What To Do When Things Go Bad: A Cardiac Surgery Perspective

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Credibility?

64th Scientific Sessions
Abstract Form
Medical Research
Nursing Research

American Heart Association
November 12-16, 1992
Anaheim Convention Center, Anaheim, California

A. M. S. 10.2010 – Lead Manage

65th Scientific Sessions
Abstract Form
Medical Research
Nursing Research

American Heart Association
November 30 – December 3, 1992
New Orleans Convention Center
New Orleans, Louisiana

PREDICTING PACING LEAD FAILURE BASED ON IMPEDANCE CHANGES UNDER SALINE
Michael Firstenberg, Stephen Severson, Olivia Newton, Bruce L. Wilkoff. The Cleveland Clinic Foundation, Cleveland, OH

Recent concerns regarding the durability of permanent pacing leads have inspired the search for a mathematical model for predicting failure based upon easily measurable clinical parameters.

METHODS: Multiple lead impedance values (n=5 tests) were obtained for 518 pacing leads over a 24 month post-implant interval.

Credibility?
When Things Go Bad: Accept Reality

- Major complications happen
- Deaths will happen
- Often unavoidable
- Institutional Commitment

Prevention and preparation is the key to optimize outcomes

What to do when things go bad?

PANIC
Major Complications in the EP Lab: Spectrum of Problems

1. Death
2. Cardiac avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair
3. Vascular avulsion or tear (requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair)
4. Pulmonary embolism requiring surgical intervention
5. Respiratory arrest or anesthesia related complication leading to prolongation of hospitalization
6. Stroke
7. Pacing system related infection of a previously non-infected site

But does this stuff really happen?

Reality: Major Complications Occur

- 10,000-15,000 Leads are explanted each year
- FDA Database:
  - 62 patients required emergent surgery
  - 56% (35) patients survived
  - Most injuries are SVC-RA lacerations
    - RV perforations
    - Access injuries -> hemo/pneumo-thorax
- Emergency surgery is rarely needed
  - “may be unsuccessful even when all appropriate pre-procedure precautions have been taken”
  - But, surgical intervention can be life-saving in unstable, bleeding, patients.
- Hypothesis: Gross underestimation!

Hauser RG, et al. Europace 2010
A Surgeon’s Perspective?
Is this reality?

Laser-Assisted Extraction of Pacemaker and Defibrillator Leads: The Role of the Cardiac Surgeon
Jeffrey G. Gaca, MD, Brian Lima, MD, Carmelo A. Milano, MD, Shu S. Lin, MD, PhD, R. Duane Davis, MD, James E. Lowry, MD, and Peter K. Smith, MD
Division of Cardiothoracic Surgery, Department of Surgery, Duke University Medical Center, Durham, North Carolina

Emergent Surgery:
3.5%
Closer to truth?

Major Complications: Specific Injuries

<table>
<thead>
<tr>
<th>Major Complications</th>
<th>Count (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subclavian vein injury</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Pericardial tamponade</td>
<td>3 (2.6%)</td>
</tr>
<tr>
<td>SVC disruption</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>RA injury</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>IVC-RA injury</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Death</td>
<td>3 (2.6%)</td>
</tr>
</tbody>
</table>
Is This A Problem?  
HRS Expert Consensus  
Wilkoff BL and a few other “lesser” known people

- **1996:** 226 centers  
  - 2,338 patients/3,540 leads  
  - Major complications: 1.4%  
    - <1% with >300 extractions  
- **2000:** 7,823 patients/12,833 leads  
  - Major complications: 1.6%  
  - Implant date of oldest lead  
  - Female genders  
  - ICD lead removal  
  - Use of Laser extraction  
  - Operator (center?) Experience  
- **Other reports:** 0.8 – 1.9% “major”

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Prevention: Required Personnel

- **Primary Operator:** A physician performing the lead extraction who is properly trained and experienced in device implantation, lead extraction and the management of complications.  
- **Cardiothoracic surgeon** well versed in the potential complications of lead extraction and techniques for their treatment, on site and immediately available  
- **Anesthesia** support  
- Personnel capable of operating fluoroscopic equipment “Scrubbed” assistant (nurse/technician/physician)  
- Non “scrubbed” assistant  
- **Echocardiographer**  
  ... only part of the story
Rates of Complications: Operator Volume

<table>
<thead>
<tr>
<th>Complication</th>
<th>&gt;300</th>
<th>20-120</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>Sternotomy/Thoracotomy</td>
<td>0.4</td>
<td>0.8</td>
<td>0.7</td>
</tr>
<tr>
<td>Transfusions</td>
<td>0</td>
<td>0.6</td>
<td>0.1</td>
</tr>
<tr>
<td>Pericardiocentesis/Chest tube</td>
<td>0.6</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Other major</td>
<td>0</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Total Major</strong></td>
<td><strong>1.0</strong></td>
<td><strong>1.8</strong></td>
<td><strong>1.6</strong></td>
</tr>
<tr>
<td>Minor Complications</td>
<td>1.2</td>
<td>2.6</td>
<td>1.6</td>
</tr>
<tr>
<td><strong>Total Complications</strong></td>
<td><strong>2.2</strong></td>
<td><strong>4.4</strong></td>
<td><strong>3.2</strong></td>
</tr>
</tbody>
</table>

Hmmmmm?

