

ORIGINAL RESEARCH

Subcutaneous Implantable Cardioverter-Defibrillator Therapy in Women

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ABSTRACT

BACKGROUND The subcutaneous implantable cardioverter-defibrillator (S-ICD) is an established therapy for sudden cardiac death prevention, but sex-specific outcomes remain incompletely characterized.

OBJECTIVES This study evaluated sex-related differences in baseline characteristics, appropriate shocks, complications, reinterventions, and mortality among S-ICD recipients.

METHODS The nationwide HONEST (S-ICD French Cohort Study) cohort enrolled all patients who received an S-ICD in France between 2012 and 2019. Clinical endpoints were centrally adjudicated. Sex-specific associations with outcomes were assessed by using propensity score-based inverse probability weighting.

RESULTS Among 4,924 S-ICD recipients, 1,148 were women (23.3%). Compared with men, women were younger (47.3 ± 15.6 years vs 50.6 ± 14.7 years; $P < 0.001$), less frequently received an implant for primary prevention (57.6% vs 65.1%; $P < 0.001$), less often had coronary artery disease (38.9% vs 56.5%; $P < 0.001$), and more often had electrical heart disease (26.3% vs 20.4%; $P < 0.001$). After adjustment, women had a lower 5-year risk of appropriate shocks (HR: 0.85; 95% CI: 0.74–0.98; $P = 0.023$) and similar overall complication and reintervention rates but a distinct complication profile, with higher risks of chronic pain (HR: 2.63; 95% CI: 1.61–4.29; $P < 0.001$) and lead dislodgment (HR: 1.79; 95% CI: 1.09–2.95; $P = 0.022$) and a lower risk of inappropriate shocks (HR: 0.64; 95% CI: 0.50–0.82; $P < 0.001$). All-cause mortality was lower in women, whereas S-ICD-unresponsive sudden death and device-related mortality were similar.

CONCLUSIONS Women receiving an S-ICD experienced fewer appropriate shocks, with similar overall complication and reintervention rates, but a distinct complication profile. These findings support sex-informed S-ICD selection and follow-up. (S-ICD French Cohort Study [HONEST]; [NCT05302115](https://doi.org/10.1016/j.jacep.2026.06.013)) (JACC Clin Electrophysiol. 2026;■:■–■) © 2026 by the American College of Cardiology Foundation.

ABBREVIATIONS
AND ACRONYMSICD = implantable
cardioverter-defibrillatorS-ICD = subcutaneous
implantable cardioverter-
defibrillator

Implantable cardioverter-defibrillators (ICDs) are effective in preventing sudden arrhythmic death and remain recommended for patients at increased risk.^{1,2} However, device- and lead-related complications associated with transvenous ICDs have driven the development of the subcutaneous ICD (S-ICD).³⁻⁷ Contemporary studies have shown that the S-ICD reliably terminates life-threatening ventricular arrhythmias while substantially reducing lead-related complications.⁸⁻¹⁰ However, this benefit does not necessarily extend to all-cause or pocket-related complications, which remain a clinically relevant concern across both randomized and real-world settings.¹¹⁻¹³

Women have been consistently underrepresented in randomized trials of ICDs,^{9,14} and available observational data suggest a lower incidence of ventricular arrhythmias and sudden cardiac death in women than in men, reflected by fewer appropriate ICD therapies.¹⁵⁻¹⁷ In contrast, women experience higher rates of certain device-related complications.^{18,19} Although these sex differences are well documented for transvenous ICDs, their relevance to S-ICD therapy remains insufficiently characterized.²⁰ This uncertainty is clinically important, as the S-ICD is implanted in the subcutaneous tissue of the left hemithorax,²¹ where breast tissue, thoracic anatomy, and pocket characteristics may plausibly influence

perioperative complications and oversensing-related inappropriate shocks.

The HONEST (S-ICD French Cohort Study) cohort is a nationwide, ongoing observational study designed to capture all patients undergoing S-ICD implantation in France between 2012 and 2019. In this prespecified analysis, sex-related differences in baseline characteristics, procedural and long-term complications, appropriate and inappropriate shocks, and all-cause and cause-specific mortality over 5 years of follow-up were examined.

METHODS

STUDY DESIGN. The HONEST cohort is a nationwide, multicenter, nonrandomized observational ongoing study designed to capture all consecutive patients undergoing de novo implantation of an S-ICD (EMBLEM; Boston Scientific) at the 150 French centers accredited for S-ICD procedures ([Supplemental Table 1](#)).^{22,23} Enrollment spanned from the first French S-ICD implant (October 2012) through December 2019 and included patients with primary or secondary prevention of sudden cardiac death.

To ensure near-complete national ascertainment, the device manufacturer provided the serial numbers of all S-ICD systems distributed during the enrollment period. Cross-reconciliation identified 4,924 eligible de novo implants, representing

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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](#).

Manuscript received February 16, 2026; revised manuscript received May 26, 2026, accepted June 1, 2026.

98.2% of all S-ICD recipients in France during this interval. Baseline, procedural, and follow-up data were retrospectively collected in 2019²⁴; prospective annual follow-up was initiated in 2020. Participating centers comprised 39 university hospitals, 60 non-university teaching hospitals, and 51 private hospitals.

All participants provided written informed consent. The study was approved by the French Data Protection Authority (Commission Nationale Informatique et Liberté under the number 2217196) and the relevant institutional review board and was conducted in accordance with the Declaration of Helsinki. Study details were registered at ClinicalTrials.gov (NCT05302115). This report follows the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

PATIENT DATA. Data were collected by using standardized electronic case report forms and included demographic characteristics; indication for implantation (primary vs secondary prevention); underlying heart disease; left ventricular ejection fraction; prior ICD history; presence of a concomitant pacing system; and procedural characteristics, including anesthesia type, number of incisions, generator position, generator model (EMBLEM 1010, A209, A219; Boston Scientific), and defibrillation testing. Routine annual in-person follow-up was supplemented by continuous remote monitoring via the LATITUDE system (Boston Scientific), which generated real-time alerts related to device status, lead integrity, and delivered therapies. Data were centrally managed by using REDCap (Vanderbilt University) at the Paris Cardiovascular Research Center (INSERM U970, Hôpital Européen Georges-Pompidou).

