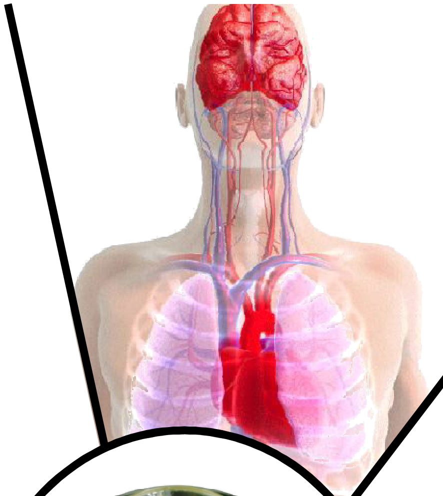

ResQPOD®

Impedance Threshold Device

Strengthening the Chain of Survival

ADVANCED CIRCULATORY SYSTEMS, INC.

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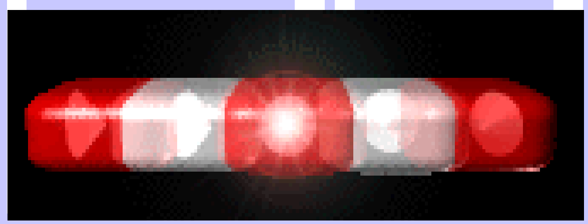
- **Katie Talk**
  - **NREMT-P**
  - **AHA Faculty (NC)**
  - **Clinical Educator for Advanced Circulatory Systems, Inc. (ResQPOD®)**

- Conflict of Interest



Learning Objectives

❶ Describe how CPR circulates blood.

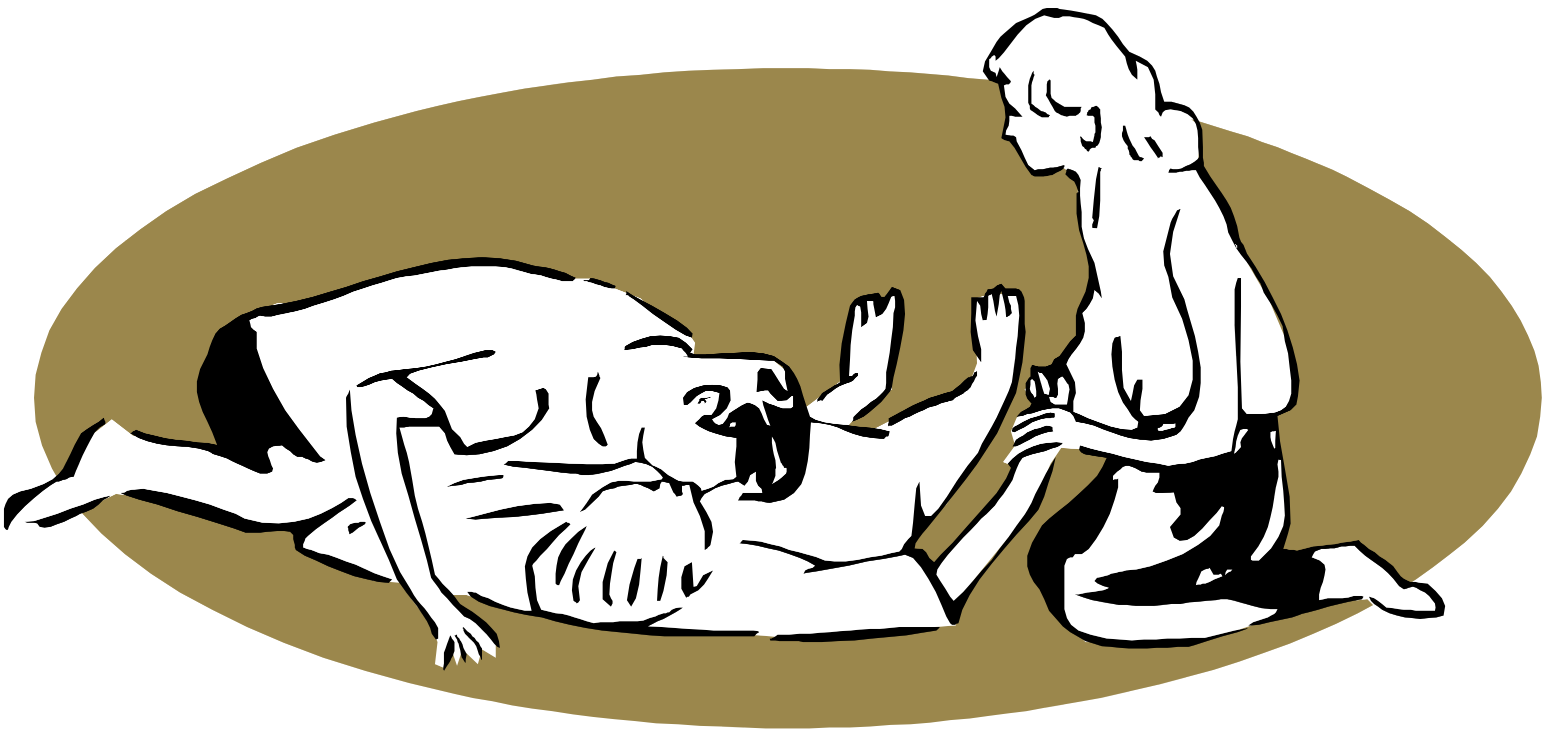
❸ Describe how to use an ITD during CPR.

Improved Patient Care & Opportunity for Survival!

❷ Describe what an ITD is & how it works.

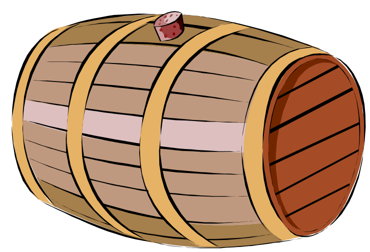
❹ Perform optimal CPR.

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

CLOSED-CHEST CARDIAC MASSAGE

W. B. Kouwenhoven, Dr. Ing., James R. Jude, M.D.
and
G. Guy Knickerbocker, M.S.E., Baltimore

Cardiac resuscitation after cardiac arrest or ventricular fibrillation has been limited by the need for open thoracotomy and direct
of exhaustive
od of external
has been de-
tive measures
ot only mouth-
but also ade-
thoracotomy.
The use of this technique on 20 patients has given an over-all 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.

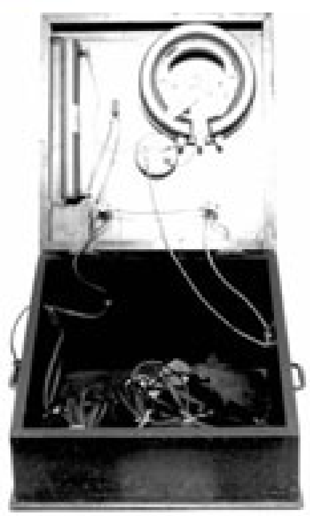
UHS/CMS MHW 9/82

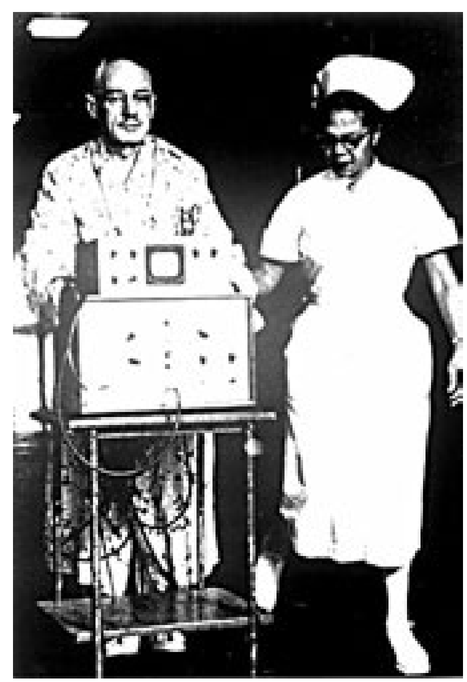
Sudden Cardiac Arrest

- 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

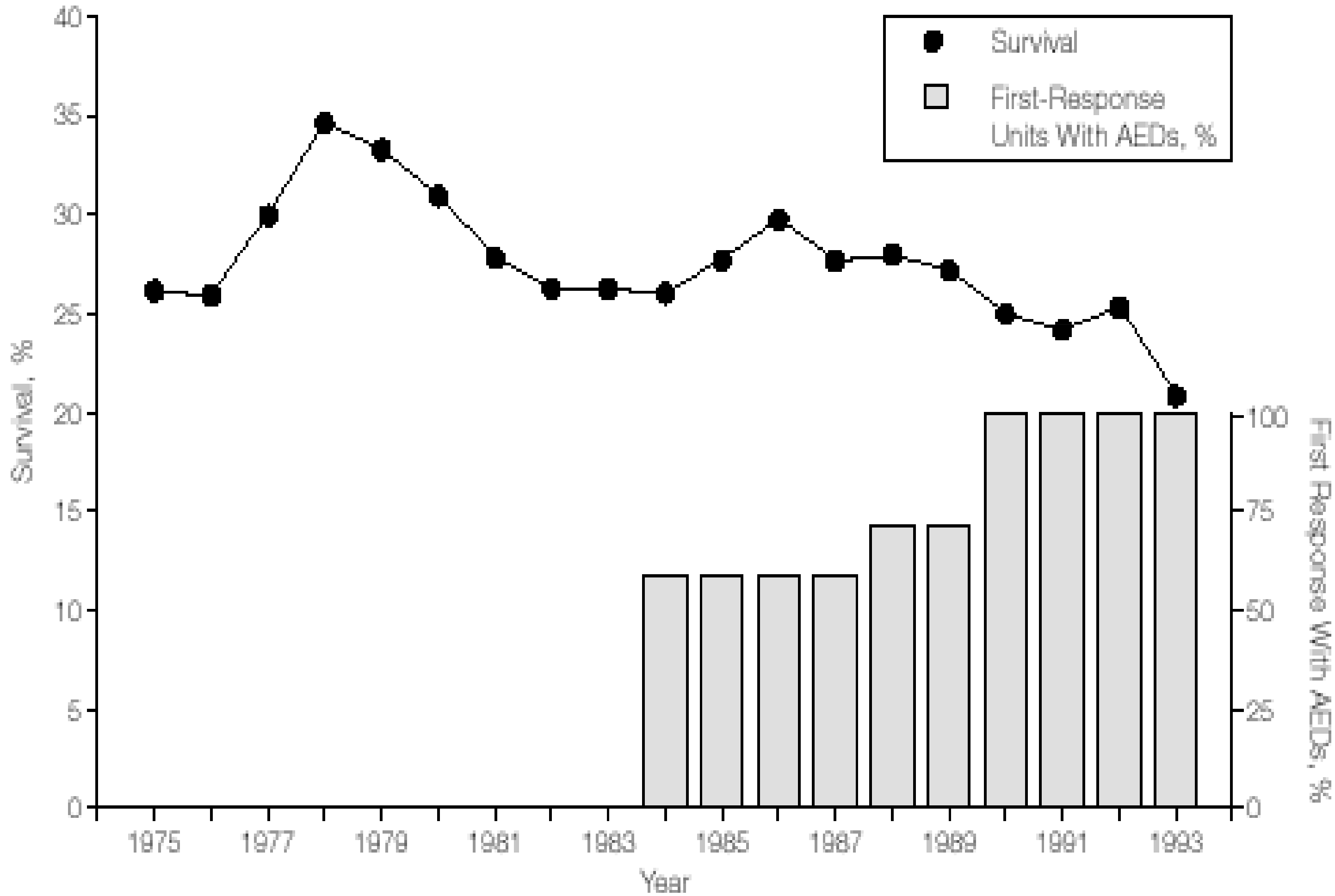
- 1947, Claude Beck
- Successfully defibrillated of a 14yr boy after surgery open chest in V-Fib.
- 1956, Paul Zoll
- First closed chest successful defibrillation
- 1969, first defibrillation in EMS by City of Miami, had to call over radio for order, pt survived, walked out of hospital.





