

ORIGINAL ARTICLE

Subcutaneous Implantable Defibrillators in Young Patients: Arrhythmias, Complications, and Physical Activity

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BACKGROUND: The safety of subcutaneous implantable cardioverter defibrillator (S-ICD) recipients who lead active lifestyles and engage in recreational sports is unknown. We aimed to evaluate the association between lifestyle and recreational sports and the occurrence of arrhythmia- and device-related complications, appropriate and inappropriate shocks in S-ICD recipients.

METHODS: We assessed a cohort of young-adult (15–65 years) S-ICD patients, evaluated their physical activity with IPAQ (International Physical Activity Questionnaire), and assessed the association between lifestyle and recreational sports on S-ICD safety and shocks.

RESULTS: We enrolled 602 S-ICD recipients (77% males; age, 46±14 years). According to the IPAQ, patients were categorized as inactive subjects (26.4%), moderately active subjects (45.2%), or highly active subjects (28.4%). Among moderately/highly active subjects, 163 (27.1%) were recreational athletes. During follow-up (47.3 [interquartile range, 27.0–67.6] months), 23 patients (3.8%) reached the safety end point of arrhythmia- or device-related complications, with moderately and highly active subjects showing in multivariate analysis similar incidence compared with inactive subjects ($P=0.59$ and $P=0.83$, respectively). Forty-four patients had 87 appropriate shocks. In multivariate analysis, moderately and highly active subjects showed a nonsignificantly lower incidence of appropriate shocks compared with inactive subjects ($P=0.12$ and $P=0.11$, respectively). Consistently, there was a nonsignificant lower incidence of appropriate shocks in athletes versus nonathletes ($P=0.06$). Thirty-nine patients had 46 inappropriate shocks. Moderately and highly active subjects had similar incidence of inappropriate shocks compared with inactive subjects ($P=0.92$ and $P=0.88$, respectively).

CONCLUSIONS: Young S-ICD patients often lead active lifestyles and participate in sports. Higher activity levels were not associated with increased implantable cardioverter defibrillator-related complications or increased risk of implantable cardioverter defibrillator shocks.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: arrhythmias, cardiac ■ follow-up studies ■ incidence ■ life style ■ sports

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WHAT IS KNOWN?

- Many athletes with transvenous implantable cardioverter defibrillators engage in sports without significant risk of complications, physical injury, or failure to terminate ventricular arrhythmia.
- There is limited information on the association between physical activity and the incidence of arrhythmia- or device-related complications in subcutaneous implantable cardioverter defibrillator recipients.

WHAT THE STUDY ADDS

- The majority of young individuals with subcutaneous implantable cardioverter defibrillators are at least moderately active, with nearly one-fourth regularly participating in recreational sports.
- Higher activity levels in young subcutaneous implantable cardioverter defibrillator recipients are not associated with an increased incidence of device-related complications or arrhythmias.
- Moderately/highly active subjects and recreational athletes tend to have lower incidence of appropriate shocks and do not show an increased incidence of inappropriate shocks.

Nonstandard Abbreviations and Acronyms

ARVC	arrhythmogenic right ventricular cardiomyopathy
ATLAS	Avoid Transvenous Leads in Appropriate Subjects
CAD	coronary artery disease
EF	ejection fraction
HR	hazard ratio
ICD	implantable cardioverter defibrillator
IPAQ	International Physical Activity Questionnaire
PRAETORIAN	Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator
S-ICD	subcutaneous implantable cardioverter defibrillator
VF	ventricular fibrillation
VT	ventricular tachycardia

Maintaining an active lifestyle and participating in recreational sports are widely acknowledged as essential for promoting the overall well-being and cardiovascular health.^{1,2} A significant proportion of young individuals with implantable cardioverter defibrillators (ICD) are actively involved in these pursuits. These individuals not only seek to maintain an active lifestyle

but also often aspire to engage in recreational sports activities, thereby necessitating a thorough understanding of the potential risks and benefits associated with such endeavors.³⁻⁶

Within the realm of ICD candidates, younger individuals face a heightened risk of long-term complications stemming from intravenous leads,⁷ making them prime candidates for adopting the subcutaneous ICD (S-ICD).⁸ Previous studies⁹⁻¹¹ described the experiences of competitive and recreational athletes with transvenous ICDs, reporting sport-related appropriate and inappropriate shocks but negligible risk of physical injury or arrhythmia termination failure while engaging in sports. However, the impact of physical activity and sports engagement on the risk of ventricular arrhythmias and appropriate shocks, inappropriate shocks, and device integrity has never systematically been explored in S-ICD recipients.

This study aims to fill this knowledge gap by assessing the outcomes of maintaining an active lifestyle and engaging in recreational sports among S-ICD recipients.

METHODS

Study Design and Patient Population



This study is a retrospective analysis of prospectively collected data of patients who underwent S-ICD (Boston Scientific, Inc, Natick, MA) implantation at 19 Italian centers participating in the Rhythm Detect Registry (<https://www.clinicaltrials.gov>; unique identifier: NCT02275637). At the centers, 1445 patients received an S-ICD between October 2013 and October 2022. Of these, 1236 patients were aged between 15 and 65 years and were considered eligible for this analysis. The lower age limit for enrollment was set at 15 years, as the IPAQ (International Physical Activity Questionnaire) is designed and validated for individuals older than this age. From October to December 2023, the centers were asked to consecutively contact the greatest number of patients from the list of the remaining 1192 surviving patients and invite them to complete 2 questionnaires: the IPAQ and an ad hoc questionnaire aimed at assessing the impact that the S-ICD implantation had on their physical and sporting activity. At the end of the data collection period, 602 contacted patients agreed to participate and constituted the population in analysis. The remaining 590 patients not included did not differ clinically from those in the analysis (age: 47±13 years, *P*=0.262; male gender: 78%, *P*=0.704; ejection fraction [EF]: 47±14, *P*=0.353). The institutional review board approved the study, and all patients provided written informed consent for data storage and analysis.

The data that support the findings of this study are available from the corresponding author upon reasonable request.

IPAQ and Sport Questionnaire

The IPAQ is a widely used tool for assessing physical activity levels. The IPAQ short-form is specifically designed for adults aged 15 to 69 years.¹² Participants were categorized into 3 qualitative groups based on their habitual physical activity levels¹³: highly active, moderately active, and inactive subjects.

In addition, we administered a Sport Questionnaire, which included several questions aimed at identifying patients engaging in systematic and regular sports activities and describing the impact of S-ICD implantation on their exercise programs. Specifically, it was designed to distinguish the psychological effects of the underlying heart disease from that of the defibrillator, regarding decisions to interrupt, reduce, or maintain an active lifestyle, including participation in sports. Patient questions are reported in Table S1. Based on the results of Sport Questionnaire, we identified a subset of recreational athletes. These patients self-identified as recreational athletes based on their regular and systematic engagement in ≥ 1 sports disciplines, for pleasure and leisure-time activity. To be classified as recreational athletes, patients were required to be moderately or highly active according to the IPAQ.

