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Subcutaneous Implantable Cardioverter-Defibrillators in Patients With Congenital Heart Disease

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ABBREVIATIONS AND ACRONYMS

CHD = congenital heart disease; ICD = implantable; cardioverter-defibrillator;
SICD = subcutaneous; implantable cardioverterdefibrillator.

KEY WORDS

congenital heart disease, implantable cardioverter defibrillator, sudden death, ventricular arrhythmia

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BACKGROUND

Very few data have been published on the use of subcutaneous implantable cardioverter-defibrillators (S-ICDs) in patients with congenital heart disease (CHD).

OBJECTIVES

The aim of this study was to analyze outcomes associated with S-ICDs in patients with CHD.

METHODS

This nationwide French cohort including all patients with an S-ICD was initiated in 2020 by the French Institute of Health and Medical Research. Characteristics at implantation and outcomes were analyzed in patients with CHD.

RESULTS

From October 12, 2012, to December 31, 2019, among 4,924 patients receiving an S-ICD implant in 150 centers, 101 (2.1%) had CHD. Tetralogy of Fallot, univentricular heart, and dextro-transposition of the great arteries represented almost one-half of the population. Patients with CHD were significantly younger (age 37.1 +/-15.4 years vs 50.1 +/- 14.9 years; $P < 0.001$), more frequently female (37.6% vs 23.0%; $P < 0.001$), more likely to receive an S-ICD for secondary prevention (72.3% vs 35.9%; $P < 0.001$), and less likely to have severe systolic dysfunction of the systemic ventricle (28.1% vs 53.1%; $P < 0.001$). Over a mean follow-up period of 1.9 years, 16 (15.8%) patients with CHD received at least 1 appropriate shock, with all shocks successfully terminating the ventricular arrhythmia. The crude risk of appropriate S-ICD shock was twice as high in patients with CHD compared with non-CHD patients (annual incidences of 9.0% vs 4.4%; HR: 2.1; 95% CI: 1.3-3.4); however, this association was no longer significant after propensity matching (especially considering S-ICD indication, $P = 0.12$). The burden of all complications (HR: 1.2; 95% CI: 0.7-2.1; $P = 0.4$) and inappropriate shocks (HR: 0.9; 95% CI: 0.4-2.0; $P = 0.9$) was comparable in both groups.

CONCLUSIONS

In this nationwide study, patients with CHD represented 2% of all S-ICD implantations. Our findings emphasize the effectiveness and safety of S-ICD in this particularly high-risk population. (S-ICD French Cohort Study [HONEST]; [NCT05302115](https://clinicaltrials.gov/ct2/show/study/NCT05302115))

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.Sudden cardiac death remains a major cause of death in the continuously growing population of adults with congenital heart disease (CHD).¹⁻⁴ Although transvenous implantable cardioverter-defibrillators (ICDs) have been shown to be highly effective in preventing arrhythmic death in high-risk patients, the burden of long-term complications is considerable.⁵⁻⁸ Subcutaneous ICDs (S-ICDs) have relatively recently been introduced,⁹ with the aim to reduce lead-related complications and the risk of systemic infection or endocarditis. Considering the relatively young age of patients with CHD and frequent vascular access issues, the S-ICD seems to be an appealing option to improve the benefit/risk balance in this specific population. However, since the first human pilot study initiated in 2008,⁹ data regarding the use of the S-ICD in these patients remain very sparse.¹⁰⁻¹⁵

Through a large nationwide study, we aimed to analyze outcomes associated with S-ICD use in patients with CHD, with a particular focus on the effectiveness of S-ICD therapies and on the burden of device-related complications, including inappropriate shocks.

METHODS

STUDY SETTING.

