ResQPOD® Impedance Threshold Device

Strengthening the Chain of Survival

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• Conflict of Interest
Learning Objectives

1. Describe how CPR circulates blood.
2. Describe what an ITD is & how it works.
3. Describe how to use an ITD during CPR.
4. Perform optimal CPR.

Improved Patient Care & Opportunity for Survival!
History of CPR
Early Resuscitation Efforts

• Hitting, slapping, whipping the victim
• Stretching rectum
• Tickling nose with a feather
• Rhythmically stretching tongue
• Bloodletting
• Placing victim across a trotting horse
• Rolling victim across a barrel
Early Resuscitation Efforts

- Applying warm ashes, heated bricks, burning excrement or hot water to abdomen
- Burying victim in warm sand or warm bath
- Placing victim in bed with 1 or 2 volunteers
- Lighting a fire next to victim
Cardiac resuscitation after cardiac arrest or ventricular fibrillation has been limited by the need for open thoracotomy and direct application of exhaustive external cardiac compressions. The technique of closed-chest cardiac massage, however, has been developed for use at the scene of cardiac arrest and has been adopted by many agencies as a valuable adjunct to standard emergency care.

W. B. Kouwenhoven, Dr. Ing., James R. Jude, M.D., and G. Guy Knickerbocker, M.S.E., Baltimore. The use of this technique on 20 patients has shown an overall permanent survival rate of 70%. Anyone, anywhere, can now initiate cardiac resuscitative procedures. All that is needed are two hands.

Courtesy Depart. of Surgery
Johns Hopkins Univ. Hosp.
Sudden Cardiac Arrest

• Prevalence
  – 1000/day out-of-hospital & in-hospital

• Current survival has been dismal
  – In-hospital: ≈20%
  – Out-of-hospital: 5 – 10%
  – 1 BILLION DOLLARS SPENT EVERY YEAR ON PATIENTS THAT WE DO NOT RESUSCITATE.

• Optimal CPR is key!
  – Good CPR provides <25% of normal blood flow
  – Provides adequate blood flow to vital organs and increases opportunity for meaningful survival
History of Resuscitation Devices

- 1947, Claude Beck
  - Successfully defibrillated of a 14yr boy after surgery open chest in V-Fib.
- 1956, Paul Zoll
  - First closed chest successful defibrillation
- 1969, first defibrillation in EMS by City of Miami, had to call over radio for order, pt survived, walked out of hospital.
Despite AEDs, Survival Rates Remain Low
Seattle Experience with AEDs – one of the best

Cobb et al. JAMA 281:1182, 1999
Priming the Pump:

For VF, 90-180 sec of CPR before and after shock if VF > 4 min (Class IIb)

Key to Successful Defibrillation

Key to Successful Resuscitation for patients not in ventricular fibrillation

AEDs were a step forward, but …
We still need more blood flow to the heart and brain
Better ways to protect the vital organs after resuscitation
Key to Survival

Adequate blood flow to vital organs during cardiac arrest is the key to patient survival and quality of life!
How CPR Circulates Blood

Compression Phase

Cardiac Pump Theory
- Heart is squeezed between sternum (breast bone) & spine.

Thoracic Pump Theory
- Chest acts like a bellows.
- Compression causes a positive pressure that forces:
  - Blood to leave the heart (cardiac output)
  - Air to leave the lungs
How CPR Circulates Blood

- Vacuum (negative pressure) forms in the chest, drawing:
  - Air back into the lungs
  - Blood back into the heart (preload)

- ↑ PRELOAD leads to ↑ CARDIAC OUTPUT
- Coronary blood flow occurs
How CPR Circulates Blood

- Ventilation
- Chest compressions (cardiac output)
- Chest decompressions (preload)
Three-Phase Model of Resuscitation

Arrest Time (min)

Weisfeldt ML et al. JAMA 2002:288:3035-8
# AHA Class Recommendations

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Should be performed.</td>
</tr>
<tr>
<td>IIa</td>
<td>Weight of evidence supports the therapy; acceptable and useful</td>
</tr>
</tbody>
</table>
| IIb   | May be considered;  
|       | (1) Optional: “can be considered”  
|       | (2) Recommended despite lack of high-level evidence: “we recommend” |
| III   | Do not use; not helpful; may be harmful |
| Indeterminate | Cannot recommend “for” or “against” |
Inefficiency of CPR