STUDY ENDPOINTS. This prespecified analysis compared outcomes between women and men receiving an S-ICD. Endpoints included device-related complications, appropriate and inappropriate shocks, all-cause mortality, and heart transplantation. An appropriate shock was defined as any shock delivered for ventricular tachycardia/fibrillation above the programmed detection zone, excluding slow ventricular tachycardia with T-wave oversensing or double counting. An inappropriate shock was defined as any shock delivered for non-ventricular rhythms or due to T-wave oversensing, myopotential oversensing, or electromagnetic interference. Surgical reintervention was defined as any postindex invasive procedure prompted by device-related complications. Local complications

included pocket hematoma, pocket infection, delayed wound healing, and lead dislodgment; systemic infections were captured separately. Chronic pain was defined as persistent device-related pain at the generator pocket and/or along the subcutaneous lead course beyond the initial postimplant recovery period, as documented during follow-up by the treating team. This endpoint was identified from clinical follow-up records and adverse event reporting. Occurrence of a given event did not preclude subsequent events.

Deaths were classified as cardiovascular, non-cardiovascular, or S-ICD related (directly attributable to implantation or device-related complications). Vital status and date of death, including for patients censored for extraction or lost to routine follow-up, were confirmed through deterministic linkage with the French national registry (INSEE). Shocks and complications were reported by site investigators, with S-ICD-related deaths, infections, and shock episodes undergoing centralized adjudication by an independent expert committee. Loss to follow-up was 9.1% as of December 2023.

STATISTICAL ANALYSIS. Categorical variables are presented as counts (percentages) and continuous variables as mean $\pm$ SD or medians (Q1-Q3), as appropriate. Between-group comparisons were performed by using the chi-square or Fisher exact test for categorical variables and the Student's *t*-test or Mann-Whitney *U* test for continuous variables. Follow-up time accrued from the index S-ICD implantation to the earliest of the event of interest, last contact, or December 31, 2023.

Cumulative incidence of first appropriate shock was estimated with the Aalen-Johansen method treating death as a competing risk. Other time-to-event outcomes were analyzed by using Kaplan-Meier estimates and compared with log-rank tests. Associations between sex and outcomes were initially evaluated in the unweighted cohort using Cox proportional hazards models, with results expressed as HRs and 95% CIs; a shared frailty term accounted for clustering by implanting center. Recurrent inappropriate shocks were analyzed by using Andersen-Gill models with robust variance estimation; all other outcomes were modeled as time to first event.

Adjusted analyses used inverse probability weighting based on propensity scores derived from logistic regression models, including age, body mass index, prevention type, underlying heart disease, left ventricular ejection fraction, concomitant

TABLE 1 Clinical Characteristics of Patients at Baseline

	Women (n = 1,148)	Men (n = 3,776)	P Value
Age at implantation, y	47.3 ± 15.6	50.6 ± 14.7	<0.001
Body mass index, kg/m ²	25.60 ± 5.98	26.58 ± 6.38	<0.001
ICD indication			<0.001
Primary prevention	661 (57.6)	2,458 (65.1)	
Secondary prevention	487 (42.4)	1,318 (34.9)	
Type of heart disease			<0.001
Structural	846 (73.7)	3,005 (79.6)	
Electrical	302 (26.3)	771 (20.4)	
Type of structural disease			
Coronary artery disease	329 (38.9)	1,697 (56.5)	<0.001
Dilated cardiomyopathy	206 (24.4)	665 (22.1)	0.173
Hypertrophic cardiomyopathy	156 (18.4)	341 (11.4)	<0.001
Congenital	38 (4.5)	63 (2.1)	<0.001
Valvular	36 (4.3)	67 (2.2)	0.001
Other	81 (9.6)	172 (5.7)	<0.001
Type of electrical disease			
Idiopathic VF	145 (48.0)	303 (39.3)	0.009
Brugada	88 (29.1)	385 (49.9)	<0.001
Long-QT syndrome	42 (13.9)	31 (4.0)	<0.001
Other	27 (8.9)	52 (6.7)	0.215
LVEF at implantation, %	45.5 ± 16.9	41.3 ± 16.6	<0.001
Previous ICD history	143 (12.5)	508 (13.5)	0.383
Associated pacing system	24 (2.09)	58 (1.54)	0.198
Use of general anesthesia	934 (81.4)	2,949 (78.1)	0.018
Testing at implantation	958 (83.5)	3,107 (82.3)	0.362
No. of incisions			0.617
2	1,026 (89.37)	3,394 (89.88)	
3	122 (10.63)	382 (10.12)	
Type of generator			0.865
First-generation 1010	72 (6.27)	242 (6.41)	
Second- and third-generation A209/A219	1,076 (93.73)	3,532 (93.59)	
Smart Pass	580 (50.52)	1,910 (50.58)	0.972

Values are mean ± SD or n (%).

LVEF = left ventricular ejection fraction; ICD = implantable cardioverter-defibrillator; VF = ventricular fibrillation.

pacing system, prior ICD, anesthesia type, number of incisions, generator position, generator generation/type, and the Smart Pass filter (Boston Scientific). Covariate balance before and after weighting was assessed by using standardized mean differences, with values <0.10 indicating adequate balance, and values are displayed in Love plots (Supplemental Figures 1 and 2).

The proportional hazards assumption was evaluated by using scaled Schoenfeld residuals. Missing baseline covariates were handled by using multiple imputation by chained equations. Missing data are presented in Supplemental Table 2. All statistical tests were two-sided with $P < 0.05$ considered statistically significant. Analyses were performed in R version 4.4.1 (R Foundation for Statistical Computing).

