Cardiac sarcoidosis: managing risk of sudden cardiac death

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Disclosures: speakers fees for Abbott, BSC, Biosense, Medtronic, Biotronik
Sarcoid

• Sarcoidosis (amyloidosis, haemochromatosis, myotonic dystrophy)

• Granulomatous disease – aetiology unknown

• Pulmonary involvement

• Heart, liver, lymph nodes, spleen, skin, eyes, bones, parotid, brain, other organs/tissues.

• May be immunological response to unidentified antigen

• Prevalence: 5-64/100,000

• Incidence: 10-35/100,000
**Cardiac sarcoidosis - diagnosis**

### Expert Consensus Recommendations on Criteria for the Diagnosis of CS

There are 2 pathways to a diagnosis of Cardiac Sarcoidosis:

1. **Histological Diagnosis from Myocardial Tissue**
   CS is diagnosed in the presence of non-caseating granuloma on histological examination of myocardial tissue with no alternative cause identified (including negative organismal stains if applicable).

2. **Clinical Diagnosis from Invasive and Non-Invasive Studies:**
   It is probable* that there is CS if:
   a) There is a histological diagnosis of extra-cardiac sarcoidosis
   
   and

   b) One or more of following is present
   - Steroid +/- immunosuppressant responsive cardiomyopathy or heart block
   - Unexplained reduced LVEF (<40%)
   - Unexplained sustained (spontaneous or induced) VT
   - Mobitz type II 2nd degree heart block or 3rd degree heart block
   - Patchy uptake on dedicated cardiac PET (in a pattern consistent with CS)
   - Late Gadolinium Enhancement on CMR (in a pattern consistent with CS)
   - Positive gallium uptake (in a pattern consistent with CS)

   and

   c) Other causes for the cardiac manifestation(s) have been reasonably excluded

*In general, ‘probable involvement’ is considered adequate to establish a clinical diagnosis of CS.\(^\text{33}\)
Cardiac sarcoidosis - diagnosis

**Expert Consensus Recommendations on Screening for Cardiac Involvement in Patients With Biopsy-Proven Extracardiac Sarcoidosis**

**Class I**
1. It is **recommended** that patients with biopsy-proven extracardiac sarcoidosis **should be** asked about unexplained syncope/presyncope/significant palpitations.
2. It is **recommended** that patients with biopsy-proven extracardiac sarcoidosis **should be** screened for cardiac involvement with a 12-lead electrocardiogram (ECG).

**Class IIa**
1. Screening for cardiac involvement with an echocardiogram can be **useful** in patients with biopsy-proven extracardiac sarcoidosis.
2. Advanced cardiac imaging, CMR or FDG-PET, at a center with experience in CS imaging protocols *can be useful* in patients with one or more abnormalities detected on initial screening by symptoms/ECG/echocardiogram.

**Class III**
1. Advanced cardiac imaging, CMR or FDG-PET, **is not recommended** for patients without abnormalities on initial screening by symptoms/ECG/echocardiogram.

*Palpitations were defined as “a prominent patient complaint lasting > 2 weeks.”*

**Table 2** Prevalence of abnormalities, sensitivity, and specificity of diagnostic criteria

<table>
<thead>
<tr>
<th>Abnormality on baseline testing</th>
<th>Prevalence</th>
<th>Sensitivity (95% CI) (%)</th>
<th>Specificity (95% CI) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of cardiac symptoms</td>
<td>12 (19)</td>
<td>46 (26–27)</td>
<td>95 (82–99)</td>
</tr>
<tr>
<td>Electrocardiogram</td>
<td>3 (50)</td>
<td>8 (1–27)</td>
<td>97 (86–100)</td>
</tr>
<tr>
<td>Holter</td>
<td>13 (21)</td>
<td>50 (29–71)</td>
<td>97 (86–100)</td>
</tr>
<tr>
<td>Echocardiogram</td>
<td>8 (13)</td>
<td>25 (10–47)</td>
<td>95 (82–99)</td>
</tr>
<tr>
<td>Any screening variable</td>
<td>29 (47)</td>
<td>100 (88–100)</td>
<td>87 (72–96)</td>
</tr>
<tr>
<td>Two or more screening variables</td>
<td>7 (11)</td>
<td>25 (10–47)</td>
<td>97 (86–99)</td>
</tr>
<tr>
<td>Three or more screening variables</td>
<td>1 (2)</td>
<td>4 (1–21)</td>
<td>100 (92–100)</td>
</tr>
</tbody>
</table>

