

Cardiac Arrest Research Minneapolis Community Consultation

May 18, 2005

Minneapolis City
Council



Overview

- Minneapolis 1 of 5 cities chosen to study two devices to augment blood flow during CPR
- 3 year study of the National Institute of Health
- Approved by Food and Drug Administration for Investigational Device Exemption

Cardiac Arrest

- Definition: heart suddenly stops beating
- Treatment: immediate CPR

CPR's effectiveness
is poor...

Forward blood flow
during CPR is less than
25% of normal.



Cardiac Arrest

- Minneapolis Fire Department treats 150 cardiac arrests per year
- Survival rate in Minneapolis
 - 21% for witnessed V Fib arrest



Informed Consent for Emergency Research

- To do any procedure or research on people need their informed consent
- Impossible in CPR
- Emergency nature of the research
- Exception issued by FDA
 - (21 CFR 50.24)



FDA Requirements for an Exception from Informed Consent Requirements

- Life threatening situation that requires immediate action from someone
- Obtaining informed consent is not possible or reasonable
- Participation has prospect of direct benefit because other studies have shown a possible benefit
- Risks are reasonable compared to the subject's condition

FDA Requirements for an Exception from Informed Consent Requirements

- Research could not practicably be done without waiver
- Potential therapeutic window is short
- Institutional Review Board approves a consent process that provides the opportunity for the subject (or legal representative) to object afterwards.

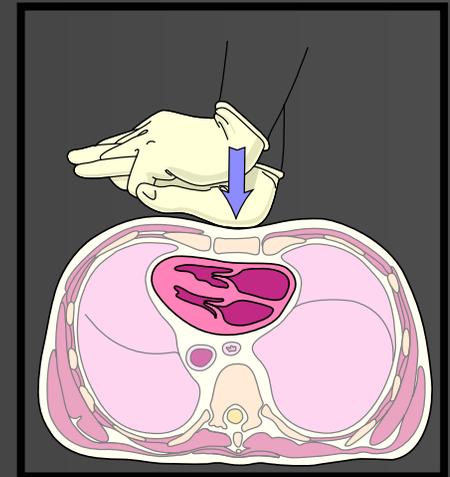
FDA Requirements for an Exception from Informed Consent Requirements

- Community consultation
- Public disclosure about the study
 - Before and after
- Independent Data Safety Monitoring Committee
- Subject notification

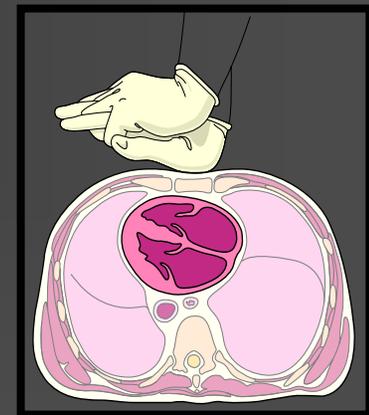
Why CPR Works...

Blood flow during CPR is due to:

- ① Direct compression of the heart between the sternum and spine
- ② Pressure differences in the chest that result from chest compression and relaxation



Compression



Decompression

ResQPump®

- Performs active compression decompression CPR (ACD-CPR)
 - Same as standard CPR (S-CPR):
 - Actively compresses the chest
 - Different from standard CPR (S-CPR):
 - Actively decompresses the chest, which assists in the creation of a vacuum within the chest



ResQPOD™

Impedance Threshold Device (ITD)

Prevents unnecessary air from rushing into the chest during chest decompression, thus assuring that the vacuum created draws in blood and augments circulation



