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Incidence of appropriate therapy and mortality after ICD generator replacement: results from a real-world nationwide prospective cohort

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Implantable Cardioverter / Defibrillator

Citation:

Background
The safety of omitting implantable cardioverter-defibrillator (ICD) generator replacement in patients with no prior appropriate ICD therapy, comorbid conditions and advanced age is unclear. Data to guide decisions regarding generator replacement are lacking.

Purpose
To investigate incidence and predictors for appropriate ICD therapy after generator replacement

Methods
We identified all patients implanted with a primary prevention ICD (n=4,630) from 2007 to 2016, who subsequently underwent an elective ICD generator replacement (n=670) from the National Danish Pacemaker and ICD Register. The data were linked to several other nationwide databases and evaluated on the outcomes of appropriate ICD therapy and death. Predictors of ICD therapy were identified using multivariate Cox regression analyses.

Results
A total of 670 patients underwent elective ICD generator replacement (mean age 69.3 ±9.7 years, 79.1% male, 76.9% ischemic, 50% CRT system). Of these 197 (29.4%) patients had experienced appropriate ICD therapy in their first generator period. During mean follow-up of 2.0 ±1.6 years, 95 (14.2%) patients experienced an appropriate ICD therapy. Predictors of appropriate ICD therapy in 2nd generator period was low initial left ventricular ejection fraction (LVEF) (=25%) (HR 1.87, CI 1.13-1.95) and appropriate ICD therapy in 1st generator period (HR 3.95, CI 2.57-6.06). For patients with appropriate therapy in first generator period, 4-year cumulative incidence of appropriate therapy was 50.6% versus 16.4% in those without (P <0.001). Among patients above the age of 80 without appropriate ICD in first generator period therapy 5 out of 57 (8.8%) patients experienced appropriate therapy after replacement. In secondary analyses comorbidity burden and advanced age were associated with reduced device utilization in 2nd generator period and a high competing risk of death without preceding appropriate ICD therapy.

Conclusion
In this nationwide real-life cohort of primary prevention ICD patients, we observed a significant residual risk of appropriate ICD therapy in their second generator life even among patients with advanced age and with a full prior generator period without any appropriate ICD events. Besides LVEF and prior ICD therapy, comorbidity burden, advanced age and high competing risk of non-cardiac death should be considered when deciding whether to replace ICDs.
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<table>
<thead>
<tr>
<th>Years after replacement</th>
<th>No prior appr.</th>
<th>Prior appr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0%</td>
<td>473 (0.0)</td>
<td>187 (20.3)</td>
</tr>
<tr>
<td>12.5%</td>
<td>310 (4.3)</td>
<td>94 (20.3)</td>
</tr>
<tr>
<td>25.0%</td>
<td>196 (7.4)</td>
<td>60 (27.8)</td>
</tr>
<tr>
<td>37.5%</td>
<td>98 (13.9)</td>
<td>23 (31.8)</td>
</tr>
<tr>
<td>50.0%</td>
<td>48 (16.4)</td>
<td>6 (50.8)</td>
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