Birnie et al. Heart Rhythm 2014;11:1304–23
Cardiac sarcoidosis - diagnosis

Birnie et al. Heart Rhythm 2014;11:1304–23
Cardiac sarcoidosis - prevalence

- 25% of cases at autopsy (> in Japanese)\(^1\)
- Clinically occurs in 2-7% cases\(^2\)
- CMR imaging may detect small areas of oedema and/or fibrosis (subclinical cardiac involvement)\(^3\)
- Sensitivity and specificity of CMR imaging 100% (95% confidence interval, 78–100%) and 78% (64–89%)\(^4\)

Cardiac sarcoidosis
## Table 1: Prevalence of asymptomatic CS in patients with extracardiac sarcoidosis

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>% of patients with asymptomatic CS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>155</td>
<td>25.5</td>
</tr>
<tr>
<td>2011</td>
<td>152</td>
<td>19</td>
</tr>
<tr>
<td>2009</td>
<td>81</td>
<td>25.9</td>
</tr>
<tr>
<td>2008</td>
<td>62</td>
<td>38.7</td>
</tr>
<tr>
<td>2005</td>
<td>82</td>
<td>3.7</td>
</tr>
<tr>
<td>2003</td>
<td>50</td>
<td>14.0</td>
</tr>
<tr>
<td>2002</td>
<td>31</td>
<td>54.9</td>
</tr>
</tbody>
</table>

CS = cardiac sarcoidosis; LGE-CMR = late gadolinium–enhanced cardiovascular magnetic resonance; PET = positron emission tomography.

### 5-50%
Deposition of abnormal substance (maybe patchy) → progressively rigid ventricular myocardium

- Conduction abnormalities
- Ventricular arrhythmias
- Heart failure
LV dysfunction

- Heart failure predicts mortality
- Steroid treated LVEF > 50% 10 year survival 89%
- Steroid treated LVEF < 50% 10 year survival 27%
- Timing of steroids? (early vs. late)
- Standard heart failure treatments
- CRT/heart transplantation
ECG abnormalities

- AV block, bundle branch block, nonspecific interventricular conduction delay, premature ventricular contractions (PVCs)
- 30%+ in cardiac sarcoid (but 10-15% in normal)
- Presence of ECG abnormality ↑ likelihood of cardiac involvement
### Table 3
Studies evaluating the effect of corticosteroids on atrioventricular conduction recovery in patients

<table>
<thead>
<tr>
<th>Study</th>
<th>Steroids</th>
<th>No steroids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Okamoto et al</td>
<td>3 patients</td>
<td>3 (100)</td>
</tr>
<tr>
<td>Kato et al</td>
<td>7 patients</td>
<td>4 (57.1)</td>
</tr>
<tr>
<td>Chapelon-Abric et al</td>
<td>9 patients</td>
<td>7 (75)</td>
</tr>
<tr>
<td>Banba et al</td>
<td>9 patients</td>
<td>5 (56.6)</td>
</tr>
<tr>
<td>Yodogawa et al</td>
<td>12 patients</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>Kandolin et al</td>
<td>17 patients</td>
<td>4 (23.5)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>57 patients</td>
<td>27 (47.4)</td>
</tr>
</tbody>
</table>

**Notes:**
- AV recovery, n (%)
- No steroid results not available.
### Expert Consensus Recommendations for the Management of Conduction Abnormalities in CS