Follow-Up and End Points

The total follow-up time spanned from the implantation of the first S-ICD to the last contact with the patient for questionnaire completion. In cases where patients received multiple S-ICDs due to replacement, the follow-up began from the implantation of the first device. For patients who received an S-ICD after the extraction of a previous transvenous ICD, the follow-up started from the implantation of the S-ICD.

The primary end point was defined as the occurrence of (1) cardiac arrest or externally resuscitated tachyarrhythmia caused by shock failure, incessant ventricular arrhythmia, or postshock pulseless electric activity, (2) failure of the first maximum-energy shock to defibrillate, (3) any lead malfunction (defined as documented noise on the sensing vector or impedance rise compatible with lead fracture) or system inability to provide reliable sensing (ie, frequent occurrence of cardiac and noncardiac oversensing) that required system revision or explant, and (4) any lead- or device-related complication that required surgical reintervention (eg, pocket or sternal wound revision for hematoma, erosion, infection, pulse generator, or lead repositioning).

Secondary end points included (1) a number of appropriate and inappropriate shock episodes; (2) electrical storms, defined as >3 ventricular tachycardia (VT)/ventricular fibrillation (VF) episodes within 24 hours; and (3) recurrent inappropriate shocks, defined as multiple inappropriate shocks within 1 episode. All end points were adjudicated at the participating study centers.

Statistical Analysis

Continuous variables were presented as mean \pm SD or median (interquartile range) as appropriate. Categorical variables were presented as total number (percentage). The Student *t* test or Wilcoxon test was used to compare continuous variables. When comparing >2 groups, 1-way ANOVA or Kruskal-Wallis test was used, as appropriate. χ^2 or Fisher exact test was used to compare categorical variables, as appropriate. Kaplan-Meier curves and the log-rank test were used to assess cumulative events of the primary end point, appropriate and inappropriate shocks. The occurrence of end points was compared among the 3 groups of patients with different levels of physical activity (inactive, moderately active, and highly active subjects), as well as between recreational athletes and nonathletes. Recreational athletes and nonathletes were compared after 1:1 propensity

matching. To balance the patients' baseline clinical characteristics, a 1:1 matched analysis was performed. The variables used for the matching model were all patients' baseline characteristics that were significantly different between the 2 groups compared in the study before propensity score matching; for the analysis, we used a caliper width equal to 0.2. Cox proportional hazards models were used to determine the risk of primary end point, appropriate and inappropriate shocks during the follow-up according to patient physical activity group. A level of $P < 0.05$ was considered for statistical significance. Data were analyzed with the R, version 3.6.2, software (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

We enrolled 602 S-ICD recipients (77% males; age, 46 ± 14 years). Common diagnoses included hypertrophic cardiomyopathy (24%), ischemic heart disease (20%), and idiopathic dilated cardiomyopathy (17%; Table 1).

The IPAQ was administered on average 47.2 (interquartile range, 26.2–67.5) months post-S-ICD implantation. According to the questionnaire results, patients were classified as inactive ($n=159$; 26.4%), moderately active ($n=272$; 45.2%), and highly active subjects ($n=171$; 28.4%; Figure 1A). One hundred sixty-three (27.0%) moderately or highly active subjects reported to be regularly practicing a sport and constituted the subgroup of recreational athletes.

The most prevalent sports are reported in Figure 1B. Demographic and clinical characteristics are shown in Table 1 for inactive, moderately active, and highly active patients, and for recreational athletes versus nonathletes. Patients with higher activity levels and recreational athletes were more commonly males, had younger age, had higher EF, and were less frequently affected by coronary artery disease (CAD; Table 1).

Questionnaires

There were 87 (14.4%) patients who experienced a reduction in their physical activities following the implantation of the S-ICD. Others experienced some reduction in physical engagement due to the underlying heart disease ($n=200$; 33.2%), no reduction at all ($n=184$; 30.6%), or an increase in physical/sports activity ($n=60$; 9.9%) following S-ICD implantation (Figure 1C). Among recreational athletes ($n=163$), the majority ($n=113$; 69.3%) maintained their type of sport and regular exercise programs unchanged after S-ICD implantation.

Primary End Point

During follow-up (47.3 [interquartile range, 27.0–67.6] months), 23 (3.8%) patients reached the primary end point. Of these, 1 patient had externally resuscitated tachyarrhythmia due to multiple shock failures, 2 had at least 1 shock failure, and 20 had lead- or device-related

Table 1. Demographic and Clinical Characteristics and Device Programming According to IPAQ Categories and Sport Participation

	Total (602)	IPAQ groups			P value	Nonathletes (439)	Athletes (163)	P value
		Inactive (159)	Moderate (272)	High (171)				
Age, y	46±14	49±14	46±13	44±14	0.002	47±14	43±13	<0.001
Male sex, n (%)	463 (76.9)	109 (68.6)	209 (76.8)	145 (84.8)	0.002	327 (74.5)	136 (83.4)	0.02
Underlying heart disease, n (%)								
CAD	121 (20.1)	42 (26.4)	57 (21.0)	22 (12.9)	0.007	96 (21.9)	25 (15.3)	0.09
Dilated cardiomyopathy	102 (16.9)	26 (16.4)	46 (16.9)	30 (17.5)	0.97	88 (20.0)	14 (8.6)	<0.001
HCM	145 (24.1)	35 (22.0)	62 (22.8)	48 (28.1)	0.36	103 (23.5)	42 (25.8)	0.59
ARVC	60 (10.0)	14 (8.8)	32 (11.8)	14 (8.2)	0.41	38 (8.7)	22 (13.5)	0.09
Channelopathy	86 (14.3)	17 (10.7)	41 (15.1)	28 (16.4)	0.30	51 (11.6)	35 (21.5)	0.004
Congenital heart disease	15 (2.5)	5 (3.1)	7 (2.6)	3 (1.8)	0.71	11 (2.5)	4 (2.5)	0.99
Myocarditis	14 (2.3)	4 (2.5)	8 (2.9)	2 (1.2)	0.51	11 (2.5)	3 (1.8)	0.77
Valvular heart disease	11 (1.8)	5 (3.1)	3 (1.1)	3 (1.8)	0.26	9 (2.1)	2 (1.2)	0.74
Other	48 (8.0)	11 (6.9)	16 (5.9)	21 (12.3)	0.06	32 (7.3)	16 (9.8)	0.31
Primary prevention	491 (81.6)	131 (82.4)	223 (82.0)	137 (80.1)	0.84	367 (83.6)	124 (76.1)	0.04
Intermuscular/submuscular S-ICD implantation	492 (81.7)	129 (81.1)	232 (85.3)	131 (76.6)	0.07	353 (80.4)	139 (85.3)	0.19
Previous TV-ICD implantation	78 (13.0)	21 (13.2)	39 (14.3)	18 (10.5)	0.50	59 (13.4)	19 (11.7)	0.68
EF, %	54 (33–61)	49 (32–60)	53 (32–61)	56 (35–61)	0.08	48 (32–60)	60 (36–61)	<0.001
β-Blocker therapy	406 (67.4)	114 (71.7)	184 (67.6)	108 (63.2)	0.25	320 (72.9)	86 (52.8)	<0.001
Atrial fibrillation	68 (11.3)	25 (15.7)	26 (9.6)	17 (9.9)	0.14	51 (11.6)	17 (10.4)	0.77
3-incision technique	43 (7.1)	8 (5.0)	23 (8.5)	12 (7.0)	0.43	31 (7.1)	12 (7.4)	0.86
VT conditional zone, bpm	210 (200–220)	210 (200–220)	210 (200–220)	210 (200–220)	0.79	210 (200–220)	210 (200–220)	0.76
VF zone, bpm	250 (240–250)	250 (240–250)	250 (240–250)	250 (240–250)	0.55	250 (240–250)	250 (240–250)	0.29
Observation period, mo	47.3 (27.0–67.5)	42.3 (26.0–62.0)	49.3 (29.5–66.9)	52.7 (26.8–70.6)	0.06	47.3 (29.1–67.3)	48.3 (25.2–68.2)	0.93

