Implantation of endocardial vs epicardial leads in congenital heart diseases: What have we been up to?

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Cardiac pacing in pediatric and congenital heart disease patients

- Higher overall incidence of lead fracture than adults
  14% in children & adolescents vs 4% in adults
  - active life style
  - patient growth
  - higher overall percentage of epicardial devices.
Implantation of endocardial vs epicardial leads in CHD: What have we been up to?

- Epicardial vs endocardial system in overall
  - Indication & Long term outcome

- Transvenous pacemaker in the young children

- Modified positioning of lead and device in congenital heart disease (CHD)
Conditions requiring epicardial pacemaker in children and CHD patients

- Age: Infant and young children
- CHD with **R → L shunt**
  - Unrepaired or residual CHD
  - Eisenmenger complex
- Functional single ventricle, s/p Fontan palliation
- BiV pacemaker in children

- Risk of thromboembolism
- Valve regurgitation
Case
-Noonan syndrome, 10y old now
-Aortic stenosis (subvalvar and valvar), interruption of aortic arch, VSD
-Surgical complete heart block; PMD (pacemaker dependent; no escape rhythm)
pulmonary hypertension, poor airway and lung condition s/p aortopexy
-Residual significant ASR

2 years of age
Epicardial DDD
   → LV dysfunction
d/y dyssynchrony

4 years of age
Epicardial CRT (Medtronic INSYNC III)
Redundant ventricular lead

9 years of age, 21.3 kg
Poor epicardial lead function
   high threshold 3.5~4V, both
Seizure-like episode

   → Transvenous VVIR
Right isomerism, s/p ECC Fontan operation
Ventricular dysfunction with QRS widening
s/p epicardial CRT (6 years old)
Extracardiac ICD implantation in a Fontan patient

20y /male, Syncope during exercise, induced VF

- Via thoracoabdominal approach
- Right anterolateral thoracotomy; 5th ICS
- Upper abdominal midline incision

good DFT; <10J
Endocardial vs. epicardial in pediatric pacing system

497 patients, 1007 leads
Children’s Hospital Boston, 1980–2002
FU: median 6.2 years (0–22).

Lead failure:
155 leads (15%)
115 patients (23%)

Younger patients (<12 years) more lead fractures than older children (P .005),

Average lead longevity of epicardial vs endocardial leads by age category.

Heart Rhythm (2004) 1, 150–159
The rates of lead failure and fracture

epicardial systems 28% vs. 4% endocardial in adult
epicardial 23-36% vs 7~19% endocardial 5-7y FU in children
epicardial 40-44% 10y FU in children

1982 and 2008, 287 patients with CHD

Heart Rhythm 2004;1:150–159
Europace 2006; 8, 530–536

292 patient
Europace 2006; 8, 530–536
Epicardial lead outcome in congenital heart disease

S-CHD ?

Atrial Epicardial Leads

<table>
<thead>
<tr>
<th>Time Since Lead Implantation (Years)</th>
<th>Bi-V, 31</th>
<th>SV, 48</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>21</td>
<td>43</td>
</tr>
<tr>
<td>2</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>10</td>
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<tr>
<td>15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td></td>
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</tbody>
</table>

Log-rank p-value = 0.59

S-CHD

non-S-CHD

39
28
18
16
6

P = 0.008

Time from Lead Implantation (years)

39
28
18
16
6

S-CHD

70
37
13
4
1


Single ventricle?

Ventricular Epicardial Leads

<table>
<thead>
<tr>
<th>Time Since Lead Implantation (Years)</th>
<th>Bi-V, 54</th>
<th>SV, 62</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>41</td>
<td>54</td>
</tr>
<tr>
<td>2</td>
<td>28</td>
<td>30</td>
</tr>
<tr>
<td>5</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
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Log-rank p-value = 0.57

Heart Rhythm 2015;12:566–573
Risk factors associated with lead malfunction in CHD

Table 1 Results of Cox regression to identify predictive factors for failure of the pacing system

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Univariate</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>HR</td>
<td>95% CI</td>
<td>P value</td>
<td>HR</td>
<td>95% CI</td>
</tr>
<tr>
<td>Epicardial system</td>
<td>4.7</td>
<td>2.7–8.2</td>
<td>&lt;0.0001</td>
<td>5.4</td>
<td>2.7–10.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>AV block</td>
<td>2.2</td>
<td>1.4–3.6</td>
<td>0.001</td>
<td>1.6</td>
<td>0.9–2.7</td>
<td>0.065</td>
</tr>
<tr>
<td>Complex CHD</td>
<td>0.9</td>
<td>0.5–1.5</td>
<td>0.574</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at implant</td>
<td>0.9</td>
<td>0.9–1.0</td>
<td>&lt;0.0001</td>
<td>0.9</td>
<td>0.9–1.0</td>
<td>0.028</td>
</tr>
<tr>
<td>Year of implant</td>
<td>0.9</td>
<td>0.9–1.0</td>
<td>0.066</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart surgery</td>
<td>1.2</td>
<td>0.4–3.7</td>
<td>0.802</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of heart surgeries</td>
<td>1.2</td>
<td>1.1–1.3</td>
<td>0.035</td>
<td>0.8</td>
<td>0.6–1.0</td>
<td>0.032</td>
</tr>
<tr>
<td>No. of leads</td>
<td>1.6</td>
<td>1.4–1.9</td>
<td>&lt;0.0001</td>
<td>1.5</td>
<td>1.3–1.8</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

CI, confidence interval; HR, hazard ratio; No., number.