<table>
<thead>
<tr>
<th>Class</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>It is recommended that physicians should be guided by the American College of Cardiology/American Heart Association/Heart Rhythm Society 2012 guidelines (see sections on Acquired Atrioventricular Block and Chronic Bifascicular Block) for decisions regarding permanent pacing in CS patients.</td>
</tr>
</tbody>
</table>

| Class IIa | 1. Device implantation can be useful in CS patients with an indication for pacing even if the AV block reverses transiently.  
2. Immunosuppression can be useful in CS patients with Mobitz II or third-degree heart block.  
3. Implantable cardioverter-defibrillator implantation can be useful in patients with CS and an indication for permanent pacemaker implantation. |
Ventricular arrhythmias

- SCD from presumed VT initial manifestation of cardiac sarcoid in 35%
- Use of immunosuppression – variable effect (+ve and –ve)
- Sotalol and amiodarone
- Catheter ablation

Table 4: Studies assessing the role of VT ablation in cardiac sarcoidosis

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>EF (%)</th>
<th>Noninducible post, n/N (%)</th>
<th>Partial success, n/N</th>
<th>Recurrence, n/N (%)</th>
<th>Follow-up period (mo= months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Koplan et al</td>
<td>8</td>
<td>34</td>
<td>2/8 (25)</td>
<td>4/9</td>
<td>6/8 (75)</td>
<td>6–84</td>
</tr>
<tr>
<td>Jefic et al</td>
<td>9</td>
<td>42</td>
<td>5/9 (56)</td>
<td>3/9</td>
<td>4/9 (44)</td>
<td>19.8</td>
</tr>
<tr>
<td>Dechering et al</td>
<td>8</td>
<td>36</td>
<td>5/8 (63)</td>
<td></td>
<td></td>
<td>6</td>
</tr>
</tbody>
</table>
Ventricular arrhythmias

Expert Consensus Recommendations for the Management of Ventricular Arrhythmias

Class IIa 1. Assessment of myocardial inflammation with FDG-PET can be useful in CS patients with ventricular arrhythmias.
2. Immunosuppression can be useful in CS patients with frequent ventricular ectopy or nonsustained VT and evidence of myocardial inflammation.
3. Immunosuppression can be useful in CS patients with sustained ventricular arrhythmias and evidence of myocardial inflammation.
4. Antiarrhythmic medication therapy can be useful in patients with ventricular arrhythmias refractory to immunosuppressive therapy.
5. Catheter ablation can be useful in patients with CS and ventricular arrhythmias refractory to immunosuppressive and antiarrhythmic therapy.
6. Catheter ablation can be useful in patients with incessant ventricular arrhythmias.
The case for ICD implantation in all patients with cardiac sarcoid

- Sudden death is seen in cardiac sarcoidosis patients with normal ventricular function and without any cardiac symptoms
- Sarcoidosis is a progressive disease without a cure, and therefore the risk of sudden death will likely increase over time
- No clear identifiable risk stratification method to predict sudden death risk in patients with cardiac sarcoidosis yet
# 1° prevention for all CS

<table>
<thead>
<tr>
<th></th>
<th>Year</th>
<th>N</th>
<th>AV block (%)</th>
<th>BBB (%)</th>
<th>VT (%)</th>
<th>CHF (%)</th>
<th>SCD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Matsui</td>
<td>1976</td>
<td>42</td>
<td>62</td>
<td>48</td>
<td>14</td>
<td>10</td>
<td>41</td>
</tr>
<tr>
<td>Roberts</td>
<td>1977</td>
<td>26</td>
<td>27</td>
<td>12</td>
<td>35</td>
<td>30</td>
<td>65</td>
</tr>
<tr>
<td>Fleming</td>
<td>1981</td>
<td>300</td>
<td>26</td>
<td>61</td>
<td>73</td>
<td>24</td>
<td>26</td>
</tr>
<tr>
<td>Yazaki</td>
<td>1998</td>
<td>95</td>
<td>45</td>
<td>N/A</td>
<td>18</td>
<td>26</td>
<td>12</td>
</tr>
</tbody>
</table>
Sufficient clinical data are not available to stratify risk of SCD among patients with cardiac sarcoidosis. Accordingly, clinicians must use the available literature along with their own clinical experience and judgment in making management decisions regarding ICD therapy. Consideration should be given to symptoms such as syncope, heart failure status, LV function, and spontaneous or induced ventricular arrhythmias at electrophysiological study to make individualized decisions regarding use of the ICD for primary prevention of SCD.
Risk stratification

