MINI-REVIEW: EXPERT OPINIONS

Regional Systems of Care to Optimize Timeliness

The New England Journal of Medicine

A Regional System to Provide Timely Access to Percutaneous Coronary Intervention for ST-Elevation Myocardial Infarction

Timothy D. Henry, MD; Scott W. Sharkey, MD; M. Nicholas Burke, MD; Ivan J. Chavez, MD; Kevin J. Graham, MD; Christopher R. Henry, BS; Daniel L. Lips, MD; James D. Madison, MD; Katie M. Men sena, BA; Michael R. Mooney, MD; Marc C. Newell, MD; Wes R. Pederson, MD; Anil K. Poulse, MD; Jay H. Traverse, MD; Barbara T. Unger, RN; Yale L. Wang, MD; David M. Larson, MD
Level 1 MI Treatment Times
2003-2009

<table>
<thead>
<tr>
<th>Patients</th>
<th>Total in door to balloon</th>
<th>Mortality at 30 days/1 yr</th>
<th>Overall cv mortality at 1 yr</th>
<th>Stroke rate At 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>94 min</td>
<td>5.7%/7.9%</td>
<td>6.60%</td>
<td>0.90%</td>
</tr>
<tr>
<td>(1198)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td>123 min</td>
<td>6.8%/10.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(842)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANW</td>
<td>65 min</td>
<td>5.3%/8.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(599)</td>
<td></td>
<td></td>
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</tbody>
</table>

Outcomes with exclusions used by other programs and clinical trials:
Mortality at 30 days 0.70%
Mortality at 1 yr 1.20%
Kaplan-Meier Survival Curve

Level 1 Demographics
N=2639 (2003-2009)

- Age: Median = 62.4
  \( \geq 65 = 43.2\% \), \( \geq 80 = 14.3\% \)
- Sex: Male 72%
- Diabetes: 16%
- HTN: 57%
- Smoking: 63\% (current 39\%)
- Ant MI or LBBB 37.20\%
- Previous revascularization: 20\%
- Cardiogenic shock: 11.3\%
- Cardiac Arrest: 11\%
Level 1 High Risk Patients

<table>
<thead>
<tr>
<th></th>
<th>AN (n=496)</th>
<th>Zone 1 (n=1,031)</th>
<th>Zone 2 (n=735)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiogenic shock</td>
<td>57 (11.5%)</td>
<td>96 (9.3%)</td>
<td>60 (8.2%)</td>
<td>0.15</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>29 (5.9%)</td>
<td>112 (10.9%)</td>
<td>55 (7.5%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Out of hosp cardiac arrest</td>
<td>13 (2.6%)</td>
<td>73 (7.1%)</td>
<td>33 (4.5%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>TIMI Risk score</td>
<td>4.3 ± 2.5</td>
<td>4.0 ± 2.3</td>
<td>4.3 ± 2.5</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Cardiac Arrest

- Out-of-hospital cardiac arrest (OOHCA) affects 295,000 people annually in the US
- 7.9% median survival rate
- Anoxic encephalopathy and neurologic deficits are common and disabling - among survivors
- Modest gain with CPR advances, many failed clinical trials – BRCT - barbiturates
- Enormous public health issue - personal, family & societal burdens
- Growing awareness of needed cardio-cerebral protection

**Hypothermia Pivotal Studies**

The New England Journal of Medicine

**HACA, 2002**

**TREATMENT OF COMATOSE SURVIVORS OF OUT-OF-HOSPITAL CARDIAC ARREST WITH INDUCTED HYPOTHERMIA**

**Bernard, 2002**

**Hypothermia: mechanisms**

- Ischemia → Reperfusion
- Reactive oxygen species (ROS)
- Mitochondrial Dysfunction /Ca influx
- Inflammatory cascades
- Vascular dysfunction/hypotension
- Apoptosis – organ dysfunction
- Cerebral edema

*Dr. Abella, University of Pennsylvania*
Hypothermia Trials: Outcomes

<table>
<thead>
<tr>
<th>Hypothermia (%)</th>
<th>Normothermia (%)</th>
<th>RR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alive at hospital discharge with favourable neurological recovery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HACA</td>
<td>72/136 (53%)</td>
<td>50/137 (36%)</td>
<td>1.51 (1.14-1.89)</td>
</tr>
<tr>
<td>Bernard</td>
<td>21/43 (49%)</td>
<td>9/34 (26%)</td>
<td>2.65 (1.0-6.88)</td>
</tr>
</tbody>
</table>