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

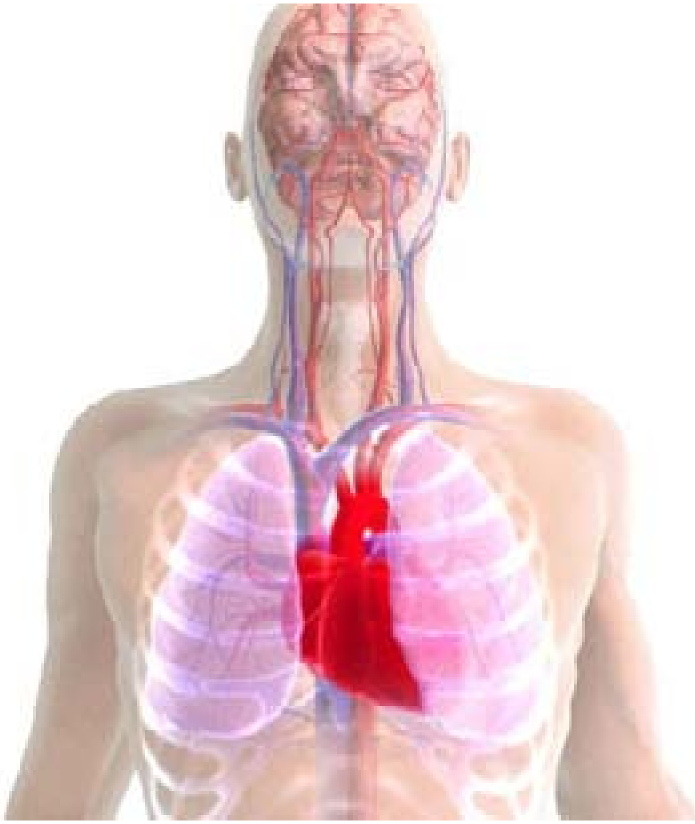
Key to Successful Resuscitation for patients not in ventricular fibrillation

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

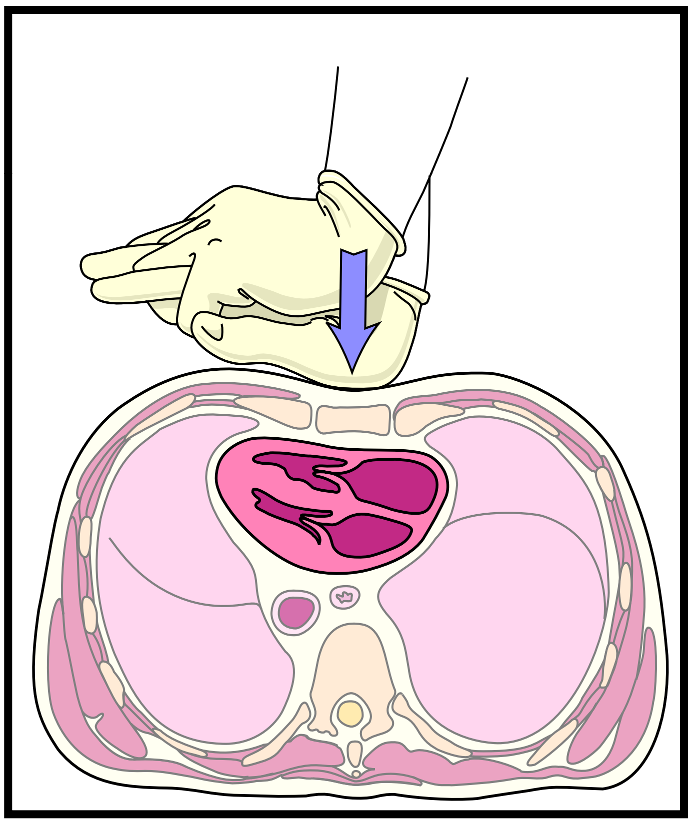
Key to Survival



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

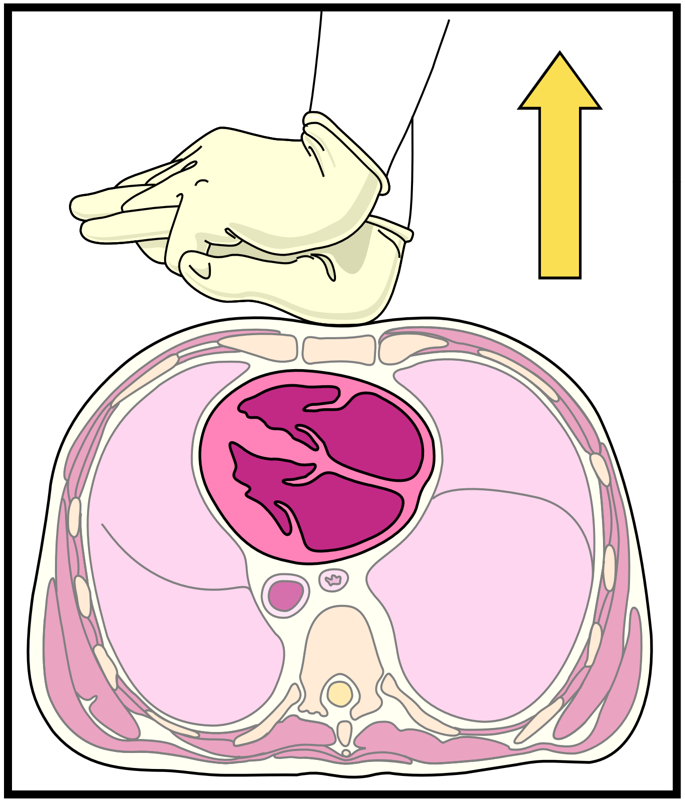
- Heart is squeezed between sternum (breast bone) & spine.

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

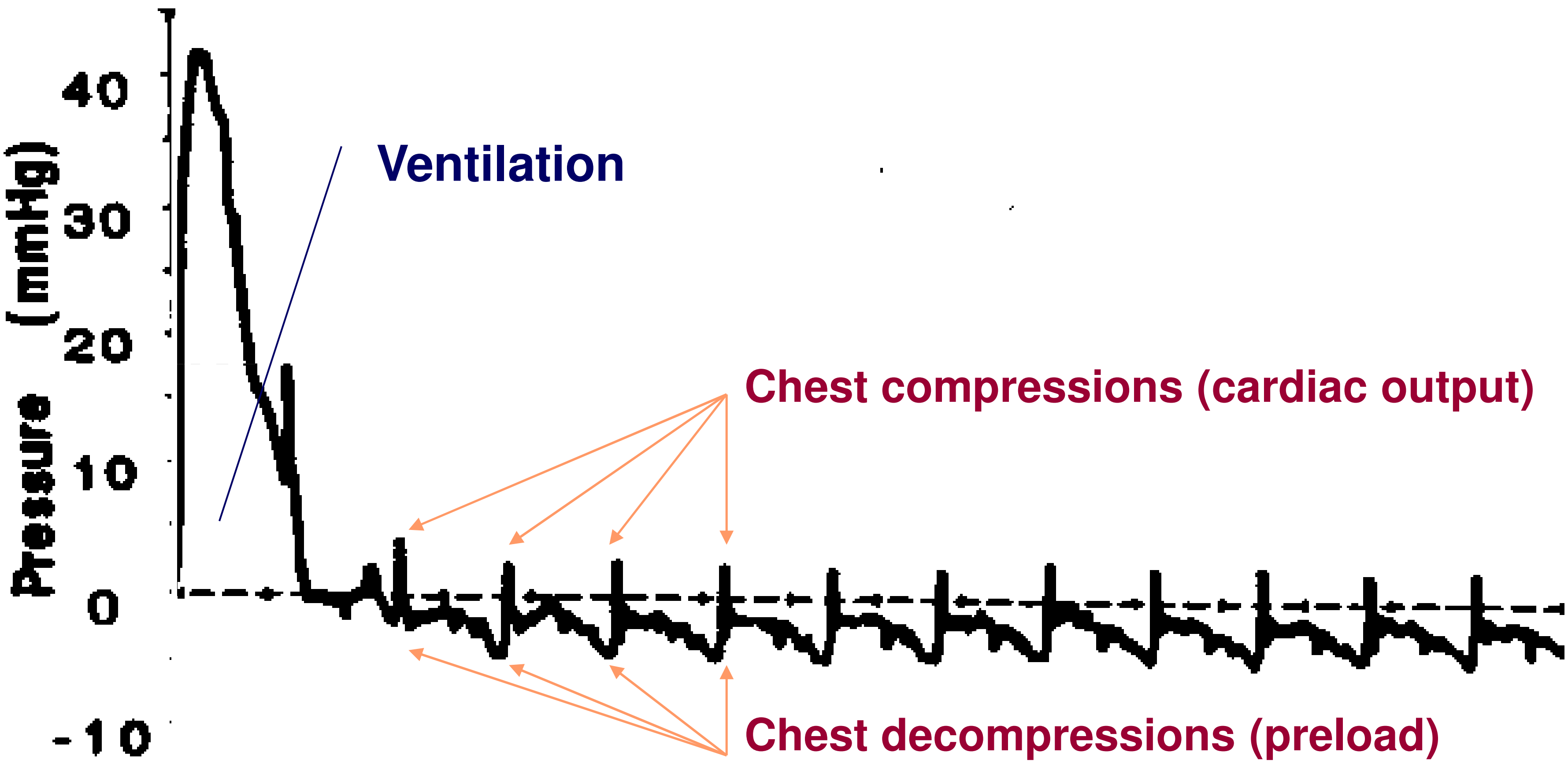
How CPR Circulates Blood

Decompression Phase

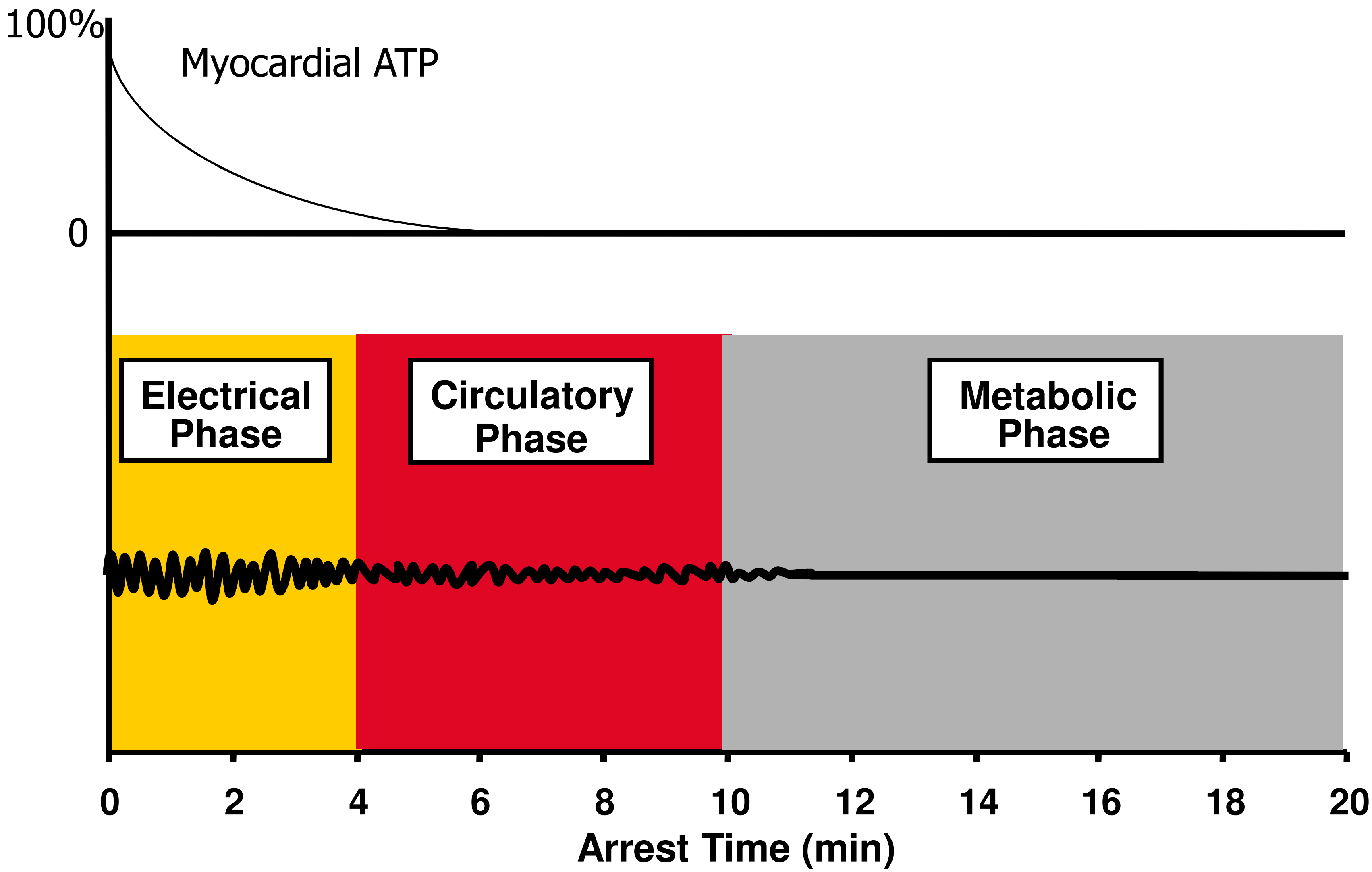


- Vacuum (**negative pressure**) forms in the chest, drawing:
  - Air back into the lungs
  - Blood back into the heart (preload)
- ↑ **PRELOAD** leads to ↑ **CARDIAC OUTPUT**
- Coronary blood flow occurs

How CPR Circulates Blood



Three-Phase Model of Resuscitation



Weisfeldt ML et al. JAMA 2002:288:3035-8

AHA Class Recommendations

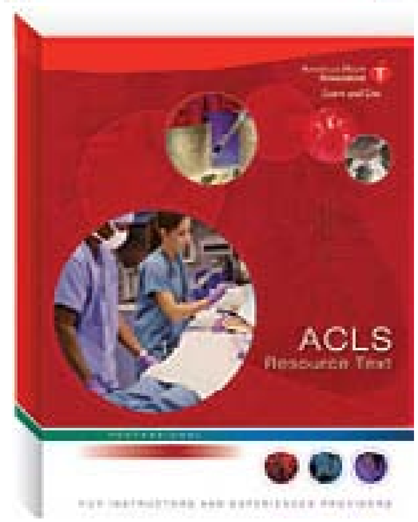
Class		Description
I		**Should be performed.**
IIa		**Weight of evidence supports the therapy; acceptable and useful**
IIb		May be considered; (1) Optional: “can be considered” (2) Recommended despite lack of high-level evidence: “we recommend”
III		Do not use; not helpful; may be harmful
Indeterminate		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