ARVC indicates arrhythmogenic right ventricular cardiomyopathy; CAD, coronary artery disease; EF, ejection fraction; HCM, hypertrophic cardiomyopathy; IPAQ, International Physical Activity Questionnaire; S-ICD, subcutaneous implantable cardioverter defibrillator; TV-ICD, transvenous implantable cardioverter defibrillator; VF, ventricular fibrillation; and VT, ventricular tachycardia.

complications requiring reintervention (Figure 2). The patient requiring resuscitation was a male diagnosed with arrhythmogenic right ventricular cardiomyopathy (ARVC) who experienced an electrical storm with multiple ineffective S-ICD shocks, which required resuscitation and external defibrillation. This clinical event occurred at rest, 46 months after S-ICD implantation. The patient was in the inactive subject's group and did not practice any regular exercise. Two patients had an episode of VT requiring multiple shocks for cardioversion. The first patient experienced VT at rest, and 3 shocks were required for cardioversion. The second patient experienced VT during a mild physical activity, and 2 shocks were required.

There were 20 device-related complications. Seven patients had pocket revision for hematoma, erosion, or severe discomfort, and 3 patients underwent device extraction for infection. Two highly active patients (1 athlete) experienced lead dislodgement. Four patients (all moderately or highly active, including 2 athletes) required revision for noncardiac oversensing due to detectable

myopotentials, and 4 additional patients (all moderately or highly active, including 2 athletes) reported lead failure.

Overall, 7 (4.1%) primary end-point patients were highly active, 10 (3.7%) were moderately active, and 6 (3.8%) were inactive ($P=0.90$). All lead-related complications (dislodgement and failure, $n=6$) and oversensing requiring device revision ($n=4$) occurred in moderately or highly active subjects ($P=0.05$ versus inactive subjects), with 5 of them being recreational athletes (2 speed walking, 2 fitness/gym, and 1 running; Figure 2).

The 5-year cumulative rate of the primary end point was similar among inactive (5.6% [95% CI, 0.8%–10.1%]), moderately active (5.2% [95% CI, 1.6%–8.7%]), and highly active subjects (4.4% [95% CI, 0.8%–7.8%]; $P=0.93$; Figure 3A). After adjusting for age, sex, CAD, EF, and intermuscular and 2/3-incision technique of implantation, moderately active (hazard ratio [HR], 0.75 [95% CI, 0.27–2.11]; $P=0.59$) and highly active subjects (HR, 0.88 [95% CI, 0.28–2.73]; $P=0.83$) had similar risk of arrhythmia- or device-related primary end point as compared with inactive subjects.

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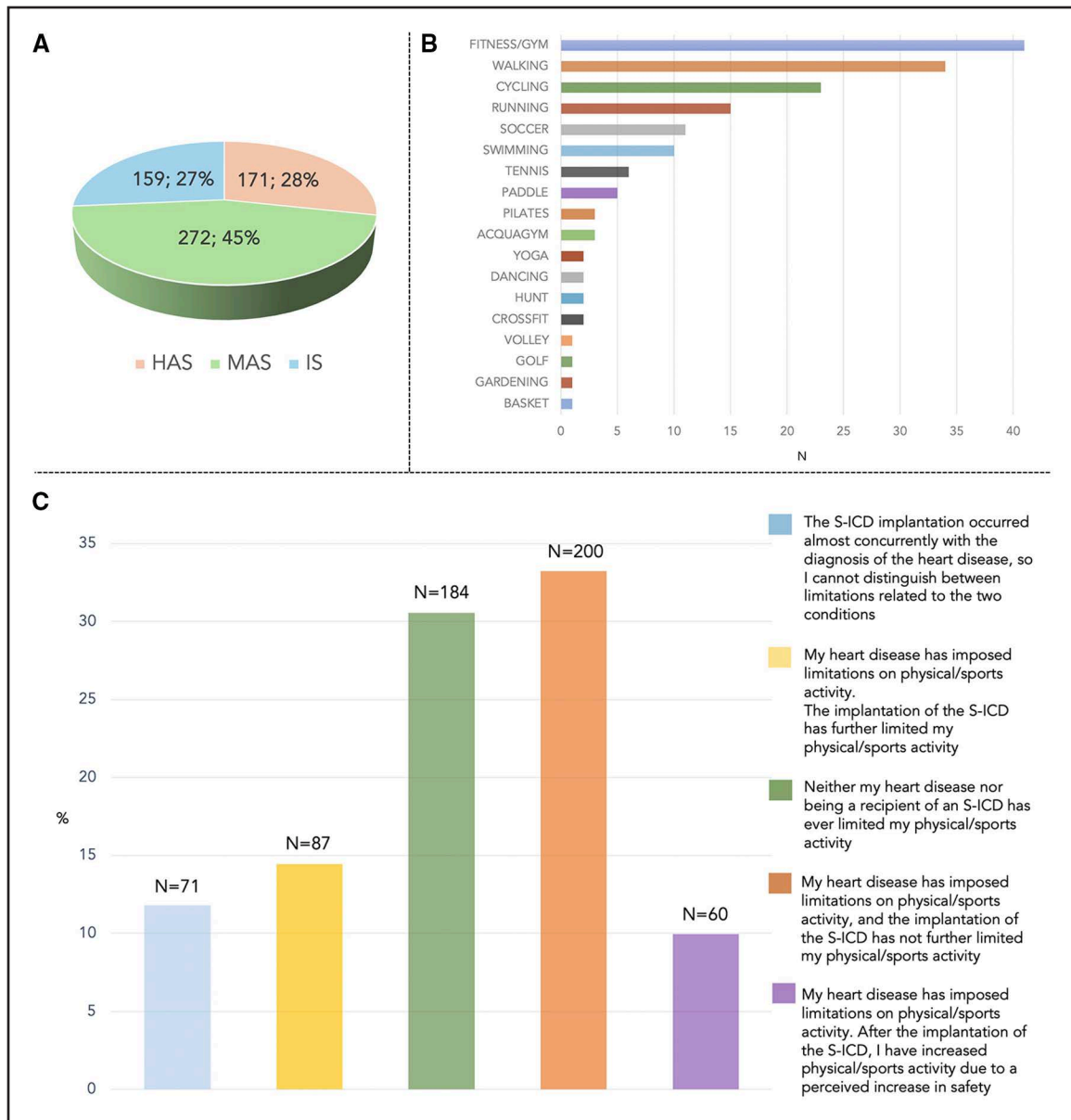


Figure 1. xxx.