Alive at 6 months with favourable neurological recovery

HACA | 71/136 (55%) | 50/137 (39%) | 1.44 (1.11-1.76) | 0.009 |

ILCOR Advisory Statement

Unconscious adult patients with ROSC after out-of-hospital VF cardiac arrest should be cooled to 32°C - 34°C for 12 - 24 hours

Possible benefit for other rhythms or in-hospital cardiac arrest.
New Guidelines – more aggressive, 30' CPR
- Full recoil. 30:2
- Less defib use
- Hypothermia Level II A recommendation

Hypothermia guidelines
Theory meets Practice? – not yet

- Less than 7% of OOHCA pts get TH - <15,000 of 295,000
- Fewer than 300 hospitals have programs or equipment of 6,000 eligible hospitals
- Awareness and funding limited – FDA approval and perceived complexity are barriers
- Yet innovation and iteration flourish and successful programs lead the way
- Research continues – despite challenges b/o enormous persistent unmet need

3rd International Hypothermia Symposium

Neurocritical care
Neurophysiologist
Trauma surgeon
Neonatal intensivist
Neurologist
Critical care
Basic science and translational work

September 2-5, 2009
Lund, Sweden
Arctic Sun Energy Transfer Pad™ Placement
Our Goals in Program Implementation

- Establish the role of a tertiary cardiac center in providing advanced emergency cardiac care for STEMI, Cardiac Arrest, Aortic Dissection and other critical CV Emergencies

- A comprehensive protocol for TH can be integrated into a regional STEMI network and achieves broad dispersion of this essential therapy for OOHCA.
The Main Concepts a Cardiac Emergency Program

ACCESS  TRANSPORTATION  STREAMLINE CARE

DATA COLLECTION  FEEDBACK  RESEARCH

Prehospital  Outstate Hospital  EMS Transport  Tertiary Center

When a heart attack brings a brain attack

Can you provide STEMI care simultaneously with Cardiac Resuscitation and do it within a “System of Care”?
Team Approach

- Same approach outstate vs ANW “Standardized Approach”
- Constant Feedback
- Paramedics on Committee
- Quality Measures
  - Esophageal Probe
  - 1st Temp
  - ECG repeat
  - 1st Application of Ice

Patient Meets Eligibility Requirements

Eligible patients:
- Post non-traumatic cardiac arrest
- Cardiac arrest for < 60 minutes from collapse to return of spontaneous circulation (ROSC)
- Unresponsive

Excluded Patients:
- SBP < 90 mm Hg for > 30 minutes after ROSC despite the use of pressors
- Active bleeding
- Comatose or vegetative state before cardiac arrest
- DNR/DNI

Call 3-3900 to page “COOL IT”
Key Components

1) Extensive training
2) Individualized transfer arrangements
3) Single phone call
4) Standardized protocol
5) Feedback/quality assurance
6) KEY: Coordinator

Demographics

• 140 patients (Feb ‘06 – August ‘09)
• Mean age: 62
• Gender: 108 Male, 32 Female
• Initial rhythms: 102 VT/VF, 32 PEA / Asystole
• Transferred: 75.7%
• Level 1 STEMI: 54.3%
• Cardiogenic Shock: 43.57%
# Outcomes

**Abbott Northwestern Hospital** 72/140 51.4%

*Alive at hospital discharge with favourable neurological recovery*

- **Survival by diagnosis**
  - STEMI: 49/76 64.5%
  - Other: 29/64 45.3%

- **Survival by initial rhythm**
  - VF/VT: 68/102 66.7%
  - PEA/Asystole: 7/32 21.9%

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**Outcomes**

*Alive at hospital discharge with favourable neurological recovery*

- **Survival by Age**
  - ≤75 years: 60/96 62.5%
  - >75 years: 11/25 44%

- **Survival by Early Response**
  - Witnessed: 61/97 63%
  - Unwitnessed: 10/24 42%
  - Bystander CPR: 49/78 63%
  - No Bystander CPR: 17/33 51%
  - Bystander AED: 23/35 66%
  - No Bystander AED: 47/84 56%
Level 1 STEMI Outcomes
STEMI = Blue line, others = Red line

Transfer and Nontransfer Outcomes
Transfer = Blue line, ANW = Red line

75% of total patients in the Cool It Program are transfers
Hypothermia Trials: Comparison

**Alive at hospital discharge with positive neurological recovery:**

Positive neurological outcome was defined as Cerebral Performance Category (CPC) 1 or 2 at discharge.