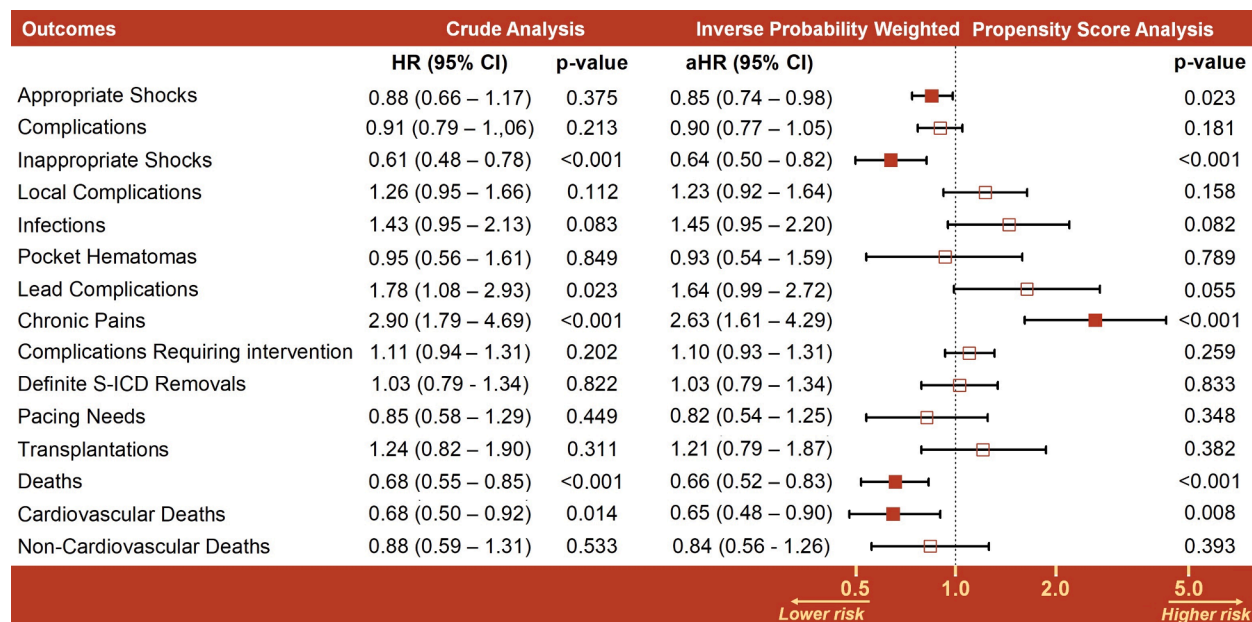
RESULTS

PATIENT CHARACTERISTICS AND PERIPROCEDURAL DETAILS. Among 4,924 patients undergoing S-ICD implantation, 1,148 (23.3%) were women. Women were younger than men (47.3 ± 15.6 years vs 50.6 ± 14.7 years; $P < 0.001$) and less frequently received an implant for primary prevention (57.6% vs 65.1%; $P < 0.001$). Structural heart disease predominated in both groups; however, women more often had electrical heart disease (26.3% vs 20.4%; $P < 0.001$). Among women with electrical heart disease, idiopathic ventricular fibrillation was most common ($n = 145$ [48.0%]), followed by Brugada syndrome ($n = 88$ [29.1%]) and long-QT syndrome ($n = 42$ [13.9%]). Among women with structural heart disease, coronary artery disease was most frequent ($n = 329$ [38.9%]), followed by dilated cardiomyopathy ($n = 206$ [24.4%]) and hypertrophic cardiomyopathy ($n = 156$ [18.4%]) (Table 1). At implantation, women had a higher left ventricular ejection fraction ($45.5\% \pm 16.9\%$ vs $41.3\% \pm 16.6\%$; $P < 0.001$). General anesthesia was administered more frequently in women than in men (81.4% vs 78.1%; $P = 0.018$), whereas defibrillation testing and the 2-incision technique were performed at similar rates in both sexes (83.5% vs 82.3% [$P = 0.362$] and 89.4% vs 89.9% [$P = 0.617$], respectively).

APPROPRIATE SHOCKS DURING FOLLOW-UP. Mean follow-up was 52 ± 26 months in women and 51 ± 27 months in men ($P = 0.999$). Appropriate shocks occurred in 127 women (11.1%; 437 episodes) and 471 men (12.5%; 1,567 episodes; $P = 0.200$). The cumulative incidence of first appropriate shock at 5 years was 12.9% (95% CI: 10.7%-15.2%) in women vs 15.1% (95% CI: 13.8%-16.5%) in men ($P = 0.122$). Among patients receiving appropriate therapy, the per-patient number of shocks did not differ by sex (median [Q1-Q3]: women 2.0 [1.0-3.0] vs men 2.0 [1.0-4.0]; $P = 0.411$).

After adjustment, women had a lower risk of appropriate shocks than men (HR: 0.85; 95% CI: 0.74-0.98; $P = 0.023$) (Figures 1 and 2A). In pre-specified subgroups, the risk was lower in women with structural heart disease (adjusted HR [aHR]: 0.81; 95% CI: 0.73-0.91; $P < 0.001$) and in primary prevention (aHR: 0.85; 95% CI: 0.75-0.97; $P = 0.004$), higher in electrical heart disease (aHR: 1.25; 95% CI: 1.05-1.50; $P = 0.005$), and similar in secondary prevention (aHR: 0.99; 95% CI: 0.87-1.14; $P = 0.923$).

COMPLICATIONS DURING FOLLOW-UP. Within 30 days, any complication occurred in 4.9% of women and 4.1% of men ($P = 0.375$) (Supplemental Table 3).

FIGURE 1 Crude and Multivariate Analyses of Outcomes in Women Compared With Men

This figure illustrates sex-specific differences in major clinical outcomes after subcutaneous implantable cardioverter-defibrillator implantation. HRs were estimated by using crude models and inverse probability weighted propensity score analysis to account for baseline differences between women and men. Squares represent point estimates, horizontal bars represent 95% CIs, and the dashed vertical line indicates no difference between groups. After weighting, women had lower risks of appropriate shocks, inappropriate shocks, all-cause death, and cardiovascular death. Women had a higher risk of chronic pain and a numerically higher risk of lead complications. These findings suggest that women may experience a distinct benefit-risk profile, with fewer arrhythmic therapies but persistent device-related morbidity. aHR = adjusted HR; S-ICD = subcutaneous implantable cardioverter-defibrillator.

