DESIGN PAPER

Safety of Sports for Patients with Subcutaneous Implantable Cardioverter Defibrillator (SPORT S-ICD): study rationale and protocol

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BACKGROUND Recent studies suggest that participation in recreational and even competitive sports is generally safe for patients with implantable cardioverter-defibrillators (ICDs). However, these studies included only patients with implanted transvenous ICD (TV-ICD). Nowadays, subcutaneous ICD (S-ICD) is a safe and effective alternative and is increasingly implanted in younger ICD candidates. Data on the safety of sport participation for patients with implanted S-ICD systems is urgently needed.

OBJECTIVES The goal of the study is to quantify the risks (or determine the safety) of sports participation for athletes with an S-ICD, which will guide shared decision making for athletes requiring an ICD and/or wishing to return to sports after implantation.

METHODS The SPORT S-ICD (Sports for Patients with Subcutaneous Implantable Cardioverter Defibrillator) study is an international, multicenter, prospective, noninterventional, observational study, designed specifically to collect data on the safety of sports participation among patients with implanted S-ICD systems who regularly engage in sports activities.

RESULTS A total of 450 patients will undergo baseline assessment including baseline characteristics, indication for S-ICD implantation, arrhythmic history, S-ICD data and programming, and data regarding sports activities. LATITUDE Home Monitoring information will be regularly transferred to the study coordinator for analysis.

CONCLUSION The results of the study will aid in shaping clinical decision making, and if the tested hypothesis will be proven, it will allow the safe continuation of sports for patients with an implanted S-ICD

KEYWORDS Implantable cardioverter-defibrillator; Subcutaneous ICD; Sports participation; Sudden cardiac death; Recreational sport; Competitive sports

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Introduction

Patients engaged in sports at the time of implantation of an implantable cardioverter-defibrillator (ICD) justifiably inquire about the risks involved with continuation of eventual sportive activities after device implantation.[1] Since 2015, eligibility and disqualification recommendations for competitive athletes with cardiovascular disease state that competitive sports may be considered for athletes with ICDs.[2] These recommendations are based on data demonstrating that continuation of sports with an implanted ICD is generally safe. Indeed, the Multinational ICD Sports Safety Registry showed that after a median follow-up of 44 months, there were no events of death or shock-related physical injury among 440 athletes who continued organized, competitive,

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KEY FINDINGS

- Data on the safety of sport participation for patients with implanted subcutaneous implantable cardioverter-defibrillator (S-ICD) systems are urgently needed.
- The SPORT S-ICD (Sports for Patients with Subcutaneous Implantable Cardioverter Defibrillator) study is an international, multicenter, prospective, noninterventional, observational study, designed specifically to collect data on the safety of sports participation among patients with implanted S-ICD systems.
- The results of the study will aid in shaping clinical decision making, and if the tested hypothesis is proven, it will allow the safe continuation of sports for patients with an implanted S-ICD.

or high-risk sports after ICD implantation.[3,4] Furthermore, a European substudy demonstrated that the risk of definite or probable lead malfunction is <9% at 10 years among patients who continued competitive or recreative sports after ICD implantation.[5] Finally, sports activity, other than perhaps intense weight lifting, has not been linked to an increased risk of ICD lead fracture.[6] All these data, however, relate exclusively to patients implanted with transvenous ICD (TV-ICD) systems.

Young ICD candidates, the patient subgroup more likely to engage in sports activities, are also the patient population that is most likely to receive a subcutaneous ICD (S-ICD) system.[7,8] This is because S-ICD systems decrease most of the long-term complications of intravenous leads.[9,10] However, there are also features of the system that could impact risk of system damage in the athlete. The long path of the subcutaneous electrode, from beyond the latissimus dorsi muscle (where the S-ICD is commonly implanted) through subcutaneous tissue in the lateral and anterior chest wall, could potentially increase the risk for electrodes fracture or far-field noise detection during strenuous sport.[11,12] Furthermore, sports with static and dynamic components involving chest and shoulder muscles, like weight lifting or swimming, and even sports that are traditionally considered safe for patients with heart disease and/or an implanted TV-ICD, like golf, could impose risk for patients with S-ICD because of the proximity of the active muscles to the site of S-ICD and electrode implantation. In addition, as the lead is located outside the thorax, whether the danger of lead damage from collision either with another player, or with a ball, is greater for an S-ICD than TV-ICD system is unknown.