<table>
<thead>
<tr>
<th></th>
<th>HACA</th>
<th>Bernard</th>
<th>ANW</th>
<th>ANW *using HACA exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alive at Discharge</td>
<td>72/136 (53%)</td>
<td>21/43 (49%)</td>
<td>72/140 (51.4%)</td>
<td>44/65 (67.7%)</td>
</tr>
</tbody>
</table>

**ANW patient population includes:**
- all initial rhythms
- transfers (75.7%)
- STEMI (54.3%)
- cardiogenic shock (43.6%)

*HACA exclusion criteria: cardiogenic shock, PEA, asystole

“Cool It” Outcomes

<table>
<thead>
<tr>
<th></th>
<th>All Patients</th>
<th>HACA criteria (VT &amp; VF)</th>
<th>Non-HACA criteria (PEA, asystole, shock)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Number</strong></td>
<td>103</td>
<td>52</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td><strong>Survival at Discharge</strong></td>
<td>58 (56%)</td>
<td>38 (73%)</td>
<td>20 (39%)</td>
<td>0.0007</td>
</tr>
</tbody>
</table>
“Cool It” vs. HACA Survivors

<table>
<thead>
<tr>
<th>% of Survivors</th>
<th>CPC 1</th>
<th>CPC 2</th>
<th>CPC 3</th>
<th>CPC 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Cool It&quot; n=58</td>
<td>80%</td>
<td>60%</td>
<td>20%</td>
<td>10%</td>
</tr>
<tr>
<td>HACA n=84</td>
<td>62%</td>
<td>30%</td>
<td>8.6%</td>
<td>23.8%</td>
</tr>
</tbody>
</table>

Neurologic Outcome at Discharge

Early Cooling is Critical

<table>
<thead>
<tr>
<th>Source</th>
<th>Chi Square</th>
<th>DF</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>Time ROSC to First Cooling min</td>
<td>5.0785</td>
<td>1</td>
<td>0.0242</td>
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</table>

<table>
<thead>
<tr>
<th>Estimate</th>
<th>Lower CL</th>
<th>Upper CL</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.25</td>
<td>1.06</td>
<td>1.44</td>
<td>0.0081</td>
</tr>
</tbody>
</table>

If the time to first cooling increases by an hour the hazard of death increases 25%.
Cardiovascular Emergency Centers must provide:

- Advanced emergency care includes high risk patients ie age, complex conditions
- Extensive training on resuscitation
- Use of newest technologies ie adjunct treatments
- Set protocols
- Develop interhospital transfers independently by each site and service available

JM

- 60 yr Male with hx of cardiomyopathy (EF 20%)  
- CAD, S/P CABG in ’95  
- PCI S/P BiV/ICD, DM  
- Became a patient of MHI in 1/2009  
- Sprint Fidelis lead malfunctioning, inappropriate shock removed 2009  
- Appropriate shock in March 2010  
- Cardiologist appt 3/1/2010 following 2nd syncopal event with ICD discharge.

- “I talked with him about the possibility of considering heart transplant. At this time he is a New York Heart Class 3. I would recommend we continue with his Amiodarone, beta blocker, and Imbur. I will make arrangements for him to be followed up in our Heart Failure Clinic for initial evaluation and assessment of possible cardiac transplantation.” 3/1/2010 Dr Mark Hougland
At home with significant other who had recently taken the “new CPR” through work!