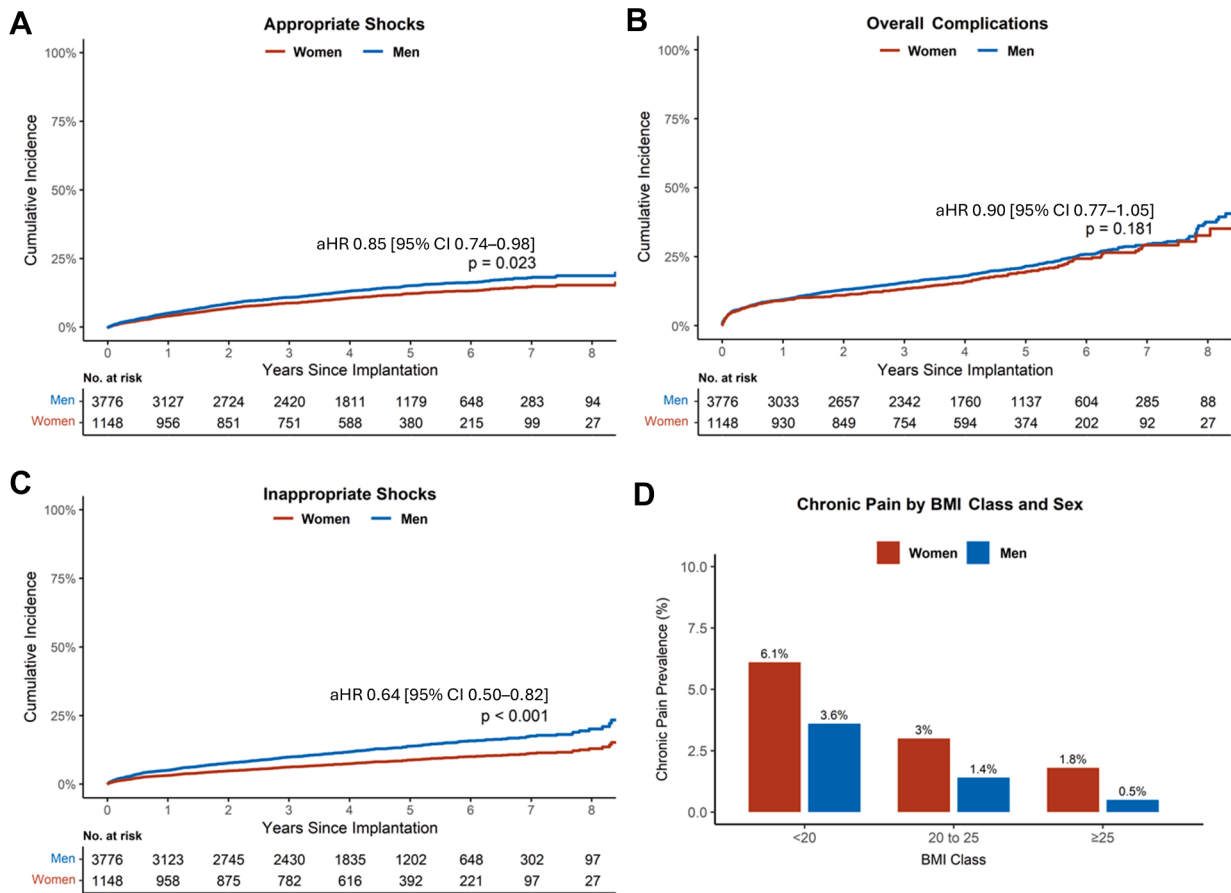
In adjusted analysis, female sex was not associated with early complications (aHR: 1.12; 95% CI: 0.79-1.59; $P = 0.513$). Local complications were more frequent in women (2.9% vs 1.9%; $P = 0.046$), driven by higher rates of local infection (1.2% vs 0.6%; $P = 0.032$) and delayed wound healing (1.0% vs 0.3%; $P = 0.011$); pocket hematoma occurred at similar rates (1.1% vs 1.3%; $P = 0.555$). Early complications requiring reoperation occurred more frequently in women than in men (2.2% vs 1.1%; $P = 0.006$).

Overall, 302 women (26.3%) experienced a total of 447 complication events and 1,012 men (26.8%) experienced 1,794 events ($P = 0.740$) during follow-up. The Kaplan-Meier-estimated incidence of any complication in women was 26.4% (95% CI: 23.1%-29.6%) at 5 years, similar to men (27.2% [95% CI: 25.4%-29.0%]; $P = 0.258$). After adjustment, the risk of complications did not differ according to sex (aHR: 0.90; 95% CI: 0.77-1.05; $P = 0.181$) (Figure 2B). Findings were consistent across subgroups defined by underlying heart disease and clinical indication. Complications requiring intervention occurred in 16.6% of women and 15.0%

of men ($P = 0.190$). The cumulative incidence of reoperation in women was 16.2% (95% CI: 13.3%-18.9%) at 5 years vs 14.8% (95% CI: 13.3%-16.3%) in men ($P = 0.331$). After adjustment, women were not more likely to undergo reintervention (aHR: 1.10; 95% CI: 0.93 - 1.31; $P = 0.259$).

Premature battery depletion was the most frequent complication and occurred at similar rates (women, 9.4%; men, 9.4%; $P = 0.973$) (Table 2).