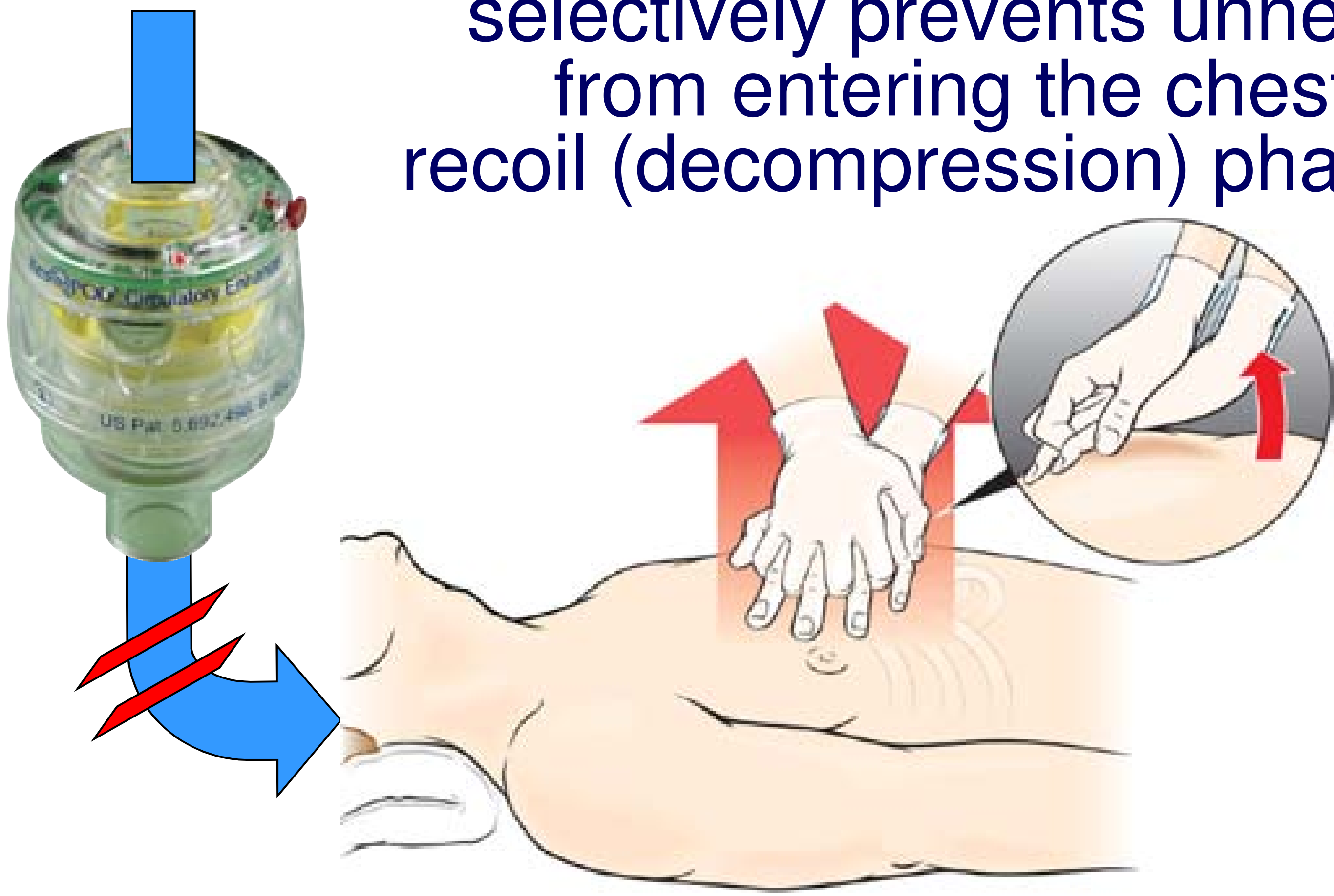
Device/Drug	Class Recommendation
Impedance Threshold Device	***IIa***
Hypothermia	IIa
Vest CPR	IIb
Epinephrine	IIb
Amiodarone	IIb
Vasopressin	Indeterminate
Lidocaine	Indeterminate
Atropine	Indeterminate



Source: 2005 AHA Guidelines for CPR and Emergency Cardiac Care; Part 6. Circulation 2005;112:IV-48

ResQPOD Impedance Threshold Device

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

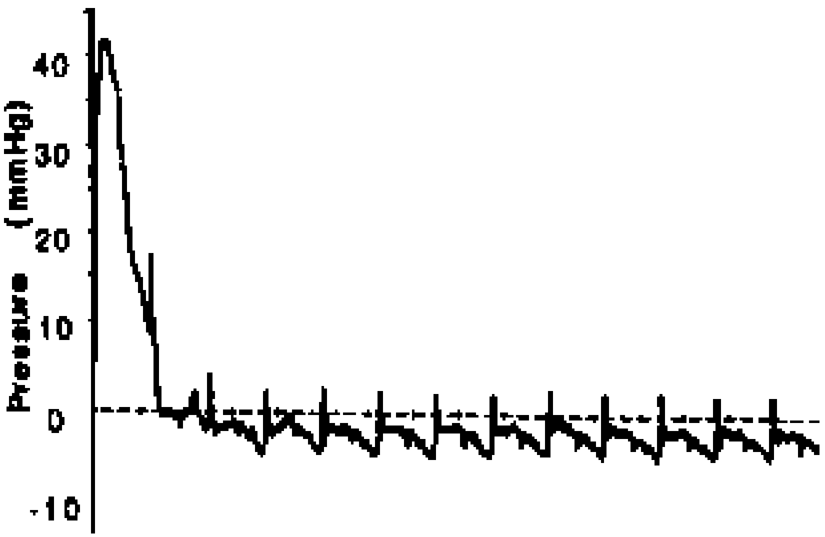
leads

to...

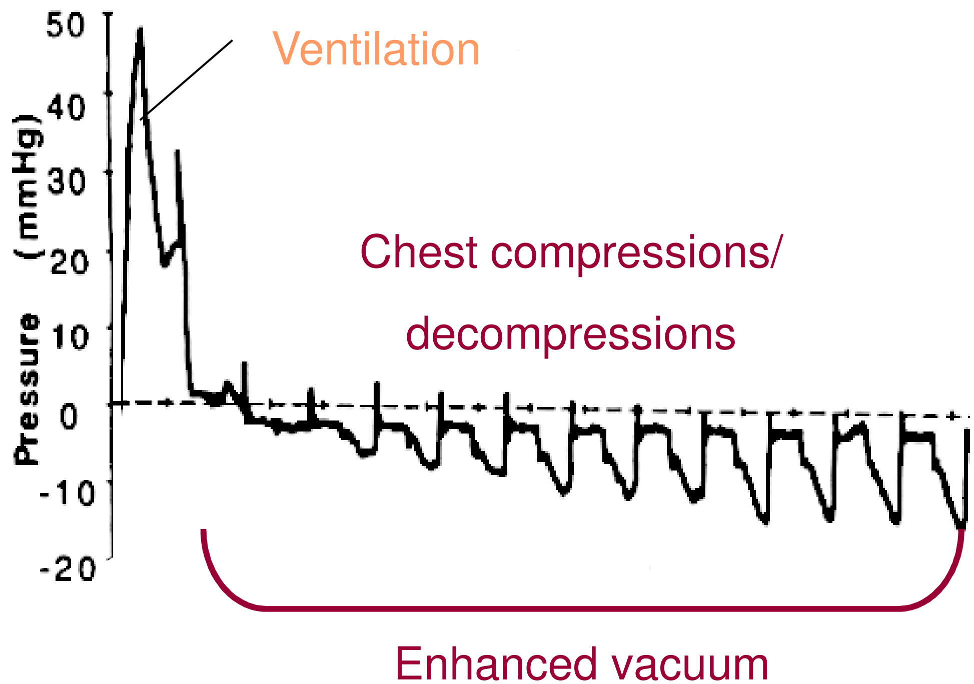
Effect of Inspiratory Impedance

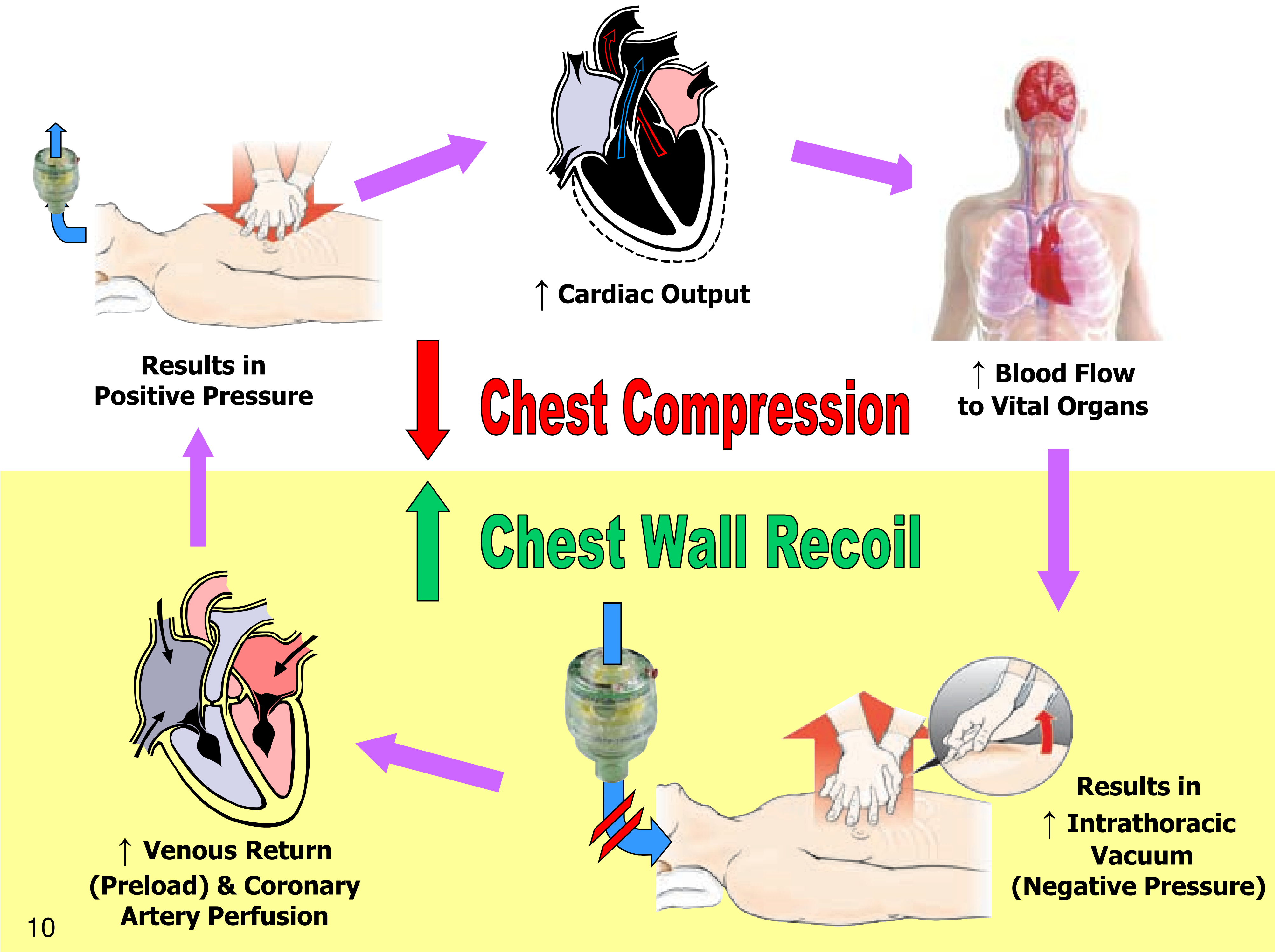
Greater vacuum (negative pressure) in the chest during chest decompressions

Conventional CPR



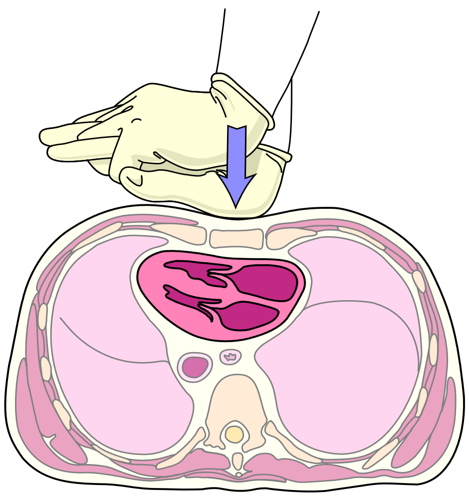
Conventional CPR w/ ResQPOD

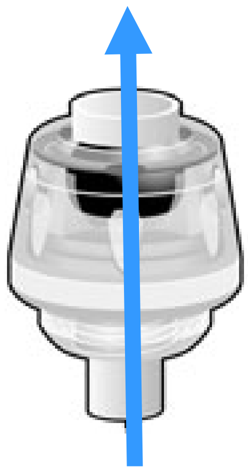



↑ Cardiac Output
Results in
Positive Pressure
Chest Compression
↑ Blood Flow
to Vital Organs
Chest Wall Recoil
Results in
↑ Intrathoracic
Vacuum
(Negative Pressure)
↑ Venous Return
(Preload) & Coronary
Artery Perfusion

Airflow Through the ResQPOD

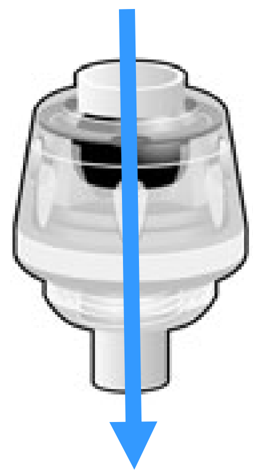
Chest Compression





Patient can freely exhale.

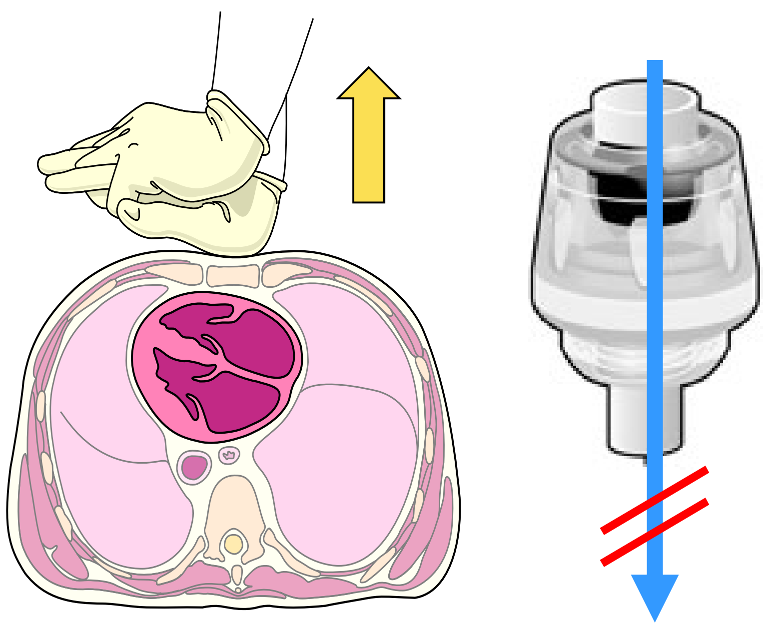
Patient Ventilation



Patient can be freely ventilated.