A, The pie chart indicates the distribution of the study population into inactive subjects (IS), moderately active subjects (MAS), and highly active subjects (HAS). Both absolute numbers and relative percentages are reported. **B**, Sports practiced by the 163 recreational athletes (absolute numbers). **C**, Distribution of the population according to the impact that heart disease or subcutaneous implantable cardioverter defibrillator (S-ICD) have had on physical/sports activity.

In the matched cohorts, recreational athletes (n=163) were matched 1:1 to the nearest nonathlete pair by gender (males, 86% versus 83%; $P=0.64$), age (42.8 ± 13.2 versus 43.2 ± 13.5 ; $P=0.78$), dilated cardiomyopathy (10% versus 9%; $P=0.84$), channelopathy (20% versus 22%; $P=0.78$), EF (56 [35–62] versus 60 [37–61]; $P=0.41$), primary prevention indication (83% versus 76%; $P=0.16$), and drug therapy with β -blockers (61% versus 53%; $P=0.21$). The 5-year cumulative rate of arrhythmia- or device-related primary end point was similar among recreational athletes (5.5% [95% CI, 0.6%–10.2%]) and

matched nonathletes (7.4% [95% CI, 1.9%–12.6%]; $P=0.41$; Figure 3B).

Appropriate Shocks

During follow-up, 44 (7.3%) patients experienced 78 discrete VT/VF episodes and 9 electrical storms treated with appropriate shocks. Total appropriate shock episodes that occurred at any time were comparably distributed among inactive, moderately active, and highly active subjects (Table 2), and the 5-year cumulative rate of first appropriate shock showed a similar trend (inactive,

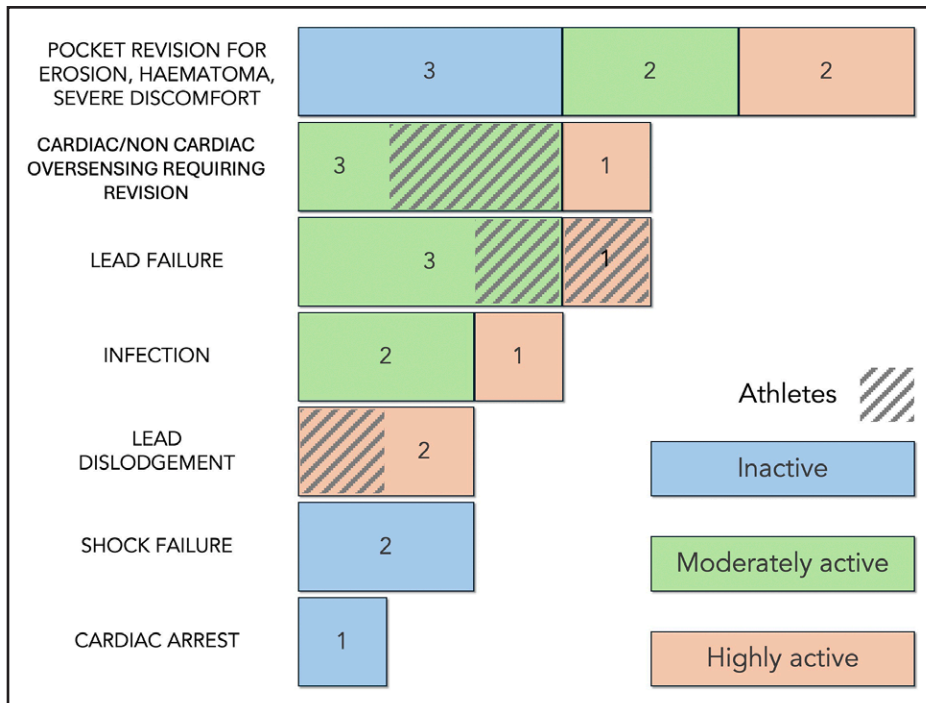


Figure 2. The chart depicts the distribution of complications composing the primary end point among inactive subjects (IS), moderately active subjects (MAS), highly active subjects (HAS), recreational athletes, and nonathletes. The color within each rectangle indicates the activity level of the patient (IS, MAS, and HAS), and the oblique lines texture identifies recreational athletes. Within each colored rectangle, the number indicates the number of patients with the specific complication.

12.3% [95% CI, 5.9%–18.3%]; moderately active, 9.3% [95% CI, 4.6%–13.7%]; and highly active, 6.4% [95% CI, 2.1%–10.4%]; $P=0.27$; Table 2; Figure 4A). In multivariate Cox regression, after adjusting for age, sex, CAD, and EF, moderately active (HR, 0.58 [95% CI, 0.29–1.16]; $P=0.12$) and highly active subjects (HR,

0.51 [95% CI, 0.22–1.15]; $P=0.11$) showed a nonsignificant lower risk of appropriate shocks compared with inactive subjects. In the matched cohorts, recreational athletes showed a borderline-significant lower 5-year cumulative rate of appropriate shocks compared with nonathletes (3.9% [95% CI, 0.3%–7.4%] versus 12.3%

