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RESEARCH LETTER

Safety of Omitting Defibrillation Efficacy Testing With Subcutaneous Defibrillators: A Propensity-Matched Case-Control Study

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The noninferiority of defibrillation testing (DT) omission at the time of implantation was demonstrated in transvenous implantable cardioverter defibrillators (ICD).[1] Thus, guidelines included DT omission during implantation of transvenous ICDs.[2] The subcutaneous ICD (S-ICD) is an effective alternative to the transvenous ICD,[3] but it still requires DT.[2] We evaluated the outcome of S-ICD patients with omitted DT in comparison with those who had undergone DT per physician's discretion. From 2013 to 2019, consecutive patients undergoing S-ICD implantation (Boston Scientific, Inc, Natick, MA) were enrolled at 60 Italian centers. Patients were followed up until 2020 within the framework of a prospective registry (REGISTRATION: URL: https://www.clinicaltrials.gov; Unique identifier: NCT02275637). The Institutional Review Boards approved the study, and all patients provided informed consent. The study data are available from the corresponding author upon reasonable request. The composite primary end point consisted of all-cause death and ineffective S-ICD therapy. The secondary end point was the composite of all-cause death, ineffective shock, inappropriate shock, and complication. We implemented 1:1 nearest neighbor propensity score matching without replacement, with propensity score estimated using logistic regression of the treatment on the covariates. The variables considered for propensity score calculation were sex, age, body mass index, and ejection fraction. A total of 1652 S-ICD procedures were performed within the observation period. Defibrillation testing was performed in 1300 patients and omitted in 325 patients (27 patients excluded because of incomplete data). The median proportion of patients who underwent DT at the study centers was 86% (25th–75th percentile: 71%–96%). Cardioversion at shock energy of ≤65J was successful in 1225 (94.2%) and ineffective in 33 (2.6%). Forty-two patients were successfully tested at initial shock energy of >65J. Overall, successful cardioversion was achieved with ≤80J shocks in 1298 (99.8%) patients. In the 1300 patients with DT, 2 (0.15%) episodes of electromechanical dissociation (1 fatal) because of testing were reported. DT-omitted patients were more frequently female (79 [24%] versus 247 [19%], P=0.033), were older (51±16 versus 48±15 years, P=0.001), and had higher body mass index (26±5 versus 25±4 kg/m^2, P=0.024). Moreover, DT-omitted patients more frequently had dilated cardiomyopathy with reduced ejection fraction (38±16% versus 46±16%, P<0.001) and were affected by more comorbidities (ie, chronic kidney disease, diabetes). After propensity score matching, the analysis was restricted to 650 patients, 325 DT-omitted versus 325 DT-performed, all standardized mean differences for the covariates were below 0.1, indicating adequate balance and clinical variables of the matched cohort were equally distributed between the 2 study groups. In the overall matched cohort, over

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*A list of all S-ICD Rhythm Detect Investigators is given in the Appendix.

For Sources of Funding and Disclosures, see page 1094.

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Nonstandard Abbreviations and Acronyms

DT	defibrillation testing
ICD	implantable cardioverter defibrillator
S-ICD	subcutaneous ICD

a median follow-up of 19 (25th–75th percentile: 11–29) months, 27 (4%) deaths occurred and 38 patients (5.8%) received appropriate shocks. The first shock was effective in 34 (89%) patients, while the final conversion rate was 100% for all events. Inappropriate shocks were reported in 36 (5.5%) patients. Procedure-related complications occurred in 13 (2.0%) patients, and device-related complications were reported in 12 (1.8%) patients during follow-up. There was no significant difference in the risk of primary or secondary end points between matched DT-omitted and DT-performed groups, in the overall population and in prespecified subgroups (Figure).

Large trials have documented high rates (>90%) of successful conversion on DT with S-ICDs.[3] We confirmed this finding, as we recorded a conversion rate of 94.2% with 65J shock energy in a large unselected population, and a high rate of conversion of clinical ventricular arrhythmias during follow-up. Previous studies have found that adherence to the DT recommendation is declining in clinical practice and that testing is frequently omitted in patients who are at higher risk of complications.[4] We confirmed this finding. Indeed, DT was more frequently omitted in patients with more severe systolic dysfunction.

The rate of the combined end point was low, and we did not observe a higher risk associated with DT omission. Moreover, we did not observe an association between the risk of the secondary end point and the DT group assignment. Overall, 5.5% of patients received inappropriate shocks (5.8% received appropriate shocks). Moreover, complications were rare and not associated with the group assignment. Nonetheless, in the wider unselected population, we observed 2 serious adverse events and one DT-associated death. Our analysis did not show any interaction between baseline variables and the primary and secondary end points. Nonetheless, some factors have previously proved to be associated with lower shock efficacy and should be considered in the decisional process, as still happens in the case of transvenous ICDs for patients at high risk of elevated defibrillation threshold (eg, hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, right-sided implantation), for which DT is still recommended.[2]