Factor associated with lead malfunction

| Atrial                      | Ventricular
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Single ventricle palliation</td>
<td>2.55 (0.63–10.28), P = .189</td>
</tr>
<tr>
<td>Age at first pacer</td>
<td>0.91 (0.81–1.02), P = .092</td>
</tr>
<tr>
<td>Race: black vs white</td>
<td>1.12 (0.12–10.57), P = .918</td>
</tr>
<tr>
<td>Sex: male vs female</td>
<td>3.88 (0.98–15.34), P = .054</td>
</tr>
<tr>
<td>Non-steroid vs steroid eluting</td>
<td>1.02 (0.12–8.47), P = .984</td>
</tr>
<tr>
<td>No. of surgeries</td>
<td>0.68 (0.34–1.34), P = .265</td>
</tr>
<tr>
<td>Thoracotomy vs sternotomy</td>
<td>2.76 (0.71–10.67), P = .142</td>
</tr>
<tr>
<td>Subxiphoid vs sternotomy</td>
<td>1.37 (0.26–7.09), P = .707</td>
</tr>
</tbody>
</table>

Data are presented as hazard ratio (95% confidence interval), P value.
(Heart Rhythm2015;12:566–573)
Predictor of lead failure

- Epicardial lead system
- Younger age at implant
- Lower body weight
- # of previous heart surgeries
- # of leads
- Sex
- Era of implantation
- non-steroid
Transvenous pacemaker in infants

Initial studies on transvenous PM implantation in small infants: technically feasible with good short-term
Long term outcome of transvenous pacemaker in infants?

- Lack of long term FU of transvenous lead in infancy and very young children
- no double blinded controlled study
Long-term outcome of transvenous pacemaker implantation in infants: a retrospective cohort study

7 patients tv-lead , <10kg
Median FU: 14 years

2/7 functioning original tv-lead

19 re-interventions
12/19 before EoL of the generator
• Removal of tv lead ; 5/7
• Sw to epi-lead; 3/7

Vascular occlusion 4/7 (57%)
skin necrosis 2/7

Twenty-Seven Years Experience With Transvenous Pacemaker Implantation in Children Weighing <10 kg

The 28 patients
FU: median of 17.2y

Total 88 redo-procedures
- pacemaker generator changes
- lead advancements
- Lead changes±lead extraction
- pacemaker upgrades

7/28(25%): functioning original tv-lead

SCV occlusion 12/28 (43%)
In median 9.2 (range, 0.25–12.9)y

(Circ Arrhythm Electrophysiol. 2016;9:e003422.)
(A) 4.3 kg infant for congenital complete heart block
(B) At 8 y of age, EOL, straightened-out lead → (C) occluded subclavian vein
90 consecutive patients (mean 15.0 years of age at implant) median interval of 6.5 years complete obstruction: 13% partial obstruction: 12%

Patient age, body size, and lead characteristics at implant did not clearly predict venous occlusion

Venous occlusion

- Adult patients
  - complete occlusion rates of 12%, meta-analysis
- Children <18y
  - complete occlusion rate 13-15%
- Infancy, body weight < 10 kg
  - complete occlusion rate 43-57% in 14-17y of FU

- Venous occlusion:
  - usually asymptomatic
  - a major clinical concern
    - patients who require lifelong pacing
    - lead extraction & replacement: exceedingly difficult challenge

Pacing Clin Electrophysiol 2003;26:1649-1652
HeartRhythm2004;1:150–159
Europace 2006; 8, 530–536
Disadvantage of epicardial lead in the young

- Lead malfunction and lead fracture
- Sternotomy
- Pericardial effusion
- Cardiac Strangulation
- Generator Migration
- MRI-incompatible

Disadvantage of endocardial lead in the young

- Vascular thrombosis, occlusion
- Lead dislodgement
- Valve dysfunction
- Wall perforation, hemothorax
- Lead traction requiring revision (lead advancement)
- Lead extraction
- Pocket infection
- Lead dysfunction and isolation defects
- Imminent skin necrosis and scar traction
Controversy in the clear superiority of either epicardial or endocardial pacing

Performance of steroid eluting bipolar epicardial leads in pediatric and congenital heart disease patients: improving long term outcome

(158 epicardial leads Medtronic 4968, bipolar, steroid - eluting)
Lead survival at 2, 5 and 10 years was 98.7%, 93% and 92.4%.

