Alternative CIED (Re)Implantation Techniques

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Webinar Information

• Sponsorship and Support
  – Boston Scientific, Medtronic, EBR Systems, and Spectranetics provided the funding for this CME activity
  – Postgraduate Institute for Medicine has accredited this activity
  – Medtelligence organized this activity

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Indications for Alternative Implantation Techniques

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Approach to Young Patient with ARVD

- New ICD lead extracted with standard techniques
- Older ICD lead
  - complete fracture (insulation/conductor)
  - Retracted into axillary vein
  - Inserted over the 3rd anterior rib (very lateral)
  - Extraction/snared from right femoral vein in two pieces
- New ICD lead
  - Inserted via new axillary venous access over the 1st anterior rib
  - Extensive mapping to find good sensing located on the distal septum posteriorly
Assumptions & Limitations

Strength of CIED Indicated Therapy
2) Risk with CIED < Risk without CIED
3) Low Impact on Comorbid Conditions
4) Sustainable Implementation
5) Reversibility/Flexibility
Strength of CIED Indicated Therapy

1) Goals:
   1) Survival
   2) Quality of Life
   3) Predictable Outcomes
   4) Facilitates Therapy of Co-morbid Conditions
Risks with CIED < Risk without CIED

1) Risks
   1) Arrhythmia
   2) Surgery
   3) Bleeding
   4) Infection
   5) Clotting
Low Impact on Comorbid Conditions

1) Venous stenosis/occlusion
2) Anticoagulation
3) Valvular regurgitation
4) Ventricular function/Cardiac Synchronization
5) Infection
6) Chronic Kidney Disease and/or Dialysis
7) Indicated or previous cardiothoracic surgery
Sustainable Implementation

1) Current leads are reliable
2) Veins will sustain lead and vascular access needs
3) Lowest risk of infection
4) Supplies all required therapy
5) Ready for next device change
Reversibility/Flexibility

1) Program around issues
2) Extraction feasible
## Indications for Lead Extraction

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Infection</td>
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<td>2.</td>
<td>Lead Dysfunction</td>
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<td>3.</td>
<td>Vascular Access</td>
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One Year Mortality with Infection

Scenario #1a
Pacemaker Infection – Young Patient

1) Symptomatic bradycardia (Atrial or AV Block)
2) Pacemaker Infection
   1) Extraction!!!
   2) Reimplant other side, iliac, epicardial if still needed
   3) Use fewest leads consistent with good therapy
      1) Leadless, single chamber, dual chamber, CRT
Scenario #1b
Pacemaker Infection – Older Patient

1) Symptomatic bradycardia (Atrial or AV Block)

2) Pacemaker Infection
   1) Consider comorbidities (If Prognosis >2 yrs, consider young)
   2) Extraction!!!
   3) Evaluate for continued requirement for therapy
   4) Extraction & Reimplant other side, iliac, epicardial if still needed!
   5) Comorbidities (Dialysis, renal dysfunction, other OHS indication)
   6) Use fewest leads consistent with good therapy
      1) Leadless, single chamber, dual chamber, CRT
Scenario #1c
ICD Infection – Young Patient

1) **Primary or Secondary Prevention ICD**
2) ICD Infection
   1) Evaluate for alternative approach therapy (Ablation, Rx)
   2) Extraction!!!
   3) Reimplant **other side, iliac, epicardial** if still needed vs SICD
   4) Use fewest leads consistent with good therapy
      1) SubQ, single chamber, dual chamber, CRT
CIED Infection Survival with ESRD


10% Survival @ 5 years
Scenario #1d
CIED Infection – Older Patient

1) **Primary or Secondary Prevention ICD**

2) ICD Infection
   1) Evaluate for alternative approach therapy (Ablation, Rx)
   2) Extraction! Consider no reimplantation
   3) Reimplant **other side, iliac, epicardial** if still needed vs SICD
   4) Use fewest leads consistent with good therapy
      1) SubQ, single chamber, dual chamber, CRT
Leads vs Pulse Generators

- **Leads**
  - Saturated w/ Body Fluids
  - Mechanically Stressed
  - Intrathoracic
  - Implant Technique Sensitive
  - Patient Activity Sensitive
  - High Frequency of Recalls
  - **HIGH RISK**

- **Pulse Generators**
  - Hermetic Sealed
  - Mechanically protected
  - Extrathoracic
  - Implant Technique Insensitive
  - Patient Activity Insensitive
  - Lower Frequency of Recalls
  - **LOW RISK**
How Long do Pacemaker Leads Last?