In conclusion, DT is frequently omitted in current clinical practice, especially in older patients with worse systolic function. Omitting DT does not compromise the effectiveness of the S-ICD, and no additional risk seems to be associated with DT omission in a patient population resembling the analyzed cohort. However, the observational design of the study may have introduced an inherent bias. The findings of an ongoing randomized trial will confirm our results.[5]

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APPENDIX

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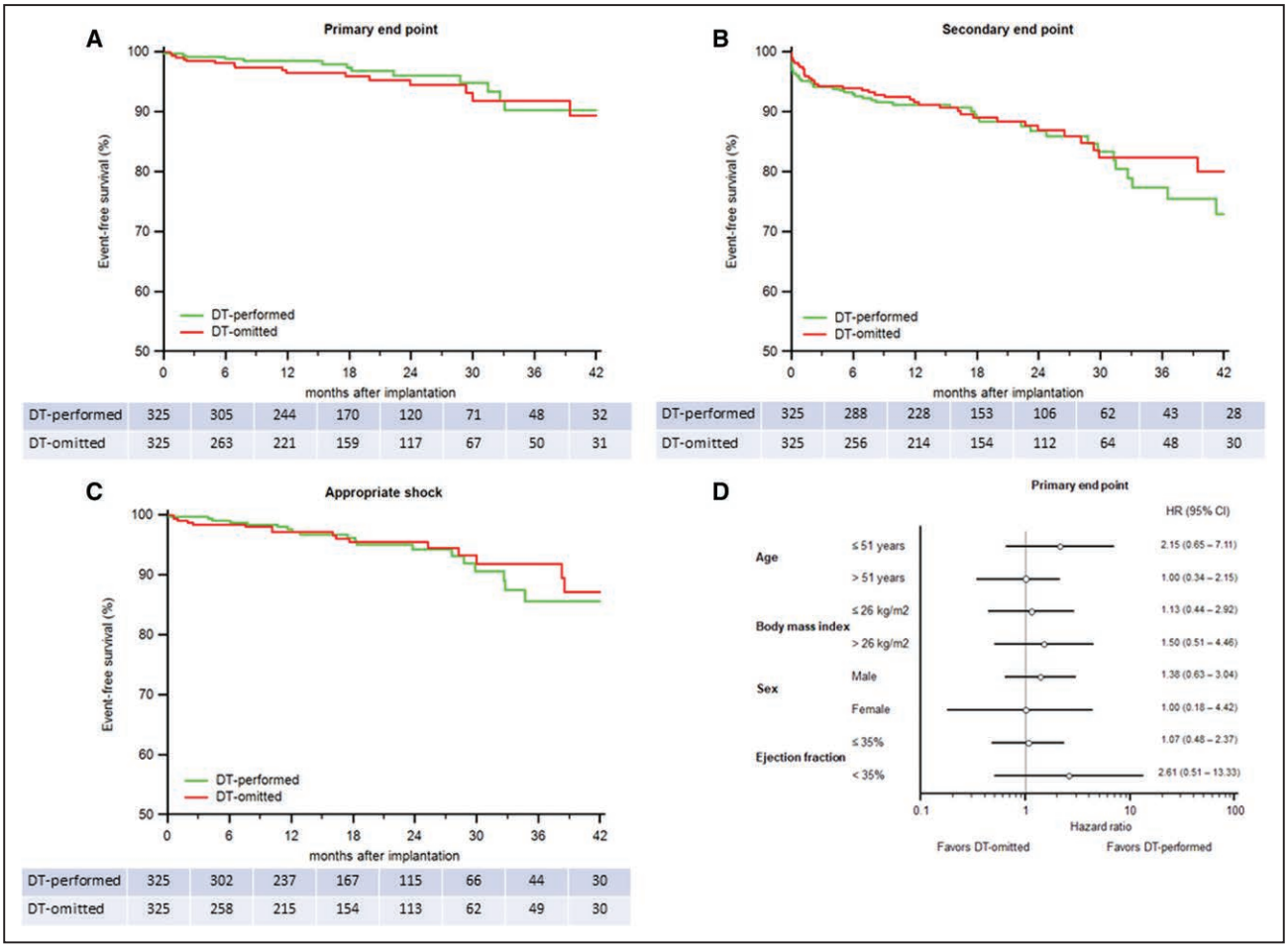

Figure. Kaplan-Meier estimates of time to the study endpoints and pre-specified subgroup analysis of the primary endpoint. Time to primary endpoint (unadjusted hazard ratio 1.26, 95%CI 0.62 -2.54, p=0.523) (**A**), time to secondary endpoint (unadjusted hazard ratio 0.86, 95%CI 0.57 -1.32, p=0.497) (**B**), and to first appropriate shock (unadjusted hazard ratio 0.84, 95%CI 0.44 -1.58, p=0.585) (**C**). Association between DT omission and the risk of primary endpoint in pre-specified subgroups (no interaction was detected between DT omission and the variables that defined the subgroups) (**D**). DT indicates defibrillation testing; and HR, hazard ratio.