University of Leipzig
Shorter FU duration
Median 4 y ,

a revival in the use of epicardial pacing in children!

Controversy in the clear superiority of either epicardial or endocardial pacing

age of 18 years
73 patients, 149 pacemaker
**Epi (2.2 years old at first implant)**; pacing threshold rise
**Endo (8.3 years old at first implant)**; higher other Cx

(Ann Thorac Surg 2015;100:147–53)

University Hospital of Düsseldorf between 1985 and 2010

Fig 1. Kaplan-Meier graph of months to first revision.
Indications for revision of epicardial (gray bar) vs. endocardial (black bar) systems

(Ann Thorac Surg 2015;100:147–53)
(PACE 2010;33:1112)

Endocardial lead
High other lead related complication: 18%
Lead dislocation etc.
Challenging lead extraction in pediatric and CHD patients

Total Extraction Attempts
203 leads

Simple Extraction-Successful
59 (29%) (median lead age=2.1 yrs)

Simple Extraction-Failed
144 (71%) (median lead age=7.0 yrs)

Abandoned Leads
35/144 (24%)

Complex Extractions
109/144 (76%)

Success
103/109 (94%)
- Complete 93 (85%)
- Partial 10 (9%)

Failure
6/109 (6%)

(Circ Arrhythm Electrophysiol. 2010;3:437-444.)
Complex Extraction - Technique Success

- LS only: 10
- LS + SS: 10, 18, 56, 10
- LS + SS + RF: 10, 18, 56
- LS + SS + RF + Fem: 10

Locking stylet
Rotational sheath
Stainless steel sheath
RF sheath
Laser sheath
Trends, epi vs. endo

- Implant lead with expectation of the life long pacing or defibrillation
- Life expectancy, longer than 80y
- Epicardial pacing system in children
- Subcutaneous ICD in adult CHD and Fontan pts.
- Leadless pacemaker in adult CHD
Modified application of pacemaker in pediatric and CHD patients
PMD

Epicardial pacing system and pacemaker dependent patient
- escape heart rate < 40bpm?

Epicardial pacing safety net:
  - dual chamber, dual V lead system

Ventricular lead redundancy (VLR): biventricular pacing
An epicardial pacing safety net: an alternative technique for pacing in the young

placing a second ventricular lead, and attaching it to the atrial port of a dual chamber pacemaker

Cardiol Young 2009; 19: 228–232
PacingClin Electrophysiol2004;27:1161–113
PacingClinElectrophysiol1984;7:296–300
Ventricular lead redundancy (VLR) to prevent cardiovascular events and sudden death from lead fracture in pacemaker-dependent children (PMD)

**BiV pacing systems** and redundant ventricular lead systems (RVLS)

13 pts with RVLS in PMD

CV event rate
RVLS vs SiV groups
(RVLS 0/13 events [0%]
Vs SiV 3/24 events [13%], P = .18),

Ix. PMD and Epicardial system

(Heart Rhythm 2015;12:111–116)
23y/F Endocardial pacemaker in Fontan patients
left isomerism, AVSD, criss-cross heart, s/p Fontan operation
MVR, V lead insertion via the closed right side TV

VVI epicardial, fractured A lead

Endocardial lead at RV apex through closed TV

Endocardial  DDD
23y/F Endocardial pacemaker in Fontan patients
left isomerism, AVSD, criss-cross heart, s/p Fontan operation
MVR, V lead insertion via the closed right side TV
Submammary ICD
13y/ F, s/p cardiac arrest
LQTS type 2
A would-be K-pop star, refused ICD implantation
Generator related complication in neonate

Intra-thoracic positioning of generator
7 days old, 3.2kg, left isomerism,
complete heart block (HR.43/min), single ventricle

Failed ventilator weaning
Vessel and air way compression
Continued.....
Failed intra-abdominal positioning of generator
left isomerism, f- single ventricle, DORV ,PS
2 m of age
Continued.....
Failed intra-abdominal positioning of generator
10m of age migration of generator, bowel perforation
→ resection colostomy
Continued.....
Failed intra-abdominal positioning of generator
10 months of age, repositioning of generator to left pleural cavity
Conclusions

• Lead related complication:
  epicardial 23-36% vs endocardial 7-19% at 5-7y FU in children
• Vascular thrombosis occurred after transvenous lead
  in 13-20% (<18y old), and 43-57% (Bwt <10kg)

• Recent steroid eluting bipolar epicardial lead shows improved outcome.

• A “save the veins and valves in children” approach may still be prudent.
• Switching from an epi- to endocardial pacing system may have less morbidities than dealing with chronic endocardial leads once implanted in young children.
Thank you for your attention!