Only 72% survive after a 10-year period

ICD leads: How long do they last?

Failure 15% at 5 years, 40% at 8 years
Scenario #2a
Lead is Unreliable – Young Patient

1) Symptomatic bradycardia (Atrial or AV Block)
2) Pacemaker Lead failure
   1) Evaluate for alternative approach therapy
   2) Extraction!
   3) Reimplant same side if still needed
   4) Use fewest leads consistent with good therapy
      1) Leadless, single chamber, dual chamber, CRT
**Scenario #2b**

**Lead is Unreliable – Older Patient**

1) Symptomatic bradycardia (*Atrial or AV Block*)
2) Pacemaker Lead failure
   1) Consider comorbidities (If Prognosis >10 yrs, consider young)
   2) Evaluate for alternative approach therapy
   3) Extraction & Reimplant *same side* if still needed!
   4) Implant on other side if prognosis very poor
   5) Use fewest leads consistent with good therapy
      1) Leadless, single chamber, dual chamber, CRT
Scenario #2c
Lead is Unreliable – Young Patient

1) **Primary or Secondary Prevention ICD**
2) ICD Lead failure
   1) Evaluate for alternative approach therapy (Ablation, Rx)
   2) Extraction!!!
   3) Reimplant **same side** if still needed
   4) Use fewest leads consistent with good therapy
      1) SubQ, single chamber, dual chamber, CRT
Scenario #2d
Lead is Unreliable – Older Patient

1) **Primary or Secondary Prevention ICD**
2) ICD Lead failure
   1) Evaluate for alternative approach therapy (Ablation, Rx)
   2) Extraction unless prognosis poor (<3 years)
   3) Reimplant **same side** if still needed
   4) Use fewest leads consistent with good therapy
      1) SubQ, single chamber, dual chamber, CRT
Poor Judgment
Scenario #3a
Veins are Occluded – Young Patient

1) Symptomatic bradycardia (**Atrial or AV Block**)
2) Needs another Pacemaker lead to deliver therapy
   1) Evaluate for alternative approach therapy
   2) Extraction! vs Venoplasty
      1) Leads unuseful vs useful
   3) Reimplant **same side**!!!
3) Use fewest leads consistent with good therapy
   1) Leadless, single chamber, dual chamber, CRT
Scenario #3b
Veins are Occluded – Older Patient

1) Symptomatic bradycardia (Atrial or AV Block)
2) Needs another Pacemaker lead to deliver therapy
   1) Consider comorbidities
      (If Prognosis >10 yrs, consider young)
   2) Extraction! vs Venoplasty
      1) Leads unuseful vs useful
   3) Extraction & Reimplant same side!!
   4) Implant on other side if Prognosis <3 yrs
   5) Use fewest leads consistent with good therapy
      1) Leadless, single chamber, dual chamber, CRT
Scenario #3c
Veins are Occluded – Young Patient

1) **Primary or Secondary Prevention ICD**
2) Needs another ICD lead to deliver therapy
   1) Evaluate for alternative approach therapy (Ablation, Rx)
   2) Extraction!!!
3) Reimplant **same side**!!!
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Veins are Occluded – Older Patient

1) **Primary or Secondary Prevention ICD**
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   1) Evaluate for alternative approach therapy (Ablation, Rx)
   2) Extraction unless prognosis poor (<3 years)
   3) Reimplant **same side!!!**
   4) Use fewest leads consistent with good therapy
      1) SubQ, single chamber, dual chamber, CRT
## All Cause Mortality 30 Days – Post Extraction

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<tr>
<th>Category</th>
<th>Odds Ratio</th>
<th>P value</th>
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<tr>
<td>Body mass index &lt;25 kg/m²</td>
<td>1.8</td>
<td>0.043</td>
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<tr>
<td>End Stage Renal Disease</td>
<td>4.8</td>
<td>&lt;0.001</td>
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<tr>
<td>NYHA FC</td>
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<td>0.006</td>
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<tr>
<td>II</td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>2.0</td>
<td></td>
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<tr>
<td>IV</td>
<td>8.5</td>
<td></td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>3.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>INR</td>
<td>1.3</td>
<td>0.01</td>
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<tr>
<td>Infection</td>
<td>1.3</td>
<td>0.002</td>
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<tr>
<td>Dual Coil ICD Lead</td>
<td>2.7</td>
<td>&lt;0.001</td>
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Assumptions & Limitations