HONEST (S-ICD French Cohort Study) is an observational, standard-of-care evaluation of clinical-, system-, and patient-related outcome data of all patients receiving an S-ICD system (EMBLEM; Boston Scientific) in all 150 French hospitals accredited to implant S-ICD, from the first implantation in October 1, 2012, to December 31, 2019. Of 5,175 S-ICDs manufactured in France during this period, 4,924 S-ICD patients with de novo implantations and 129 with generator replacements ($n = 5,053$ [97.6%]) were enrolled in HONEST. Eight (0.2%) patients (including 1 patient with a CHD) have already been reported in a recent European registry (The SIDECAR [S-ICD registry in European paediatric and young Adult patients with congenital heart defects] project).¹⁵ Among the participating sites, 39 were university hospitals, 60 non-university teaching hospitals, and 51 private hospitals. To guarantee the exhaustivity of the data and that every single S-ICD implantation in France was included in the registry, the manufacturer supplied a list of all French S-ICD implants for the aforementioned period, including 5,175 generators and their serial numbers. Physicians performing the implantations were asked to complete an online electronic data spreadsheet for each patient. Patient data at the time of implantation as well as procedural and follow-up data were collected retrospectively during the 2020 to 2022 period, and a yearly prospective follow-up was initiated in 2022 for a minimum of 5 years.

Written informed consent for data storage and analysis was provided by all patients at the time of inclusion. Data were centrally collected and managed by using REDCap electronic data capture tools hosted at the Cardiovascular Epidemiology Unit of the Paris Cardiovascular Research Center (Inserm 970, European Georges Pompidou Hospital, Paris, France).¹⁶ The HONEST cohort was declared to, and authorized by, the French data protection committee (Commission Nationale Informatique et Liberté), and the study was approved by the appropriate Institutional Review Boards. The registry was conducted according to the guidelines of the Declaration of Helsinki. Study information, including the objectives, inclusion and exclusion criteria, and the names of participating hospitals, was published in the publicly available ClinicalTrials.gov network ([NCT05302115](https://clinicaltrials.gov/ct2/show/study/NCT05302115)).

COLLECTED DATA AND OUTCOMES.

In addition to data collection regarding medical history, indication of S-ICD, implantation procedure characteristics, arrhythmic events during follow-up, and complications associated with S-ICD, comprehensive information was recorded regarding the underlying type of CHD and the previous cardiac surgeries. CHD were classified according to the latest American Heart Association/American College of Cardiology and European Society of Cardiology classifications.^{17,18}

Survival free from S-ICD–appropriate shock and from S-ICD–related complications was analyzed. S-ICD–related complications included pocket hematoma, device infection, lead or generator dysfunction, and inappropriate S-ICD shock. ICD programming was left to the discretion of the managing physician. Other outcomes included S-ICD–related reinterventions, heart transplantation, and vital status with cause of death (where appropriate).

A specific working group ensured systematic follow-up of patients at least once a year, and more frequently in case of clinical events, using electronic case report forms. A first audit was conducted on every case of arrhythmic event by an expert committee composed of independent adjudicators (trained electrophysiologists) using event recordings of the S-ICD to assess if classification of appropriate vs inappropriate shock was correct, thereby confirming the integrity of the data. A second audit consisted of the analysis of all event data reported in the electronic form by the individual investigating sites, including the occurrence of S-ICD shocks, device-related complications, and cause of death, which were adjudicated according to protocol. Any case of discordance was discussed with independent reviewers. The full study data were subsequently reassessed by an external auditor to confirm the integrity of the data.

STATISTICAL ANALYSIS.

This report was prepared in compliance with the Strengthening the Reporting of Observational Studies in Epidemiology checklist for observational studies.¹⁹ Categorical data are reported as number (%). Continuous data are reported as mean \pm SD or median (IQR) for normally and non-normally distributed data, respectively. Comparisons used the chi-square or Fisher exact test for categorical variables and Student's t-test or Mann-Whitney-Wilcoxon test, when appropriate, for continuous variables. Survival curves were plotted by using the Kaplan-Meier method and compared by using a log-rank test.

The primary time to event endpoint was the time from S-ICD implantation (time zero) to first appropriate S-ICD therapy or first S-ICD–related complication. Censoring occurred in the event of loss to follow-up, heart transplantation, or death. Comparative analyses were performed between patients with CHD and those without CHD. Cox proportional hazards models were used to provide HRs associated with the different outcomes in patients with CHD. Proportional hazards assumptions were checked for all variables (Shoenfeld residuals) and nonlinearity for continuous variables (Martingale residuals) with the use of appropriate functional forms. A complementary analysis using a propensity score weighting by inverse probability was also conducted to better appreciate to what extent the difference regarding the risk of appropriate S-ICD shocks was primarily related to the CHD or to other factors. Age, sex, systemic ventricular function, and S-ICD indication (primary vs secondary prevention of sudden cardiac death) were included in a logistic regression model to calculate the propensity

score. After weighting, variables depicting a standardized effect size >0.1 were included in the Cox regression model for adjustment.