- Can we risk stratify LVEF > 35%?
Risk stratification

- VT stimulation study

Primary Prevention of Sudden Cardiac Death in Silent Cardiac Sarcoidosis: Role of Programmed Ventricular Stimulation
Davendra Mehta, Neil Mori, Seth Goldbarg, Steven Lubitz, Juan P. Wisnivesky and Alvin Tierstein
Circ Arrhythm Electrophysiolog published online December 30, 2010;
DOI: 10.1161/CIRCEP.110.958322
## Risk stratification

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Positive PES* (n=8)</th>
<th>Negative PES* (n=68)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age +/- SD (yrs)</td>
<td>48.7 +/- 5.7</td>
<td>49.3 +/- 13.3</td>
<td>0.8994</td>
</tr>
<tr>
<td>Male</td>
<td>5 (62.5%)</td>
<td>28 (41.2%)</td>
<td>0.2497</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td>0.6177</td>
</tr>
<tr>
<td>African-American</td>
<td>4 (50.0%)</td>
<td>34 (50.0%)</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>2 (25.0%)</td>
<td>25 (36.8%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2 (25.0%)</td>
<td>9 (13.2%)</td>
<td></td>
</tr>
<tr>
<td>Corticosteroid use (%)</td>
<td>71.4</td>
<td>61.0</td>
<td>0.5913</td>
</tr>
<tr>
<td>Median length of follow-up (yrs)</td>
<td>5.6</td>
<td>5.0</td>
<td>0.26</td>
</tr>
<tr>
<td>Patients with LVEF† &lt; 40% at time of PES* (%)</td>
<td>5 (62.5%)</td>
<td>18 (26.5%)</td>
<td>0.0359</td>
</tr>
</tbody>
</table>
Risk stratification

- 8 had +EPS → ICD (5/8 EF <40%)
- 2 deaths, 4 with appropriate ICD shocks
- Of those with events 4 LVEF < 40%
- 1 +EPS normal LVEF – no events
- 68 had –EPS (18/68 EF <40%)
- 1 death, asymptomatic arrhythmias unknown
Risk stratification
Risk stratification

- MRI Findings (Scar Burden)
- 44 Patients with LVEF > 35% and Cardiac MRI
- Collaboration with University of Colorado and University of Michigan
- Precise Quantification of Delayed Contrast Enhancement
- Expressed as % of LV or RV Mass

Crawford, et al. JACC (abstracts) 2012
Risk stratification

![Graph showing the distribution of patients based on percent LV scar range. The graph has categories for 0%, 1-9%, 10-19%, 20-29%, and >30% LV scar range. The number of patients decreases as the percent LV scar range increases.]

Crawford, et al. JACC (abstracts) 2012
Risk stratification

- DE involving >9.5% on the combined LV/RV analysis resulted in 90% sensitivity and 100% specificity for VT/VF (AUC 0.999 p < 0.001)

- DE > 3.5% of the LV mass was associated with 90% sensitivity and a specificity of 97% for identifying patients with VT/VF (AUC 0.898, p=0.001)

- DE of <1% was not associated with any VT/VF

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>LV DE</td>
<td>100%</td>
<td>62%</td>
<td>53%</td>
<td>100%</td>
</tr>
<tr>
<td>RV DE</td>
<td>90%</td>
<td>100%</td>
<td>100%</td>
<td>97%</td>
</tr>
<tr>
<td>Multifocal DE</td>
<td>100%</td>
<td>91%</td>
<td>77%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Crawford, et al. JACC (abstracts) 2012
So who should have an ICD