Additional OR Preparations

- Proper tools in the EP Lab
- OR prepared for emergencies
  - Protocols in place – “CPR in progress”
  - Phone Tree of communication
- Stand-by for High Risk Cases
- Initial Experiences?
  - Done in OR: EP and Surgeon

Smith MC, Love CJ. PACE 2008
Signs of Trouble

- Hypotension
- Hypotension
- Hypotension
- Hypotension
- Cardiac Arrest
- Pericardial Effusion
- Unexplained Arrhythmias
- Respiratory Distress

…. Did I say “hypotension”

De’Nile is a River In Egypt: Recognition of the Problem

CALL FOR HELP AT THE FIRST SIGN OF A PROBLEM!
Initial Response:

- Call a surgeon!
- Immediate transthoracic Echo
- Low threshold for a pericardial drain
  - Experience counts – not a novice role
  - RV perforations in haste
  - Contrast study – confirm placement
- Low threshold for a chest tube
  - Real tube not a “pneumo-dart”
- Reverse anticoagulation
- Call for blood

Types of problems: Decision Making

- Vascular Access
  - Subclavian Vein Injuries/Lacerations
- Cardiac
  - Right Atrial/Ventricular Perforations
- Pulmonary
  - Embolic complications
- True, True, and Unrelated
  - Patients have heart disease!
  - Unstable situations can occur

Question: Does this patient need to go to the OR?
**Decision Making: To OR or not OR**

- On-going bleeding
- Refractory hypotension
- Arrest/CPR
- Subxiphoid Window
- Avoid temptation to open in EP Lab
- Good communication
  - In EP Lab
  - Open discussion of potential injury site
  - Nothing wrong with going to OR for monitoring

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**If not OR......**

- Communication with the “Night Team”
- Specific goals/interventions clarified
- ICU Monitoring
- On-going bleeding
- Repeat Echo in am (daily)
- Frequent re-assessment of drainage patency
Once the decision is made….

• Immediate transfer – “haste makes waste”
  – Even if CPR in progress
  – Lines in the OR
  – TEE in all patients

• Standard “emergency” protocol
  – Standard drape and prepping
  – Extra antibiotics… just to be sure
  – Order blood and products
  – Cell saver and prepare for CPB
  – Full sternotomy

Operative Management

• Find the source of bleeding (obvious?)
  – May have more than 1 hole
  – Digital control – if possible

• Open cardiac massage if needed

• Assess need for bypass
  – Assist in resuscitation & recovery
  – Hemodynamic control

• Heparinization and standard CPB
Operative Management: How to Fix It?

- Simple holes can often be repaired primarily
  - Small pericardial patches.
- Complex injuries may require CPB
- LA/LV (very rare)
  - Avoid air embolism - need aortic vent
  - Arrest the heart reluctantly
- RV: Primary repair of lacerations
- RA: May require a small patch
- SVC Injuries: Another story...

Innominate Vein and SVC-RA

- Often fatal – large/extensive “unzipping”
- Torrential bleeding – hard to control
  - Even with various vascular clamps
  - Balloons only make things worse
- May require brief period of hypothermic circulatory arrest to get control
- More extensive patch or graft reconstructions may be needed.
- Salvage interventions
  - Cooling, ECMO, Open chest…. Hope?
RA-SVC Tears: Mechanism of Injury

Another Problem: Delayed Injuries

• Role of anticoagulation
  – Late lead erosions
  – Late perforations
• Presentation:
  – Symptomatic pericardial effusions
  – Chronic pericarditis
• Lead removal (elective)
  – Close monitoring
  – Echo guidance
OSU Experience

Problems can occur with any procedure:
   – Ablations
   – Device Implants
   – Extractions

OSU Experience: Jan 2007 – July 2010

<table>
<thead>
<tr>
<th>LEAD:</th>
<th>Implant</th>
<th>Extraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial</td>
<td>2854</td>
<td>548</td>
</tr>
<tr>
<td>Ventricular</td>
<td>2342</td>
<td>613</td>
</tr>
<tr>
<td>ICD</td>
<td>1989</td>
<td>466</td>
</tr>
<tr>
<td>Coronary Sinus</td>
<td>547</td>
<td>19</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>19</td>
</tr>
<tr>
<td>TOTAL</td>
<td>7732</td>
<td>1826</td>
</tr>
</tbody>
</table>
OSU Experience: Major Complications

