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Subcutaneous vs Transvenous Implantable Cardioverter-Defibrillator Therapy in Patients With Tetralogy of Fallot

Data regarding the use of the subcutaneous implantable cardioverter-defibrillator (S-ICD) in patients with tetralogy of Fallot (TOF) remain very sparse.

The DAI-T4F (French National Registry of Patients With Tetralogy of Fallot and Implantable Cardioverter Defibrillator) is a nationwide French observational study including all patients with surgically repaired TOF implanted with an ICD since 2000.¹ The study was approved by the appropriate Institutional Review Boards. Survival curves were plotted by the Kaplan-Meier method and log rank tests were used to compare patients with S-ICD with patients with transvenous (TV)-ICD. The primary time to event endpoint was the time from ICD implantation to first appropriate ICD therapy, appropriate ICD shock, or ICD-related complication.

A total of 238 patients (mean age 42.9 ± 14.1 years) were enrolled from 47 centers, including 34 patients with S-ICD (14.3%). The first S-ICD was implanted in 2013, and from 2013-2015 to 2018-2021, the proportion of S-ICDs increased from 4.0% to 36.5% ($P < 0.001$). After exclusion of patients with cardiac resynchronization therapy or epicardial ICDs, characteristics of patients with S-ICD were comparable to those of patients with single-chamber or dual-chamber TV-ICD ($n = 171$), except a younger median (IQR) age at corrective surgery (3 years [IQR: 1-6 years] vs 7 years [IQR: 4-12 years]; $P = 0.004$) and shorter QRS duration (155 ± 29 milliseconds vs 169 ± 31 milliseconds; $P = 0.028$).

Over a median (IQR) follow-up period of 2.5 years in patients with S-ICD vs 8.1 years in patients with TV-ICD ($P < 0.001$), 97 patients (47.3%) received at least 1 appropriate ICD therapy, including 11 patients (32.4%) with S-ICD. All shocks by S-ICD were successful in terminating the ventricular arrhythmias at first attempt. The risk of appropriate ICD therapy was similar in both groups (HR: 1.2; 95% CI: 0.6-2.3)

(Figure 1) but the risk of appropriate ICD shock was higher in patients with S-ICD (HR: 2.4; 95% CI: 1.2-4.9). In the TV-ICD group, 65.6% of effective appropriate therapies were antitachycardia pacing. These results were consistent when only patients implanted after 2013 were considered (appropriate ICD therapy: HR: 1.5; 95% CI: 0.6-3.3; appropriate ICD shock: HR: 3.6; 95% CI: 1.4-9.6).