Conventional CPR is inherently inefficient because just as the chest wall begins to recoil, air rushes in through an open airway and wipes out the vacuum (negative pressure) that is critical for returning blood to the heart!
## 2005 AHA CPR Guidelines

<table>
<thead>
<tr>
<th>Device/Drug</th>
<th>Class Recommendation</th>
</tr>
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<tbody>
<tr>
<td><strong>Impedance Threshold Device</strong></td>
<td><strong>IIa</strong></td>
</tr>
<tr>
<td>Hypothermia</td>
<td>IIa</td>
</tr>
<tr>
<td>Vest CPR</td>
<td>IIb</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>IIb</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>IIb</td>
</tr>
<tr>
<td>Vasopressin</td>
<td>Indeterminate</td>
</tr>
<tr>
<td>Lidocaine</td>
<td>Indeterminate</td>
</tr>
<tr>
<td>Atropine</td>
<td>Indeterminate</td>
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The ResQPOD is an **impedance threshold device (ITD)** that selectively prevents unnecessary air from entering the chest during the recoil (decompression) phase of CPR, which leads to...
Effect of Inspiratory Impedance

Greater vacuum (negative pressure) in the chest during chest decompressions

Conventional CPR

Conventional CPR w/ ResQPOD

Ventilation

Chest compressions/decompressions

Enhanced vacuum
Chest Compression

Results in Positive Pressure

↑ Cardiac Output

↑ Blood Flow to Vital Organs

↑ Venous Return (Preload) & Coronary Artery Perfusion

↑ Chest Wall Recoil

↑ Intrathoracic Vacuum (Negative Pressure)
Airflow Through the ResQPOD

Chest Compression

Patient can freely exhale.

Patient Ventilation

Patient can be freely ventilated.
Airflow Through the ResQPOD

Chest Decompression

Influx of air is prevented, enhancing the vacuum in the chest.

Spontaneous Breathing

Air will enter if patient creates at least -10 cmH$_2$O pressure with respiratory effort.
Survival & Neurologic Recovery

![Bar chart showing survival and neurologic recovery of animals with and without ITD.]

- **24-Hr Survival**:
  - Sham ITD: 11
  - Active ITD: 17
  - *p<0.05

- **Neuro Recovery**:
  - Sham ITD: 1
  - Active ITD: 12
  - *p<0.05

*n = 20/group*

Hemodynamics

**Common Carotid Blood Flow (ml/min)**

- 15:2
- 15:2 + ITD
- 30:2
- 30:2 + ITD


*p < 0.05*
Animal and clinical studies have shown that the ResQPOD:

- Doubles blood flow to the heart
- Increases blood flow to the brain by 50%
- Doubles systolic blood pressure
- Increases survival

Clinical Benefits

The generally cleared indication for the ResQPOD is for a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Studies are on-going in the United States to evaluate the long-term benefit of the ResQPOD for indications related to patients suffering from cardiac arrest, hypotension during dialysis and severe blood loss. The presentation of clinical data is not intended to imply specific outcome-based claims not yet cleared by the US Food and Drug Administration.
Human Data: Blood Pressure

Milwaukee, WI

Blood Pressure after 14 Minutes of ITD Use

- Sham (Non-functional) ITD
- Active (Functional) ITD

*p<0.05


n = 22
Clinical Features & Benefits

- No contraindications in cardiac arrest
- FDA approved for all ages
- Rapidly increases circulation non-invasively & without fluids or medications
- Lights promote proper:
  - Ventilation rate
  - Compression rate
- Latex free
- Compatible with variety of airway adjuncts (e.g. ET tube, facemask) and any method of CPR
- Compatible with any ventilation source
- No resistance to rescuer ventilation or patient exhalation
- Single Patient Use
Using ResQPOD on a Facemask

1. Connect the ResQPOD to the facemask.
2. Open airway; establish & maintain tight face seal during chest compressions.
3. Connect ventilation source to ResQPOD.
4. Perform CPR @ recommended compression to ventilation ratio (e.g. 30:2).
5. Leave lights OFF.
Using ResQPOD on a Facemask without a Head Strap

During 30 Chest Compressions

Maintain a tight facemask seal during 30 chest compressions using a 2-handed technique.

