

# Subcutaneous Intracardiac Defibrillator (S-ICD): The Better ICD-Alternative in Athletes with Arrhythmogenic Risks?

*Subkutaner intrakardialer Defibrillator (S-ICD): Die bessere ICD-Alternative für Sportler mit Arrhythmierisiko?*

## Summary

› **Sudden Cardiac Arrest (SCA)** is the leading cause of sudden death (SCD). In athletes under 35 years, SCA is believed to be mostly arrhythmogenic and often due to an underlying structural or electrical pathological heart condition, whereas coronary atherosclerosis is the most frequent aetiology of SCA among athletes above 35 years. Implantable Cardioverter Defibrillators (ICDs) with a transvenous lead are the therapy of choice for individuals at risk of SCD in both primary and secondary prevention. It bears the risk of lead-associated complications (fracture, dislocations, infection), which occur significantly more often in physically active patients like athletes. Considering these limitations, a completely subcutaneous ICD (S-ICD) system was designed to provide the life-saving benefit of the conventional TV-ICD, while avoiding the shortcomings of TV-lead ICD systems. Randomized comparison of S-ICD versus traditional TV-ICD confirmed S-ICD systems as a valid alternative in patients in whom bradycardia pacing or cardiac resynchronization therapy is not required. Because lead complications are associated with physical activity level (i.e. chest/shoulder/upper arm), S-ICD is the better ICD-therapy not only in young patients with an anticipated long-term need for defibrillation function but also in athletes.

## KEY WORDS:

S-ICD, Subcutaneous Intracardiac Defibrillator, Athletes, Arrhythmogenic Risk

## Zusammenfassung

› **Sudden Cardiac Arrest (SCA)** ist die führende Ursache des plötzlichen Herztodes (PHT). Bei Sportlern unter 35 Jahren ist der rhythmogen verursachte SCA bei meist zugrunde liegender struktureller- bzw. elektrophysiologischer Pathologie die häufigste Ursache des PHT, während die akute Myokardischämie (u.a. KHK, Herzinfarkt) die häufigste PHT-Ursache bei >35-jährigen Sportlern ist. Implantierbare kardiale Defibrillatoren (ICD) mit transvenösen Sonden sind die Therapie der Wahl zur Primär- und Sekundärprävention des SCA, gehen aber mit einem meist durch Bewegung verursachtem erhöhten Risiko an Sondenkomplikationen (u.a. Frakturen, Dislokationen, Infektionen) einher, was der Grund zur Entwicklung von vollständig subkutan implantierbaren ICD (S-ICD) war. Bei Patienten, in denen keine bradycarde bzw. antitachykarde ICD-Funktion notwendig ist, zeigten randomisierte Studien eine vergleichbar gute Therapieeffizienz des S-ICD im Vergleich zum transvenösen ICD bei signifikant reduzierter Sondenkomplikationsrate. Da Sondenkomplikationen hauptsächlich mit dem Grad der physischen Aktivität assoziiert sind (Sportler), scheint der S-ICD sogar die bessere ICD-Alternative bei Sportlern und jungen Patienten mit langfristig antizipierter ICD-Indikation zu sein

## SCHLÜSSELWÖRTER:

S-ICD, subkutaner intrakardialer Defibrillator, Athleten, Arrhythmierisiko

## Background

Sudden Cardiac Arrest (SCA) is the leading cause of sudden death (SCD) not only in athletes. The actual mechanism that leads to SCA is largely unknown (16). SCD is defined as an unexpected natural death due to cardiac causes that occurs within 1 hour of symptoms onset, in a person with known or unknown cardiac disease (26). In athletes below 35 years, SCA is believed to be mostly arrhythmogenic

and often on the background of an underlying structural or electrical pathological heart condition (18,5) whereas coronary atherosclerosis is the most frequent aetiology of SCA among athletes above 35 years (16,26,18,6). The most common cause of death in this group is hypertrophic cardiomyopathy, followed by anomalous origin of the left coronary artery from the right (anterior) sinus of Valsalva, com- ➤

## CASE REPORT

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Table 1

Complication rates S-ICD vs. TV-ICD (2012-2016): IDE, EFFORTLESS-registry (12, 14).

COMPLICATION RATE (REGISTRY DATA 2012-2016)(17,24)	S-ICD	TV-ICD
Infection	1.3 - 5.9%	0.13 - 1.9%
Hematoma	0.2 - 1.4%	0.86 - 2.4%
Device erosion	1.7 - 1.8%	usually reported with infection
Lead related complications	0.86% lead migration	20% leads failure over 10y

Table 2

Complication rates S-ICD vs. TV-ICD (2020): PRAETORIAN-study (20).