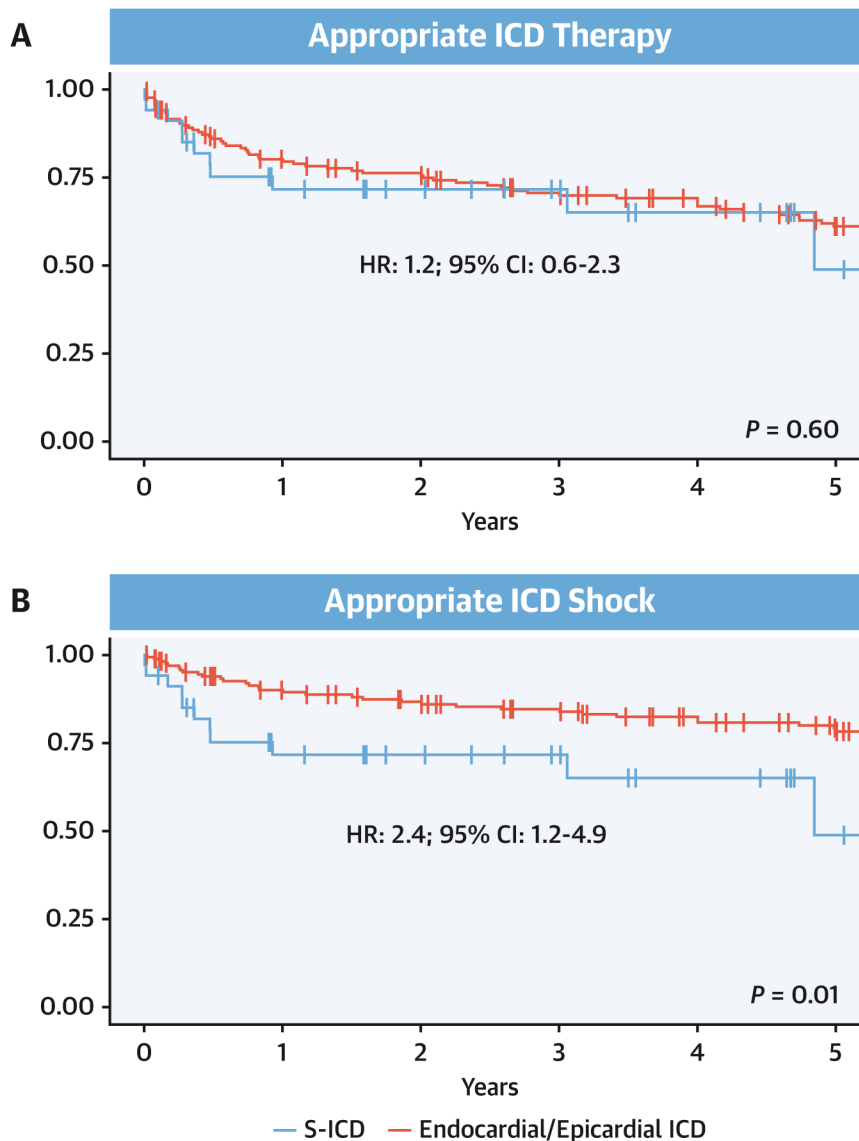
A total of 8 patients (23.5%) with an S-ICD presented at least 1 complication during follow-up (3 inappropriate shocks, 2 pocket infections, 1 pocket hematoma, 1 generator dysfunction, 1 lead impedance increase caused by significant growth). The risks of any ICD-related complication (HR: 1.5; 95% CI: 0.7-3.2), inappropriate ICD shock (HR: 0.7; 95% CI: 0.2-2.3), lead/generator dysfunction (HR: 0.9; 95% CI: 0.2-3.8), and ICD-related infection (HR: 2.2; 95% CI: 0.4-10.9) were comparable in both groups.

Through this nationwide study, we observed a significant increase in the use of S-ICDs among patients with TOF in recent years. S-ICDs were highly effective in preventing arrhythmic death in this high-risk population. Compared with use of TV-ICDs, the use of S-ICD was associated with a similar incidence of appropriate ICD therapies but a higher incidence of appropriate ICD shocks.

Despite the absence of specific data, the very rapid adoption of this new technology (representing more than one-third of implantations in the last period of time) reflects the high expectations regarding the potential improved benefit/risk ratio associated with S-ICDs in these fragile patients. These high expectations, however, should not overshadow the importance of evaluating this still relatively new technology in this specific population.

Concerning the defibrillation properties of S-ICDs, all clinical ventricular arrhythmias were successfully treated during follow-up. These findings confirm the efficacy of S-ICDs with the usual defibrillation thresholds in patients with repaired TOF, as already demonstrated in patients with acquired heart disease. Furthermore, the higher incidence of appropriate ICD shocks with S-ICDs is in line with the results of the PRAETORIAN (A PROspective, rAndomizEd Comparison of subcuTaneOous and tRansvenous ImplANTable Cardioverter Defibrillator Therapy) trial² and has to be considered in the decision-making process regarding

FIGURE 1 Survival Without Appropriate ICD Therapy and Appropriate ICD Shock



Kaplan-Meier survival curves of appropriate implantable cardioverter-defibrillator (ICD) therapy (A) and ICD shock (B) in patients with subcutaneous implantable cardioverter-defibrillator (S-ICD) (blue) versus transvenous ICD (red).

the choice of the defibrillation system, particularly according to previous documented ventricular arrhythmias (eg, rate and potential efficacy of overdrive pacing in secondary prevention patients). Because monomorphic ventricular tachycardias account for >80% of ventricular arrhythmias in patients with TOF, the absence of antitachycardia pacing likely underlies this higher risk of appropriate ICD shocks.

Finally, the overall burden of ICD-related complications was similar in both groups. Considering the

median duration of follow-up of patients with S-ICDs (2.5 years), however, we cannot draw firm conclusions on the potential long-term benefit/risk ratio improvement, particularly regarding lead-related complications, systemic infections, and vascular issues.

We acknowledge several limitations. First, we had limited information on ICD programming that was left to the discretion of the treating physician. Second, patients included in this study were enrolled during a

large period of time (2000-2021) with potential improvement of overall medical management and surgical approaches. However, no significant difference regarding appropriate ICD therapies or complications rates were observed according to ICD implantation date.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

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