Lift the lower jaw to the mask!

Delivering 2 Ventilations

Option 1: Have a 3rd rescuer deliver 2 ventilations over 1 sec each.

Option 2: Have the chest compressor deliver 2 ventilations over 1 sec each.
Using ResQPOD on an ET Tube

1. Confirm tube placement.
2. Secure with commercial tube restraint.
4. Connect ventilation source to ResQPOD.
5. Turn on timing lights.
7. Ventilate asynchronously @ timing light flash rate (10/min).
8. Administer ET meds directly into ET tube.
Using ResQPOD on an ET Tube

Place ETCO$_2$ detector between ResQPOD & ventilation source.
ResQPOD Use

- **Remove ResQPOD as soon as a spontaneous pulse returns!**
- Clear fluids or secretions
  - Shaking it
  - Blowing it out using the ventilation source
- With advanced airway use, use timing assist lights to:
  - Guide compression rate: 10/flash
  - Guide ventilation rate: 1/flash
- Give the ResQPOD the best opportunity to work – do the most optimal CPR!
- Prime the pump!
Performing Optimal CPR
Hyperventilation

Ventilating patients too often and/or over a long duration prevents the development of a vacuum (negative pressure) in the chest, which in turn, compromises forward blood flow to vital organs!
Porcine Survival Study

**Group 1**
- Seven pigs
- V-fib for 6 min
- Comp: 100/min
- Vent: 30/min
- CPR for 6 min
- Shock(s) as necessary

**Survival:** 1/7 (14%)

**Group 2**
- Seven pigs
- V-fib for 6 min
- Comp: 100/min
- Vent: 12/min
- CPR for 6 min
- Shock(s) as necessary

**Survival:** 6/7 (86%*)

Aufderheide et al. *Circulation* 2004;109:1960-1965. *p<0.05
Lessons from Hemorrhagic Shock

• Sedated, spontaneously breathing pigs \((n = 8)\)
• Bled out to < 65 mmHg systolic BP
• 5 min: ventilation @ 12/min (steady state)
• 10 min: ventilation @ 6/min
• 10 min: ventilation @ 20/min
• 10 min: ventilation @ 30/min

Example: RR = 6/min

SBP ≈ 76 mmHg
Example: RR = 20/min

SBP ≈ 63 mmHg

Rate: 20 breaths x min⁻¹

One respiratory cycle

Copyright 2008 ACSI
Example: RR = 30/min

SBP ≈ 52 mmHg
Maximum Ventilation Duration

Before Training:

Duration: \( \approx 1 \) secs  
Rate: 38 breaths/min

Overall mean breath duration: 0.85 \( \pm \) 0.07 secs
Maximum Ventilation Duration

After Training:

Duration: >4 secs  Rate: 11 breaths/min

Time available for negative pressure: 20%

Overall mean breath duration: $1.18 \pm 0.06^* \text{ secs (↑ 39%)}$
Ventilation Duration

“If each breath is delivered to patients with or without an advanced airway over 1 second and delivers a tidal volume that is sufficient to produce a visible chest rise (Class IIa).”
Hyperventilation & ventilations of long duration are deadly!
How important is mouth-to-mouth?
Are no ventilations better?

16 pigs with induced V-fib; 8 min. downtime; then CPR for 8 min with chest compressions @ 100/min

- **N = 9 pigs (NV)**
- CPR w/ 🆗 ventilations

- **N = 7 pigs (PPV)**
- CPR w/ ventilations @ 10/min & O$_2$

Epinephrine and shocks as needed to resuscitate.

Primary endpoint: survival to 24 hours neurologically intact (CPC of 1 or 2)

Lurie et al. To be presented at SCCM in 2/09.
Results

After 8 min of CPR, aortic, cerebral perfusion and coronary perfusion pressures were similar. At 7.5 min of CPR, arterial $pO_2$ measured.

