

Prediction of sudden arrhythmic death in patients with heart failure: towards validation in a worldwide broader range of patients

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Online publish-ahead-of-print 18 March 2021

This commentary refers to ‘Predict benefit of an implantable cardioverter defibrillator: the MADIT-ICD benefit score’ by A. Youins et al., <https://doi.org/10.1093/eurheartj/ehaa1057> and the discussion piece ‘Extending the MADIT-ICD benefit score to heterogeneous heart failure populations’ by A. Youins and I. Goldenberg, <https://doi.org/10.1093/eurheartj/ehab162>.

We read with great interest Youins et al.’s¹ recently published article in the *European Heart Journal* concerning the Multicenter Automatic Defibrillator Implantation Trial (MADIT)-implantable cardioverter defibrillator (ICD) benefit score. They stated that ICD use for the primary prevention of sudden arrhythmic death in patients with heart failure (HF) was supported through results derived from multiple large-scale randomized controlled trials (RCTs) and that current guidelines propose individual risk stratification. Their novel MADIT-ICD benefit score predicts the likelihood of a prophylactic ICD benefit through the personalized risk assessment of life-threatening ventricular tachycardia/ventricular fibrillation weighed against the risk of non-arrhythmic mortality.

The MADIT-ICD benefit score was developed from patients with ICDs enrolled in four MADIT studies and then externally validated in patients with ICDs for primary prevention in the Ranolazine in High-Risk ICD Patients trial. However, in patients with HF, characteristics, phenotypes, and clinical outcomes vary widely.² Patients registered in the RCTs were generally young, without advanced frailty or comorbidities such as systemic malignancy or severe renal dysfunction, and predominantly from Western countries. Performance evaluation in a broader range of HF registry patients reflecting real-world data is warranted. There are important differences in clinical characteristics and long-term outcomes between East Asian patients with HF and those in Western countries. East Asians tend to be older, have a

lower body mass index, and present with non-ischaemic HF more frequently.² Regional differences in primary prevention ICD use in eligible patients have also been reported, with 10% use in the most recent Swedish HF registry³ and 6.6% use in a recent Japanese cohort study.⁴ Moreover, based on data from a single Japanese university hospital, the mortality rate of Japanese patients who met MADIT-II study criteria but were without ICDs was comparable with that in a defibrillator group, but lower than that in a conventional therapy group in the MADIT-II study.⁵ These results suggest the need for international validation of this novel score.

Finally, statistical models such as those in Younis et al. rely heavily on the ejection fraction (EF). Recent findings from large-scale observational studies have indicated that sudden arrhythmic death is also common in patients with HF with a preserved EF. In a cohort of hospitalized patients with HF, 31.6% who experienced sudden cardiac death within 2 years after acute decompensation had an EF of $\geq 50\%$.² Relatively little is known about the risk factors associated with sudden arrhythmic death in these patients. Exploring the performance of this novel score in this unique but heterogeneous population may assist in the design of future clinical ICD trials.

We conclude that validation of the MADIT-ICD benefit score should be performed, not only in patients in an RCT setting but also in a broader range of patients worldwide. The repetitive validation and modification enable more accurate stratification of patients at higher risk for sudden arrhythmic death and might improve the appropriate use of ICDs to help address this life-threatening event more effectively.

Conflict of interest: S.K. received an unrestricted research grant for the Department of Cardiology, Keio University School of Medicine from Bayer Pharmaceutical Co., Ltd and Daiichi Sankyo Co. Ltd. R.F. and A.K. declare that there is no conflict of interest.

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References

1. Younis A, Goldberger JJ, Kutyla V, Zareba W, Polonsky B, Klein H, Aktas MK, Huang D, Daubert J, Estes M, Cannom D, McNitt S, Stein K, Goldenberg I. Predicted benefit of an implantable cardioverter-defibrillator: the MADIT-ICD benefit score. *Eur Heart J* 2021;doi:10.1093/eurheartj/ehaa1057.
2. Fukuoka R, Kohno T, Kohsaka S, Shiraishi Y, Sawano M, Abe T, Nagatomo Y, Goda A, Mizuno A, Fukuda K, Shadman R, Dardas TF, Levy WC, Yoshikawa T. Prediction of sudden cardiac death in Japanese heart failure patients: international validation of the Seattle Proportional Risk Model. *Europace* 2020;**22**:588–597.
3. Schrage B, Uijl A, Benson L, Westermann D, Stahlberg M, Stolfo D, Dahlstrom U, Linde C, Braunschweig F, Savarese G. Association between use of primary-prevention implantable cardioverter-defibrillators and mortality in patients with heart failure: a prospective propensity score-matched analysis from the Swedish heart failure registry. *Circulation* 2019;**140**:1530–1539.
4. Satake H, Fukuda K, Sakata Y, Miyata S, Nakano M, Kondo M, Hasebe Y, Segawa M, Shimokawa H. and CHART-2 Investigators. Current status of primary prevention of sudden cardiac death with implantable cardioverter defibrillator in patients with chronic heart failure—a report from the CHART-2 Study. *Circ J* 2015;**79**: 381–390.
5. Tanno K, Miyoshi F, Watanabe N, Minoura Y, Kawamura M, Ryu S, Asano T, Kobayashi Y, Katagiri T, Madit II; The Multicenter Automatic Defibrillator Implantation Trial. Are the MADIT II criteria for ICD implantation appropriate for Japanese patients? *Circ J* 2005;**69**:19–22.