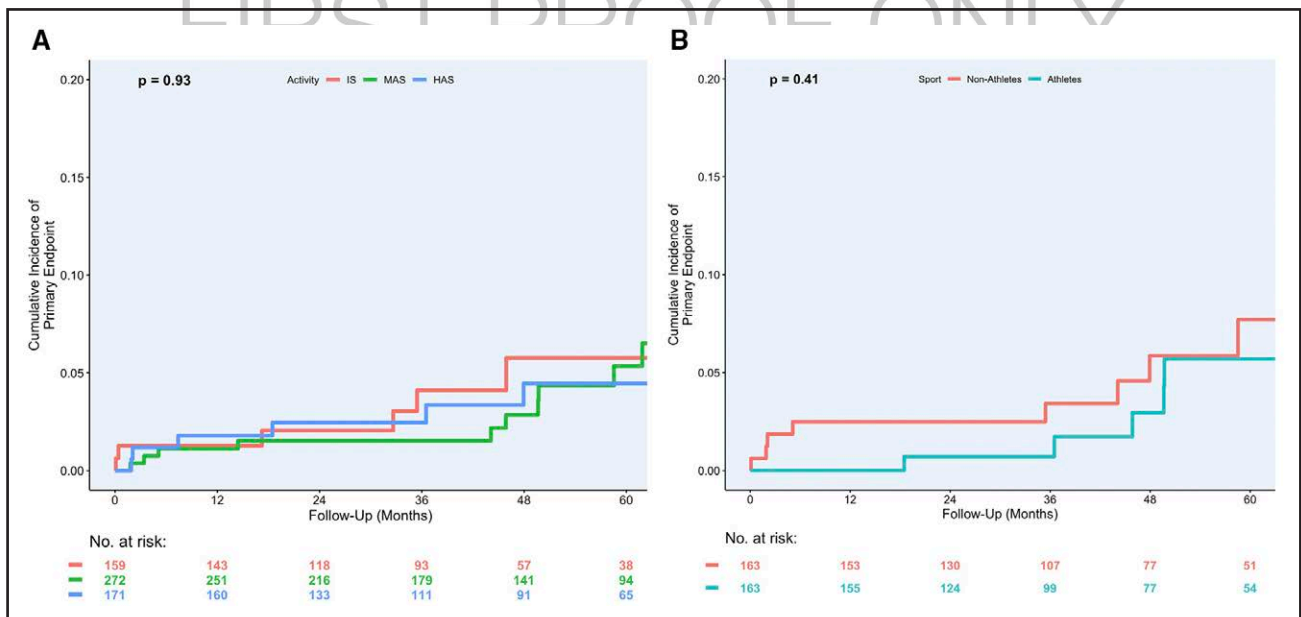


Figure 3. xxx. Kaplan-Meier curves showing time to arrhythmia- or device-related primary end point event in (A) inactive subjects (IS), moderately active subjects (MAS), and highly active subjects (HAS), and (B) recreational athletes vs nonathletes.

Table 2. Appropriate and Inappropriate Shocks According to IPAQ Categories and Sport Participation

	IPAQ categories						P value	Nonathletes (439)		Athletes (163)		P value
	Inactive (159)		Moderate (272)		High (171)			Episodes	Patients	Episodes	Patients	
	Episodes	Patients	Episodes	Patients	Episodes	Patients						
VT/VF with appropriate shocks	30	15 (9.4)	39	19 (7.0)	18	10 (5.8)	0.20	75	37 (8.4)	12	7 (4.3)	0.08
Inappropriate shocks	10	8 (5.0)	21	17 (6.2)	15	14 (8.2)	0.49	29	24 (5.5)	17	15 (9.2)	0.09
SVT/AF	3	3 (37.5)	1	1 (5.8)	4	4 (28.7)	0.12	7	7 (29.2)	1	1 (6.7)	0.09
TWO	3	3 (37.5)	3	3 (17.6)	1	1 (7.1)	0.20	4	4 (16.7)	3	3 (20.0)	0.79
NCO	4	2 (25)	12	9 (53.0)	8	7 (50.0)	0.39	15	10 (41.6)	9	8 (53.3)	0.47
NSVT	0	0	2	2 (11.8)	1	1 (7.1)	0.58	2	2 (8.3)	1	1 (6.7)	0.84
Not reported	0	0	3	2 (11.8)	1	1 (7.1)	0.58	1	1 (4.2)	3	2 (13.3)	0.29

P values refer to the proportions of patients. AF indicates atrial fibrillation; IPAQ, International Physical Activity Questionnaire; NCO, noncardiac oversensing; NSVT, nonsustained ventricular tachycardia; SVT, supraventricular tachycardia; TWO, T-wave oversensing; VF, ventricular fibrillation; and VT, ventricular tachycardia.

[95% CI, 5.5%–18.6%]; $P=0.06$; Table 2; Figure 4B). The single heart disease that was associated with a significant risk of appropriate shocks was ARVC (HR, 2.36 [95% CI, 1.13–4.92]; $P=0.02$). In particular, 9 of 60 (15%) patients with ARVC developed a total of 19 discrete episodes of VT/VF and 2 arrhythmic storms. Of these events, 10 (48%) occurred during intense physical activity ($n=8$) or sport practice ($n=2$).

Of 87 total appropriate shocks, 7 (8.0%) occurred during sports participation (soccer, $n=2$; basket, $n=2$; dancing, $n=1$; running, $n=1$; cycling, $n=1$), 22 (25.3%) during nonsporting physical activities, and 58 (66.7%) at rest.

Among 163 recreational athletes, 7 (4.3%) experienced 12 distinct appropriate shocks, with 3 (25.0%) occurring during sports activities, while of 439 nonathletes, 37 (8.4%) had 75 episodes of VT/VF treated with appropriate shocks, including 4 (5.3%) during physical exercise ($P=0.02$). The 9 electrical storms occurred in 7 patients (all nonathletes), of which 7 occurred at rest and 2 during nonsport physical activity. No patients experienced arrhythmic storms while engaging in sports. Syncope episodes occurred after 32 (36.8%) of 87 appropriate shocks, being more frequent after at-rest episodes (47.5%) than during any physical activity (14.3%) or while engaging in sports (14.3%; $P=0.01$).

Inappropriate Shocks

Thirty-nine (6.5%) patients experienced 38 discrete inappropriate shocks and 8 recurrent inappropriate shocks. Total inappropriate shock episodes ($n=46$) that occurred at any time were comparably distributed among inactive, moderately active, and highly active subjects (Table 2), and the 5-year cumulative rate of first inappropriate shocks was also similar (inactive, 6.2% [95% CI, 1.5%–10.6%]; moderately active, 6.8% [95% CI, 2.9%–10.5%]; and highly active, 8.5%

[95% CI, 3.6%–13.1%]; $P=0.70$; Table 2; Figure 4C). In multivariate Cox regression after adjusting for age, sex, CAD, EF, and history of atrial fibrillation, moderately active (HR, 1.04 [95% CI, 0.45–2.43]; $P=0.92$) and highly active subjects (HR, 1.07 [95% CI, 0.44–2.61]; $P=0.88$) had similar risk of inappropriate shocks as compared with inactive subjects. In the recreational athletes matched cohorts, the 5-year cumulative rate of inappropriate shocks was also comparable (8.9% [95% CI, 3.8%–13.8%] versus 7.9% [95% CI, 2.1%–13.3%]; $P=0.24$; Table 2; Figure 4D). There were no single underlying heart diseases that were associated with an increased risk of inappropriate shocks.

Of 46 inappropriate shock events, 9 (19.6%) occurred during sports participation (fitness/gym, $n=3$; treadmill, $n=2$; dancing, $n=1$; skydiving, $n=1$; soccer, $n=1$; trekking, $n=1$), 19 (41.3%) during nonsporting physical activities, and 18 (39.1%) at rest. Among 163 recreational athletes, 15 (9.2%) experienced 16 distinct appropriate shocks and 1 recurrent inappropriate shock, with only 4 (23.5%) occurring during sports activities, while of 439 nonathletes, 24 (5.4%) had 29 inappropriate shock episodes (22 discrete+7 recurrent inappropriate shocks), including 5 (17.2%) during physical exercise ($P=0.60$).

DISCUSSION

The main findings of this study are that most young S-ICD patients maintain active lifestyle and that those who are engaged in recreational sports do not exhibit a higher incidence of S-ICD–related complications or ICD shocks.