3/17/2010

1912 “Worst feeling ever”, collapses, immediate CPR, while calling 911
1919 EMS arrives, takes over CPR
1937 EMS leaves (18 min on scene) ice packs applied
ICD fired 3 times as EMS watched, manual defib followed
37 min (Time from arrest to ROSC)
1947 arrival at Monticello ED
1952 Air arrival (called before ground arrived with patient)
2017 Departure for ANW
2031 Arrive ANW
79 minutes from arrest to arrival at tertiary center
8 miles from home to 1st ED; 41 miles from 1st ED to ANW total of close to 50 miles from home to cardiologist

MHI Cardiologist meets in ED

- Patient Active Hospital Problem List:
  - ICD (Implantable Cardiac Defibrillator) Discharge (1/4/2009)
    - due to a fractured Medtronic Fidelis 6949 ICD lead.
  - S/P RV ICD lead extraction and reimplantation of a new implantable cardioverter defibrillator lead. 1/6/2009
  - CAD (Coronary Artery Disease) (1/4/2009)
  - CABG 1995
  - PCI 2 years ago
  - Ischemic Cardiomyopathy (1/4/2009)
  - LVEF 15% by patient report
  - Echo 1/4/09 with LVEF 20-25%, global HK, BAE, RVE, sclerotic AV, trace
  - AI, MR, TR, PI
  - Diabetes Mellitus Type II (8/15/2009)
  - CA - Cardiac Arrest (3/17/2010)
  - Coma - anoxic encephalopathy (3/17/2010)
  -
  -
  - P: angio .. No major source of ischemia noted .. all grafts patent .. Cool-it protocol activated .. Full consult dictated .. Metabolic acidosis
• Almost 50 miles from cooling/cath lab/shock treatment center
• CPR, ICD fired > 3 x; manual defib x 1
• Insertion of IV, RSI, Ice applied, ASA®, at referring (collaborating ED)
• CoronaryAngio, IABP placed
• Meds hung for BP in cath lab
• Cooling pads applied in cath lab upon arrival
### Summary/Conclusions

**Cardiogenic Shock**

- 100% on the peripheral/monitoring lines
- Ventricular fibrillation
- Cardiac arrest
- Emergent procedure

**Diagnosis:**

- The LAD has multivessel ischemia/artery and is free of significant disease.
- 100% stenosis in the Proximal LAD
- 100% stenosis in the Proximal Circumflex
- 100% stenosis in the left diagonal
- 100% stenosis in the V1/V2 area. Right dominant.
- The LAD graft from the 'R' to the LAD is patent.
- The SVG graft from the 'R' to the LAD is patent.
- The sequential SVG graft from the 'R' to the RPA and to LAD is patent.

**Procedural Approach**

- Prediction of vessel failure
- Intra-aortic balloon pump was placed during the procedure for circulatory support.
- The patient is being monitored and on ventilator support prior to and throughout the procedure.
- The patient is being monitored and on ventilator support prior to and throughout the procedure.

**Recommendations & Plan**

- Medical ICU
D/C following neuropsych testing and sent to Sister Kinney Rehab when testing showed a slowed response and difficulty with decision making.

PMR, OT, PT working with patient as he recovers neurologically.

Transplant team became a critical partner in the recovery, they joined the team on day 2 of the recovery process.

On 6/24, Jim had a heart transplant and went home from ANW on 7/3/2010.
Summary—Cardiogenic Shock Post Arrest

“IV chilled Saline”

• Continuum of aggressive care (pre-hospital, ER, definitive correction of initial insult (when possible), and aggressive, ongoing “Code Status” in first 36 hours is critical for successful outcomes.

• Many of our current medical therapies may not be as efficacious as we thought and perhaps may increase mortality — the rules are different post arrest

• Assist Devices must now be considered

• High Risk Group (4% of MIs) — pooled results from “Resuscitation Centers” will be needed to guide future care.

Shock Post Cardiac Arrest: Scope of Problem

• HF is the single largest expense for Medicare
  - > 7 million hospital days/yr for acute HF
  - Almost all literature focused on Acute → Chronic CHF

• MHI@ANW—2700 “Level One” MIs since 2003
  - 12% present with shock

• “COOL IT” Program — Resusitated Cardiac Arrests
  - MHI@ANW—201 patients (3/4 transferred)
  - 43% (not including DOA) in shock upon arrival.
  - Mortality rate exceeds 50%

Graves EJ, Kozak LJ. Vital and Health Statistics. 1999;Series 13:1
AHA. Heart Disease and Stroke Statistics—2005 Update. Available at:
### CARDIOGENIC SHOCK Def.