Recent data suggest that the risk of inappropriate shocks from newer-generation S-ICD systems is very low.[13,14] In fact, a recent study suggested that the risk of receiving an inappropriate shock from an S-ICD is as low as that for patients with an implanted TV-ICD, even when the latter has optimal programming.[15,16] However, these recent studies did not specify the degree of sportive activities performed by S-ICD recipients, and whether failure to differentiate ventricular from supraventricular rhythm would be greater in those engaged in vigorous exercise is not known.

Clearly, data on the impact of athletic activities on the short- and long-term safety of S-ICD systems are urgently needed. This is particularly true because physicians may disfavor the selection of an S-ICD system for a young patient who intends to continue sport activities or may advise against performance of sports without data to support such recommendations. We therefore propose a multicenter observational study designed to collect data on the safety of sports activities in patients with implanted S-ICD systems.

Design

The SPORT S-ICD (Sports for Patients with Subcutaneous Implantable Cardioverter Defibrillator) study is an international, multicenter, prospective, observational study, designed to collect data on the safety of sport participation among patients with implanted S-ICD systems who regularly engage in sport activities. The study conforms to the Declaration of Helsinki, and ethical approval has been granted by the Tel Aviv Medical Center Research Ethics Committee. The study is registered in ClinicalTrials.gov (NCT05754138). The official website for the study is https://sport-sicd.org.

The goal of the study is to quantify the risks (or determine the safety) of sports participation for athletes with an S-ICD, which will guide shared decision making for athletes requiring an ICD and/or wishing to return to sports after implantation. The primary endpoints will include (1) arrhythmia-related primary endpoints (A: tachyarrhythmia-related death or externally resuscitated cardiac arrest due to S-ICD shock failure, incessant ventricular arrhythmia, or postshock pulseless electrical activity; B: injury requiring hospitalization, due to shock or syncopal arrhythmia; C: unexpected sudden death without arrhythmia documentation due to absence of device interrogation), and (2) S-ICD system–related primary endpoint (A: lead fracture leading to lead/device replacement; B: lead fracture/malfunction leading to S-ICD inactivation; and C: device repositioning).

The secondary endpoints will include (1) arrhythmia-related secondary endpoints (A: number of appropriate shocks [for ventricular tachyarrhythmia] and their relation to sport activity; B: number of inappropriate shocks [for supraventricular tachyarrhythmia] and their relation to sport activity; C: multiple shocks within 1 appropriate episode [ie, failure of first maximum-energy shock or recurrent arrhythmia], electrical storm (>3 events in 24 hours), or recurrent inappropriate shocks]; D: moderate injury [requiring emergency room visit] associated with a shock), 2. S-ICD–related secondary endpoints (A: inappropriate shock due to noise [and its relation to sport] leading to device reprogramming [if the inappropriate shock leads to S-ICD system (device/lead) replacement, this is a primary endpoint]; B: noise detected that does not lead to inappropriate shock but leads to device reprogramming), and (3) clinical

secondary endpoint (interruption or cessation of sports for reasons other than ICD shocks or ICD related complications).

Patient recruitment

Patient recruitment is from 2 sources (Figure 1). The first is recruitment via physicians, in which physicians/medical centers taking care of patients with an implanted S-ICD proceed to screen and recruit patients who fulfill the inclusion criteria (see the following) and are willing to provide informed consent. For enrolled patients, physicians provide coded (anonymous) demographic data, clinical data, and information on sportive activities at the time of enrollment. Follow-up data, collected periodically, include clinical data, sports participation, and adverse events (see the following). Data collected during follow-up are transmitted periodically by the recruiting physician at each of the participating centers to the Study Coordinating Center directly at the Tel Aviv Medical Center. The second is direct patient recruitment, in which patients with an implanted S-ICD are approached via existing patients' groups on social media (eg, the "Living with the S-ICD" group on Facebook [https://www.facebook.com/groups/livingwithSICD/]) and nonprofit organizations (https://sads.org/research/get-involved/sads-research-survey/). Also, physicians from participating institutions are invited to direct their patients to posted fliers advertising the study. Patients then approach the Study Coordinating Center directly. These patients are then invited by the Study Coordinating Center to participate in the screening process.

