Determants of outcomes following outpatient placement of implantable cardioverter defibrillators in a Medicare Advantage population

Background

The Centers for Medicare & Medicaid Services initiated a National Coverage Analysis in 2017 to reconsider coverage indications for implantable cardioverter defibrillators (ICDs).1 Subsequent to the original CMS National Coverage Determination for ICDs in 1998, the Food and Drug Administration approved a substantially ICD (S-ICD). The relative benefits of S-ICD versus transvenous ICD (TV-ICD) have not been well studied. Nevertheless, some patient factors have also been considered as possible determinants of outcomes following ICD procedures. Age appears to diminish the effectiveness of ICDs, as does comorbidity2, but there is uncertainty about the influence of sex on health outcomes and complications.3 Some experts have concerns about whether nonischemic heart disease is associated with lack of benefit from ICDs.4,5 Furthermore, there is a paucity of data regarding the adverse events of ICD.

Methods

Study Design

Retrospective cohort study, with ICD implantation as the index date

Data Source

Claims data for patients who had Medicare Advantage health plans from one health insurer

Inclusion Criteria

ICD implantation January 1, 2014 – September 30, 2015 and continuous enrollment in the prior 12 months

Exclusion Criteria

End stage renal disease or hospice care in the 12 months prior to implantation

Nonlead complications

Results may not be generalizable to the small body of previously published research. The influence of age on complication rates and the influence of sex on health outcomes require further study.2,6 The direction of nonsignificant hazard ratios suggested that S-ICD may result in fewer lead complications, but more nonlead complications, consistent with prior research.2,6 Further study with more S-ICD recipients is required.

Limitations

A small proportion of the patients (1.3%) received S-ICD. Thus, the findings of this study are primarily based on patients undergoing TV-ICD implantation. The comparison of S-ICD versus TV-ICD may have been underpowered.

There were a number of differences between the populations that received the two types of devices, with recipients of TV-ICD significantly more likely to be age 65 or older, to have a diagnosis of bradycardia, to have a history of a conductive disorder, and to have a history of pacing or pacemaker. These differences may predispose individuals to certain complications, and could influence the interpretation of the results of this study. Further research would be needed to understand the impact of pacing or other conductive disorders, and to have a history of pacing or pacemaker.

Conclusions

Several prior factors were associated with greater risk of death and/or complications. However, 80% of patients survived the first post-implant year without experiencing adverse outcomes. Findings were generally consistent with the small body of previously published research. The influence of age on complication rates and the influence of sex on health outcomes require further study.2,6 The direction of nonsignificant hazard ratios suggested that S-ICD may result in fewer lead complications, but more nonlead complications, consistent with prior research.2,6 Further study with more S-ICD recipients is required.

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