Inappropriate shocks were the second most frequent complication in women ($n = 97$ [8.5%]) and were less common than in men ($n = 484$ [12.8%]; $P < 0.001$). The cumulative incidence in women was 9.72% (95% CI: 7.70%-11.71%) at 5 years (men: 15.06%; 95% CI: 13.70%-16.40%; $P = 0.002$). After adjustment, women had a lower risk of inappropriate shocks (aHR: 0.64; 95% CI: 0.50-0.82; $P < 0.001$) (Figure 2C). In women, oversensing accounted for 78.5% of inappropriate shocks, most commonly T-wave oversensing (44%); supraventricular tachycardia accounted for 21.5%. The lower risk in women reflected fewer myopotential oversensing events and fewer lead-related issues. In multivariable analysis restricted to women, electrical heart disease

FIGURE 2 Adjusted Cumulative Incidence of Appropriate Shocks, Overall Complications, and Inappropriate Shocks According to Sex. Prevalence of Chronic Pain by BMI and Sex

This figure illustrates sex-specific differences in selected outcomes after subcutaneous implantable cardioverter-defibrillator implantation. Cumulative incidence curves compare women and men for appropriate shocks (A), overall complications (B), and inappropriate shocks (C), with numbers at risk shown below each panel. A bar graph displays chronic pain prevalence according to body mass index (BMI) class and sex (D). Women had significantly lower risks of appropriate and inappropriate shocks, similar overall complication risk, and higher chronic pain prevalence across body mass index categories, particularly among underweight patients. These findings suggest sex-specific differences in arrhythmic therapy burden and device-related morbidity. aHR = adjusted HR.

(aHR: 2.52; 95% CI: 1.25–5.07; $P = 0.009$) and a concomitant pacing system (aHR: 2.44; 95% CI: 1.08–5.49; $P = 0.032$) were independently associated with higher risk of inappropriate shocks, whereas age ≥ 65 years was associated with substantially lower risk (aHR: 0.11; 95% CI: 0.02–0.49; $P = 0.004$) (Supplemental Figure 3). Reintervention for inappropriate shocks occurred in 11 women (1.0%) and 75 men (2.0%; $P = 0.020$), accounting for 11 and 78 procedures, respectively.

Infection was the third most frequent complication in women ($n = 34$ [3.0%]) vs men ($n = 79$ [2.1%]; $P = 0.079$) (Table 2). Four (11.4%) systemic infections were identified in women (compared with 4 [4.9%] in

men; $P = 0.239$) and 31 (88.6%) were local (compared with 77 (95.1%) in men; $P = 0.159$) (Supplemental Table 4). Infections led to reoperation in 28 women (2.4%) and 60 men (1.6%; $P = 0.056$).

Lead dislodgment occurred in 16 women (1.4%) and 18 men (0.5%; $P = 0.001$). After adjustment, women had a higher risk of dislodgment (aHR: 1.79; 95% CI: 1.09–2.95; $P = 0.022$); in women, lead dislodgment rates were stable across body mass index categories (1.3%–1.6%) (Supplemental Figure 4). Reoperation was required in 12 women (1.0%) and 11 men (0.3%; $P < 0.001$).

Chronic pain was reported in 31 women (2.7%) and 35 men (0.9%; $P < 0.001$). After adjustment,

including body mass index, women had a higher risk of chronic pain (aHR: 2.63; 95% CI: 1.61-4.29; $P < 0.001$). **Figure 2D** depicts chronic pain according to body mass index; rates were higher in women across the spectrum. Reoperation for chronic pain was undertaken in 18 women (1.6%) and 13 men (0.3%; $P < 0.001$).

PACING NEED, DEFINITE S-ICD EXTRACTIONS, AND MORTALITY ANALYSIS. During follow-up, pacing systems were implanted in 28 women (2.4%) and 107 men (2.8%; $P = 0.434$). In women, primary indications were antibradycardia pacing (50.0%; men, 14.0%; $P < 0.001$), cardiac resynchronization therapy (35.7%; men, 38.3%; $P = 0.820$), and antitachycardia pacing (14.3%; men, 47.7%; $P = 0.001$).

Definitive S-ICD explantation without reimplantation occurred in 97 women (8.4%) and 290 men (7.7%; $P = 0.489$), most commonly for complications (43 [3.7%] in women vs 126 [3.3%] in men; $P = 0.449$). Leading indications for explant in women were local infection ($n = 20$ [1.7%]), inappropriate shock ($n = 9$ [0.8%]), and chronic pain ($n = 9$ [0.8%]) (differences vs men were not significant except for chronic pain) (**Supplemental Table 5**).

Heart transplantation was performed in 30 women (2.6%) and 79 men (2.1%; $P = 0.310$). Overall, 95 women (8.3%) and 452 men (12.0%) died during follow-up ($P < 0.001$) (**Table 2**). After adjustment, mortality was lower in women (aHR: 0.66; 95% CI: 0.52-0.83; $P < 0.001$). Cardiovascular causes accounted for 49 deaths (51.6%) in women and 234 (51.8%) in men ($P = 0.01$), predominantly progressive heart failure in women (39 of 49 [79.6%]); sudden cardiac death represented 5 of 49 (10.2%). Noncardiovascular causes accounted for 31 deaths (32.6%) in women; the distribution was similar in men. Deaths related to S-ICD-unresponsive sudden death or device-related complications did not differ between sexes.

DISCUSSION

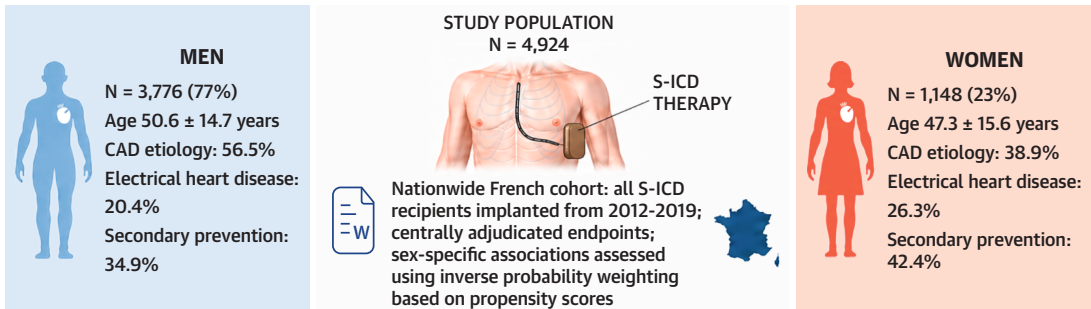
In this prespecified analysis of the nationwide HONEST cohort, capturing nearly all S-ICD implants in France from 2012 through 2019, we show that the benefit-risk profile of S-ICD therapy differs substantially between women and men. Women represented less than one-quarter of recipients,