The majority of young individuals with S-ICDs in our cohort were at least moderately active, with nearly one-fourth regularly participating in recreational sports. Higher levels of activity and engagement in sports were

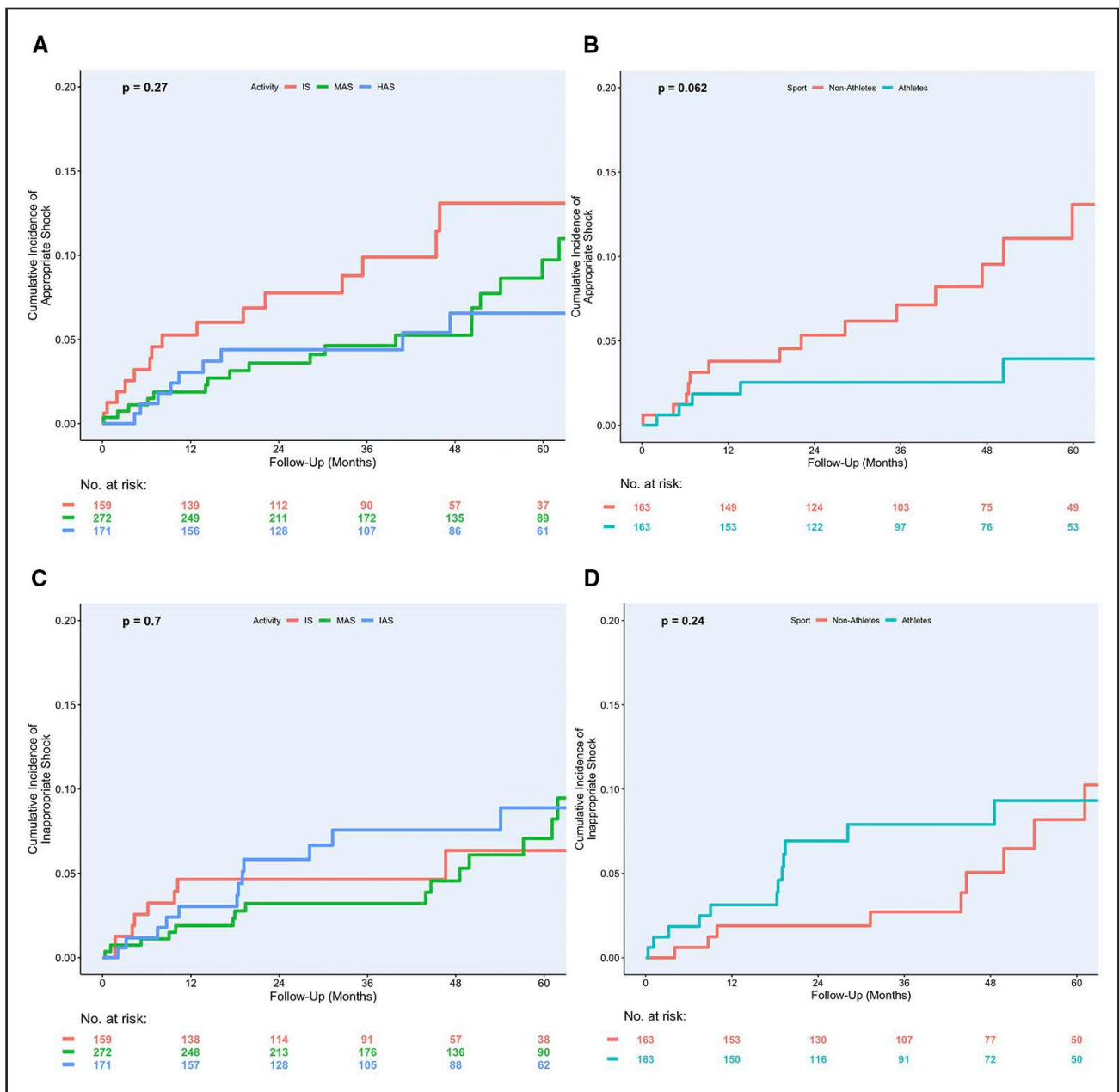


Figure 4. xxx.

Kaplan-Meier curves showing time to first appropriate therapy in (A) inactive subjects (IS), moderately active subjects (MAS), and highly active subjects (HAS), and (B) recreational athletes vs nonathletes. C and D show the time to first inappropriate therapy in the same subject categories.

associated with younger age, male sex, higher EF, and lower prevalence of CAD.

Most S-ICD patients perceived that their disease itself, rather than the implantation of the defibrillator, was the main factor limiting physical activity. In fact, for the vast majority of patients, the implantation of the S-ICD had either a neutral effect or enhanced their perception of safety, enabling them to engage in physical and sports activities with greater confidence. Indeed, both device-specific and generic quality-of-life outcomes were recently reported as favorable for S-ICD patients

enrolled in the ATLAS trial (Avoid Transvenous Leads in Appropriate Subjects).¹⁴ This acceptance of the device and the tendency to maintain an active lifestyle after implantation is broadly consistent with the previous findings from the Multinational ICD Sports Safety Registry,¹¹ in which only a minority of athletes stopped their sport activity due to incidence of shocks, suggesting that the negative impact of ICD therapies was outweighed by the benefits of continued sports participation.

Concerns about restricting ICD recipients from more than light sports activity include the risk of

exercise-triggered ventricular arrhythmias, shock failure in the context of autonomic and metabolic changes that occur during intense physical activity, the risk of injuries resulting from loss of control due to syncopal arrhythmias or shocks, and the possibility of damage to leads or the generator.¹⁴ The multinational ICD Sports Safety Registry investigated the risks associated with sports participation for transvenous ICD patients^{10,11} and found no deaths or arrhythmia- or shock-related physical injuries in a cohort of athletes who continued competitive or high-risk sports after ICD implantation. Ventricular arrhythmias requiring multiple shocks occurred in 2% of transvenous ICD patients, while electrical storms occurred in 2% of competitive athletes during physical activity and in none of the recreational athletes in the European cohort of the ICD Sports Safety Registry.¹¹ In our study, no occurrences of cardiac arrest, ineffective shocks, or arrhythmic storms were observed during sports activities, and there were no injuries as a direct consequence of traumatic events during sports participation. Indeed, the single episode of multiple ineffective shocks requiring external defibrillation and resuscitation occurred at rest. Moreover, only 1% of patients reported electrical storms, none of which occurred while engaging in sports. Finally, with only 3 (0.4%) patients reporting single or multiple shock failures, S-ICD 80J shock efficacy seems reassuring¹⁵ and in line with the general population of S-ICD recipients.¹⁶

Notably, we did not observe a significant difference in the incidence of the primary arrhythmia- and device-related composite safety end point across different physical activity levels or between recreational athletes and nonathletes. However, lead-related complications and oversensing requiring implant revision were predominantly observed in more active patients. This finding from our retrospective analysis is hypothesis generating and requires prospective confirmation.¹⁷

Due to the subcutaneous and anterior position of the parasternal S-ICD coil, lead-related complications resulting from direct impacts or collisions during sports practice were of particular concern. Nonetheless, we observed lead failure in only 4 (0.66%) patients over the 4-year follow-up period, a proportion that is lower than that reported in transvenous ICD competitive (4%) and recreational (3%) athletes over a 5-year follow-up.¹¹ This finding is in agreement with previous studies on cardiomyopathy patients^{18,19} and with the results of the PRAETORIAN trial (Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator)²⁰ and the ATLAS S-ICD trial,²¹ which demonstrated the noninferiority of S-ICD compared with transvenous ICD with respect to device-related complications and its superiority with respect to lead-related complications.