A 2-tailed P value <0.05 was considered statistically significant. All data were analyzed at INSERM, Unit 970, Cardiovascular Epidemiology and Sudden Death (Paris, France), using R version 3.6.3 (R Project for Statistical Computing, Vienna, Austria).

RESULTS

PATIENT CHARACTERISTICS AT S-ICD IMPLANTATION.

Among 4,924 patients who underwent an S-ICD implantation, 101 (2.1%) had CHD (including 9 children <18 years of age). The proportion of patients with a CHD among patients undergoing implantation remained stable over the study period. The main types of CHD are presented in [Figure 1](#). The most common underlying phenotypes were tetralogy of Fallot ($n = 28$), univentricular heart ($n = 13$), dextro-transposition of the great arteries with atrial switch ($n = 10$), pulmonary atresia ($n = 7$), congenitally corrected transposition of the great arteries ($n = 6$), congenital aortic or mitral disease ($n = 6$), and Ebstein anomaly ($n = 5$). The median number of cardiac surgeries before S-ICD implantation was 2 (IQR: 1-3) with a mean delay of 27.7 ± 13.9 years between corrective surgery and S-ICD implantation.

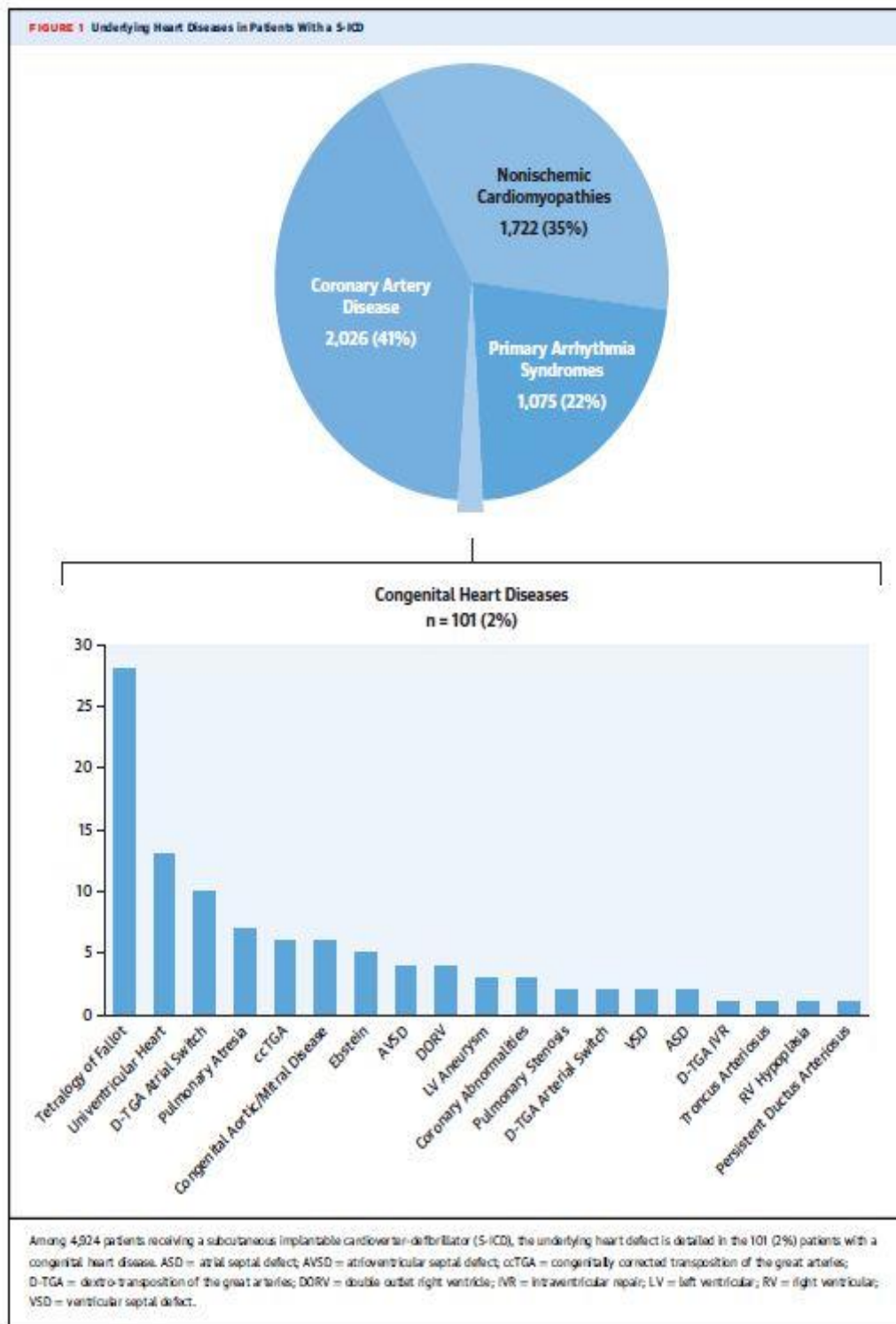
Compared with non-CHD patients, patients with CHD were significantly younger (age 37.1 ± 15.4 years vs 50.1 ± 14.9 years; $P < 0.001$), more frequently female (37.6% vs 23.0%; $P < 0.001$), more likely to receive an S-ICD for secondary prevention (72.3% vs 35.9%; $P < 0.001$), and less likely to have severe systolic dysfunction of the systemic ventricle (28.1% vs 53.1%; $P < 0.001$) ([Table 1](#)). General anesthesia use and S-ICD testing were comparable in both groups, but a 3-incision surgical approach was more common in patients with CHD (23.4% vs 10.2%; $P < 0.001$). Among patients with CHD who had defibrillation threshold testing ($n = 76$), cardiac rhythm was restored at first shock in the majority (65 J; $n = 68$ [97.1%]), with just 2 patients requiring a second shock (80 J; 2.9%) (information not available in 6 patients). A previous pacing system was more frequently associated with patients with CHD (12.1% vs 1.4%; $P < 0.001$).