TABLE 2 Appropriate, Inappropriate Shocks and Complications During Follow-Up: Nonadjusted Analysis

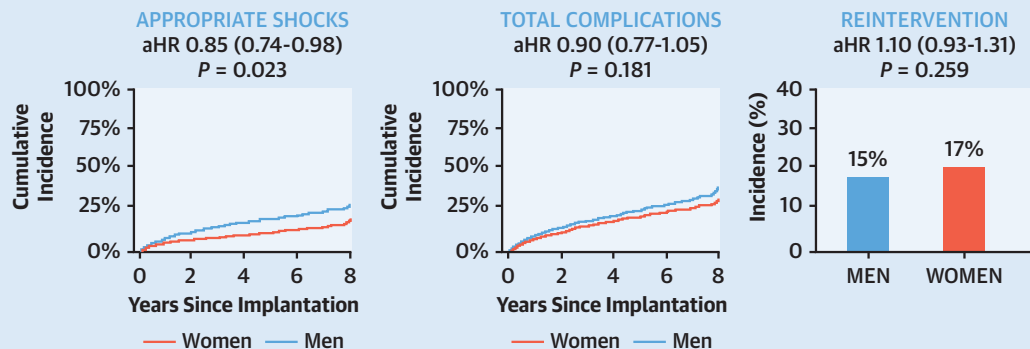
	Women (n = 1,148)		Men (n = 3,776)		P Value
	No. of Events	No. (%) of Subjects	No. of Events	No. (%) of Subjects	
Complications	447	302 (26.3)	1,794	1,012 (26.8)	0.740
Inappropriate shocks	191	97 (8.5)	1,073	484 (12.8)	<0.001
Local complications	74	67 (5.8)	196	176 (4.7)	0.099
Infection	35	34 (3.0)	81	79 (2.1)	0.079
Pocket hematoma	18	18 (1.6)	65	62 (1.6)	0.885
Poor wound healing	19	19 (1.7)	39	39 (1.0)	0.081
Other complications	2	2 (0.2)	11	11 (0.3)	0.221
Lead complications	24	24 (2.1)	45	44 (1.2)	0.019
Lead dislodgment	16	16 (1.4)	18	18 (0.5)	0.001
Lead fracture	3	3 (0.3)	14	14 (0.4)	0.777
Lead noise	4	4 (0.4)	4	4 (0.1)	0.092
Other	1	1 (0.1)	9	9 (0.2)	0.756
Recalls/battery depletions	111	110 (9.6)	374	371 (9.8)	0.808
Early battery depletion	109	108 (9.4)	356	354 (9.4)	0.973
Recall	2	2 (0.2)	18	17 (0.5)	0.277
Chronic pain	31	31 (2.7)	35	35 (0.9)	<0.001
Other complications	16	16 (1.4)	71	69 (1.8)	0.323
Complications requiring intervention	217	191 (16.6)	614	568 (15.0)	0.190
Inappropriate shocks	11	11 (1.0)	78	75 (2.0)	0.020
Local complications	51	36 (3.1)	106	88 (2.3)	0.127
Infection	39	28 (2.4)	76	60 (1.6)	0.056
Pocket hematoma	3	2 (0.2)	4	3 (0.1)	0.328
Poor wound healing	7	5 (0.5)	16	13 (0.3)	0.584
Lead complications	19	19 (1.7)	37	36 (1.0)	0.043
Lead dislodgment	12	12 (1.0)	11	11 (0.3)	<0.001
Lead fracture	3	3 (0.3)	14	14 (0.4)	0.777
Lead noise	3	3 (0.3)	4	4 (0.1)	0.206
Recalls/battery depletions	108	108 (9.4)	353	350 (9.3)	0.846
Early battery depletion	106	106 (9.2)	336	334 (8.8)	0.644
Recall	2	2 (0.2)	17	16 (0.4)	0.277
Chronic pain	20	18 (1.6)	13	13 (0.3)	<0.001
Other	8	8 (0.7)	27	27 (0.7)	0.952
Overall definite extractions	97	97 (8.4)	290	290 (7.7)	0.489
Definite S-ICD removal for Complications	43	43 (3.7)	126	126 (3.3)	0.449
Pacing need	28	28 (2.4)	107	107 (2.8)	0.434
Appropriate shocks	437	127 (11.1)	1,567	471 (12.5)	0.200
Heart transplantation	30	30 (2.6)	79	79 (2.1)	0.310
Death	95	95 (8.3)	452	452 (12.0)	<0.001
Death cause					
Cardiovascular	49	49 (4.3)	234	234 (6.3)	0.014
Progressive heart failure	39	39 (3.40)	176	176 (4.66)	0.067
Sudden cardiac death	5	5 (0.44)	18	18 (0.48)	0.858
Non-cardiovascular	31	31 (2.7)	114	114 (3.0)	0.576
S-ICD related	1	1 (0.1)	7	7 (0.2)	0.986
Unknown	14	14 (1.2)	97	97 (2.6)	0.007

The sections are defined by the **bold** headings.

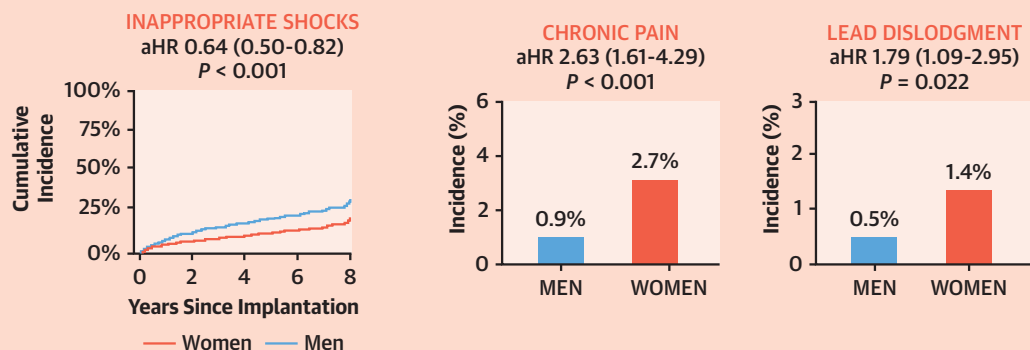
S-ICD = subcutaneous implantable cardioverter defibrillator.