Overall, the proportion of patients with appropriate shocks did not differ according to physical engagement and was lower as compared with typical cohorts implanted

with transvenous ICDs (24). However, participation in recreational sports appeared to be associated with a reduced likelihood of receiving appropriate shocks. Of note, recreational athletes experienced arrhythmia episodes more frequently during sports participation compared with nonathletes. This is expected, as nonathletes are not regularly engaged in sports and only occasionally experience exercise-associated shocks, with the majority occurring at rest. Therefore, while exercise can acutely trigger ventricular arrhythmias in athletes,²² it is generally protective against sudden death.²³ Although this result should be interpreted with caution as it is derived from a retrospective analysis, it is consistent with the paradox of exercise²³ and is in line with previous observations.¹¹

As far as arrhythmia substrates are concerned, some heart diseases (eg, catecholaminergic polymorphic VT and idiopathic VF) are associated with a higher risk of physical activity-related ICD shocks,^{10,24} while in others (eg, ARVC) vigorous exercise may also impair myocardial function.²⁵ In our cohort, ARVC was associated with a higher risk of appropriate shocks, mostly during physical activity. Accordingly, our findings suggest significant caution in shared decision-making for advising sport participation in patients with ARVC.

Competitive athletes are known to receive more inappropriate shocks than recreational ones,^{10,11} particularly during physical activity. Furthermore, conflicting evidence suggests that certain structural heart diseases may raise per se the risk of inappropriate shocks in S-ICD recipients,^{26,27} and it is reasonable that physical exercise could further challenge the discrimination between ventricular arrhythmias, supraventricular rhythms, T wave, and myopotentials in these patients. In our study, no specific cardiovascular diagnosis was linked to an increased incidence of inappropriate shocks. Instead, we did not observe higher inappropriate shock rate in recreational athletes versus nonathletes. Of note, in our cohort of nonathletes, most inappropriate shocks were due to atrial arrhythmias, while in athletes, T-wave oversensing and noncardiac oversensing were more prevalent. Considering the preferential indication for S-ICD in young and active individuals, this pattern of inappropriate shocks suggests opportunities for improvements in S-ICD programming²⁸ and the development of algorithms that enhance VT/VF discrimination specificity.

Limitations

Our study has several limitations.

First, due to its retrospective design, we cannot definitely rule out the possibility of selection biases, such as the exclusion of patients who did not respond to the survey for various reasons (eg, lack of interest or motivation, concerns about privacy, or a negative experience with the device). However, we did not observe significant clinical differences between included and excluded patients.



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Second, all end points were adjudicated locally, and individual S-ICD interventions were analyzed and classified at the recruitment centers. This policy did not allow for a centralized analysis of either appropriate or inappropriate shock. Third, exercise levels were self-reported by the patients, without objective measures of physical activity, and the custom sport questionnaire lacks psychometric validation and should be interpreted with caution. Although the measurement properties of IPAQ have been shown to be acceptable,¹² and self-reported physical activity levels correlate with directly measured fitness,¹³ the use of more objective activity metrics is warranted to confirm our findings. Fourth, as all patients in this study are White, our results may not apply to all ethnicities. In addition, the long mean time of this survey from implantation prevents analysis of data early after the implant.

Lower activity might be associated with a worse underlying substrate and arrhythmia frequency. Therefore, the activity itself may not have a role in determining subsequent arrhythmia occurrence. Nonetheless, most enrolled patients reported no substantial lifestyle changes post-implantation, which supports the appropriateness of correlating IPAQ categorization with outcomes.

Finally, our study population may not be fully representative of all ICD-indicated patients involved in sports, especially those engaged in more intense or contact sports.

Conclusions

The majority of young S-ICD patients lead an active lifestyle, with almost a third regularly participating in recreational sports. Those who are more active and engaged in sports did not experience a higher incidence of arrhythmia- or ICD-related complications or incidence of appropriate shocks. Lead-related complications and oversensing were observed in more active patients or athletes. Overall, our findings support the trend in recent guidelines¹⁴ toward more permissive recommendations regarding sports participation for patients with an ICD and extend this approach to S-ICD patients. Furthermore, our results support the concept that, regardless of recreational sports participation, a physically active lifestyle is not associated with greater complications or arrhythmias.

ARTICLE INFORMATION

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Supplemental Material

Table S1
List of S-ICD Rhythm Detect Investigators

REFERENCES

- Nystoriak MA, Bhatnagar A. Cardiovascular effects and benefits of exercise. *Front Cardiovasc Med*. 2018;5:135. doi: 10.3389/fcvm.2018.00135
- Kyu HH, Bachman VF, Alexander LT, Mumford JE, Afshin A, Estep K, Veerman JL, Delwiche K, Lannarone ML, Moyer ML, et al. Physical activity and risk of breast cancer, colon cancer, diabetes, ischemic heart disease, and ischemic stroke events: systematic review and dose-response meta-analysis for the Global Burden of Disease Study 2013. *BMJ*. 2016;354:i3857. doi: 10.1136/bmj.i3857
- Ponamgi SP, DeSimone CV, Ackerman MJ. Athletes with implantable cardioverter defibrillators. *Clin Sports Med*. 2015;34:473–487. doi: 10.1016/j.csm.2015.03.010
- Marjion E, Uy-Evanado A, Reinier K, Teodorescu C, Narayanan K, Jouven X, Gunson K, Jui J, Chugh SS. Sudden cardiac arrest during sports activity in middle age. *Circulation*. 2015;131:1384–1391. doi: 10.1161/CIRCULATIONAHA.114.011988
- Maron BJ, Doerer JJ, Haas TS, Tierney DM, Mueller FO. Sudden deaths in young competitive athletes: analysis of 1866 deaths in the United States, 1980–2006. *Circulation*. 2009;119:1085–1092. doi: 10.1161/CIRCULATIONAHA.108.804617
- Corrado D, Basso C, Rizzoli G, Schiavon M, Thiene G. Does sports activity enhance the risk of sudden death in adolescents and young adults? *J Am Coll Cardiol*. 2003;42:1959–1963. doi: 10.1016/j.jacc.2003.03.002
- Olde Nordkamp LR, Postema PG, Knops RE, van Dijk N, Limpens J, Wilde AA, de Groot JR. Implantable cardioverter-defibrillator harm in young patients with inherited arrhythmia syndromes: a systematic review and meta-analysis of inappropriate shocks and complications. *Heart Rhythm*. 2016;13:443–454. doi: 10.1016/j.hrthm.2015.09.010
- Bardy GH, Smith WM, Hood MA, Crozier IG, Melton IC, Jordaens L, Theuns D, Park RE, Wright DJ, Connelly DT, et al. An entirely subcutaneous