APPROPRIATE S-ICD THERAPIES DURING FOLLOW-UP.

Over a mean follow-up period of 1.9 ± 1.5 years (2.0 ± 1.6 years vs 1.9 ± 1.5 years in CHD patients and non-CHD patients, respectively; $P = 0.566$), 16 (15.8%) patients with CHD received at least 1 appropriate S-ICD shock. The median number of appropriate S-ICD shocks was 2 (IQR: 1.0-2.3) in patients with CHD, with only 1 shock in 7 patients, 2 shocks in 5 patients, and 3 shocks in 4 patients. All shocks successfully terminated the ventricular arrhythmia at first attempt. The crude risk of appropriate S-ICD shock was significantly higher in patients with CHD (HR: 2.1; 95% CI: 1.3-3.4; $P = 0.003$), with a corresponding annual incidence of 9.0% in patients with CHD vs 4.4% in non-CHD patients ([Central Illustration](#)). The 1-year, 2-year, and 5-year incidences of appropriate S-ICD shocks were 13.0%, 16.8%, and 37.5% in patients with CHD vs 5.2%, 9.1%, and 16.7% in non-CHD patients. Among patients with CHD, appropriate shocks were 7 times more common among secondary prevention patients (annual rate of 12.5% vs 1.7% in primary prevention; HR: 7.2; 95% CI: 1.1-54.4; $P = 0.03$). A higher risk of appropriate S-ICD shock in patients with CHD vs non-CHD patients was observed in secondary prevention patients (HR: 1.9; 95% CI: 1.1-3.2; $P = 0.02$) but not in those receiving an implant for primary prevention (HR: 0.6; 95% CI:

0.1-4.0; P = 0.6). No interaction was found between CHD and S-ICD indication (primary vs secondary prevention; P = 0.3).

In a complementary propensity score weighting analysis by the inverse probability, the higher risk of appropriate S-ICD shocks in patients with CHD vs those without CHD was attenuated and no longer statistically significant (HR: 1.5; 95% CI: 0.9-2.4; P = 0.12).



COMPLICATIONS ASSOCIATED WITH S-ICD.