CENTRAL ILLUSTRATION Subcutaneous Implantable Cardioverter-Defibrillator in Women**LOWER GLOBAL BENEFIT**

Lower risk of appropriate shocks, similar risk of total complications and reinterventions

**DIFFERENT COMPLICATION PROFILE**

Lower risk of inappropriate shocks, higher risk of chronic pain and lead dislodgement



Women receiving S-ICD therapy had a lower global benefit of defibrillation therapy with lower risk of appropriate therapy and a similar risk of complications as compared to men. However, complication profile was different with lower risk of inappropriate shocks but higher risk of chronic pain and lead dislodgement. These findings support a more tailored sex-specific approach to SCD prevention.

Garcia R, et al. JACC Clin Electrophysiol. 2026;■(■):■-■.

In the nationwide, all-comers French HONEST cohort (2012-2019) with central endpoint adjudication, sex-related differences in outcomes after subcutaneous implantable cardioverter-defibrillator (S-ICD) implantation were assessed by using propensity score-based inverse probability weighting. Among 4,924 recipients, 1,148 (23.3%) were women. Over 5 years, women had fewer appropriate shocks (aHR: 0.85) and lower all-cause mortality (aHR: 0.66), with similar overall complications and reinterventions compared with men. However, complication phenotypes differed: women had higher risks of chronic pain and lead dislodgement but fewer inappropriate shocks (aHR: 0.64). These findings support sex-informed counseling and follow-up strategies in S-ICD recipients. aHR = adjusted HR; CAD = coronary artery disease.

and, compared with men, more often received an implant for secondary prevention and more frequently had electrical heart disease (**Central Illustration**). Women experienced significantly fewer appropriate shocks, suggesting a lower incidence of ventricular arrhythmic events requiring device therapy during follow-up. In contrast, the overall burden of device-related complications and the need for reintervention were similar between sexes over 5 years, indicating that this lower arrhythmic event burden was not accompanied by a reduction in procedural or long-term risk. Importantly, although the global complication rate did not differ, the nature of complications varied markedly according to sex: women were more likely to experience chronic pain and lead dislodgment, whereas men had a higher risk of inappropriate shocks, largely driven by oversensing-related mechanisms. Together, these findings highlight a sex-specific trade-off between benefit and risk with S-ICD therapy and underscore the need for sex-informed approaches to patient selection, implantation strategy, and follow-up.

Whether women derive less benefit from ICD therapy remains debated.²⁵ Although ICD implantation is standard for prevention of sudden cardiac death in women, they have been underrepresented in randomized trials evaluating defibrillation efficacy.²⁶ Moreover, absolute benefit may be attenuated by a lower baseline risk of sudden cardiac death in women (lifetime risk ≈ 1 in 30 vs 1 in 9)²⁷⁻²⁹ and by a higher proportion of cardiac arrests presenting with nonshockable rhythms not amenable to ICD therapy.³⁰⁻³³ In pivotal S-ICD studies (PRAETORIAN [Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy], EFFORTLESS [Evaluation of Factors Impacting Clinical Outcome and Cost Effectiveness of the S-ICD], and UNTOUCHED [Understanding the Outcomes with the EMBLEM S-ICD in Primary Prevention Patients with Low Ejection Fraction]), sex-stratified analyses were uncommon, and sex-specific substrates were rarely detailed.^{9,34,35} Against this backdrop, the current finding of fewer appropriate shocks in women, most evident in structural heart disease and in primary prevention, extends prior observations from transvenous ICD cohorts to the S-ICD setting.

Device-related complications have historically been reported more frequently in women receiving transvenous ICDs, for which lead-related adverse events (eg, tamponade, pneumothorax) contribute substantially.^{18,36,37} In S-ICD recipients, vulnerability may shift toward anatomical and tissue-plane

determinants. Prior work by Gold et al³⁸ reported higher rates in women of discomfort, hematoma, device movement, and delayed incision healing. In the current cohort, early (≤ 30 days) complications were modestly more frequent in women, driven by local events, but this excess did not persist over longer follow-up. Over time, women experienced higher risks of chronic pain and lead dislodgment, whereas overall complication rates and the need for reintervention were broadly similar. Wound-related complications remained a leading reason for surgical revision, consistent with prior reports.³⁹⁻⁴¹ Although uncommon, chronic pain has already been recognized as a driver of reintervention.⁸ In the current study, chronic pain varied inversely with body mass index categories, suggesting a combination of anatomical and procedural contributors. Plausible mechanisms include a higher device-to-body-weight ratio, thinner subcutaneous tissue, and discomfort related to generator position, including potential bra-strap friction with axillary chest-wall placement. Technique refinements, including intermuscular pocketing, careful tunneling and fixation, and pocket positioning tailored to thoracic dimensions, may mitigate these risks. Similarly, the higher risk of lead dislodgment in women may relate to differences in thoracic dimensions, breast tissue and subcutaneous composition, and the stability of tunneling and pocket planes; anchoring within more adipose tissue may be less secure, and variable tissue thickness could influence sensing stability and pocket mechanics, with potential downstream effects on lead stability and defibrillation performance.^{21,42} These findings support heightened attention to fixation strategy, pocket selection (including intermuscular placement when feasible), and early wound surveillance in women.

