Assessing the benefit of a replacement implantable cardioverter-defibrillator device for primary prevention of sudden cardiac death

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Background: Implantable cardioverter-defibrillators (ICDs) have been shown to reduce the burden of sudden cardiac death in at-risk populations. However, data reflecting contemporary device programming and medication would be valuable, particularly when evaluating patients for a replacement ICD when they did not receive therapy from their original device.

Purpose: This real-world analysis examined the incidence of ICD therapy after routine generator replacement due to battery depletion in patients who didn’t receive therapy from their first ICD.

Methods: Data were obtained from a query of a deidentified database from 2007 to present. The final analysis included patients that underwent a generator replacement after 2012 due to battery depletion and who had received no therapy from their first ICD. Patients were divided into two groups based on their ICD indication status (primary prevention [PP] or secondary prevention [SP]). The main endpoint was time to first appropriate shock therapy, antitachycardia pacing (ATP) therapy, or any therapy (ATP or shock) after ICD replacement. Time to first therapy was plotted using the Kaplan-Meier method. Appropriateness of therapy was modeled via LASSO regression using characteristics present in both our dataset and the adjudicated PainFree SST trial. The model was fit on episodes from 80% of PainFree SST patients and validated on the remaining 20% before applying it to our dataset.

Results: A total of 8,383 patients were identified who met the criteria outlined above. Of these patients, 7,299 (66.3 ± 12.6 years old; 30.3% female) had a PP indication for an ICD and 1,084 (64.2 ± 14.0 years old; 30.3% female) had an SP indication. The mean longevity of initial ICD implants before replacement was similar in PP and SP patients (91.4 ± 16.2 vs 90.9 ± 16.3 months). At 7 years post-replacement, the incidence of first shock, ATP, or any therapy received by PP patients who did not receive first-device therapy was 16%, 23% and 27% respectively. After applying the model to estimate appropriateness of therapy, the appropriate therapy rates were 14%, 22%, and 26%, respectively (Figure 1).

Conclusion: In this large, long-term, real-world evaluation of ICD PP patients who hadn’t experienced a treated event with their initial device, 1 in 4 eventually received appropriate therapy from their second device. The results suggest that the underlying risk persists in these patients and device replacement may be necessary to protect them from experiencing a deadly event.
Figure 1. Incidence of appropriate (modeled) ICD therapy in primary prevention patients after replacement

- **ATP**
- **Shock**
- **Any Therapy**

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