A total of 15 (14.9%) patients with CHD had at least one S-ICD–related complication during follow-up vs 599 (12.4%) patients without CHD, with a corresponding annual incidence of 8.7% vs 7.0% (HR: 1.2; 95% CI: 0.7-2.1; P = 0.4) (Central Illustration). The 1-year, 2-year, and 5-year incidences of S-ICD–related complications were 13.8%, 15.7%, and 23.0% in patients with CHD vs 8.8%, 12.4%, and 25.9% in non-CHD patients, respectively. The complications are listed in Table 2. The risk of all complications was similar in both groups, including the annual rate of inappropriate S-ICD shock (3.7% vs 4.0%, HR: 0.9; 95% CI: 0.4-2.0; P = 0.9), but a higher annual risk of infection was reported in patients with CHD (2.6% vs 1.0%; HR: 2.8; 95% CI: 1.1-6.8; P = 0.02). Among patients with CHD with S-ICD–related infection (n = 5), 4 (80.0%) had a local infection, and 1 (20.0%) had a systemic infection (vs 4.7% of systemic infection in patients without CHD who had an infection; P = 0.24). A 3-incision surgical approach (HR: 2.1; 95% CI: 1.3-3.5; P = 0.003) and an associated pacing system (HR: 2.7; 95% CI: 1.1-7.3; P = 0.043) were associated with a higher risk of infection in the whole cohort, and a similar non-statistically significant trend was observed in the subgroup of patients with CHD (3-incision surgical approach: HR: 5.3; 95% CI: 0.9-31.5; P = 0.069; associated pacing system: HR: 5.1; 95% CI: 0.9-30.5; P = 0.075). Among the 9 pediatric patients with CHD receiving an S-ICD implant, 1 complication was reported (inappropriate shock).

Among patients with inappropriate shocks, T-wave oversensing was more common in patients with CHD compared with those without CHD (71.4% vs 35.8%; P = 0.045), whereas the proportion of inappropriate shocks due to supraventricular arrhythmias was similar (28.6% vs 19.0%; P = 0.52). The proportion of patients with a second-generation S-ICD (model A219 with SMART Pass sensing filter [Boston Scientific] to reduce inappropriate shocks) was comparable in both groups (54.5% in CHD patients vs 61.2% in non-CHD patients; P=0.169).

The rate of complications was similar in patients with complex CHD compared with those with simple or moderate CHD (HR: 0.8; 95% CI: 0.2-2.8; P = 0.70). The use of S-ICD remote monitoring was significantly associated with fewer complications during follow-up (HR: 0.3; 95% CI: 0.1-0.9; P = 0.020), with no other baseline variable predicting the occurrence of complications.

REINTERVENTIONS.

During follow-up, 16 (15.8%) patients with CHD had an S-ICD–related reintervention vs 387 (8.0%) without CHD (HR: 1.8; 95% CI: 1.1- 3.1; P = 0.02). The causes of reintervention were local complications in 5 (infections), generator change for battery depletion in 4 after a median delay of 5.5 years (IQR: 4.1-5.8 years), inappropriate S-ICD shock in 2, heart transplantation in 2, generator dysfunction in 1 (impossibility to interrogate the device), cardiac surgery with epicardial ICD implantation in 1, and patient's request in 1. No reintervention was related to a pacing need in patients with CHD. The 1-year and 2-year survival rates without reintervention were 86.2% vs 91.2% and 84.3% vs 87.6% in patients with vs without CHD, respectively.

TABLE 1 General Characteristics of Patients					
	All Patients (N = 4,924)	Patients With CHD (n = 101)	Non-CHD Patients (n = 4,823)		P Value
Age at implantation, y	49.9 ± 15.0	37.1 ± 15.4	50.1 ± 14.9		<0.001
Female	1,148 (23.3)	38 (37.6)	1,110 (23.0)		<0.001
Secondary prevention	1,805 (36.7)	73 (72.3)	1,732 (35.9)		<0.001
Systemic ventricle ejection fraction, %	42.1 ± 16.8	47.7 ± 13.9	42.0 ± 16.8		<0.001
Systemic ventricle ejection fraction ≤35%	2,530 (52.6)	27 (28.1)	2,503 (53.1)		<0.001
ICD before S-ICD	650 (13.2)	17 (17.2)	633 (13.1)		0.304
Associated pacing system	81 (1.7)	12 (12.1)	69 (1.4)		<0.001
General anesthesia	3,863 (78.8)	79 (79.8)	3,784 (78.8)		0.908
3-incision surgical approach	501 (10.5)	22 (23.4)	479 (10.2)		<0.001
S-ICD testing	4,025 (82.4)	76 (77.6)	3,949 (82.5)		0.249
Remote monitoring	3,355 (69.8)	73 (75.3)	3,282 (69.7)		0.286

Values are mean ± SD or n (%).

