Correspondence

Letter by Longtin et al Regarding Article, “Rates of and Factors Associated With Infection in 200909 Medicare Implantable Cardioverter-Defibrillator Implants: Results From the National Cardiovascular Data Registry”

To the Editor:

We read with great interest the article by Prutkin et al1 on rates and risk factors for infection associated with implantable cardioverter-defibrillator (ICD) implants. This study greatly improves our understanding of risk factors associated with ICD infections. However, we would like to voice our concerns about the choice of definitions used to make a presumptive diagnosis of ICD infection.

Some criteria that were used to diagnose ICD infection (such as the International Classification of Disease, Ninth Revision, Clinical Modification code 996.61, infection caused by a cardiac device) are very reliable, and patients identified through these criteria very likely represent a true ICD infection. On the other hand, other criteria that were used are, in our opinion, much less reliable. For example, patients who had an ICD implanted and shock, bacteremia, or fever during the same hospitalization were also considered to have an ICD infection and were included in the analysis. Although very sensitive, these criteria also present a significant risk of false-positive results. Certainly, patients can have bacteremia, fever, or shock after an ICD implantation for myriad reasons other than an ICD infection, for example, a central line–associated infection or ventilator-associated pneumonia. Hence, there is a possibility that some patients who were included in the analysis did not have an actual ICD infection but rather a remote infection unrelated to the ICD. The magnitude of this potential bias would depend on the relative proportion of patients who were included in the study through the use of high-certainty versus low-certainty criteria. It is important to note that, even though Voigt et al2 used similar criteria in the study through the use of high-certainty versus low-certainty criteria, the study greatly improves our understanding of risk factors associated with ICD infections. However, we would like to voice our concerns about the choice of definitions used to make a presumptive diagnosis of ICD infection.

If most patients were identified with high-certainty criteria, this issue would be of little concern. If, on the other hand, a significant proportion of the population was included on the basis of low-specificity criteria, then the risk of significant bias increases considerably. Regrettably, the authors do not provide information on the distribution of ICD infections according to the International Classification of Disease, Ninth Revision, Clinical Modification code. We would suggest that the authors include a breakdown of the cases according to the various codes. This information could be published as an online Data Supplement.

When using different definitions of varying levels of certainty to identify patients with a principal outcome, sensitivity analyses using different definitions is recommended.3,4 For example, the analysis is often performed initially while including only cases with a high level of certainty of ICD infection, and the analysis is then repeated after including cases with a lower certainty of ICD infection. This enables determination of the comparability of the associations between predictors and outcome variables regardless of the level of certainty of the diagnosis. We think the study would have benefited from such a sensitivity analysis because it could alleviate concerns about potential biases associated with the use of overly inclusive, poorly reliable definitions.

Disclosures

None.

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