Eligibility

Inclusion and exclusion criteria are shown in Table 1. Eligible patients will provide written informed consent for participation in the study. For pediatric patients, parental consent will be obtained. The informed consent provided by the patient includes (1) permission to approach the clinical electrophysiologist taking direct care of the enrolling patient and his/her implanted device and (2) authorization (by the patient and their physician) to get access to the online data on device function and arrhythmia/noise detection that are transmitted weekly by the patient's device via the LATITUDE Home Monitoring System (Boston Scientific, Marlborough, MA) for home monitoring. Informed consent includes agreement to provide all the following information: (1) clinical data (age, sex, clinical diagnosis, indication for S-ICD implantation, arrhythmic events since S-ICD implantation, adverse events since S-ICD implantation), (2) type and level of exercise and sport participation at the time of inclusion and during follow-up, and (3) information concerning endpoint events during follow-up; and (4) for patients recruited via the direct recruitment, patient agrees to allow direct access to the patients' LATITUDE Home Monitoring System data, both at the time of inclusion and all weekly reports during the follow-up period, until the study ends or until the informed consent is revoked. Access to the personal LATITUDE Home Monitoring System data is in addition to the access by the primary treating physician and only for purpose of data collection for the study (Figure 2). Consent from the patient and for the primary treating physician (monitoring the patient's LATITUDE data) are required. Once the study ends, participating patients will be notified that the study investigators are no longer monitoring their LATITUDE Home Monitoring System.

Study group

The study population will consist of patients who have all the following characteristics: (1) they have an implanted S-ICD; (b) they exercise regularly, or actively participate in

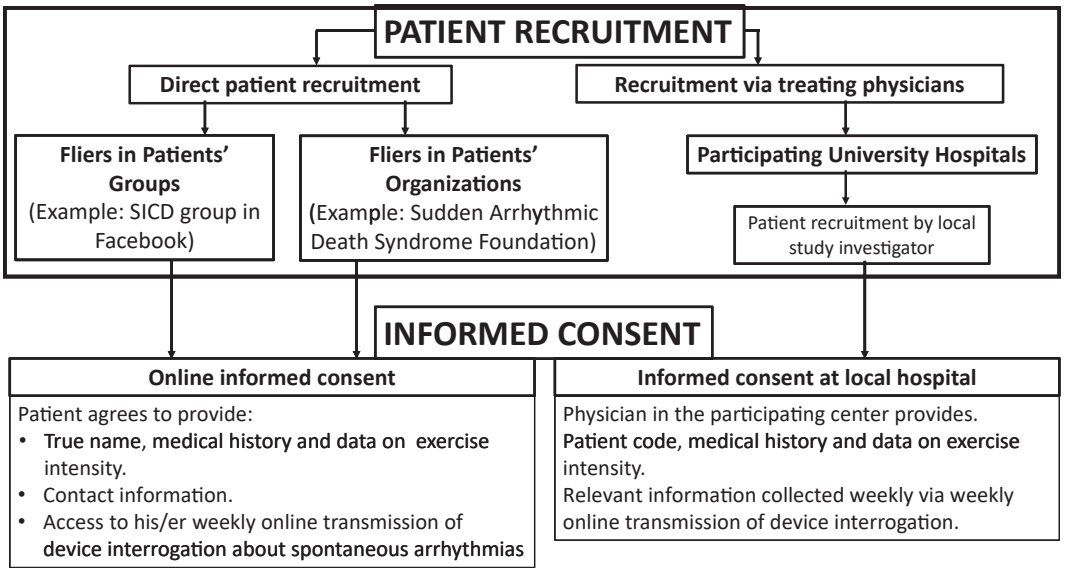


Figure 1 Patient recruitment strategies.