ITD in Respiratory Circuit

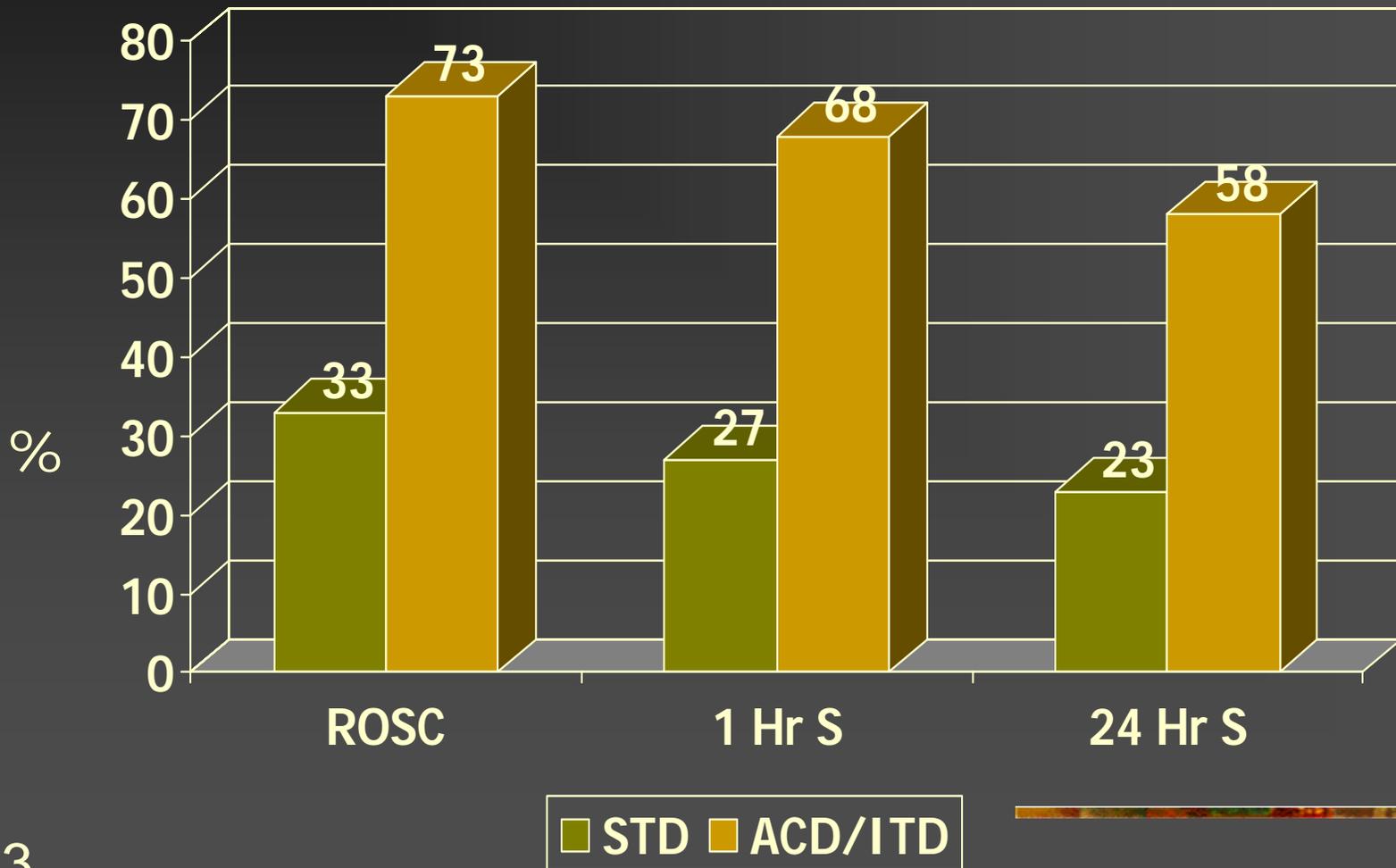
Facemask Ventilation

Basic life support
airway management



Cardiac Arrest Research

Mainz - Witnessed V-Fib (n = 70)



Cardiac Arrest Research

Information to date is encouraging
BUT...

Unknown if improved blood flow
with ACD-CPR + ITD results in
improved long term outcome for
victims of cardiac arrest.