<table>
<thead>
<tr>
<th>Expert Consensus Recommendations for ICD Implantation in Patients With CS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I</strong></td>
</tr>
<tr>
<td>ICD implantation <strong>is recommended</strong> in patients with CS and one or more of the following:</td>
</tr>
<tr>
<td>1. Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest;</td>
</tr>
<tr>
<td>2. LVEF ≤ 35%, despite optimal medical therapy and a period of immunosuppression (if there is active inflammation).</td>
</tr>
<tr>
<td><strong>Class IIa</strong></td>
</tr>
<tr>
<td>ICD implantation <strong>can be useful</strong> in patients with CS, independent of ventricular function, and one or more of the following:</td>
</tr>
<tr>
<td>1. An indication for permanent pacemaker implantation;</td>
</tr>
<tr>
<td>2. Unexplained syncope or near-syncope, felt to be arrhythmic in etiology;</td>
</tr>
<tr>
<td>3. Inducible sustained ventricular arrhythmias (&gt; 30 seconds of monomorphic VT or polymorphic VT) or clinically relevant VF.</td>
</tr>
<tr>
<td><strong>Class IIb</strong></td>
</tr>
<tr>
<td>ICD implantation <strong>may be considered</strong> in patients with LVEF in the range of 36%-49% and/or an RV ejection fraction &lt;40%, despite optimal medical therapy for heart failure and a period of immunosuppression (if there is active inflammation).</td>
</tr>
<tr>
<td><strong>Class III</strong></td>
</tr>
<tr>
<td>ICD implantation <strong>is not recommended</strong> in patients with no history of syncope, normal LVEF/RV ejection fraction, no LGE on CMR, a negative EP study, and no indication for permanent pacing. However, these patients should be closely followed for deterioration in ventricular function.</td>
</tr>
<tr>
<td>ICD implantation <strong>is not recommended</strong> in patients with one or more of the following:</td>
</tr>
<tr>
<td>1. Incessant ventricular arrhythmias;</td>
</tr>
<tr>
<td>2. Severe New York Heart Association class IV heart failure.</td>
</tr>
</tbody>
</table>

*VF with triple premature beats of < 220 ms is considered a nonspecific response.*

†Recommendations are summarized in **Figure 7**
So who should have an ICD

1. Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest AND/OR
2. The LVEF is ≤35% despite optimal medical therapy and a period of immunosuppression (if there is active inflammation)
   - Yes → ICD recommended
   - No →
     1. An indication for permanent pacemaker implantation AND/OR
     2. Unexplained syncope or near-syncope, felt to be arrhythmic in etiology AND/OR
     3. Inducible ventricular arrhythmias (>30 seconds of monomorphic VT, or clinically relevant polymorphic VT/ventricular fibrillation)
       - Yes → ICD may be considered
       - No →
         - LVEF 36-49% and/or RV ejection fraction <40%, despite optimal medical therapy and a period of immunosuppression, if appropriate. (CMR +/- an electrophysiological study may be considered to help with risk stratification of these patients)
           - Yes → ICD may be considered
           - No →
             - CMR may be considered
               - Late Gadolinium Enhancement → ICD not recommended
                 - Patient should be followed for deterioration in ventricular function
                 - An electrophysiologic study may be considered
                   - Negative → ICD not recommended
                   - Positive → ICD can be useful
               - No Late Gadolinium Enhancement → ICD may be considered
                 - Class I
                 - Class IIa
                 - Class III
                 - Class Iib
            - No → ICD may be considered
So who should have an ICD

1. Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest AND/OR
   - The LVEF is ≤35% despite optimal medical therapy and a period of immunosuppression (if there is active inflammation)

   → Yes → ICD recommended
   → No →

   1. An indication for permanent pacemaker implantation AND/OR
   2. Unexplained syncope or near-syncope, felt to be arrhythmic in etiology

   → Yes → ICD can be useful
   → No →

2. LVEF 36–49% and/or RV ejection fraction <40%, despite optimal medical therapy and a period of immunosuppression, if appropriate, (CMR +/- an electrophysiological study may be considered to help with risk stratification of these patients)