Table 1 Patient eligibility

Inclusion criteria. All the following inclusion criteria are mandatory for inclusion:
Patient (male or female) is <75 years of age.
Patient has an implanted, new-generation, S-ICD (Boston Scientific EMBLEM, Generations 2 [model A209], 3 [A219], or newer).
Patient has a functioning LATITUDE Home Monitoring System at home, knows how to use it, and sends weekly reports via the home-monitoring system.
Patient actively participates in sport activities above a predefined level of exercise.
Patient understands that, at present, there are virtually no data on the safety of sport participation for patients with implanted S-ICD system, particularly regarding potential damage caused by sport activities to the S-ICD system, including the subcutaneous electrode.
Patient understands that the level of sport activity, type of sport, and frequency of exercise activities are entirely at their own discretion and responsibility.
Patient understands that the Sport S-ICD study investigator neither encourages nor discourages performance of any given sport.
Patient understands that the Sport S-ICD study is not liable and does assume any responsibility for any damages caused by sport participation to the implanted system or the health of patients participating in the study.
Patient is willing to provide informed consent to participate in the Sport S-ICD study.
Exclusion criteria*
Subjects with an inability to communicate well with the investigators.
Subjects who are noncooperative or unwilling to sign informed consent form.
Evidence suggestive of malfunction of the implanted S-ICD system (like abnormal impedance or detected noise) at the time of screening.

S-ICD = subcutaneous implantable cardioverter-defibrillator; SPORT S-ICD = Sports for Patients with Subcutaneous Implantable Cardioverter Defibrillator.
*To avoid selection bias, evidence of a previous S-ICD appropriate shock for a sustained ventricular tachyarrhythmia and/or evidence of previous inappropriate shock for supraventricular tachyarrhythmia or for noise does not represent an exclusion criterion

competitive or recreational sports with a sport intensity above a predefined level (see the following); and (3) they wish to continue participating in recreational or competitive sport activities.

Definitions of type and level of exercise

According to the 2020 European Society of Cardiology Guidelines on Sports Cardiology and Exercise in Patients with Cardiovascular Disease,[15] competitive athletes exercise ≥6 h/wk and recreational athletes exercise ≥4 h/wk. For the present study, the minimal level of exercise required for inclusion is (1) the equivalent of recreational sports, that is, an average exercise time of ≥4 h/wk; and (2) exercise of ≥2 h/wk if the exercise involves any of forceful and/or repetitive movements of the pectoral girdle (eg, weight lifting, "pushup," "pullover," or pullup" exercises), repetitive single-arm movements (like tennis or Ping-Pong) in left-handed patients (that is, repetitive arm movements in the arm at the site of S-ICD implantation, contact sports that involve substantial risk of collision (including sports like soccer or football and sports like judo or wrestling). The type of sport and the level, frequency, and intensity of sports is decided by participating individuals.