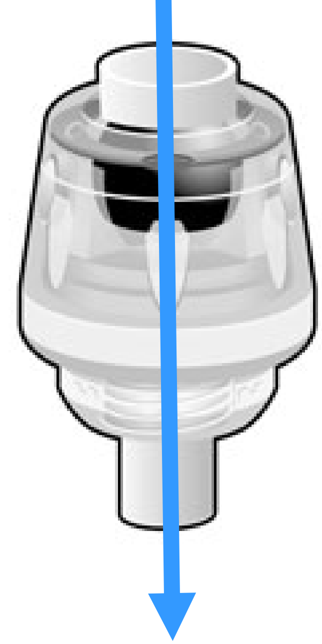
Airflow Through the ResQPOD

Chest Decompression



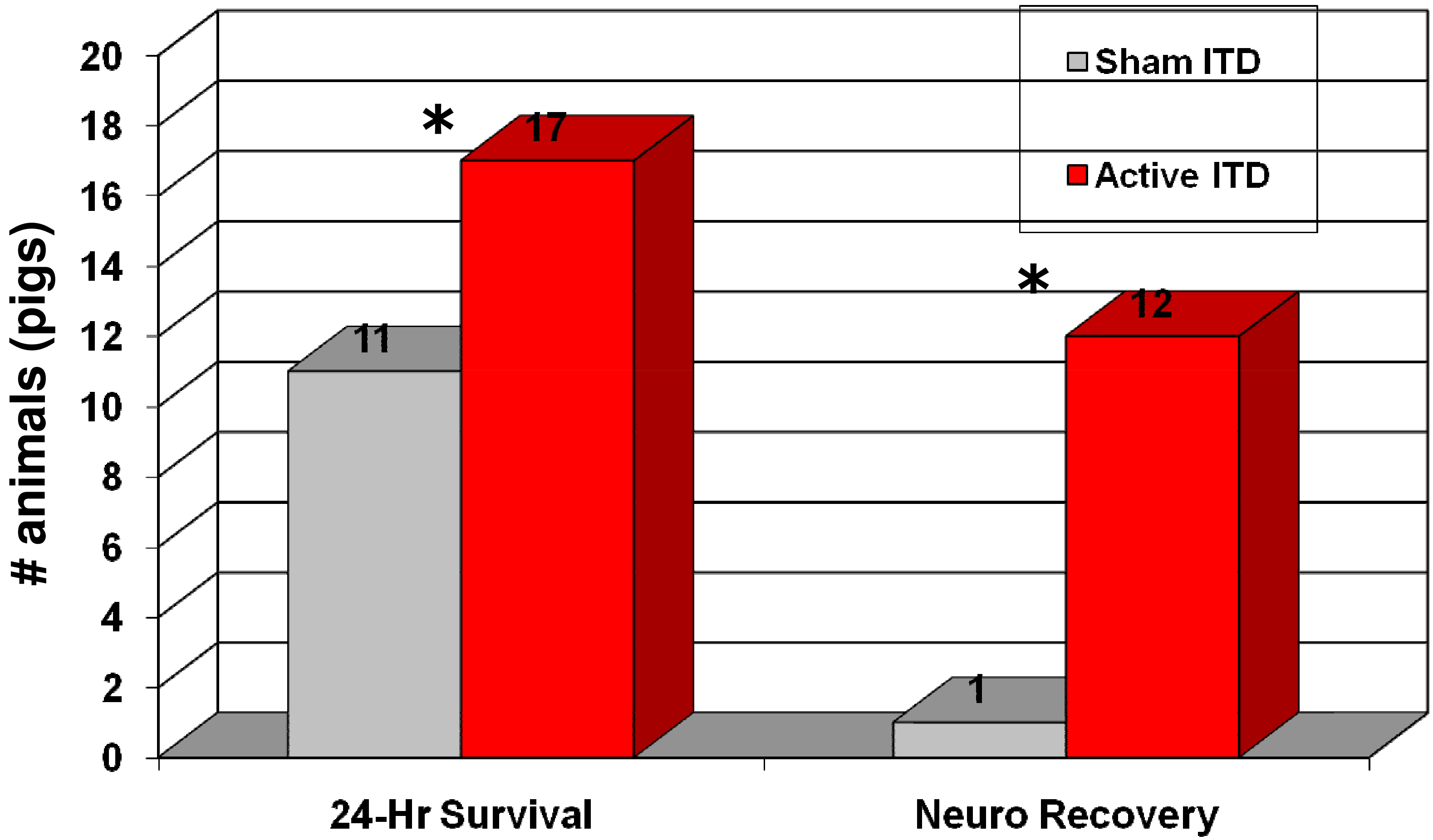
Influx of air is prevented, enhancing the vacuum in the chest.

Spontaneous Breathing



Air will enter if patient creates at least -10 cmH_2O pressure with respiratory effort.

⬆ Survival & Neurologic Recovery

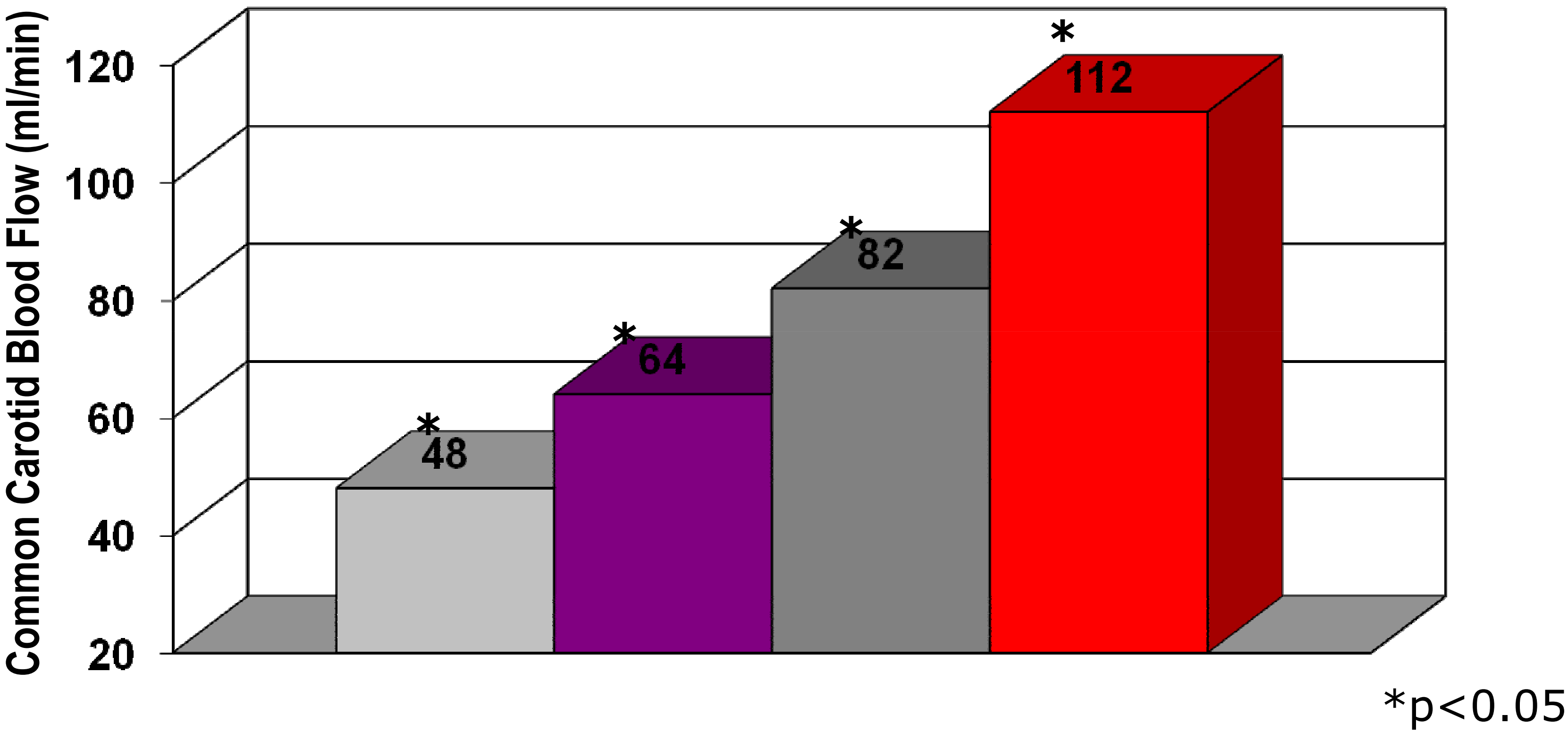


*p<0.05

n = 20/group

Lurie et al. Circulation 2002;105:124-9.

⇧ Hemodynamics



Comp:Vent Ratios:
- 15:2
- 15:2 + ITD
- 30:2
- 30:2 + ITD

Yannopoulos et al. Crit Care Med 2006;34(5):1444-9.

Clinical Benefits

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

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.

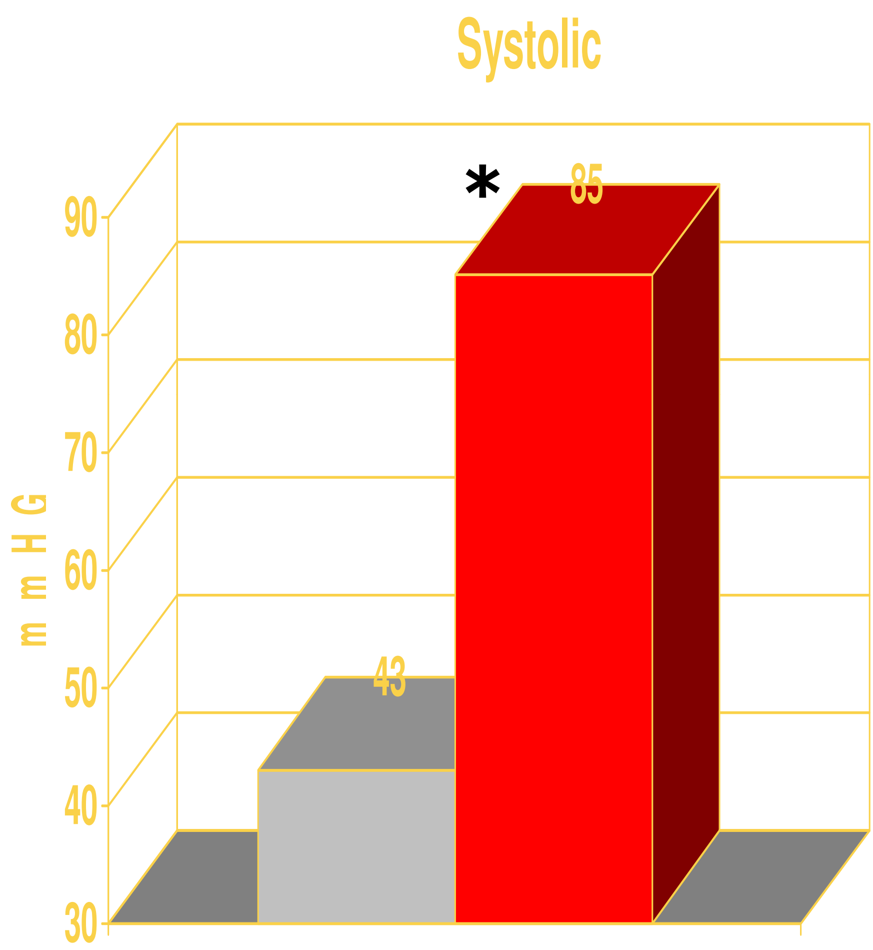
Human Data: Blood Pressure

Milwaukee, WI

Blood Pressure after 14 Minutes of ITD Use

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

*p<0.05



n = 22

Pirrallo et al. Resuscitation 2005;66:13-20.

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

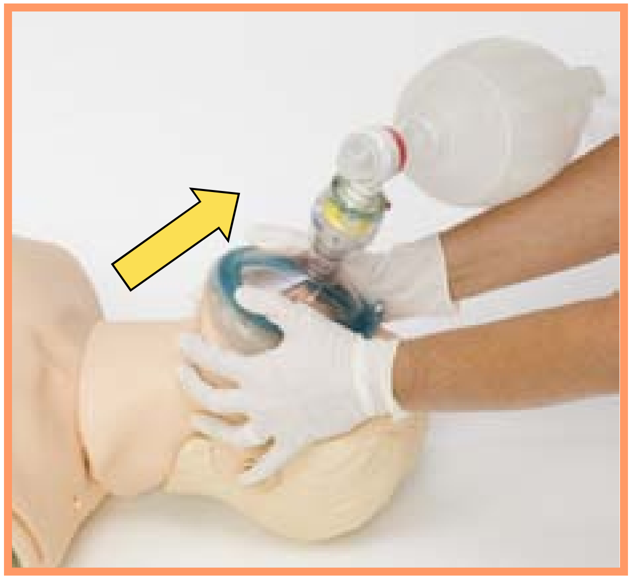
Using ResQPOD on a Facemask

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

Delivering 2 Ventilations



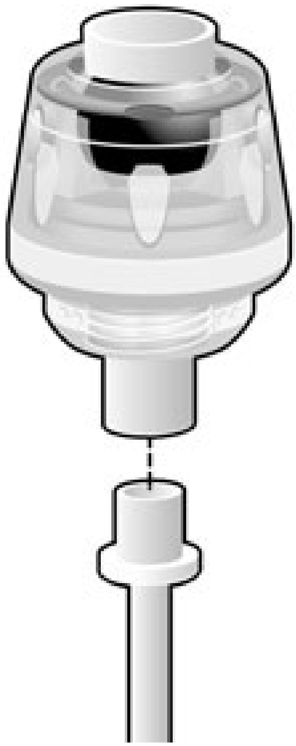
Maintain a tight facemask seal during 30 chest compressions using a 2-handed technique.