CARDIOVASCULAR FLASHLIGHT

doi:10.1093/eurheartj/ehab231

Online publish-ahead-of-print 17 May 2021

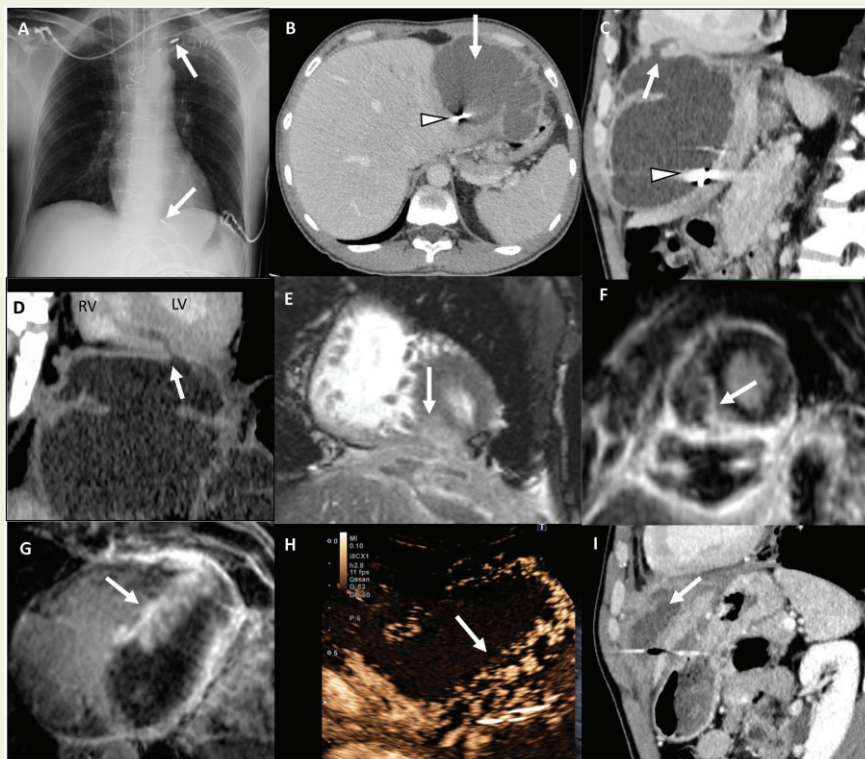
Granulomatous abscess on a migrated pacemaker probe

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A 49-year-old patient consulted for abdominal pain and fever, 2 years after treatment of infective endocarditis on a dual-chamber pacemaker (PM) with favourable outcome at this time after treatment by partial surgical removal of the PM and antibiotic therapy. The lead tips were left in the right ventricle (RV) and in the left subclavian vein (thoracic radiography, Panel A, arrows). Abdominal computed tomography (CT) evidenced a thick-walled anterior abdominal fluid collection adjacent to the left liver lobe (Panel B, arrow) communicating with the infero-apical part of the RV on sagittal (Panel C, arrow) and oblique (Panel D, arrow) reconstructions. The residual fragment of the ventricular probe was no more detected within the RV. The collection contained a high-density metallic structure (Panels B and C, arrowhead), suggesting a migration of the RV probe's fragment through the cardiac wall, the pericardium, and the diaphragm. Cardiac magnetic resonance (CMR) imaging confirmed the presence of a transmural fibrous scar of the inferior RV wall in continuity with abdominal collection (Panels E–G, arrow; [Supplementary material online, Videos S1 and S2](#)). An abdominal ultrasound (US) exploration using US contrast revealed a very inflammatory and thickened wall, suggesting a foreign body granuloma (Panel H, arrow; [Supplementary material online, Video S3](#)). A CT performed 6 months after antibiotic therapy evidenced a partial regression of the collection (Panel I, arrow). A surgical ablation was scheduled. This unique case reports highlight the interest of CT and magnetic resonance imaging (MRI) to accurately diagnose a migration of probe's fragment.



[Supplementary material](#) is available at *European Heart Journal* online.

Funding: the authors report no specific funding related to this article.

Conflict of interest: The authors have submitted their declaration which can be found in the article [Supplementary Material online](#).