COMPLICATION RATE (RANDOMIZED DATA 2020)(20)	S-ICD (N=426)	TV-ICD (N=423)
Primary composite endpoint (inappropriate shocks, complications)	68 (15.1%)	68 (15.7%)
Inappropriate shock	41 (9.7%)	29 (7.3%)

Table 3

Advantages/Disadvantages of S-ICD (1).

ADVANTAGES	DISADVANTAGES
extravascular	no bradycardia pacing no anti-tachycardia pacing
low risk of systemic infection	less advanced diagnostics
lower risk of lead-associated complications	larger size
less/no fluoroscopy	shorter battery lifetime
cosmetic considerations	shorter battery lifetime
cosmetic considerations	need for pre-implantation ECG screening
	defibrillation threshold testing (DFT) mandatory
	more expensive

paction cardiomyopathy, coronary heart disease and rarely ruptured aorta. Inherited ion channel diseases have been implicated in SCDs occurring with an apparently normal heart at autopsy (5).

The exact frequency of SCA in athletes is unknown, largely due to the absence of mandatory reporting and methods for examining the incidences of SCA are still limited. Current estimates of the incidence of sudden cardiac death in athletes range from almost one in a million (24) to 1:23.000 (8) athletes per year, while some subpopulations of athletes are reported at even higher risk with an incidence of 1 in 3.000 (10). The most commonly acknowledged incidence of SCD in athletes is 1 in 200.000, although later studies and a closer examination of methodologies have challenged this estimate as too low (7,9,17). It is well accepted, that exercise can be a trigger for arrhythmias in athletes with an underlying cardiac pathology.

Diagnosis

Structural or electrical abnormalities may be identified on a screening ECG, which is the decisive diagnostic tool for conduction anomalies like long QT and WPW syndromes including hypertrophic cardiomyopathy (HCM) and arrhythmogenic right ventricular dysplasia. The two-dimensional transthoracic echocardiography is the principal diagnostic tool for clinical recognition of many cardiac pathologies, i.e. for the diagnosis and follow-up of HCM and in addition it can also detect other relevant abnormalities possibly responsible for SCD in young athletes, such as left ventricular dysfunction e.g. due to myocarditis or dilated cardiomyopathy, valvular heart disease and aortic root dilatation. Arrhythmogenic right ventricular cardiomyopathy is often difficult to diagnose by echocardiography alone. If this condition is suspected, a cardiac MRI is generally considered. Suspected congenital coronary anomalies can unfortunately only be diagnosed by CT angiography, magnetic resonance imaging (MRI) or coronary arteriography.

While physical activity has proven benefits for cardiovascular health, the risk of sudden death is increased during bouts of exercise. Although automated external defibrillators (AED) offer the possibility of instant defibrillation in the gym during exercise, training and competition, they do not cover the risk of arrhythmias during vigorous bouts of exertion in normal life outside the gym. Cardiomyopathies are an important cause of SCD/SCA in young individuals and due to exercise has been implicated as a trigger for fatal arrhythmias, athletes must often be excluded from intense exercise and competition in accordance to the ESC-guidelines (22). Because relatively small longitudinal clinical studies have indicated more recently a considerably lower risk of SCD during exercise than initially considered and a more liberal approach to sports participation is often justified, the working group Sportcardiology of the German Society of Cardiology established a team of experts in sportcardiology in order to discuss the individual risk of sudden cardiac death of athletes (<https://dgg.org/ueber-uns/arbeitsgruppen/ag32-sportkardiologie/ag-32-expertenforum-sportkardiologie/>).

Implantable Cardiac Defibrillators

Implantable Cardioverter Defibrillators (ICDs) are the well accepted life-saving therapy option for individuals at risk of SCD in both primary (20) and secondary prevention (4). While the first generation of ICD was only capable of defibrillation, the current transvenous ICD technology (TV-ICD), utilizing a transvenous lead passed via the venous system to the right ventricle for appropriate detection and therapy of ventricular arrhythmias, evolved further with ability of bradycardia and tachycardia pacing.

Despite the proven efficacy, there are potential complications associated with its use like localized pocket-, wound or systemic infection, vascular access related complications such as pneumothorax, venous thrombosis, lead dislodgement, malfunction or perforation, which is often movement-associated. Transvenous leads placement is problematic in children due to small venous capacity and ongoing growth and in patients with venous anomaly or anatomically small thoracic outlet often seen in upper body athletes. Moreover ICD-leads often give reason to an higher risk of hemodynamic relevant tricuspid regurgitation and risk of lead fracture, which occurs significantly more often in physically active patients (19) and addition transvenous lead extraction, when needed, is associated with considerable morbidity and mortality (1).

