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Long-Term Clinical Outcomes of Subcutaneous Versus Transvenous Implantable Defibrillator Therapy

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ABSTRACT

BACKGROUND Transvenous implantable cardioverter-defibrillators (TV-ICDs) improve survival in patients at risk for sudden cardiac death, but complications remain an important drawback. The subcutaneous ICD (S-ICD) was developed to overcome lead-related complications. Comparison of clinical outcomes of both device types in previous studies was hampered by dissimilar patient characteristics.

OBJECTIVES This retrospective study compares long-term clinical outcomes of S-ICD and TV-ICD therapy in a propensity-matched cohort.

METHODS The authors analyzed 1,160 patients who underwent S-ICD or TV-ICD implantation in 2 high-volume hospitals in the Netherlands. Propensity matching for 16 baseline characteristics, including diagnosis, yielded 140 matched pairs. Clinical outcomes were device-related complications requiring surgical intervention, appropriate and inappropriate ICD therapy, and were reported as 5-year Kaplan-Meier rate estimates.

RESULTS All 16 baseline characteristics were balanced in the matched cohort of 140 patients with S-ICDs and 140 patients with TV-ICDs (median age 41 years [interquartile range: 30 to 52 years] and 40% women). The complication rate was 13.7% in the S-ICD group versus 18.0% in the TV-ICD group ($p = 0.80$). The infection rate was 4.1% versus 3.6% in the TV-ICD groups ($p = 0.36$). Lead complications were lower in the S-ICD arm compared with the TV-ICD arm, 0.8% versus 11.5%, respectively ($p = 0.03$). S-ICD patients had more nonlead-related complications than TV-ICD patients, 9.9% versus 2.2%, respectively ($p = 0.047$). Appropriate ICD intervention (antitachycardia pacing and shocks) occurred more often in the TV-ICD group (hazard ratio [HR]: 2.42; $p = 0.01$). The incidence of appropriate (TV-ICD HR: 1.46; $p = 0.36$) and inappropriate shocks (TV-ICD HR: 0.85; $p = 0.64$) was similar.

CONCLUSIONS The complication rate in patients implanted with an S-ICD or TV-ICD was similar, but their nature differed. The S-ICD reduced lead-related complications significantly, at the cost of nonlead-related complications. Rates of appropriate and inappropriate shocks were similar between the 2 groups. (J Am Coll Cardiol 2016;68:2047–55)

Implantable cardioverter-defibrillators (ICDs) improve survival of patients at increased risk of sudden cardiac death (SCD) (1,2). Advances in ICD programming have reduced the burden of shocks, but device-related complications remain an important drawback of transvenous implantable cardioverter-defibrillator (TV-ICD) therapy, resulting in significant morbidity (3). Transvenous sensing and defibrillation

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ABBREVIATIONS AND ACRONYMS

AMC = Academic Medical Center

ATP = antitachycardia pacing

CI = confidence interval

HR = hazard ratio

ICD = implantable cardioverter-defibrillator

IQR = interquartile range

LUMC = Leiden University Medical Center

SCD = sudden cardiac death

S-ICD = subcutaneous implantable cardioverter-defibrillator

TV-ICD = transvenous implantable cardioverter-defibrillator

VF = ventricular fibrillation

VT = ventricular tachycardia

leads are associated with both infective and mechanical complications, such as lead endocarditis, pneumothorax, venous occlusion, and cardiac perforation (4,5). Lead failure may cause inappropriate shocks and impede delivery of appropriate therapy for ventricular arrhythmias (6–8).

SEE PAGE 2056

The subcutaneous implantable cardioverter-defibrillator (S-ICD) was designed to eliminate complications related to transvenous leads, but lacks pacing capabilities and can therefore only be used in patients without a need for pacing (9). Studies of the S-ICD have demonstrated clinical efficacy, but also reported a 13.1% inappropriate shock rate at 3 years follow-up, which was significantly reduced with dual-zone programming (10–12). However, direct comparison of clinical outcomes of the available S-ICD cohorts to TV-ICD cohorts is limited by varying patient characteristics, follow-up durations, and definitions of complications.

The objective of the current retrospective study is to compare long-term clinical outcomes of S-ICD and TV-ICD therapy in a propensity score–balanced cohort.

METHODS

STUDY SETTING. Patients with ICDs implanted in 2 hospitals in the Netherlands, Academic Medical Center (AMC) and Leiden University Medical Center (LUMC), were included. For this analysis, patients implanted with single- and dual-chamber TV-ICDs between 2005 and 2014 at the LUMC, and patients implanted with S-ICDs between 2009 and 2015 at the AMC were selected. During this period of time, LUMC had not adopted the S-ICD into their clinical practice, and therefore, this variation in practice between AMC and LUMC was used to compare the 2 types of ICD therapy. Patients included in the ongoing PRAETORIAN (Prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy) trial were excluded from this analysis (13). The need for informed consent was waived in both centers due to the observational nature of the study.

STUDY POPULATION. At the LUMC, 1,312 patients received a TV-ICD between 2005 and 2014. In the AMC, 148 patients were implanted with an S-ICD between 2009 and 2015. Because baseline characteristics were significantly different, we used propensity score matching as the primary analysis. The devices used were S-ICDs (Boston Scientific, Marlborough, Massachusetts) and TV-ICDs (Biotronik, Berlin, Germany; Boston Scientific; Medtronic, Dublin, Ireland; and St. Jude Medical, Saint Paul, Minnesota). The majority of both S-ICD and TV-ICD patients were implanted under local anesthesia, according to the prevailing local hospital protocol (14). LUMC is an experienced implantation center for TV-ICDs, as is AMC for S-ICDs and TV-ICDs.

DATA COLLECTION. Data collection in both centers was performed at regular intervals by reviewing medical records for baseline characteristics, implantation data, and follow-up data on clinical outcomes, complications, and therapy delivery. The survival status of patients was retrieved from municipal civil registries.

DEFINITION OF OUTCOMES. Complications were defined as all device related complications requiring surgical intervention. Lead complications were defined as complications requiring replacement or repositioning of the lead, without elective pulse generator replacement. In addition, lead survival was defined as the time between lead implantation and lead failure, with or without elective pulse generator replacement. Appropriate therapy consisted of antitachycardia pacing (ATP) only and shocks (whether preceded by ATP or not) for ventricular tachycardia (VT) or ventricular fibrillation (VF). Inappropriate therapy consisted of ATP and shocks for heart rhythms other than VT or VF. Local electrophysiologists adjudicated all arrhythmia episodes.

STATISTICAL ANALYSIS. Entire cohort. Categorical variables were presented as numbers and percentages, and were compared for the entire cohort using the Fisher exact test. On the basis of their distributions, continuous variables are presented as mean ± SD or median with interquartile range (IQR) (25th to 75th) and compared using the Student *t* test or Wilcoxon rank sum test.

PROPENSITY SCORE MATCHING. Propensity score matching was performed with patients for whom complete baseline variables were available (total N = 1,154). Analysis of excluded patients due to missing baseline data did not suggest selection bias. We used logistic multivariable regression with device type (S-ICD or TV-ICD) as the dependent variable and 16 baseline variables as independent predictors to calculate the propensity score (**Table 1**, Online Table 1). The Harrell's C-statistic for the propensity score logistic regression model was 0.89. Patients were 1-to-1 greedy matched using the nearest-neighbor method. There was sufficient overlap in the propensity scores to individually match each S-ICD case to a TV-ICD control (Online Figure 1).