Produces Creativity and **Reality Check**

1) Strength of CIED Indicated Therapy
2) Risk with CIED < Risk without CIED
3) Low Impact on Comorbid Conditions
4) Sustainable Implementation
5) Reversibility/Flexibility
Indications for Alternative Implantation Techniques

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ICD & Pacemaker Implantation after Extraction

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Disclosures

- Medtronic: Consultant
- St. Jude Medical: Consultant
- Spectranetics: Consultant
Site Considerations

- Pectoral
- Sub-Mammary
- Lateral Mammary
- Axillary
- Abdomen
- Epicardial
- Limited Atriotomy
Infra-Mammary Implant
Infra-Mammary

- Very cosmetic
- Be wary of bra cup irritation
- Lateral approach is an effective alternative (similar to axillary site)
  - Device placed in the pre or subpectoral position
- Fixation of lead body may be difficult
Axillary Approach

Figure 25-61. Incision in the anterior axillary line for optimal cosmetics. (From Shefer A, Lewis SB, Gang ES: The rectopectoral transaxillary permanent pacemaker: Description of a technique for percutaneous implantation of an invisible device. PACE 16:1646, 1996.)
Abdomen Placement

• May be used for epicardial leads
• Useful when femoral vein approach is used
Femoral Implant

- Pacemaker pocket
- Inguinal ligament
- Needle in femoral vein
Inominate Vein

- May be accessed from the right with a medial “stick”
- May allow access beyond an area of thrombosis
- More difficult to access inominate from left side
Internal Jugular Implant
Transiliac / Femoral approach

- Useful when all superior vein occluded, or when congenital anomaly prevents access via superior routes
  - vein is accessed via cutdown and/or introducer technique
  - active fixation leads placed
  - pacemaker inserted in lower abdominal wall
Femoral Vein Implant

- Above the inguinal ligament
  - Guidewire in the vein
  - Stick low to avoid the peritoneum
  - Aim at the guidewire with introducer needle
  - Use usual introducer technique

- Below the inguinal ligament
  - Tunnel the lead to the pocket
- Higher Fracture Rate
Femoral Vein Implant
Inferior Vena Cava

• Useful when all superior vein occluded, or when congenital anomaly prevents access via superior routes
  – “mini-laparotomy”; right flank incision
  – retro-peritoneal identification of IVC
  – active fixation leads placed through purse-string sutures
  – ?less risk of fracture vs femoral approach
Figure 25–69.  Posteroanterior abdominal radiograph showing the position of the pacemaker and generator lead inserted into the inferior vena cava. (From West JNW, Shearmann CP, Gammange MD: Permanent pacemaker positioning via the inferior vena cava in a case of single ventricle with loss of right atrial to vena cava continuity. PACE 16:1753, 1993.)
Transatrial Approach

- Endocardial leads may be utilized
- Dual chamber pacing may be performed
- Chronic leads may be removed
  - General anesthesia
  - Incision over 3rd/4th costochondral cartilage
  - Purse-string suture in atrium / appendage
  - Introducer / sheath placed, then lead(s)
  - Pacer pocket made via incision
Figure 25-65. Endocardial lead placement by means of limited thoracotomy with removal of only the third and fourth costal cartilages. Standard fluoroscopy and peel-away introducer techniques are used with transatrial access. (From Byrd CL, Schwartz SJ, Siviona M, et al: Technique for the surgical extraction of permanent pacing leads and electrodes. J Thorac Cardiovasc Surg 89(1):142, 1985.)
Trans-Atrial Approach

Figure 25-63. Transatrial endocardial lead placement during thoracotomy allows low-threshold transvenous leads to be implanted at the time of thoracic surgery. (From Barold SS, Mugica J: New Perspectives in Cardiac Pacing. Mt Kisco, NY, Futura, 1988, p 271.)
Minimally invasive epicardial lead placement

- 2 or 3 one cm incisions are made in the intercostal space
- Thoracoscope inserted into one
- Lead advanced through the other
- Selective intubation of right and left mainstem bronchi required
- Alternative to subxiphoid, thoracotomy and sternotomy approaches
Subcutaneous-ICD System