Lift the lower jaw to the mask!

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

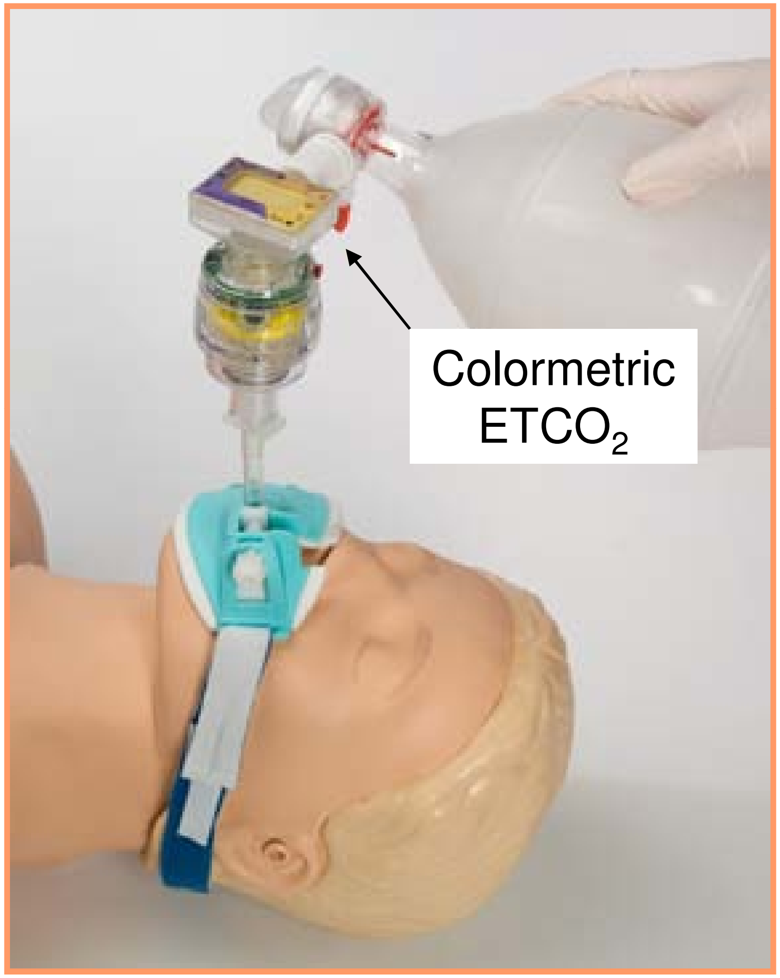
Option 2: Have the chest compressor deliver 2 ventilations over 1 sec each.

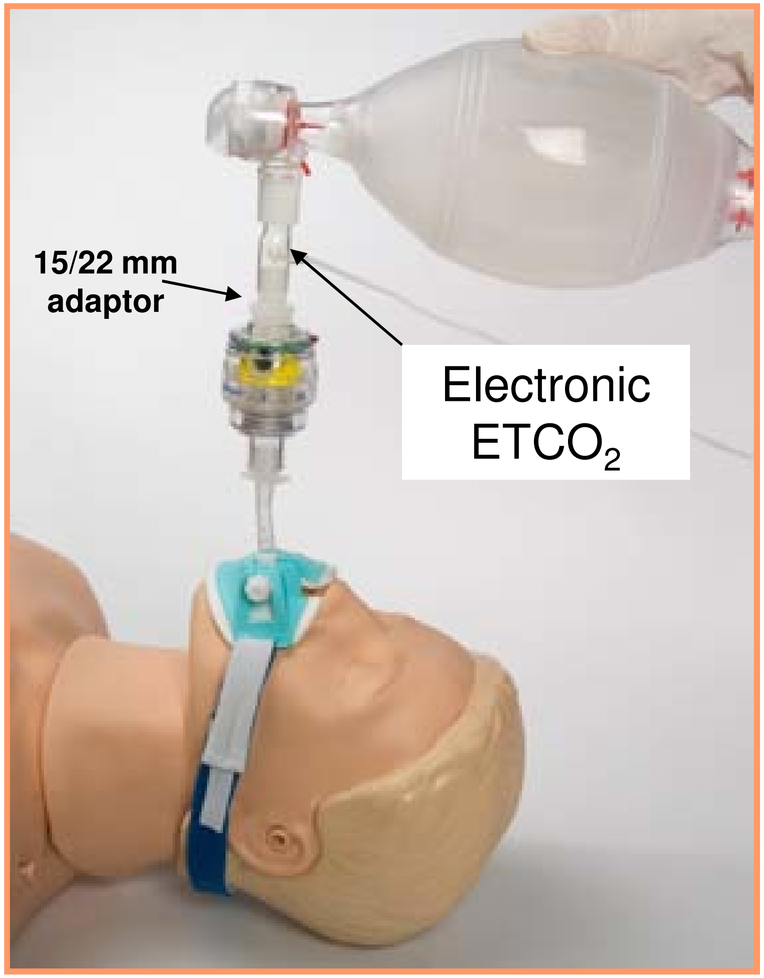
Using ResQPOD on an ET Tube



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

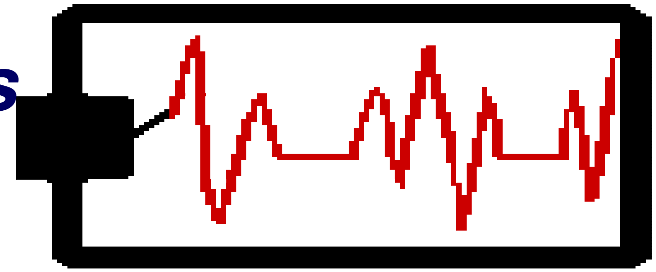
Using ResQPOD on an ET Tube





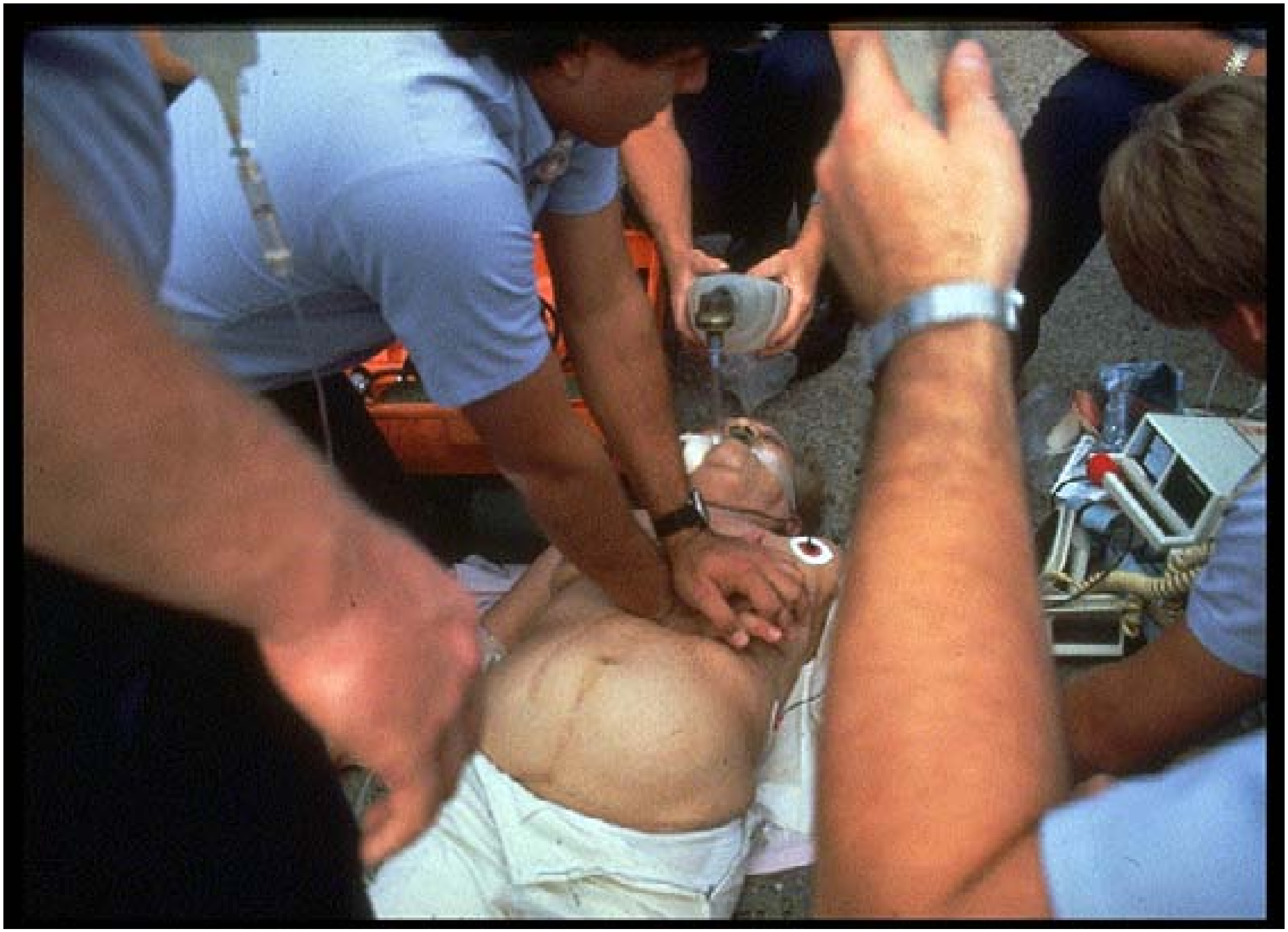
Place ETCO$_2$ detector between ResQPOD & ventilation source.

ResQPOD Use

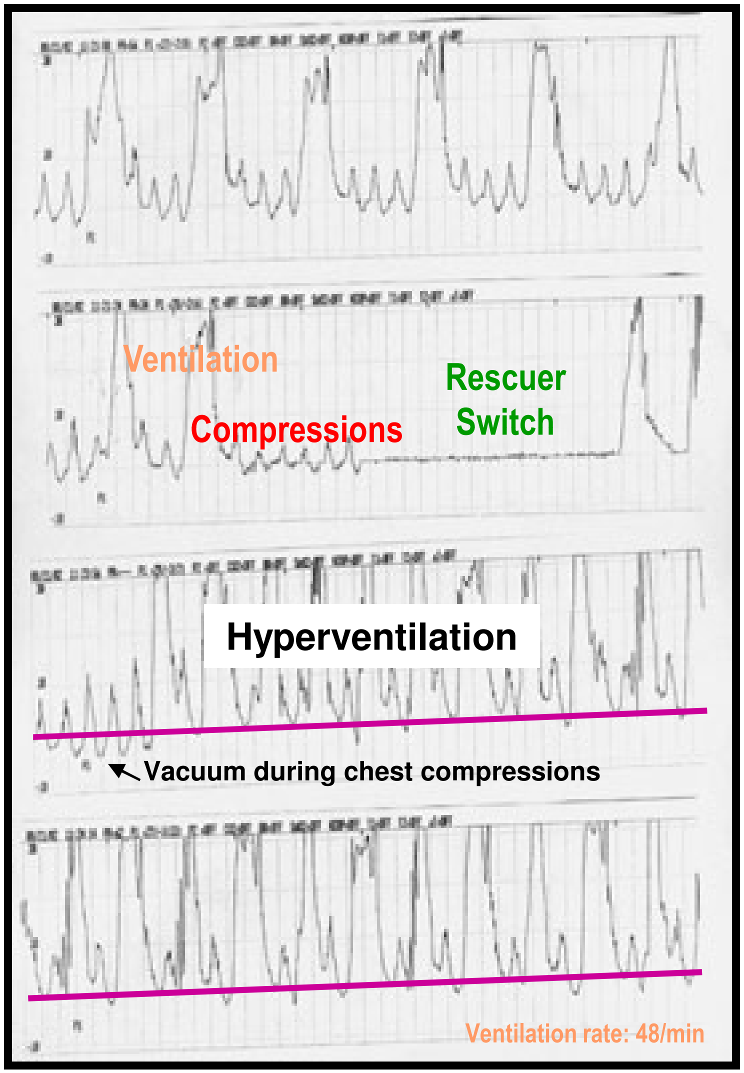


- ***Remove ResQPOD as soon as a spontaneous pulse returns!***
- Clear fluids or secretions
  - Shaking it
  - Blowing it out using the ventilation source
- With advanced airway use, use timing assist lights to:
  - Guide compression rate: 10/flash
  - Guide ventilation rate: 1/flash
- Give the ResQPOD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

Performing Optimal CPR

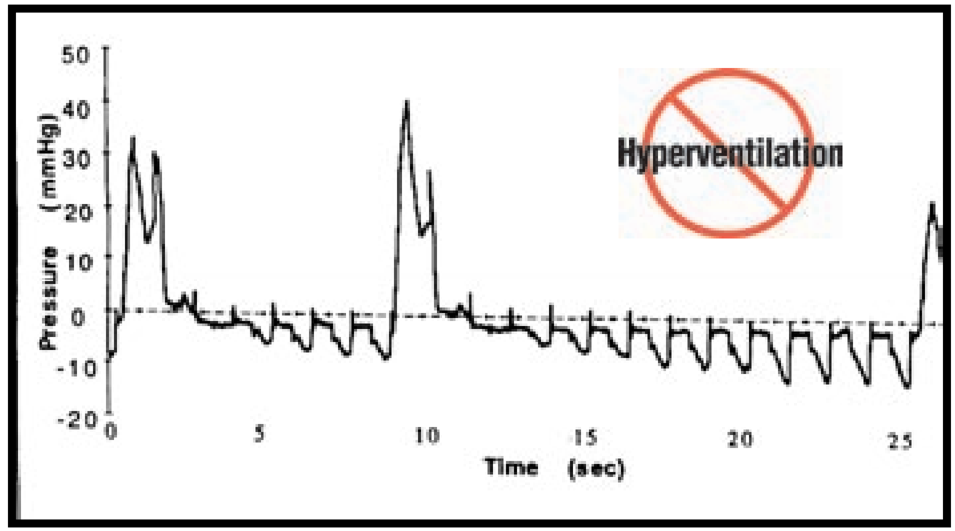


Hyperventilation



Example of Hyperventilation

Standard CPR with an ITD



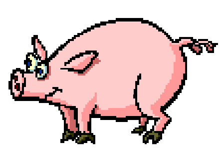
Ventilating patients too often and/or over a long duration prevents the development of a vacuum (negative pressure) in the chest, which in turn, compromises forward blood flow to vital organs!