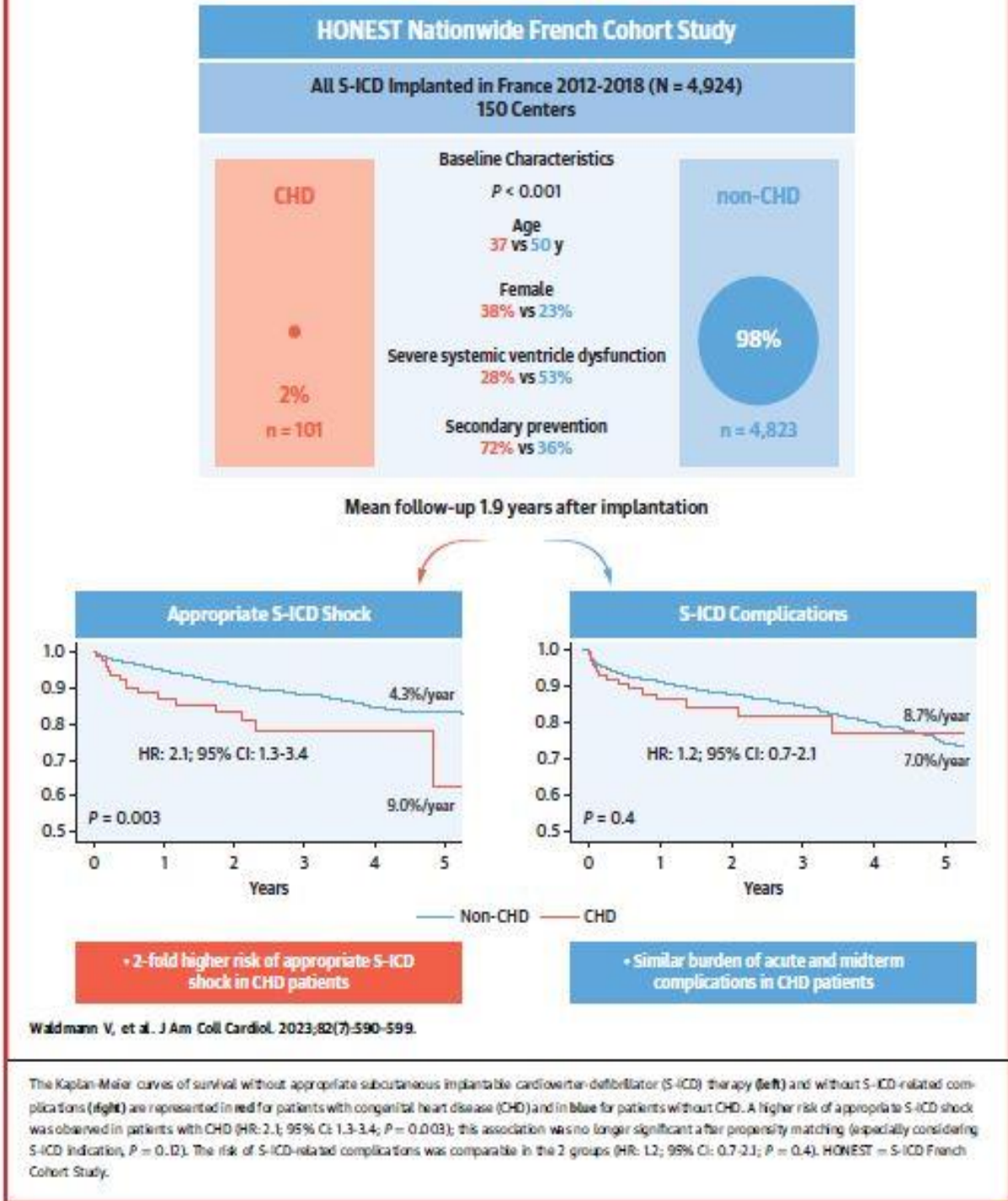
CHD = congenital heart disease; ICD = implantable cardioverter-defibrillator; S-ICD = subcutaneous implantable cardioverter-defibrillator.