- **N = 9 pigs (NV)**
  - $pO_2$: 42%
  - @ 24 Hrs: 4/9 (44%) alive
    - All 4 had poor neuro scores (CPC = 3)

- **N = 7 pigs (PPV)**
  - $pO_2$: 147%
  - @ 24 Hrs: 5/7 (71%) alive
    - 2 had CPC of 2
    - 3 had CPC of 1

All results statistically significant.

Lurie et al. To be presented at SCCM in 2/09.
Device Features

Ventilation Port

2 Timing Assist Lights
Promote proper ventilation & compression rate

Timing Assist Lights ON/OFF Switch
Turns timing assist lights on & off

Atmospheric Pressure Sensor System
Provides selective impedance to inspiratory air flow

Safety Check Valve
Enables inspiration @ -10 cmH₂O with spontaneous respiration

Patient Port
Chest Decompression

“Allow the chest wall to recoil completely after each compression.

Incomplete recoil is associated with higher intrathoracic pressures, decreased coronary perfusion and decreased cerebral perfusion.

CPR instruction should emphasize the importance of allowing complete chest recoil between compressions.”
Assure that the chest wall recoils completely after each compression in order to maximize vacuum formation that promotes preload.

Incomplete chest wall recoil after each compression significantly compromises cerebral and coronary perfusion pressures during CPR.

Porcine Hemodynamics Study

• **Model**: 9 pigs in V-fib for 6 min w/o CPR

• **Methods**: CPR @ 100/min w/ 15:2 comp to vent ratio
  – 3 min: w/ 100% decomp (complete chest wall recoil)
  – 1 min: w/ 75% decomp (incomplete chest wall recoil)
  – 1 min: w/ 100% decomp

• **Measured**: coronary & cerebral perfusion pressures

Yannopoulos et al. Resuscitation 2005;64:363-372
Results

Rotate Duties Frequently
CPR Delays & Interruptions

Blood Flow to Vital Organs During Chest Compressions
Begin performing chest compressions as soon as cardiac arrest is confirmed.
Add the ResQPOD ASAP!
Perform High-Quality CPR
Ventilate over 1 second (until chest rise) for both facemask and advanced airway.
DO NOT hyperventilate.
Use a two-handed facemask seal technique
Assure complete chest wall recoil.
Rotate duties frequently to avoid fatigue.
Avoid unnecessary delays or interruptions in chest compressions; no more than 5 – 10 seconds.

Objective: Compared analyze VF early vs analyze VF late and a sham vs active ITD simultaneously

Factorial Study Design; Factors:
   I. 30 vs 180 seconds of CPR before analysis and shock,
   II. Active vs sham ITD (sham ITD had timing lights),

Prospective, randomized, blinded

Patients: adult out-of-hospital cardiac arrest, presumed cardiac etiology

Primary endpoint: neurologically-intact survival to hospital discharge

Intended sample size: 14,000

Data Safety Monitoring Board review at 1/3 and 2/3 enrollment

Initially designed to detect a 25% or greater difference between factors
Protocols

- 3 different BLS Protocols
- ALS protocols per site medical director
- Post resuscitation care site dependent: therapeutic hypothermia used during transport and in the hospital in some but <50% of patients
## 3 ROC Site Protocols in 10 North American Cities

<table>
<thead>
<tr>
<th>Method of CPR</th>
<th>30 sec of CPR, Analyze and shock if indicated, Resume CPR with Sham ITD attached to facemask with BLS performed with a 30:2 compression:ventilation ratio</th>
<th>30 sec of CPR Analyze and shock if indicated, Resume CPR with Active ITD attached to facemask with BLS performed with a 30:2 compression:ventilation ratio</th>
<th>180 sec of CPR with Sham ITD, Analyze and shock if indicated, Resume CPR with Sham ITD attached to facemask with BLS performed with a 30:2 compression:ventilation ratio</th>
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<td>30 sec of CPR, Analyze and shock if indicated, Resume CPR with Sham ITD attached to facemask with BLS performed with a continuous compression + asynchronous ventilation 10x/min</td>
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</tr>
<tr>
<td>Method of CPR</td>
<td>No analyze early vs late comparison</td>
<td>BLS CPR with Sham ITD attached to facemask performed with a continuous compression + asynchronous ventilation 10x/min</td>
<td>No analyze early vs late comparison</td>
<td>BLS CPR with active ITD attached to facemask performed with a continuous compression + asynchronous ventilation 10x/min</td>
</tr>
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</table>
Changes from original assumptions