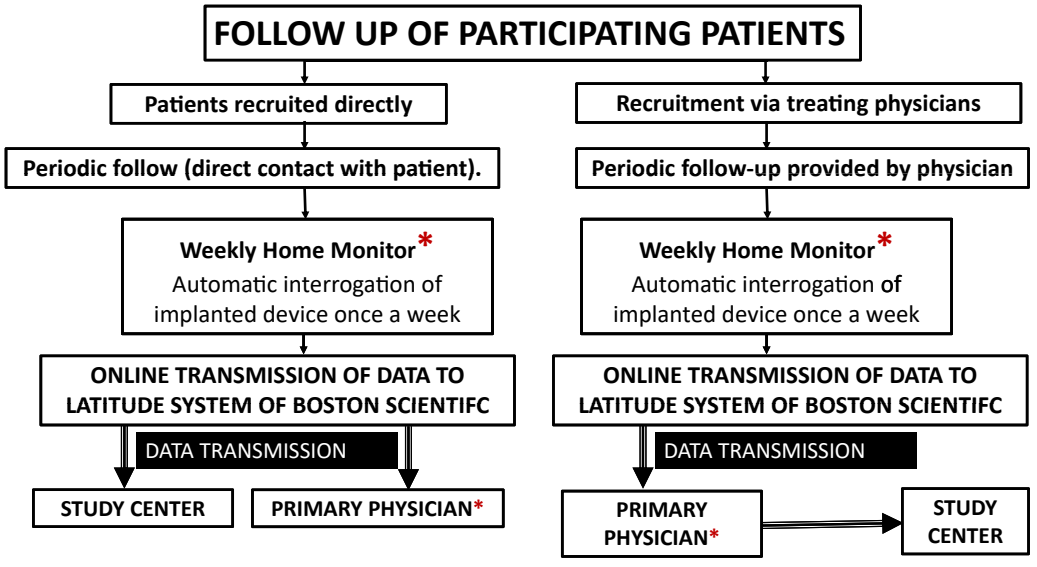


Figure 2 Patient follow-up flowchart.

Table 2 Data collected when entering the study

Gender
Date of birth
Right-handed/left-handed
Underlying heart disease
Coronary heart disease
Dilated cardiomyopathy
Hypertrophic cardiomyopathy
Arrhythmogenic cardiomyopathy
Long QT syndrome
Brugada syndrome
CPVT
Short QT syndrome
Idiopathic ventricular fibrillation
Indication for S-ICD implantation
Cardiac arrest
Syncope
Prophylactic
Arrhythmic history
Arrhythmias since your S-ICD implantation
Received 1 or more S-ICD shock for ventricular arrhythmias
S-ICD data and programming
Is this your first defibrillator?
Any signs of S-ICD or lead malfunction in your device?
S-ICD defibrillator model
S-ICD defibrillator serial number
Electrode serial number
Programmed parameters in your S-ICD

CPVT = catecholaminergic polymorphic ventricular tachycardia; S-ICD = subcutaneous implantable cardioverter-defibrillator.

Data collection

Data collected at the time of recruitment and at every follow-up (every 3 months) are shown in Tables 2 and 3. Information that will be collected on a weekly basis via the LATITUDE Home Monitoring System is shown in Table 4. Each event will be interrogated regarding programming characteristics, circumstances (during sport or not), system position, high voltage system impedance, and management.

Estimated number of participants

A total of 450 patients with an implanted S-ICD who continue to exercise after implantation is the estimated number of participants. The number of participants is not defined by risk estimation, but rather reproduces the number of patients who participated in the ICD Sports Safety Registry of athletes with TV-ICD,[3] which will facilitate ultimate comparison of the data on risks of S-ICD and TV-ICD in athletes.

The study is funded by Boston Scientific, which has no role in the design of the study, analysis of the data, or drafting and submission of this or subsequent manuscripts.

Discussion

Until recently, consensus documents recommended avoidance of moderate- and high-intensity sports for athletes with ICDs because data on the safety and efficacy of ICDs during competition were unavailable, raising concerns about increased risk.[17–19] In the absence of data, guideline recommendations for patients with ICDs willing to participate in sport activities were based exclusively on expert opinion. As a general rule, only those who had been free of arrhythmic events for at least 6 months were allowed to participate in competitive sports. Furthermore, participation was permitted only in sports involving low cardiovascular demands, limited chance for high-impact contact, and minimal risk for injury if syncope were to occur during play (eg, billiards, bowling, and golf).

During the last decade, growing evidence suggests that risks of sports participation for athletes with TV-ICDs may be lower than hypothesized. The Multinational ICD Sports Safety Registry followed 440 athletes with ICDs 10 to 60 years of age who participated in organized sports (in spite of the standing recommendations) for a median of 44 months.[3,4] Even though appropriate and inappropriate shocks occurred during sports, there were no deaths, resuscitated arrests, or arrhythmia-related injury during sports. That study concluded that many athletes with an implanted TV-ICD can participate in vigorous or competitive sports without significantly increased risk of injury, inappropriate shocks or failure of appropriate shocks.[3,4] Similarly, a European study demonstrated that the risk of definite or probable lead malfunction is <9% at 10 years' follow-up among patients who continued competitive or recreative sports after TV-ICD implantation.[5]

All these data, however, relate exclusively to patients implanted with standard, TV-ICD systems. At present, there are no data regarding the safety of sports activities in patients with implanted S-ICD systems. The course of the implanted subcutaneous electrode in the S-ICD system beneath important chest muscles creates, at least in theory, a potential risk for fracture during spots involving chest musculature.

