Background & Objective

- Concurrent with the increasing age of the population, the use of cardiac implantable electronic devices (CIEDs) in the United States is growing.
- A retrospective analysis of the Nationwide Inpatient Sample dataset reported the incidence of CIED implants increased by 96% between 1993 and 2008. Most of these patients will require a subsequent generator change in their lifetime.
- While prior studies have evaluated the incidence of lead damage following a CIED replacement procedure, many were single-center studies with limited sample sizes; with no information on costs.
- This study estimated the real-world incidence of lead damage following CIED replacement procedures using nationally representative US healthcare claims data.

Methods

- This analysis used claims data from the US Truven Health Analytics MarketScan® Commercial Research database (2009–2013).
- Three study cohorts were selected: replacement pacemaker (PM), implantable cardioverter-defibrillator (ICD), and cardiac resynchronization therapy defibrillator (CRT-D) with a one year baseline period and one year follow-up period prior to and following the replacement procedure.
- Patients were required to have at least one visit with an ICD-9 diagnosis code for history of cardiac device or an ICD-9 or CPT procedure code for CIED monitoring during baseline period to ensure the index procedure was a replacement.
- Lead damage in the follow-up period was defined as any outpatient or inpatient visit with an ICD-9 procedure code for lead revision or repair (00.52, 37.74-37.77, 37.95, 37.97), with no concurrent ICD-9 diagnosis code for infection during the same visit (infection and inflammatory reaction due to cardiac device, implant, and graft [996.61], septicemia [038.xx], or endocarditis [421.xx]).
- Differences in study measures were tested for statistical significance with the ChiSquare ($\chi^2$) test for categorical variables and Kruskal-Wallis test for continuous variables.
- Cox Proportional Hazards models were run to identify factors associated with risk of lead-related complications emerging during follow-up.

Results (continued)

- Overall (occurring in an inpatient or outpatient setting), lead damage was observed in 406 (0.90%) patients at a mean of 149 ± 125 days following the CIED replacement procedure (Table 1).
- The incidence of follow-up visits for lead damage increased with device complexity: 0.46% for PMs, 1.27% for ICDs, and 1.94% for CRT-D devices.
- Of the 406 patients with lead damage, 368 (91%) presented in an inpatient setting.
- Among visits for lead revision or repair occurring in an inpatient setting, mean LOS ranged from 4.2 to 5.7 days, but did not differ significantly by device type.

Table 2. Risk Factors for Lead Damage Following CIED Replacement

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HR</th>
<th>95% Confidence Interval</th>
<th>P-Value</th>
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<tbody>
<tr>
<td>History of pharmacological therapy</td>
<td></td>
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<tr>
<td>Warfarin or NOAC</td>
<td>0.98</td>
<td>0.78 - 1.21</td>
<td>0.822</td>
</tr>
<tr>
<td>Antiplatelets</td>
<td>0.84</td>
<td>0.64 - 1.09</td>
<td>0.185</td>
</tr>
<tr>
<td>Charlson Score 1</td>
<td>1.06</td>
<td>0.78 - 1.46</td>
<td>0.700</td>
</tr>
<tr>
<td>Charlson Score 2</td>
<td>1.00</td>
<td>0.72 - 1.38</td>
<td>0.987</td>
</tr>
<tr>
<td>Charlson Score ≥ 3</td>
<td>0.75</td>
<td>0.55 - 1.01</td>
<td>0.560</td>
</tr>
<tr>
<td>Generator type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRT-D</td>
<td>2.00</td>
<td>1.57 - 2.56</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>ICD</td>
<td>2.58</td>
<td>1.73 - 3.86</td>
<td>&lt;.0001</td>
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</table>

Reference groups included no warfarin or NOAC use, no antiplatelet use, Charlson Score Zero, pacemaker generator (continued)

- In a Cox Proportional Hazards model, controlling for patient demographics and clinical characteristics, ICD and CRT-D patients had double (HR = 2.00; 95% CI: 1.57 – 2.56) and more than two and a half times (HR = 2.58; 95% CI: 1.73 – 3.86) the risk of lead damage, respectively.
- Follow-up visits for lead repair and revision were associated with substantial total inpatient hospitalization costs, increasing with device complexity and number of leads (Figure 2).

Figure 2. Total Hospitalization Cost for a Follow-Up Visit for Lead Revision or Repair with Standard Error Bars

Results

- After applying selection criteria 45,425 patients were available for analysis (Table 1).
- Mean age was 75.5 for the PM cohort, 68.8 for ICD, and 69.1 for CRT-D; while the percent male was 54.1%, 74.5%, and 74.8% respectively.
- The mean Charlson Score (CCI) for each cohort was 1.80, 2.42, and 2.86, respectively, with 0.41%, 1.16%, and 1.68% at a mean of 149 days following the replacement procedure.
- Figure 1. Incidence of Lead Damage by Setting and Device Type

Table 1. Incidence of Lead Revision or Repair

<table>
<thead>
<tr>
<th></th>
<th>PM (N=22,577)</th>
<th>ICD (N=20,632)</th>
<th>CRT-D (N=5,261)</th>
<th>P-Value</th>
<th>Overall (N=45,250)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead revision or repair, N (%)</td>
<td>(0.46%)</td>
<td>(1.27%)</td>
<td>(1.94%)</td>
<td>&lt;.001</td>
<td>(0.90%)</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>131.4 ± 131.5</td>
<td>158.5 ± 124.1</td>
<td>136.4 ± 116.8</td>
<td>0.007</td>
<td>149.4 ± 125.6</td>
</tr>
<tr>
<td>Time to lead revision or repair (days)</td>
<td>4.213 ± 4.313</td>
<td>4.313 ± 3.84</td>
<td>5.73 ± 2.82</td>
<td>0.563</td>
<td>4.424 ± 4.313</td>
</tr>
</tbody>
</table>

*Among follow-up visits occurring in an inpatient setting

Figure 1. Incidence of Lead Damage by Setting and Device Type

- We could not differentiate between generator replacement procedures alone versus those where lead(s) were added, and had no information on manufacturer or surgical tools utilized.
- We were unable to identify specific reasons for damage from the database; lead damage could be due to electrosurgical device use or other reasons.

Conclusions

- Incidence of lead damage ranged from 0.46% following PM replacements to 1.27% for ICDs and 1.94% for CRT-Ds.
- Inpatient visits for lead revision or repair were associated with substantial increases in cost to the healthcare system.
- These findings suggest that new care algorithms are needed during generator replacement procedures for safe lead dissection.

References


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