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

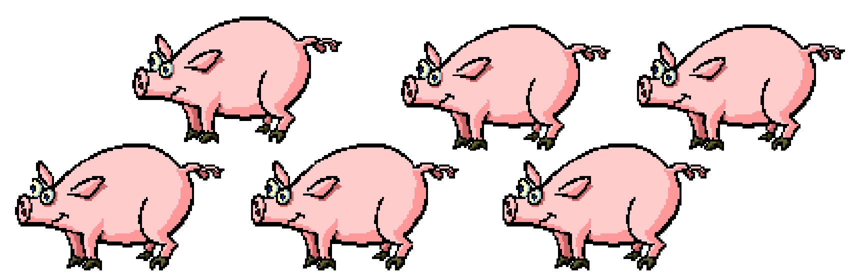
Survival: 1/7 (14%)



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. *$p<0.05$

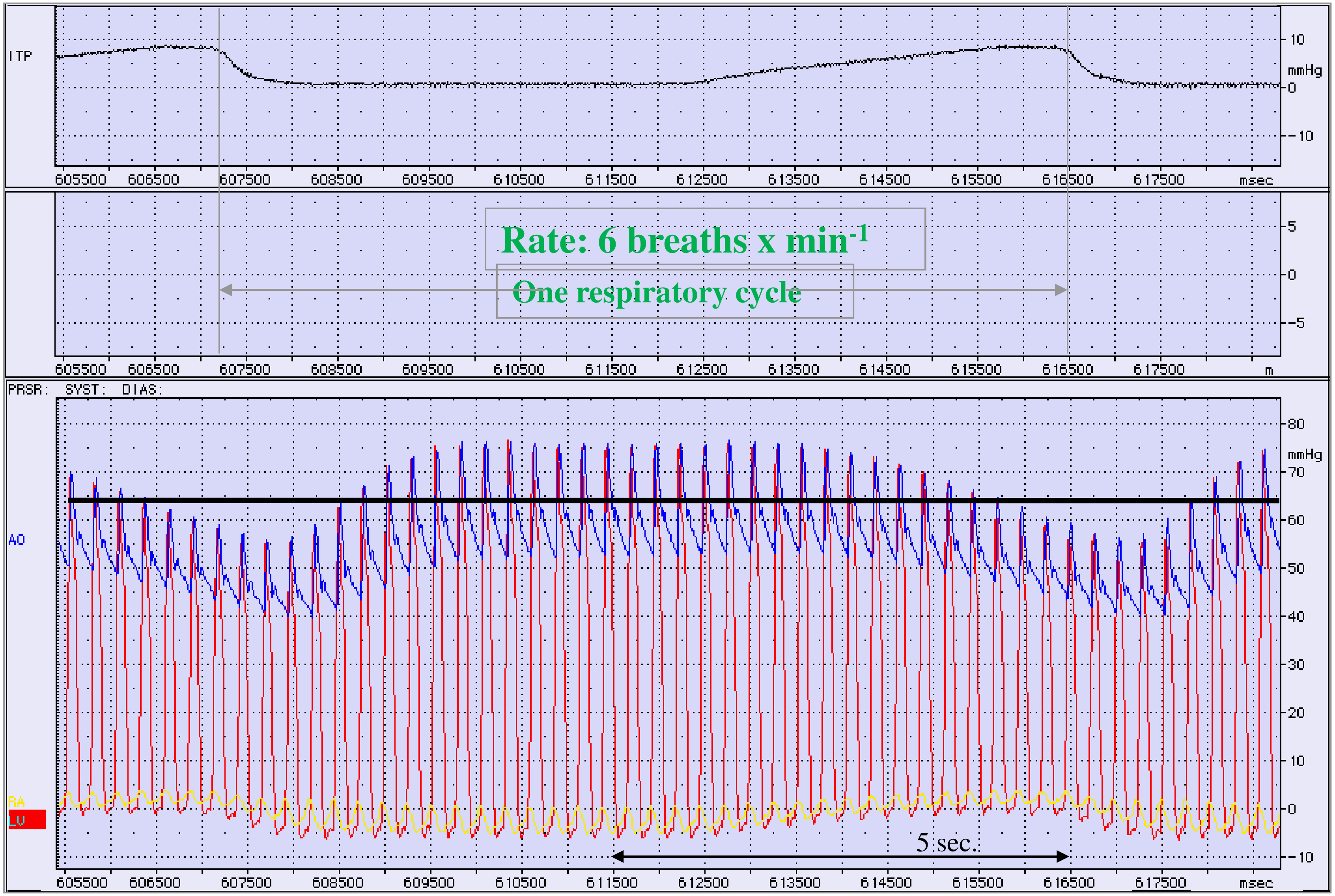
Lessons from Hemorrhagic Shock

- 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

Pepe et al. J Trauma 2003;54(6):1048-1055

Example: RR = 6/min

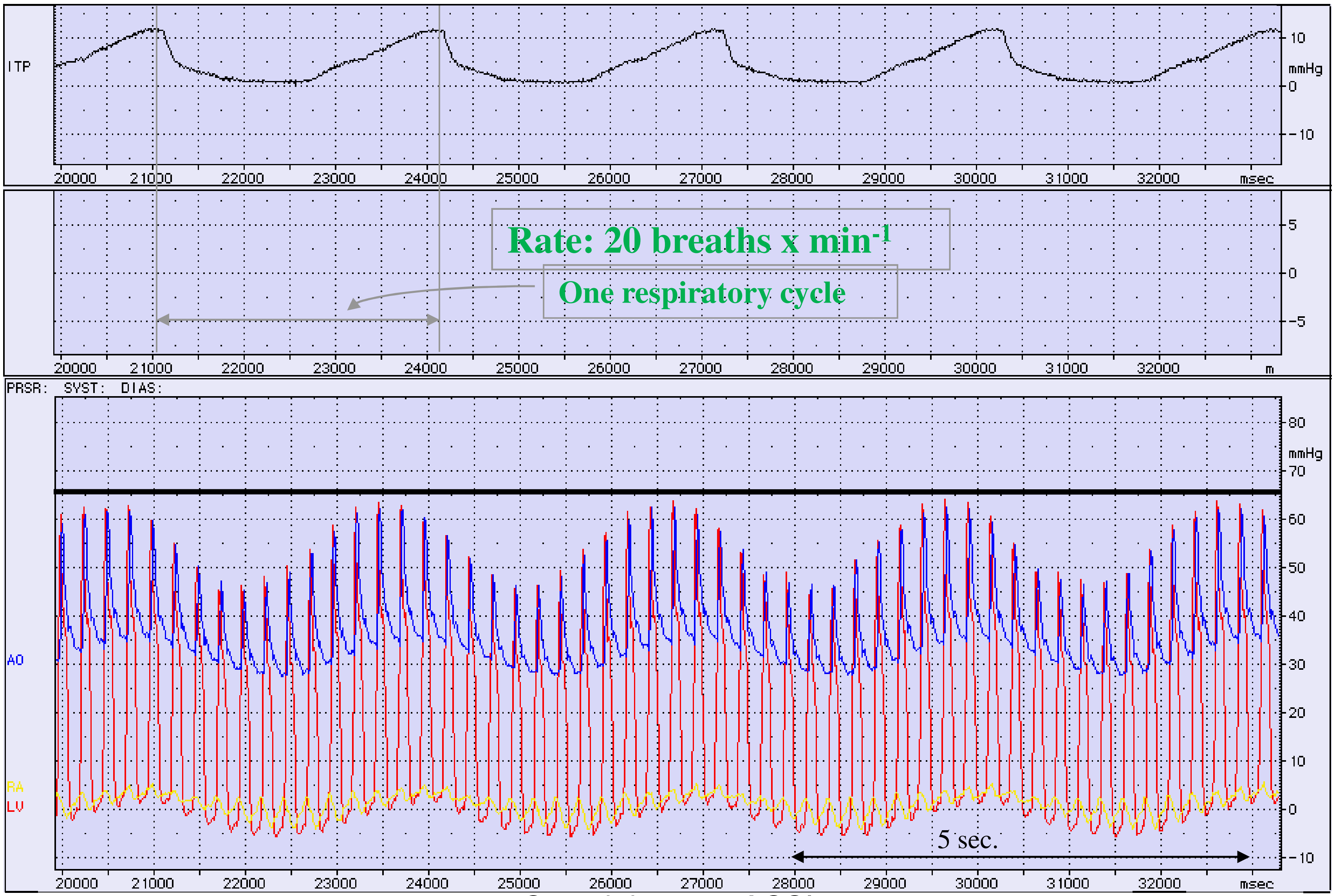
SBP ≈ 76 mmHg



Copyright 2008 ACSI

Example: RR = 20/min

SBP ≈ 63 mmHg



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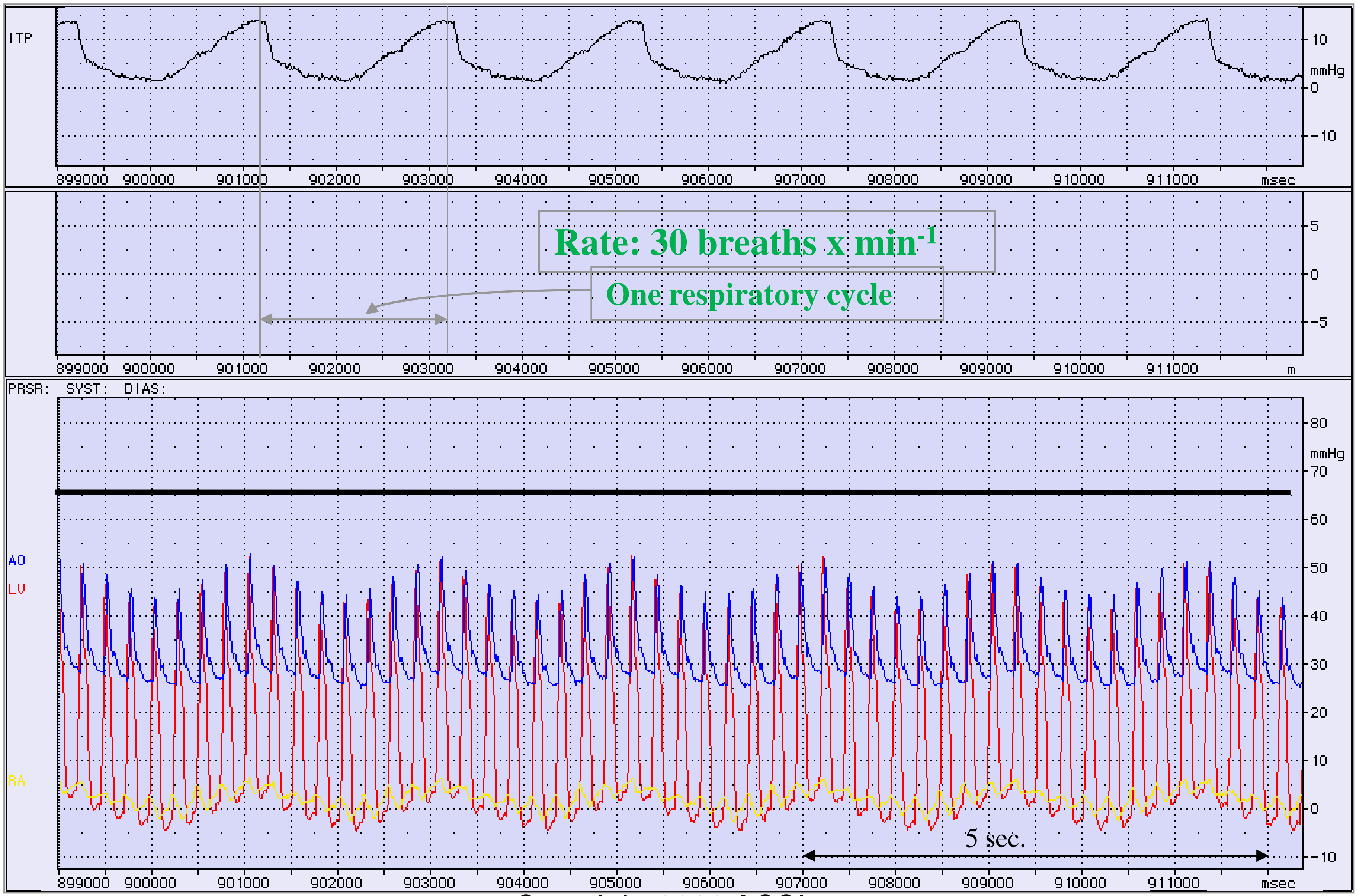
Example: RR = 30/min