**Extractions:**
- 7 emergent trips to OR → 0.38% of all leads
- 3 Infection / 4 Malfunction
- Age: 65 ± 8.5 (55-77 yrs)
- EF: 30 ± 21 (10-60%)
- LOS: 12.4 ± 12.2 (1-38)
- 4 arrests with CPR in EP LAB (50% death)
- 5 SVC tears (60% death)
- Deaths
  - 1 bridged on ECMO (EF <20%) with arrest
  - 1 extensive SVC graft reconstruction (EF=40%)
  - 1 large SVC tear (chronic occlusion) – 77 years/old

- TOTAL Survival: 57%

**Ablations:**
- 5 emergent trips to OR → 0.13% of all leads
- Age: 65 ± 7.3 (53-70 yrs)
- EF: 51 ± 12 (30-60%)
- LOS: 12.2 ± 8.0 (1-38)
- 3/5 arrests with CPR in EP LAB (20% death)
- Injuries:
  - IVC Laceration (intra-abdominal) – Death
  - RA injury
  - LA Injury
  - RA/Aortic root injury
  - RV/LA injury

- TOTAL Survival: 80%
OSU Experience: Major Complications

- **Implants:**
  - 5 emergent trips to OR → 0.065% of all leads
  - 3 Infection / 4 Malfunction
  - Age: 63 ± 16.5 (47-85 yrs)
  - EF: 28+/- 17 (15-55%)
  - LOS: 14.8+14.3 (1-38)
  - 3 arrests with CPR in EP LAB (33% death)
  - 2 deaths in EP lab – both had sternotomies
  - Injuries
    - Tension Pneumothorax with tamponade
    - PEA arrest
    - Coronary sinus perforation
    - RA perforation (late – after anticoagulation)
  - TOTAL Survival: 60%

OSU Experience: Major Complications
Jan 2007 – July 2010

- Ablations: 3798 / 5 trips (0.13%) = 1 death
- Implants: 7793 / 5 trips (0.064%) = 2 deaths
- Extractions: 1826 / 7 trips (0.38%) = 3 deaths

- LOS: 13 ± 11 days (0-38)
- EF: 36 ± 19% (10-60%)
- Age: 64 ± 10 years (47-85)
- Pericardial Drains: 32 (23 for “tamponade”)
  - Non-operative management
**Procedural Risks**

<table>
<thead>
<tr>
<th></th>
<th>Alive</th>
<th>Dead</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>11</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>63 ± 10</td>
<td>65 ± 11</td>
<td>0.38</td>
</tr>
<tr>
<td>EF</td>
<td>36 ± 24</td>
<td>24 ± 16</td>
<td>0.11</td>
</tr>
<tr>
<td>LOS</td>
<td>18 ± 11</td>
<td>4.5 ± 5.0</td>
<td>0.002</td>
</tr>
<tr>
<td>Pre-CPR</td>
<td>6/11 (55%)</td>
<td>5/6 (83%)</td>
<td>0.31</td>
</tr>
<tr>
<td>Ext vs Imp</td>
<td>1819/7791</td>
<td>3/2</td>
<td>0.05</td>
</tr>
<tr>
<td>Ext vs Abl</td>
<td>1819/3797</td>
<td>3/1</td>
<td>0.01</td>
</tr>
<tr>
<td>Imp vs Abl</td>
<td>7791/3797</td>
<td>2/1</td>
<td>NS</td>
</tr>
</tbody>
</table>

Trends? Patterns? Who knows?

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**What Have We Learned:**

**Controversies**

- **Extractions only done by surgeons vs EP**
  - Answer: Most experienced team
  - Should not be a “hobby:

- **Extractions only done in the OR vs Lab**
  - Answer: Most experienced location

- **Fixing “other problems”**
  - Afib procedures
  - Valvular repairs
  - Coronary grafting
  - Replacing leads/system
  - Goal: “Live to fight another day”
Surgical Backup?

... a few words

Operating Room Availability?
Room for Extractions or an Emergency?

Do we need it?
Surgeon Backup?
Like we have nothing else to do?

Always on a Friday Afternoon!
And when I'm drinking coffee!

Chocolate Bribe

Trends for Emergency CABG after PCI
OR/Surgeon Backup?

Not sure it is needed based on PCI model
(not an excuse not to be ready!)

Conclusions

- Horrible things can happen in the EP Lab
  - Horrible things can happen anywhere

- Overall risk is very low
  - When a complication occurs – high risk of complications.
  - Procedure related mortality is low

- With an experienced team (EP and OR)
  - Standby is not necessary: maybe in high risk cases
  - Not practical
  - Teams must be prepared for emergent interventions

- Surgical options must consider the use of bypass
  - Repairs can either be very simple or quite complex
  - Not everyone survives

If you do high risk procedures, bad things will happen.
Luck = Opportunity meets Preparation

Thank You