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## CPR Methods Compared

Standard CPR (S-CPR)



ACD CPR + ITD (ACD+ITD)



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## Hypothesis

**Unanswered Question:**

Should we use ACD+ITD on all patients, regardless of the cause of the arrest?

**Hypothesis:**

Long-term survival after OHCA is higher with ACD+ITD vs S-CPR for all study subjects randomized to one of these two methods of CPR, regardless of the cause of the arrest.

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## Methods

Secondary analysis of all subjects randomized to either S-CPR or ACD+ITD, including those in the run-in phase

Performed under FDA IDE and waiver of consent regulations in 7 US sites

Performed from 2005-2010: 4950 EMS personnel participated

Subjects randomized if CPR was required for non-traumatic cardiac arrest, regardless of etiology

Subjects followed for one year

Data from patient records, patient interviews, public death records

Statistical Analysis: Fischer's exact test and Kaplan Meier

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# Results

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## Patient Characteristics

	S-CPR (N = 1335)	ACD+ITD (N = 1403)
<b>Age, years ± SD</b>	64.5 ± 17.2	63.2 ± 17.8
<b>Males; n (%)</b>	827 (61.9)	882 (62.9)
<b>Witnessed arrest; n (%)</b>	732 (54.8)	764 (54.5)
<b>Bystander CPR; n (%)</b>	533 (39.9)	585 (41.7)
<b>911 to EMS CPR, minutes ± SD</b> <small>*does not include EMS witnessed</small>	6.6 ± 3.6	6.6 ± 3.3
<b>First recorded rhythm; n (%)</b>		
VF/pulseless VT	318 (23.8)	371 (26.4)
Asystole	673 (50.4)	696 (49.6)
PEA	326 (24.4)	318 (22.7)
data not available	18 (1.3)	18 (1.3)

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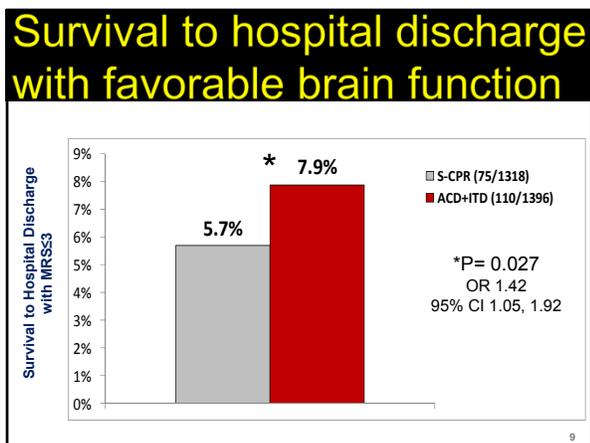
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## Neurological Function 365 days after OHCA

	S-CPR [N= 1335]	ACD+ITD [N=1403]	p-value
CPC scores at 1 year, CPC ≤2:	61 (4.7)	86 (6.4)	0.062
Scores by group:			
1	52 (4.0)	73 (5.3)	0.076
2	9 (0.7)	13 (1.0)	
3	4 (0.3)	3 (0.2)	
4	2 (0.2)	3 (0.2)	
5	1229 (94.3)	1258 (92.1)	
Survived, CPC data not available	7 (0.5)	16 (1.2)	

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## Limitations

Inherent differences in the two methods of CPR prevented blinded application of therapies

A small number of patients in each group lost to follow up

Study was stopped earlier than planned due to lack of funding

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## Conclusions

Regardless of etiology of non-traumatic OHCA, survival to hospital discharge with good neurological function was significantly higher with ACD+ITD vs S-CPR

Regardless of etiology of OHCA 1 year survival was significantly higher in the ACD+ITD group vs S-CPR,

No new safety issues identified when the entire study population was evaluated

Neurological function back to baseline for nearly all subjects a year after OHCA with both CPR methods

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## Summary

In this 2738 patient study, OHCA patients randomized to treatment with ACD+ITD who survived to hospital discharge had an 11% higher likelihood of one year survival compared with treatment with S-CPR, regardless of the etiology of the non-traumatic cardiac arrest.