TABLE 2 S-ICD-Related Complications					
	All Patients (N = 4,924)	Patients With CHD (n = 101)	Non-CHD Patients (n = 4,823)	HR (95% CI)	P Value
All complications	614 (12.4)	15 (14.8)	499 (10.3)	1.2 (0.7-2.1)	0.4
Inappropriate S-ICD shock	365 (7.4)	7 (6.9)	358 (7.4)	0.9 (0.4-2.0)	0.9
S-ICD-related infection	97 (2.0)	5 (5.0)	92 (1.9)	2.8 (1.1-6.8)	0.02
Pocket hematoma	56 (1.1)	2 (2.0)	54 (1.1)	1.8 (0.4-7.3)	0.4
Poor wound healing ^a	53 (1.1)	1 (1.0)	52 (1.1)	0.9 (0.1-6.8)	0.9
Lead dysfunction/dislodgment	16 (0.3)	0 (0.0)	16 (0.3)	-	-
Chronic pain	16 (0.3)	0 (0.0)	16 (0.3)	-	-
Death related to S-ICD	3 (0.1)	0 (0.0)	3 (0.1)	-	-
Other complication	42 (0.9)	0 (0.0)	42 (0.9)	-	-

Values are n (%) unless otherwise indicated. ^aSlow healing process of the skin incision.

Abbreviations as in Table 1.

CENTRAL ILLUSTRATION Subcutaneous Implantable Cardioverter-Defibrillator Use in Patients With Congenital Heart Disease: HONEST Nationwide French Cohort Study



OVERALL SURVIVAL AND HEART TRANSPLANT.

Overall, 5 (5.0%) patients with CHD underwent heart transplantation, and 7 (6.9%) died. Heart failure was the most common specific cause of death (n = 3), 3 patients died of noncardiovascular cause, and 1 during heart transplantation. In patients without CHD, 66 (1.4%) patients had a heart transplant, and 194 (4.0%) died. The rate of heart transplantations

(HR: 4.0; 95% CI: 1.6-10.0; P = 0.001) was higher in patients with CHD, whereas all-cause mortality was similar (HR: 1.7; 95% CI: 0.8-3.6; P = 0.2). Corresponding 1-year survival rates with no heart transplantations and no deaths were 92.2% vs 98.0% and 95.6% vs 97.6% in patients with vs without CHD, respectively.

DISCUSSION

In this large nationwide study, patients with CHD represented 2% of all S-ICD implantations in France since the market launch in 2012. This study showed that S-ICDs were highly effective in preventing arrhythmic death in this specific population, with all life-threatening ventricular arrhythmias successfully terminated. The overall burden of complications was similar to that in patients without CHD, including the risk of inappropriate S-ICD shocks, but S-ICD-related infections and reinterventions were more frequently reported in patients with CHD.

Our data revealed an early use of S-ICD in patients with CHD. Considering the young age of most patients with CHD, frequent vascular access issues, and the burden of long-term complications associated with transvenous ICDs,⁸ the rapid adoption of this new technology reflects the high expectations of patients with CHD and respective physicians. Similar very early S-ICD utilization has been reported in other high-risk populations (eg, patients undergoing dialysis), with more than one-half of eligible patients now receiving an S-ICD.¹⁹ However, the importance of evaluating this still relatively new technology in the specific CHD population cannot be overstated, with only a few small series published thus far.¹⁰⁻¹²

Several factors may increase the risk of complications associated with the S-ICD in patients with CHD. These young patients are likely to have a more active lifestyle and have a higher propensity for atrial arrhythmias and distorted anatomies, which are often associated with atypical electrocardiogram patterns with a potentially higher incidence of inappropriate shocks.^{13,20} Furthermore, as reported in the current study, these patients frequently receive an associated pacing system that may lead to additional sensing issues. Nevertheless, our results provide reassuring data showing that the overall burden of S-ICD-related complications in patients with CHD are similar to those observed in non-CHD patients, including the rate of inappropriate S-ICD shocks. No lead dysfunction was reported in patients with CHD. However, a higher rate of infection (mostly local) was seen in patients with CHD. Underlying reasons remain uncertain, but we can hypothesize that abnormal anatomies (with atypical or right-sided lead location) may prolong the implantation procedure, associated comorbidities may increase the risk of infection (eg, presence of prosthesis or other devices), and anticoagulation treatment may be more frequent, increasing the risk of hematoma (data not collected in this study). A 3-incision surgical approach and the presence of an associated pacing system were indeed more frequent in patients with CHD and associated with a higher risk of infection in our cohort. The use of remote monitoring may be warranted to improve the benefit/risk ratio and was indeed associated with a significantly lower risk of complications in our study.