**Presence of all of the following criteria immediately before or during the first 24 hours:**

- Arterial hypotension (systolic arterial blood pressure below 90 mmHg or mean arterial blood pressure below 70 mmHg for 30 minutes or longer with or without therapy);
- PCWP >18 mmHg (in patients with a pulmonary artery catheter) or an acute decrease of the left ventricular ejection fraction below 40% (in patients without a pulmonary artery catheter);
- Need for a continuous infusion of inotropic drugs


### Goals for POST ARREST HEMODYNAMIC THERAPY

<table>
<thead>
<tr>
<th>Hemodynamic</th>
<th>Clinical</th>
</tr>
</thead>
<tbody>
<tr>
<td>mAo ≥80 ≤100 mm Hg</td>
<td>SBP appropriate</td>
</tr>
<tr>
<td>PCWP &lt;18 mm Hg</td>
<td>JVP &lt; 10 cm</td>
</tr>
<tr>
<td>RAP 8-10 mm Hg</td>
<td>Lactate Levels low</td>
</tr>
<tr>
<td>SVR ?1200 dyne•s•cm⁻⁵</td>
<td>ABG – corrected acidosis</td>
</tr>
<tr>
<td>Revascularized</td>
<td>Urine output</td>
</tr>
</tbody>
</table>
Cardiogenic Shock Program: an additional Cardiovascular Emergency Center Component

- 1. ECG to rule out an ischemic event. If ischemic, revascularization is the key.
- 2. Cardiac enzymes, CBC, blood chemistries, ABGs, coagulation studies, liver function tests.
- 3. Correct magnesium and K levels.
- 4. If respiratory decompensation, intubate and support ventilations.
- 5. Lactate level a prognostic indicator for survival from cardiogenic shock.
- 6. Echocardiogram for wall motion and valve function available in cath lab at all times
- 7. Hemodynamic monitoring to optimize the components of cardiac output and to obtain a mixed venous saturation.

BE AGGRESSIVE EARLY

- SBP < 100mmHg on two episodes within first 6 hours independently associated with death
- Appropriate fluids
- Drugs (Dobutamine, Vasopressin, ? NE)
- Mechanical Support IABP, CentraMag, Tandem Heart, Impella

LFA Occlusion
**Clinical criteria**: Hypotension (systolic BP < 90) for at least 30 minutes or the need for supportive measures to maintain a systolic BP of greater than or equal to 90, end-organ hypoperfusion (cool extremities or a urine output of less than 30 ml/hr, and a HR > 60 beats per minute).

**Hemodynamic criteria**: Cardiac index of no more than 2.2 and a pulmonary wedge pressure of at least 15.

Education to outstate ED to evaluate the BP and present to Cardiologist during initial call; Cardiologist will activate the Shock Team page

“The clock is ticking when your patient is in cardiogenic shock. With a present mortality greater than 50%, there is hope it can be reduced as more patients receive early revascularization in the form of PCI or CABG. With rapid recognition of cardiogenic shock, prompt initiation of supportive measures, and immediate transport to a tertiary care center capable of intervention outcomes can be improved.”
2010 Miracle on Ice Conference
© Minneapolis Heart Institute® at Abbott Northwestern Hospital
Resuscitation Center

- Tertiary Center
- PCI Center
- Community Education Awareness
- Pre Hospital EMS Educational support Ongoing feedback Data assistance
- Ability and resources To perform continuous High quality human or mechanical CPR for 30-60 min
- Cath Lab 24/7 Meets min standards and experience for performing PT in Lab in combination with appropriate Cath/Interventional procedures

Systems of Care

- Building a collaborative system within a system, allows additional CV emergency conditions to be addressed.
- Each condition will have separate directions but by following prehospital (community awareness) outstate ED’s, Transportation and finally the receiving centers streamlined care approach, we can only expand our opportunities and successful outcomes for these patients!
To maximize benefits, cooling should be initiated as soon as possible. Survival benefits are dramatic. The best treatment are often simple. But, we under-deliver this lifesaving treatment.

**TH capable Acute MI PCI centers should offer this lifesaving treatment, it is a public health care imperative.**

To achieve equivalent access and outcomes in rural and metro patients by providing one **Standard of Care** for an entire Region for the most complex cardiac emergency.