- implantable cardioverter-defibrillator. *N Engl J Med*. 2010;363:36–44. doi: 10.1056/NEJMoa0909545
9. Lampert R, Olshansky B, Heidbuchel H, Lawless C, Saarel E, Ackerman M, Calkins H, Estes NAM, Link MS, Maron BJ, et al. Safety of sports for athletes with implantable cardioverter-defibrillators: long-term results of a prospective multinational registry. *Circulation*. 2017;135:2310–2312. doi: 10.1161/CIRCULATIONAHA.117.027828
 10. Lampert R, Olshansky B, Heidbuchel H, Lawless C, Saarel E, Ackerman M, Calkins H, Estes NA, Link MS, Maron BJ, et al. Safety of sports for athletes with implantable cardioverter-defibrillators: results of a prospective, multinational registry. *Circulation*. 2013;127:2021–2030. doi: 10.1161/CIRCULATIONAHA.112.000447
 11. Heidbuchel H, Willems R, Jordaens L, Olshansky B, Carre F, Lozano IF, Wilhelm M, Müssigbrodt A, Huybrechts W, Morgan J, et al. Intensive recreational athletes in the prospective multinational ICD Sports Safety Registry: results from the European cohort. *Eur J Prev Cardiol*. 2019;26:764–775. doi: 10.1177/2047487319834852
 12. Craig CL, Marshall AL, Sjostrom M, Bauman AE, Booth ML, Ainsworth BE, Pratt M, Ekelund U, Yngve A, Sallis JF, et al. International Physical Activity Questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc*. 2003;35:1381–1395. doi: 10.1249/01.MSS.0000078924.61453.FB
 13. Minder CM, Shaya GE, Michos ED, Keenan TE, Blumenthal RS, Nasir K, Carvalho JA, Conceição RD, Santos RD, Blaha MJ. Relation between self-reported physical activity level, fitness, and cardiometabolic risk. *Am J Cardiol*. 2014;113:637–643. doi: 10.1016/j.amjcard.2013.11.010
 14. Pelliccia A, Sharma S, Gati S, Bäck M, Börjesson M, Caselli S, Collet JP, Corrado D, Drezner JA, Halle M, et al; ESC Scientific Document Group. 2020 ESC guidelines on sports cardiology and exercise in patients with cardiovascular disease. *Eur Heart J*. 2021;42:17–96. doi: 10.1093/eurheartj/ehaa605
 15. Biffi M, Bongiorno MG, D'Onofrio A, Manzo M, Pieragnoli P, Palmisano P, Ottaviano L, Perego GB, Pangallo A, Lavallo C, et al; "S-ICD Rhythm Detect" Investigators. Is 40 joules enough to successfully defibrillate with subcutaneous implantable cardioverter-defibrillators? *JACC Clin Electrophysiol*. 2021;7:767–776. doi: 10.1016/j.jacep.2020.11.001
 16. Gold MR, El-Chami MF, Burke MC, Upadhyay GA, Niebauer MJ, Prutkin JM, Herre JM, Kutalek S, Dinerman JL, Knight BP, et al; S-ICD System Post Approval Study Investigators. Postapproval study of a subcutaneous implantable cardioverter-defibrillator system. *J Am Coll Cardiol*. 2023;82:383–397. doi: 10.1016/j.jacc.2023.05.034
 17. Chorin E, Lampert R, Bijsterveld NR, Knops RE, Wilde AAM, Heidbuchel H, Krahn A, Goldenberg I, Rosso R, Viskin D, et al. Safety of sports for patients with subcutaneous implantable cardioverter defibrillator (SPORT S-ICD): study rationale and protocol. *Heart Rhythm O2*. 2024;5:182–188. doi: 10.1016/j.hroo.2024.01.007
 18. Francia P, Ziacchi M, Adduci C, Ammendola E, Pieragnoli P, De Filippo P, Rapacciuolo A, Rella V, Migliore F, Viani S, et al. Clinical course of hypertrophic cardiomyopathy patients implanted with a transvenous or subcutaneous defibrillator. *Europace*. 2023;25.
 19. Migliore F, Biffi M, Viani S, Pittorru R, Francia P, Pieragnoli P, De Filippo P, Bisignani G, Nigro G, Dello Russo A, et al. Modern subcutaneous implantable defibrillator therapy in patients with cardiomyopathies and channelopathies: data from a large multicentre registry. *Europace*. 2023;25.
 20. Knops RE, Olde Nordkamp LRA, Delnoy PHM, Boersma LVA, Kuschyk J, El-Chami MF, Bonnemeier H, Behr ER, Brouwer TF, Kaab S, et al; PRAETORIAN Investigators. Subcutaneous or transvenous defibrillator therapy. *N Engl J Med*. 2020;383:526–536. doi: 10.1056/NEJMoa1915932
 21. Healey JS, Krahn AD, Bashir J, Amit G, Philippon F, McIntyre WF, Tsang B, Joza J, Exner DV, Birnie DH, et al; ATLAS Investigators. Perioperative safety and early patient and device outcomes among subcutaneous versus transvenous implantable cardioverter defibrillator implantations: a randomized, multicenter trial. *Ann Intern Med*. 2022;175:1658–1665. doi: 10.7326/M22-1566
 22. Albert CM, Mittleman MA, Chae CU, Lee IM, Hennekens CH, Manson JE. Triggering of sudden death from cardiac causes by vigorous exertion. *N Engl J Med*. 2000;343:1355–1361. doi: 10.1056/NEJM200011093431902
 23. Maron BJ. The paradox of exercise. *N Engl J Med*. 2000;343:1409–1411. doi: 10.1056/NEJM200011093431911
 24. Ostby SA, Bos JM, Owen HJ, Wackel PL, Cannon BC, Ackerman MJ. Competitive sports participation in patients with catecholaminergic polymorphic ventricular tachycardia: a single center's early experience. *JACC Clin Electrophysiol*. 2016;2:253–262. doi: 10.1016/j.jacep.2016.01.020
 25. Saberniak J, Hasselberg NE, Borgquist R, Platonov PG, Sarvari SI, Smith HJ, Ribe M, Holst AG, Edvardsen T, Haugaa KH. Vigorous physical activity impairs myocardial function in patients with arrhythmogenic right ventricular cardiomyopathy and in mutation positive family members. *Eur J Heart Fail*. 2014;16:1337–1344. doi: 10.1002/ejhf.181
 26. Francia P, Olivetto I, Lambiasi PD, Autore C. Implantable cardioverter-defibrillators for hypertrophic cardiomyopathy: the times they are a-Changin'. *Europace*. 2021;24:1384–1394. doi: 10.1093/eurpace/euab309
 27. Migliore F, Viani S, Bongiorno MG, Zorzi A, Silveti MS, Francia P, D'Onofrio A, De Franceschi P, Sala S, Donzelli S, et al. Subcutaneous implantable cardioverter defibrillator in patients with arrhythmogenic right ventricular cardiomyopathy: results from an Italian multicenter registry. *Int J Cardiol*. 2019;280:74–79. doi: 10.1016/j.ijcard.2019.01.041
 28. Rordorf R, Viani S, Biffi M, Pieragnoli P, Migliore F, D'Onofrio A, Nigro G, Francia P, Ferrari P, Dello Russo A, et al. Reduction in inappropriate therapies through device programming in subcutaneous implantable defibrillator patients: data from clinical practice. *Europace*. 2023;25.