It is noteworthy that no defibrillation attempt during implantation failed (with the first shock at 65 J successful in most cases) and that all ventricular arrhythmias during follow-up were successfully terminated by S-ICD shocks in patients with CHD. Considering the multiple underlying anatomies resulting in a defibrillation field that may have been suboptimal in some phenotypes, these findings strongly suggest that the S-ICD is effective in interrupting

ventricular arrhythmias and thus preventing sudden arrhythmic death in patients with CHD, confirming the results of other smaller studies.¹⁰⁻¹² The largest experience with S-ICD in patients with CHD published so far was conducted by the Pediatric and Congenital Electrophysiology Society and included 37 patients with CHD pooled with pediatric patients with cardiomyopathies or channelopathies.¹³ Global outcomes in this heterogeneous population found that 92.5% of ventricular arrhythmias were successfully converted at first shock and that the others were also successfully converted with additional shocks. Regarding detection performances, although we cannot formally exclude ventricular arrhythmia undersensing in some patients, the cause of death was known in all cases, and no unexplained sudden deaths (potentially related to arrhythmia undersensing) were reported in our study.

Patients with CHD had twice as many appropriate S-ICD therapies compared with non-CHD patients. This difference was mostly accounted for by a higher risk of appropriate therapies in the secondary prevention setting, whereas no significant difference was observed in patients receiving an implant for primary prevention. High rates of ICD therapies have been previously reported in some cases of CHD, especially in patients with tetralogy of Fallot in whom annual incidences of 7% to 8% in primary prevention patients and up to 12% in secondary prevention patients have been reported.^{6,8} The low rate of events in primary prevention patients reflects the fact that risk stratification remains challenging in this population. Specific risk factors have mainly been identified for tetralogy of Fallot.^{17,18} In other CHDs, the level of evidence for ICD implantation is lower (eg, Class IIb recommendation in patients with systemic right ventricle who receive an ICD for primary prevention, who have very low risk of appropriate ICD therapies).²¹ Because most ventricular arrhythmias in patients with CHD are monomorphic ventricular tachycardias, antitachycardia pacing may decrease the burden of shocks and should be considered in some patients, particularly according to previous documented ventricular arrhythmias (eg, rate and potential efficacy of overdrive pacing in patients receiving an ICD for secondary prevention).

STUDY LIMITATIONS.

First, implantation data were collected retrospectively, with inherent biases. However, a prospective yearly follow-up was initiated in 2022, and all S-ICDs implanted were identified by using the manufacturer list of all S-ICD implants in France, ensuring the comprehensiveness of the cohort. Thus, the information was unavailable in only a very small number of cases (2.4%). Second, the mean duration of follow-up remained relatively modest (1.9 years, with no difference between CHD and non-CHD patients). The ongoing prospective follow-up of this cohort will produce valuable information to assess the long-term complications and benefit/risk ratio associated with S-ICDs in this specific population. Third, we cannot provide information on the proportion of patients with CHD eligible for an S-ICD because patients who failed the screening for the device were not included in this study (only patients receiving an S-ICD were included). We moreover did not specifically collect potential atypical generator or lead positioning in some patients with CHD. Last, we have limited information on S-ICD programming (detection and therapy zones), which was left to the discretion of the treating physician and may have changed over time.^{22,23} However, S-ICD programming is usually consistent with less variation in zone settings compared with endovascular ICDs.

CONCLUSIONS

In this nationwide study, patients with CHD represented 2% of all S-ICD implantations. Our results show that the S-ICD is highly effective in preventing arrhythmic death in CHD, whereas the burden of acute and mid-term complications is similar to that observed in non-CHD patients. Long-term comparative data with transvenous ICD devices are awaited to better assess the potential improvement in benefit/ risk ratio associated with S-ICD in this specific population.

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