SBP ≈ 52 mmHg



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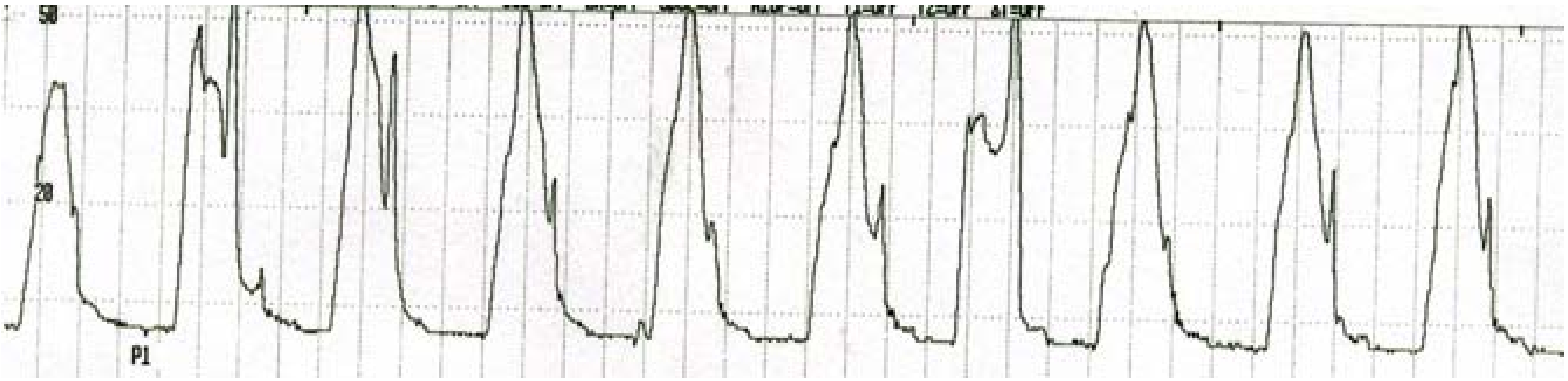
Maximum Ventilation Duration

Before Training:



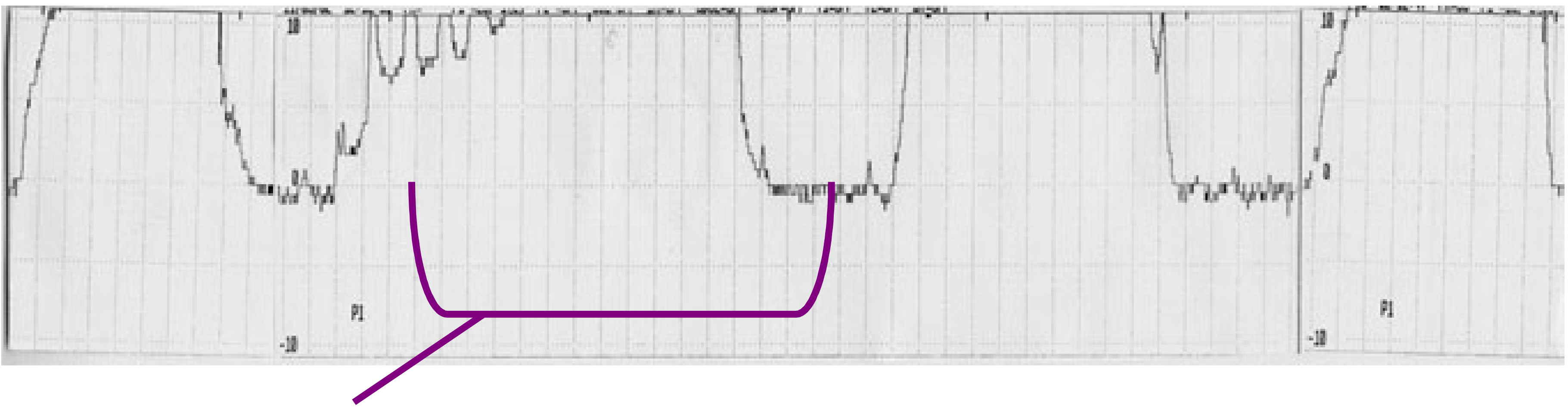
Duration: ≈1 secs

Rate: 38 breaths/min

Overall mean breath duration: 0.85 ± .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 ± .06* secs (↑ 39%)

Ventilation Duration

"Deliver each breath to patients with or without an advanced airway over 1 second and deliver 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 cmH_2O with spontaneous respiration

Patient Port

Chest Decompression

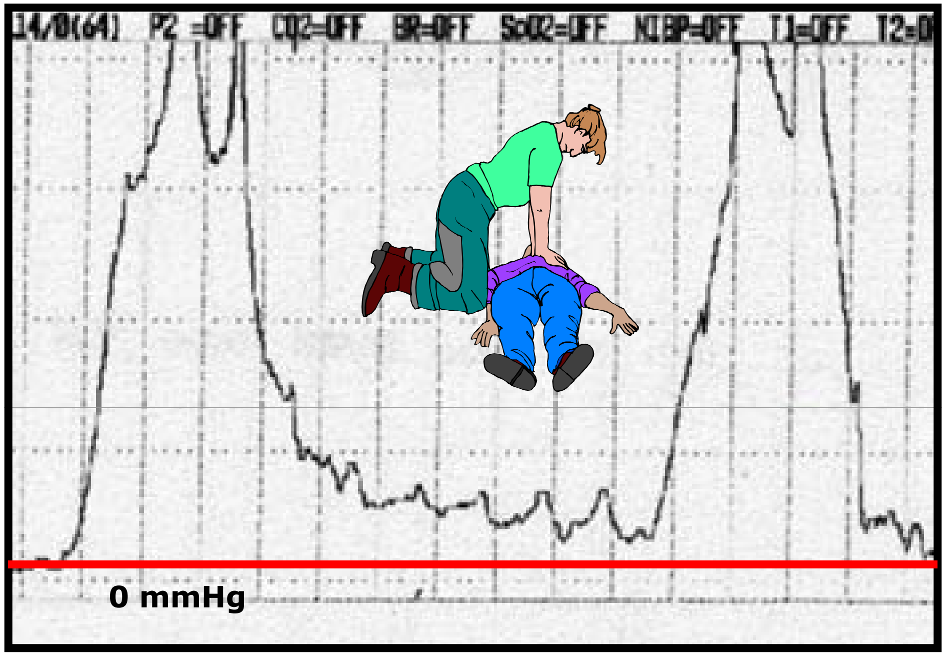
"Allow the chest wall to recoil completely after each compression.

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."

American Heart Association
GUIDELINES CPR ECC 2005

Incomplete Chest Wall Recoil



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

Assure that the chest wall recoils completely after each compression in order to maximize vacuum formation that promotes preload.

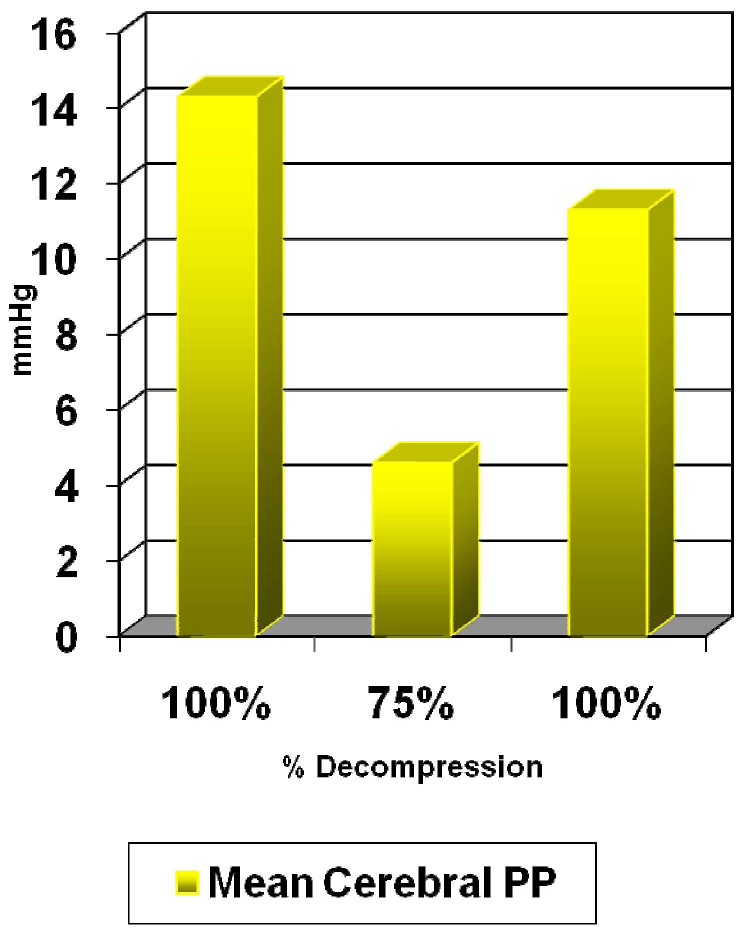
Yannopoulos et al. *Resuscitation* 2005;64:363-372.

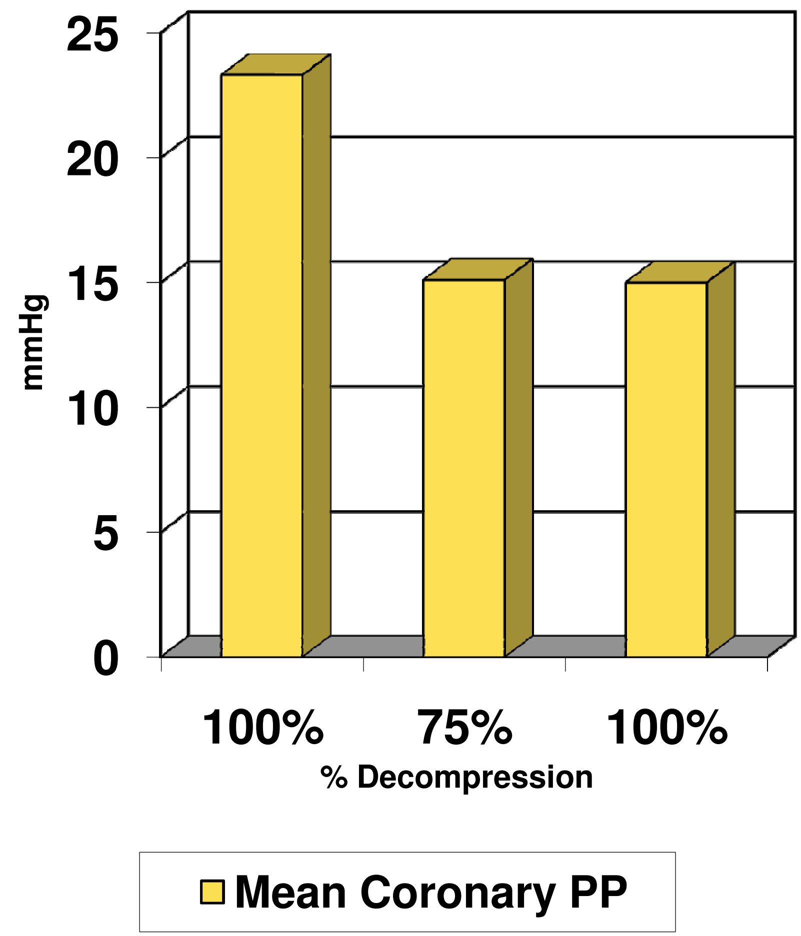
Porcine Hemodynamics Study

- 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)
  - 1min: w/ 100% decomp
- Measured: coronary & cerebral perfusion pressures

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

Results



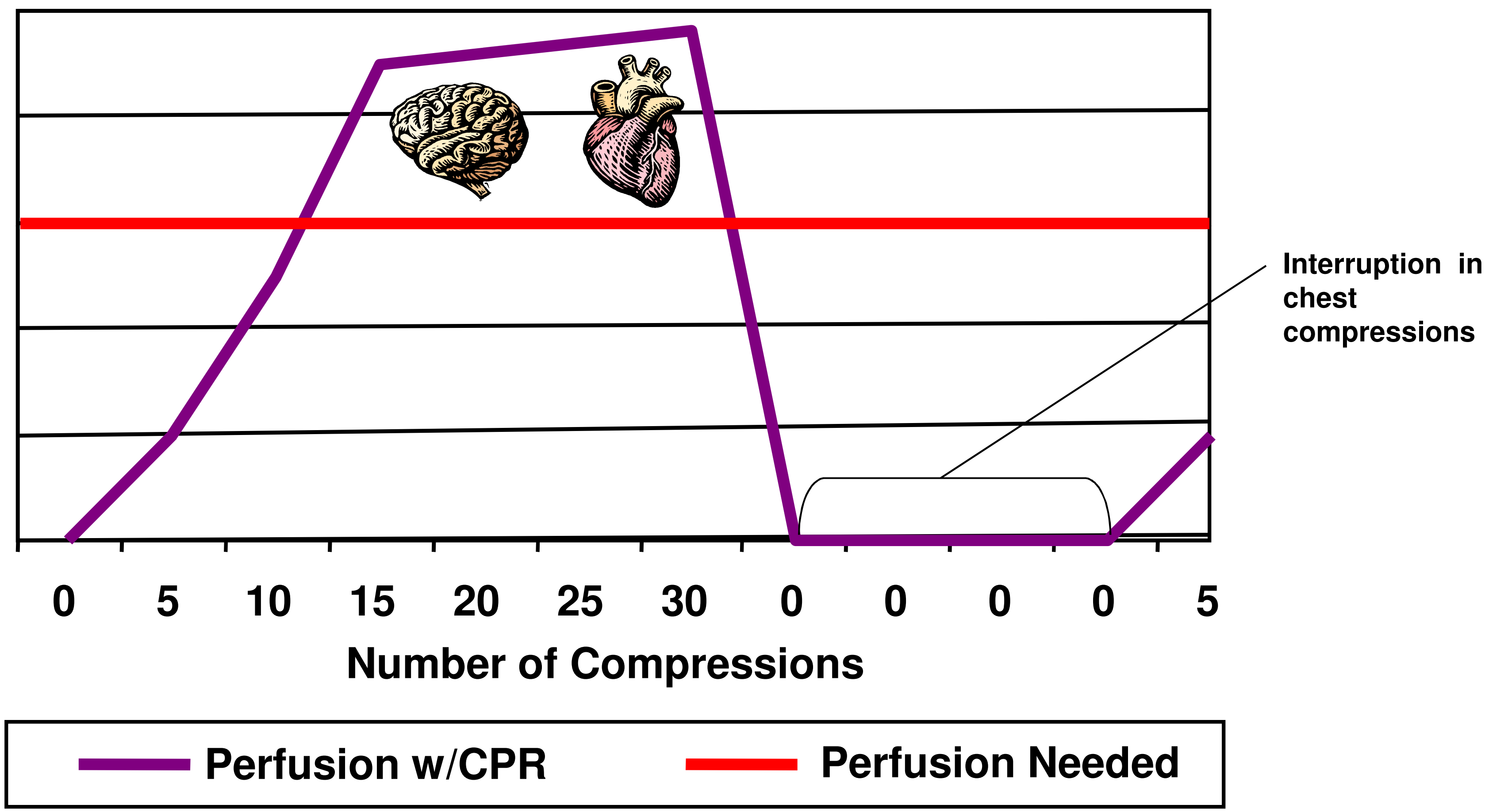


Yannopoulos D et al. Resuscitation 2005;64:363-372.