• Designed to sense, detect and treat malignant ventricular tachyarrhythmias
  – Primary Prevention
  – Secondary Prevention

• S-ICD System is entirely subcutaneous
SC-ICD

- No Fluoroscopy needed
- No venous stick
- No leads in the venous system
- No leads in the heart
- No leads across the heart valve
Leadless VVIR Pacemaker

- Intended for patients that have a Class I or II indication for a single-chamber ventricular pacemaker.
Compared to a Quarter

Micra™
Or a Euro

Nanostim™
Typical Delivery System + Introducer
Radiographic Appearance
Post Extraction CRT Implant
Novel techniques & Technologies

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Deputy Editor, Journal Am Coll Cardiol: Clinical EP

Disclosures:
Consultant: Biotronik, Boston Scientific, Impulse Dynamics, Liva Nova, Medtronic, Respicardia Inc, St. Jude Medical, theHeart.org, Research Grants: St. Jude Medical, Boston Scientific
Overview

- Post-extraction challenges, need an individualized implantation strategy

- Imaging:
  - Intra-procedural coronary venography important for assessing options
  - Sometimes pre-procedural imaging, in a staged procedure, may be useful

- Coronary venous interventional strategies
  - Venoplasty & Stenting

- Evolving LV endocardial pacing strategies
Re-implanting the LV lead
Potential Challenges

Tackling an unwilling anatomy

• Venous stenosis
• Distal Thrombotic Occlusion of Vein

Path of no return

• Thrombotic occlusion of main branch
• No alternative branches
• Coronary Sinus Occlusion
Venoplasty
Moving beyond residual venous stenosis

Altered Anatomy: Securing the Lead Proximally
Stenting as an option

Intra-luminal Interaction
Stent, Vascular tissue & Lead

- Explanted Heart examples
- Intact intimal tissue layer seen
- No sign of occluding proliferative tissue
- No lead injury

Future Implications for extraction?
- Manually extracted with gentle traction

Balazs T et al. J Cardiovasc Electrophysiol 2013; 24:468-70
Value of pre-procedural Imaging
Demonstrates options

LV Endocardial Pacing
Combined Superior & Inferior Approach

Superior route

Mullins transseptal sheath/dilator

Brockenbrough needle

Guidewire

Right femoral vein

Endocardial LV lead Implantation: Combined approach
LV Endocardial Pacing
Shoulder approach

- Endocardial approach provides the needed individualization
- Best site is variable

- Complete CRT Implant via Shoulder approach with LV lead implantation individualized to area of most delayed electrical activation (Animal Study)
- ALSYNC Study provides more insight

• Singh JP and Gras D; EHJ 2011
• Barrett CD, Singh JP, et al; HRS 2011
• Exner D, Auricchio A and Singh JP. Heart Rhythm 2012
IAS Dilation with Angioplasty Balloon
Push-pull during deflation to Advance Guide Catheter
LV Electro-anatomical Map & CRT Leads

- Shoulder Access to LV via Transseptal route

- Endocardial approach provides the needed individualization
- Best site is variable

- Animal Study
- Complete CRT Implant via Shoulder approach with LV lead implantation individualized to area of most delayed electrical activation

• Singh JP and Gras D; EHJ 2011
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• Exner D, Auricchio A and Singh JP. Heart Rhythm 2012
ALSSYNC: LV Endocardial approach

Technique

ALSYNC study: LV Endocardial Pacing (138 patients)

- Implant success: 89.4%
- 14 TIA’s
- Freedom from complications: 82.2%

Trans-apical Endocardial LV lead placement

Alternative strategies: ? role

**WISE Technology**
*(Investigational)*

- Synchronized
- Targeted LV pacing
  - Phased Array Ultrasound Transmitter is Implanted in Intercostal Space
  - Receiver Electrode (RE) is Implanted in LV endocardium
  - Converts ultrasound energy to electrical pulse.

**SELECT LV Study***
- Prospective, non randomized study with LV pacing pellet
- 35 patients who failed conventional CRT
- Early data looks good

*Reddy V et al. HRS 2015; *Singh JP. JACC: CEP August 2015.*
In Summary

- Post-extraction challenges, need an individualized implantation strategy

- Imaging:
  - Intra-procedural coronary venography important for assessing options
  - Sometimes pre-procedural imaging, in a staged procedure, may be useful

- Coronary venous interventional strategies
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- Evolving LV endocardial pacing strategies
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