• State of Iowa withdrew from study
• Enrollment took 50% longer than expected
• There would be a common BLS protocol
• All sites would begin enrollment in a relatively similar time frame
• Some sites, like City of Dallas, unable to qualify for full enrollment, prior to August 2009, when data were collected
• Baseline neurologically-intact survival rates unknown prior to selecting sites and study: the spread was greater than anticipated, from 1.1% to 8.1%
Findings

• November 2, 2009, NIH announced study terminated early (at the 2/3 enrollment point) as it was not going to be possible to detect any overall significant difference between either of the study groups (analyze early vs late or sham vs active ITD) even if study continued to 14,000 patients.

• No safety concerns for ITD.

• Due to enrollment QA requirements and FDA issues, some sites did not enroll as many patients as originally anticipated and some enrollment more.

• Differences were observed from site to site that will require further analysis.

• Since patient follow up is required for up to 6 months post ROSC, no additional data will be forthcoming and site-specific information will remain blinded for at least 6 months.
• Multiple U.S. Sites showed a trend towards benefit with active ITD – details forthcoming in publication in Fall 2010.
Overall survival increased from 2.4% using older guidelines to 6.7% after introduction of the full 2005 AHA protocol. Dr. Myers (Wake County EMS) said that “the neurologic improvement was at least as robust as the survival improvement.” The entire protocol was introduced for less than $200 per patient, he said. “All of these changes are simple, they are inexpensive, and they are incredibly effective,” he said.
Inhospital Cardiac Arrest

Survival to Hospital Discharge

62% Improvement
Odds ratio: 1.87
95% CI: 1.03, 3.41
P=0.034

Systems-Based Approach

- A Systems-Based approach is a coordinated, comprehensive approach to resuscitation therapies to substantially increase sudden cardiac arrest survival rates beyond the benefits achieved with individual therapies alone.

- Includes “High Performance” CPR, based upon 2005 AHA Guideline Recommendations:
  - Start compressions as soon as arrest is confirmed (IIa)
  - Compress at proper rate and depth (IIa)
  - Allow chest to completely recoil (IIb)
  - Do not hyperventilate (IIa)
  - ITD to enhance circulation (IIa)
  - Perform CPR before and after shocks (IIb)
## Intervention Outcome Relationships in Take Heart America

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Effect</th>
<th>Survival rate ↑ over baseline</th>
</tr>
</thead>
</table>
| **Bystander CPR: in schools, homes & public meeting places**                  | ▪ Rapid EMS notification  
▪ Start circulation                                                           | 2 - 5%                        |
| **AED Use: Widespread strategic AED deployment**                              | ▪ Reduce time to 1<sup>st</sup> shock in VF patients                    | 4 - 6%                        |
| **Improved CPR Quality**                                                     | ▪ Increase circulation to heart & brain  
▪ Increase O<sub>2</sub> & drug delivery                                     | 4 - 6%                        |
| Prevent hyperventilation, continuous chest compressions, CPR pre/post shock, intra-osseous drug delivery |                                                                         |                               |
| **Impedance Threshold Device (ITD) BLS & ALS deployment**                    | ▪ Increase circulation to heart & brain  
▪ Increase O<sub>2</sub> & drug delivery                                    | 5%                            |
| **Cooling, ICU, Cardiology**                                                 | ▪ Revascularization  
▪ Prevent sudden cardiac death                                                | 10 - 15%                      |
| Standard hypothermia protocols, cardiac angiography (including during CPR) & EP |                                                                         | 25 - 37%                      |
Questions?

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