Rotate Duties Frequently

CPR Delays & Interruptions

Blood Flow to Vital Organs During Chest Compressions



Keys to Optimal CPR

- 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.

NIH-Sponsored and Directed Resuscitation Outcomes Consortium (ROC) CPR Trial: 2005-2009

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

Method of CPR	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	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	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:ven-ilation ratio	180 sec of CPR with Active ITD Analyze and shock if indicated, Resume CPR with Active ITD attached to facemask with BLS performed with a 30:2 compression:ventilation ratio
Method of CPR	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	30 sec of CPR Analyze and shock if indicated, Resume CPR with Active ITD attached to facemask with BLS performed with a continuous compression + asynchronous ventilation 10x/min	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 continuous compression + asynchronous ventilation 10x/min	180 sec of CPR with Active ITD Analyze and shock if indicated, Resume CPR with Active ITD attached to facemask with BLS performed with a continuous compression + asynchronous ventilation 10x/min
Method of CPR	No analyze early vs late comparison BLS CPR with Sham ITD attached to facemask performed with a continuous compression + asynchronous ventilation 10x/min	No analyze early vs late comparison BLS CPR with active ITD attached to facemask performed with a continuous compression + asynchronous ventilation 10x/min		

Changes from original assumptions

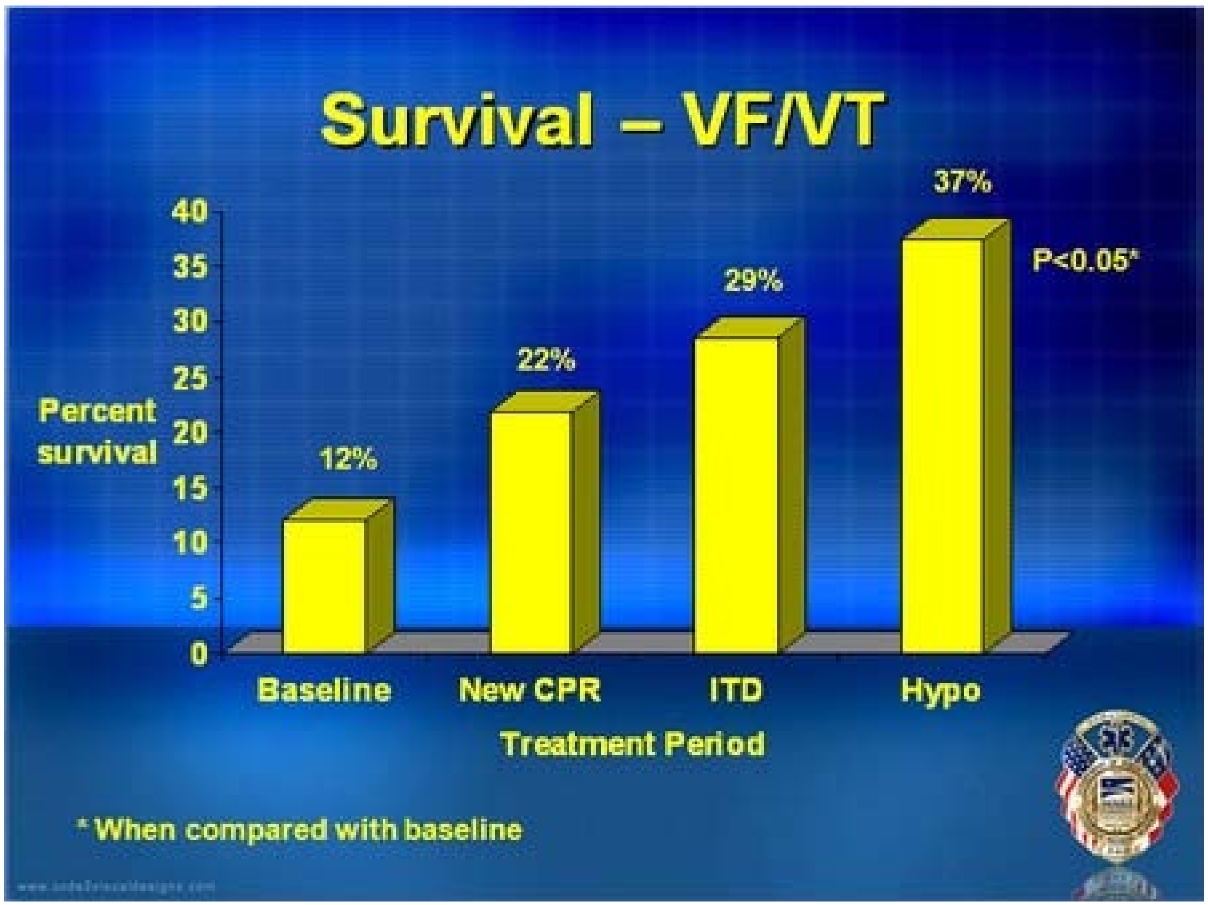
- State of Iowa withdrew from study
- Enrollment took 50% longer than expected
- There would be a common BLS protocol
- All sites would begin enrollment in a relatively similar time frame
- Some sites, like City of Dallas, unable to qualify for full enrollment, prior to August 2009, when data were collected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

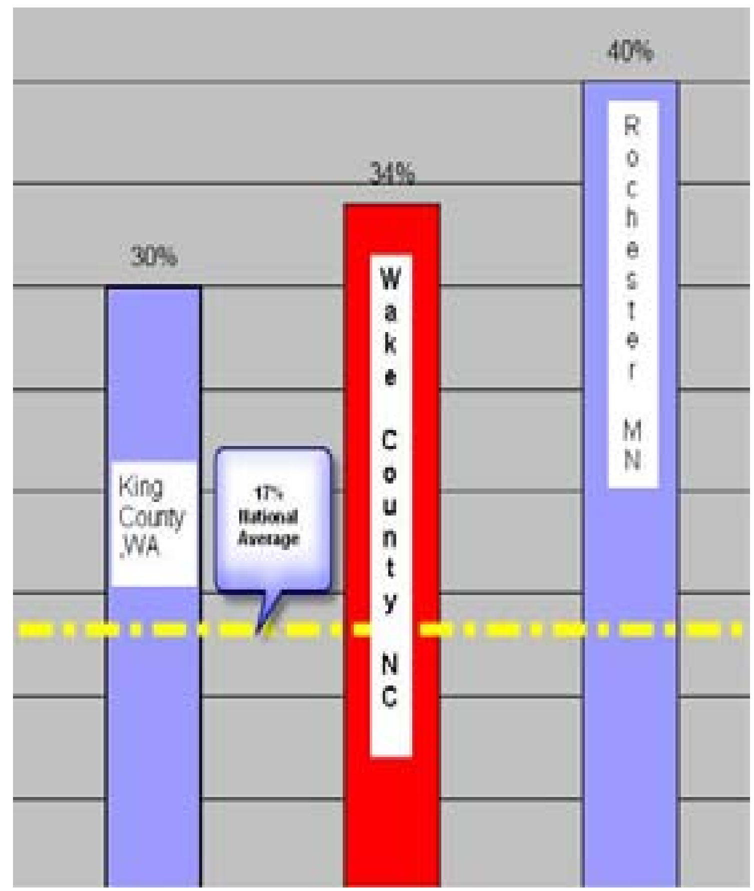
Findings

- 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.

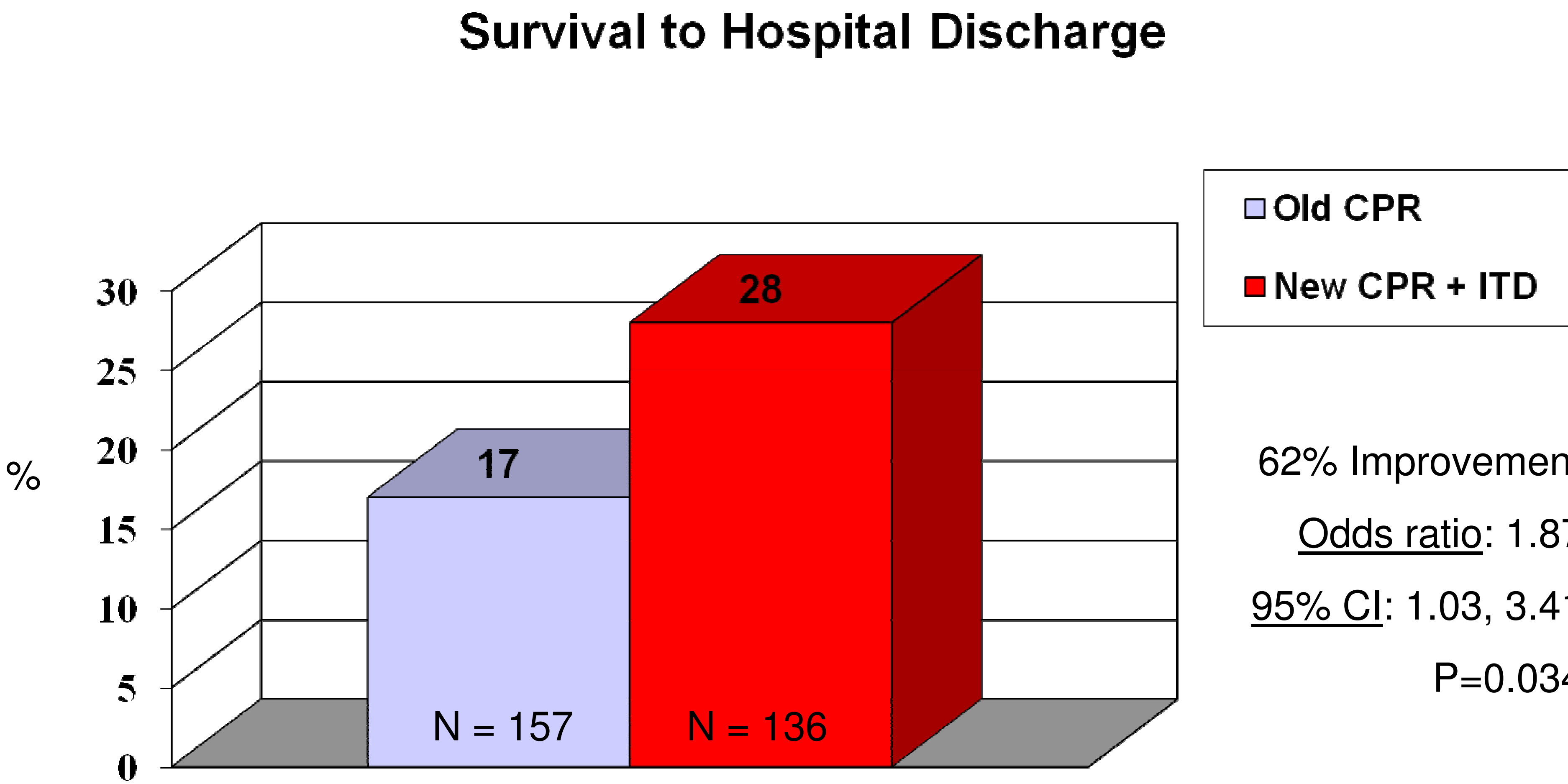
- **Multiple U.S. Sites showed a trend towards benefit with active ITD –details forthcoming in publication in Fall 2010.**

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



62% Improvement

Odds ratio: 1.87

95% CI: 1.03, 3.41

P=0.034

Thigpen et al. Ann Emerg Med 2008;51(4):475.

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

Intervention	Effect	Survival rate ↑ over baseline
Bystander CPR: **in schools, homes & public meeting places**	▪**Rapid EMS notification** ▪**Start circulation**	**2 - 5%**
AED Use : **Widespread strategic AED deployment**	▪**Reduce time to 1st shock in VF patients**	**4 - 6%**
Improved CPR Quality **Prevent hyperventilation, continuous chest compressions, CPR pre/post shock, intra-osseous drug delivery**	▪**Increase circulation to heart & brain** ▪**Increase O_2 & drug delivery**	**4 - 6%**
Impedance Threshold Device (ITD) **BLS & ALS deployment**	▪**Increase circulation to heart & brain** ▪**Increase O_2 & drug delivery**	**5%**
Cooling, ICU, Cardiology **Standard hypothermia protocols, cardiac angiography (including during CPR) & EP**	▪**Revascularization** ▪**Prevent sudden cardiac death**	**10 - 15%** ______ **25 - 37%**

Questions?

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