   → Yes → ICD may be considered
   → No →

   CMR may be considered

   → No →

   Late Gadolinium Enhancement
   → ICD Not recommended
   → Patient should be followed for deterioration in ventricular function

   → Late Gadolinium Enhancement
   → An electrophysiologic study may be considered

   → Negative → ICD can be useful
   → Positive →
Cardiac sarcoidosis & ventricular arrhythmias: VT ablation

- Prior to ablation consider:
- Inflammation imaging (PET)
- Scar imaging (CMR)
- Immunosuppression to reduce ectopy (steroids efficacy variable\(^1,2\))

Cardiac sarcoidosis & ventricular arrhythmias: VT ablation

• Predilection for certain sites:
  – IVS
  – RV basal free wall
  – RVOT
  – Basal LV
  – Other RV/LV
Cardiac sarcoidosis & ventricular arrhythmias: VT ablation
Cardiac sarcoidosis & ventricular arrhythmias: VT ablation

RVOT Scar
Cardiac sarcoidosis & ventricular arrhythmias: VT ablation
Cardiac sarcoidosis & ventricular arrhythmias: VT ablation

- VT ablation
- SR mapping for late potentials
Cardiac sarcoidosis & ventricular arrhythmias: VT ablation

- Pace mapping for exit site
- Use of stim-QRS to try and narrow down to critical isthmus
- Mid diastolic potentials may be found
- Diffuse myocardial involvement → multiple morphologies re-initiating variably\(^1\)

Cardiac sarcoidosis & ventricular arrhythmias: VT ablation

- Challenging ablation
- Diffuse myocardial involvement
- Heterogeneous scar
- Multiple VT morphologies
- Epicardial/mid-myocardial circuits
- Progressive disease $\rightarrow$ new substrate
Cardiac sarcoidosis & ventricular arrhythmias: VT ablation

- Systematic review of VT ablation in CS
- 5 studies – total of 83 patients
- Ventricular arrhythmias prior to diagnosis in most
- Varying response to steroids/immunosuppression
- Median of 3 VTs, 100% endo ablation 1% epi
- Relapse 54%, improved 88%
Summary

• Cardiac sarcoid can result in heart block and tachyarrhythmias due to myocardial scarring
• Sudden death can be the initial presentation
• Recommend screening for cardiac involvement in specific patients
• The presence of cardiac sarcoid is an Indication for ICD Implantation (Class IIa; Level of Evidence C)
Summary

- Risk of SCD in cardiac sarcoid hard to predict
- LVEF <35 - ICD
- LVEF > 35% up for debate
- Value of EPS/CMR
- LVEF 36-49%/RVEF < 40% - probably ICD
• Monitoring is important

• If CS but normal investigations repeat ECG and echo at intervals to assess change

• Repeat CMR if minimal LGE initially?

• Consider ILR if palpitation symptoms but no other risk factors
Thank you

HRS Expert Consensus Statement on the Diagnosis and Management of Arrhythmias Associated With Cardiac Sarcoidosis

David H. Birnie, MD (Chair), 1 William H. Sauer, MD, FHRS, CCDS (Chair), 2 Frank Bogun, MD, 3 Joshua M. Cooper, MD, FHRS, 4 Daniel A. Culver, DO, 5, 6 Claire S. Duvernoy, MD, 6, 7 Marc A. Judson, MD, 7, 8 Jordana Kron, MD, 8 Davendra Mehta, MD, PhD, FHRS, 9 Jens Cossedis Nielsen, MD, 10 Amit R. Patel, MD, 11, 8 Tohru Ohe, MD, FHRS, 12, 11 Pekka Raatikainen, MD, 13, 9 Kyoko Soejima, MD 14

Heart Rhythm, Vol 11, No 7, July 2014

Consensus statement on the diagnosis and management of arrhythmias associated with cardiac sarcoidosis

David H Birnie, 1 William H Sauer, 2 Marc A Judson 3
Heart March 2016 Vol 102 No 6