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## BACKUP SLIDES

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## Funding & Sponsor

- Grants/Research Support: NIH SBIR Grant R44HL06585
- Advanced Circulatory Systems, Inc. (Roseville, MN)
  - Recipient of the NIH award; trial sponsor
  - Manufacturer of study devices
- The study was conducted under a U.S. Federal Exception from Informed Consent (EFIC) guidelines (21 CFR 50.24), and under an Investigational Device Exemption (IDE) that was approved by the U.S. Food and Drug Administration

The ResQ Trial was supported by Grant No. 2-R44-HL06585-03 from the National Heart, Lung & Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services. The contents of this presentation are solely the responsibility of ACSi and do not necessarily represent the official views of the NHLBI.

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### In-hospital Procedures

	S-CPR (N = 1335)	ACD+ITD (N = 1403)
<b>Admitted to hospital (%)</b>	376 (28.2)	431 (30.7)
<b>Cardiac catheterization, (% of admitted)</b>	89 (23.7)	126 (29.2)
<b>Coronary stenting (% of admitted)</b>	29 (7.7)	46 (10.7)
<b>Coronary bypass surgery (% of admitted)</b>	8 (2.1)	15 (3.5)
<b>ICD placement (% of admitted)</b>	38 (10.1)	50 (11.6)

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### Background: Mechanism of Neuroprotection

- The combined use of an impedance threshold device (ITD) with active compression decompression CPR (ACD+ITD) has been shown to increase cerebral perfusion, as compared with standard CPR (S=CPR), by:
  - increasing antegrade blood flow to the brain
  - reducing resistance to brain flow by lowering intracranial pressure

Metzger et al. *Critical Care Medicine*, 2011  
Yannopoulos et al. *Critical Care Medicine* 2006;34:S1-6

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### ResQTrial: Study Design

- Prospective, randomized, multicenter study
- Seven US sites with population base of 2.3 million
  - 46 EMS agencies
  - 4950 EMS providers
  - 25 IRBs
- Assigned CPR method (ACD+ITD or S-CPR) based upon a 1:1 weekly block randomization scheme
- Study CPR initiated by the first arriving EMS provider
- Follow-up with neurologic assessment at hospital discharge, 90 days and 1 year
- Study personnel blinded to aggregate data, nurses performing neurologic assessments blinded to assigned CPR treatment
- Enrollment period: October 2005 – July 2009

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## ResQTrial: Final Enrollment Criteria

- **Inclusion Criteria:**
  - Known or presumed to be ≥ 18 yrs old
  - Presumed cardiac etiology (Utstein criteria)
  - Received > 1 min of EMS CPR  
(to increase likelihood that patients received intended interventions)
  - Capable of being ventilated with advanced airway or BVM
- **Exclusion Criteria:**
  - Confirmed DNR
  - Signs of obvious clinical death
  - Recent sternotomy

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## Modified Rankin Scale

SCORE	DESCRIPTION
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

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## Cerebral Performance Categories

SCORE	DESCRIPTION
1	Good cerebral performance: conscious, alert, able to work, might have mild neurological or psychological deficit
2	Moderate cerebral disability: conscious, sufficient cerebral function for independent activities of daily life, able to work in sheltered environment
3	Severe cerebral disability: conscious, dependent on others for daily support because of impaired brain function, ranges from ambulatory state to severe dementia or paralysis
4	Coma or vegetative state: any degree of coma without the presence of all brain death criteria, includes unawareness, even if appears awake (vegetative state) without interaction with environment; may have spontaneous eye opening and sleep/awake cycles, cerebral unresponsiveness
5	Includes brain death (apnea, areflexia, EEG silence) and traditional death

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### Major Adverse Events to Hospital Discharge

Adverse Event; n (%)	S-CPR (N = 1335)	ACD+ITD (N = 1403)
<b>≥ 1 AE reported*</b>	<b>1253 (93.9)</b>	<b>1320 (94.1)</b>
Pneumothorax/Hemothorax	14	18
Internal organ injury	5	6
Pulmonary edema	105	159
Rib/sternal fracture	24	22
Aspiration	21	18

\*p= 0.810

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