The potential benefits of physical activity and sports participation should not be underestimated including decreased risk for obesity, metabolic syndrome, coronary artery disease, stroke, diabetes mellitus, and cancer. Furthermore, sport participation has an undeniable positive effect on mental health, decreased risk for depression, and improvement in feelings of well-being, all of which improve overall quality of life.[20] Many young patients experience decreased quality of life and distress after ICD implantation, often directly related to restriction from sports,[21] and continuation of sport activities may be particularly important for them.

The SPORT S-ICD is a multicenter observational study designed specifically to collect data on the safety of sport activities in patients with implanted S-ICD systems. The results of the study will aid in shaping clinical decision making, and if the tested hypothesis is proven, it will allow the safe continuation of sports for patients with an implanted S-ICD.

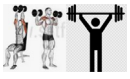
Table 3 Sport activities

Select from among the sport activities shown below all the activities that you practice on a regular basis (and number of hours per week on average).
You may select more than 1 activity and as many activates as you practice. Activities are listed by A-B-C and may be listed more than once.

Type of sport		
Badminton	Baseball	Basketball
Bicycling – mountain bicycling	Bicycling – road bicycling	Bicycling – stationary bicycling
Bowling	Cheerleading	Dancing – aerobic
Dancing – ballet/cultural	Dancing – ballroom	Dancing – other
Exercise (see list on gym/exercise below)	Fencing	Football (American football)
Football (soccer)	Golf	Gymnastics
Gym (see list on gym/exercise below)	Handball	Hiking
Horseback riding	Hockey	Ice hockey
Ice skating	Jogging	Judo
Karate	Kayaking	Lacrosse
Martial arts	Mountain climbing	Racquetball
Roller skating/blading	Rowing – boat	Rowing – stationary
Rugby	Running	Scuba diving
Skiing – water skiing	Skiing – snow skiing cross country	Skiing – snow skiing downhill
Skateboarding	Soccer	Softball
Squash	Surfing	Swimming – freestyle or front crawl
Swimming – breaststroke	Swimming – backstroke	Swimming – butterfly
Tennis	Water skiing	Weight lifting (see next below)
Windsurfing	Wrestling	Yoga

Weightlifting and gym exercises

Weight press



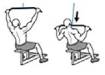
Weight lifting

Kettlebell swing

Pullups

Dips

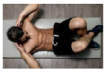
Pushups



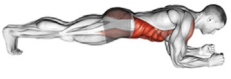
Pulldown

Side raise

Pectoralis press



Abdominals dynamic



Abdominals (static)

Table 4 Information that will be collected on a weekly basis via the LATITUDE Home Monitoring System

The information will be transmitted to the study coordinator in addition to the regular transmissions to primary physician.
Parameter to be transmitted
Device/patient identification data:
a) Identification number
b) Date of birth
c) Device
d) Clinic
e) Therapy: on/off
f) Latest device transmission
g) Last office interrogation
h) Implantation date
i) Patient group
My alerts
Device status
Events since last reset
AF monitor
a) Days with measured AF
b) Estimate of measured AF
Remaining battery life
System detail: electrode impedance status
Settings
Tachytherapy settings
a) Therapy
b) Shock zone
c) Conditional shock zone
Event counts: since last reset and since implantation
a) Untreated episodes
b) Treated episodes
c) # of shocks delivered
Electrograms of arrhythmias detected, sustained, and nonsustained
Electrograms of noise events detected (triggering or not triggering shocks)

AF = atrial fibrillation.

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Disclosures: The authors have no conflicts to disclose.

Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent: Eligible patients will provide written informed consent for participation in the study; for pediatric patients, parental consent will be obtained.

Ethics Statement: The study conforms to the Declaration of Helsinki, and ethical approval has been granted by the Tel Aviv Medical Center Research Ethics Committee.

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