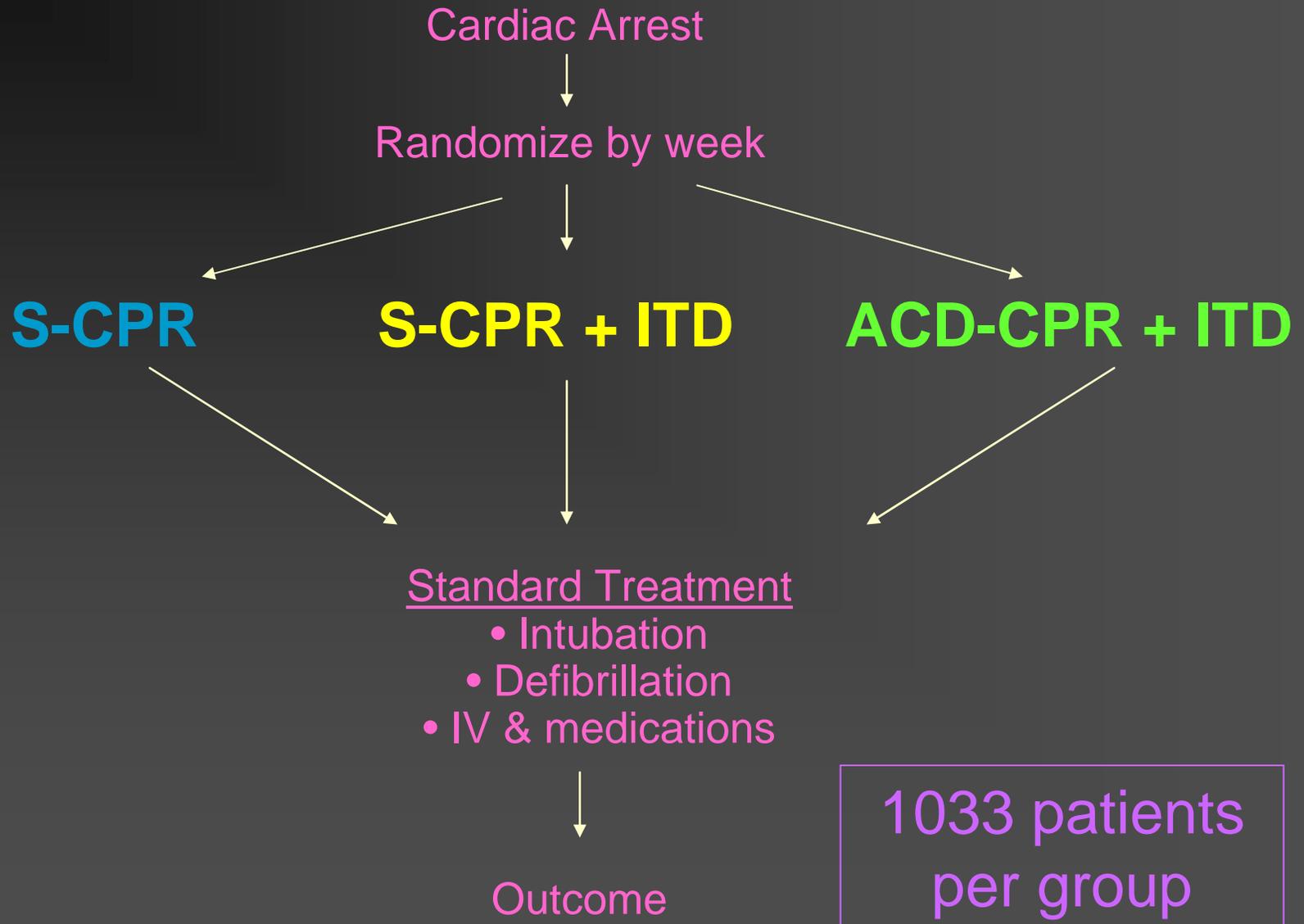
Purpose of Study

Evaluate long term outcome in victims of cardiac arrest treated with:

- S-CPR
- S-CPR + ITD
- ACD-CPR + ITD



Randomization



Study Subject Inclusion

- Adult cardiac arrest patients
 - 18 years old or greater
 - Non-traumatic
 - Out-of-hospital
- Treated by MFD personnel with CPR



Study Subject Exclusion

- Known, pre-existing “do not resuscitate” orders
- Chest surgery in the previous 6 months
- CPR cannot be performed
- Patients whose family members request discontinuation of experimental CPR method

Potential Study Risks

- Device failure
- Lack of benefit of the device
- Surviving cardiac arrest with brain damage
- Unknown or unanticipated discomfort or risks
 - Fluid buildup in lungs
 - Chest or abdominal injury

Potential Study Benefits

- Improved outcome
- Improved effectiveness of CPR
- Useful scientifically
- Benefits not guaranteed



Safety Monitoring

- Data and Safety Monitoring Board:
Monitor differences in
 - Adverse events
 - Survival rates
 - Neurologic outcome

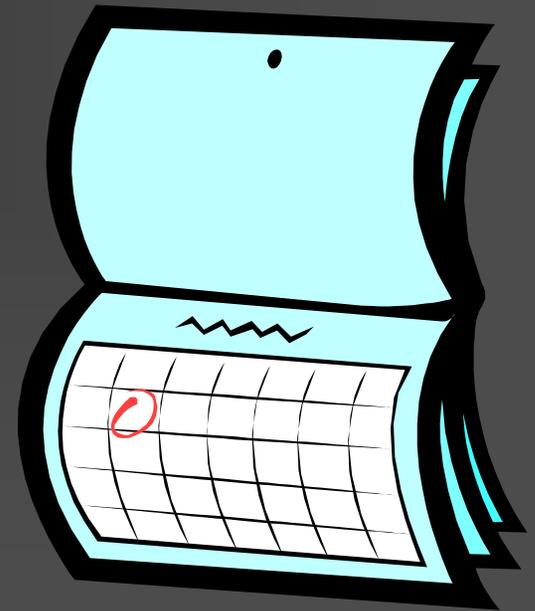


Study Endpoints

- Return of pulse
- Survival to one hour
- Survival to hospital admission
- Survival to 24 hours
- Survival to hospital discharge
- Survival to 30, 90 & 365 days
- Neurologic recovery at hospital discharge, 30 days, 90 days & 1 year
- Quality of life at 1 year
- Complication rates

Study Duration & Timeline

- Total Number: 3100 patient
- 3 years
- Start date: July, 2005



Study Approval

Study will not proceed without final approval from:

- HCMC Institutional Review Board
- FDA

For further questions, comments or information please contact:

Principal Investigator:

Name: Brian D. Mahoney, MD

Title: Medical Director HCMC Emergency Medical Services and Minneapolis Fire Department

Address: 701 Park Avenue, Minneapolis, MN 55415

Phone: 612-873-5683

FAX: 612-904-4241

Email: mahon010@umn.edu

Community Consultation

- Feedback/Concerns
- Comments
- Discussion