Women had a 36% lower adjusted risk of inappropriate shocks than men, in contrast to transvenous ICD experience, in which inappropriate shock rates are generally similar between sexes.^{16,43} Prior S-ICD data suggested a similar direction of effect, although limited by few events.²⁰ Consistent with prior work,^{44,45} T-wave oversensing was the leading mechanism overall. Notably, the etiologic profile differed according to sex: in women, inappropriate shocks more often reflected T-wave oversensing and supraventricular tachycardia, plausibly related to sex differences in QT interval and T-wave morphology, and a higher prevalence of atrioventricular nodal re-entrant tachycardia.¹⁵ In men, myopotential oversensing and lead dysfunction were more frequent. These observations reinforce the importance of rigorous vector screening and periodic re-screening after physiological change, use of

morphology-discriminating filters (eg, Smart Pass), exercise provocation when T-wave oversensing is suspected, and meticulous attention to lead stability and pocket mechanics to minimize noise-related sensing artifacts.⁴⁶

Importantly, although women had lower all-cause mortality, this finding was not paralleled by lower rates of S-ICD-unresponsive sudden death or device-related mortality. Together with the higher incidence of appropriate shocks in men, these findings suggest that the observed survival difference is more likely driven by differences in underlying disease burden, comorbidity profile, and competing non-arrhythmic causes of death than by a sex-specific effect of the device itself.

STUDY LIMITATIONS. This nationwide study, leveraging near-complete device capture, long-term follow-up, deterministic linkage for vital status, and independent adjudication, provides the largest assessment to date of sex-specific outcomes among S-ICD recipients. Several limitations merit consideration. First, despite inverse probability weighting and adjustment for center clustering, the observational design remains susceptible to residual confounding. Although the propensity model incorporated a comprehensive set of baseline covariates, several potentially influential factors were not fully captured in the registry, and unmeasured confounders may have differentially affected key outcomes, including appropriate and inappropriate shocks, device-related complications, and mortality. Second, the study was not designed to compare effectiveness vs transvenous ICDs; therefore, no conclusions regarding comparative benefit can be drawn. Third, because this analysis reflects a French nationwide cohort, generalizability to other health care systems warrants consideration. Implantation techniques, device programming strategies, patient referral patterns, and follow-up practices may differ substantially across health care systems, and may influence both complication profiles and therapy outcomes in ways that limit direct extrapolation of our findings. Fourth, rationale for preferring an S-ICD over a transvenous device and device programming parameters, including detection zones and conditional discrimination algorithms, were not systematically collected in the HONEST cohort protocol. Finally, chronic pain is an inherently subjective endpoint. In this registry, it was based on clinician-documented follow-up information. Accordingly, some degree of variability in reporting and ascertainment across patients and centers

cannot be excluded. Nonetheless, the large sample size and near-complete national ascertainment yield robust and precise estimates of sex-specific outcomes in contemporary S-ICD practice.

CONCLUSIONS

In the nationwide HONEST cohort, women accounted for fewer than one-quarter of patients receiving an S-ICD and more often received an implant for secondary prevention and in the setting of electrical heart disease. Compared with men, women experienced fewer appropriate shocks, whereas the overall complication and reintervention rates were similar. Thus, a lower realized arrhythmic benefit of defibrillation therapy in women was not accompanied by a reduction in procedural or long-term risk. Importantly, although overall complication rates were comparable, the spectrum of complications differed according to sex: women were more likely to experience lead dislodgment and chronic pain but had a lower risk of inappropriate shocks. Together, these findings define a sex-specific benefit-risk profile of S-ICD therapy and support the integration of sex into patient counseling, implantation strategy, device programming, and long-term follow-up to optimize prevention of sudden cardiac death.

DATA AVAILABILITY STATEMENT Aggregated, de-identified summary data and additional methodological details are available from the corresponding author upon reasonable request, subject to approval by the relevant data protection and regulatory bodies.

ACKNOWLEDGEMENT The authors thank all the investigators who participated in the HONEST study (list in [Supplemental Table 1](#)).

FUNDING SUPPORT AND AUTHOR DISCLOSURES

This work was supported by the French National Institute of Health and Medical Research (INSERM), French Society of Cardiology, French Federation of Cardiology, and the Fondation pour la Recherche Médicale. Dr Garcia is a consultant for Boston Scientific, Biotronik, Abbott, Zoll and MicroPort. Dr Marijon is a consultant for Abbott, Boston Scientific, Medtronic, and Zoll. Dr Champ-Rigot is a consultant/speaker for Boston Scientific, Abbott, and Medtronic. Dr Pasquie is a consultant for Medtronic, Abbott, Boston Scientific, Biotronik, and MicroPort. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCE-

DURAL SKILLS: Women receiving an S-ICD present with a distinct clinical profile compared with men, including younger age, a higher prevalence of electrical heart disease, and more frequent secondary prevention indications. Clinicians should be aware that, despite similar overall complication and reintervention rates, women face significantly higher risks of chronic pain and lead dislodgment after S-ICD implantation. These procedure-related complications may prompt refinements in implantation technique and device positioning.

COMPETENCY IN MEDICAL KNOWLEDGE: In a large, nationwide cohort of S-ICD recipients, women exhibited a lower 5-year risk of appropriate shocks and inappropriate shocks compared with men, after adjustment for baseline confounders. All-cause mortality was also significantly lower in women, whereas deaths

attributable to S-ICD-unresponsive sudden cardiac death or device-related complications did not differ according to sex. These findings indicate that the benefit-risk profile of S-ICD therapy is sex dependent and that current evidence derived predominantly from male cohorts may not be fully generalizable to women.

TRANSLATIONAL OUTLOOK: The sex-specific differences identified in S-ICD outcomes underscore the need for prospective studies designed with adequate female representation to better characterize optimal candidate selection, procedural approaches, and programming strategies in women. Future research should investigate the anatomical, hormonal, and electrophysiological determinants of sex-related disparities in S-ICD complications (particularly chronic pain and lead stability) with the goal of developing evidence-based, sex-informed guidelines for sudden cardiac death prevention.

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KEY WORDS cardiac arrest, epidemiology, gender, prevention, sex, sudden cardiac death

APPENDIX For supplemental figures and tables, please see the online version of this article.