## Totally Subcutaneous ICD (S-ICD)

Considering the limitations and in order to improve the risk-benefit balance of the TV-ICD systems, a totally subcutaneous ICD (S-ICD) system was designed and approved for use in Europe in 2009 to provide the life-saving benefit of the conventional TV-ICD, while avoiding the shortcomings of TV-lead ICD systems. It consists of a pulse generator (80J including biphasic shock system) in a titanium case implanted in the left thoracic region with the device pocket at the fifth intercostal space between the mid and anterior axillary line (Figure 1) and the subcutaneously implanted lead positioned about 1-2 cm to the left of the sternal midline (Figure 2, 3). In order to guarantee adequate function of a S-ICD system, a ECG screening is mandatory to ensure suitable subcutaneous sensing signals and to enhance the sensitivity and specificity for rhythm identification and therapy and to reduce the risk of inappropriate shocks. Cohort studies showed 7-11% failure rates of S-ICD screening, and S-ICD implantation is not recommended in these patients because of increased risk of under- or oversensing (23).

After several hardware- and software related modifications, the currently available S-ICD system are as effective as TV-ICD in appropriately detecting and treating life-threatening ventricular arrhythmias (20,4,3). Although the mean defibrillation threshold test (DFT), which is used to predict shock efficacy in the event of ventricular arrhythmia and which refers to the minimum shock strength that defibrillate the heart, is higher in S-ICD, subcutaneous ICD showed comparable spontaneous VA termination with one shock in 90.1% and within five shocks in 98.2% (Table 1) (3).

After showing its clinical efficacy in multiple observational studies (2,25), the results of the first randomized comparison of S-ICD versus TV-ICDs (13), underlined that current generation S-ICD systems as a valid alternative in patients with an ICD indication in whom bradycardia pacing or cardiac resynchronization therapy is not required (Table 2) (25).

Lead migration with need to lead revision as major reason for inappropriate shocks, identified as a worrisome problem of the first generation S-ICD system, could have been reduced effectively to 0.85% (2,14) with the introduction of the suture sleeve, which secures the lead at the lower sternal incision. In comparison to traditional TV-leads and due to its subcutaneous location (11) S-ICD-lead has less exposure to environmental stress due to, which is i.e. the case in physically active patients and athletes (Table 3) and therefore show significant less lead complications as compared to TV-ICD in randomized studies (Figure 4 lead complications PRAETORIAN)

Inappropriate shock rates could significantly be reduced to that of TV-ICD (3,20) due to dual-zone programming, careful ECG-screening and increased operator experience (12)(Table 1, 2).

Because lead complications are associated physical activity level (i.e. chest/shoulder/upper arm), patients (and athletes) at a young age with an anticipated long-term need for defibrillation function without need for bradycardia pacing or those who likely benefit from anti-tachycardia pacing (ATP) are the ideal candidates for S-ICD therapy.

## Case Report

After recurrent syncope, each after strenuous physical efforts in everyday life and suspicious for sudden cardiac arrests, hereditary hypertrophic cardiomyopathy (HCM) was diagnosed in a 17-year old selection basketball player. Due to this, the

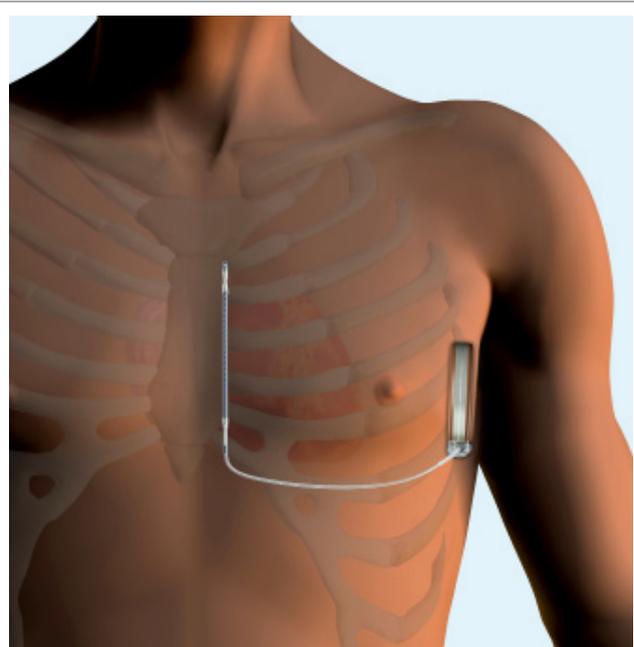


Figure 1

S-ICD Situs (courtesy of Boston Scientific Corporation, all rights reserved).



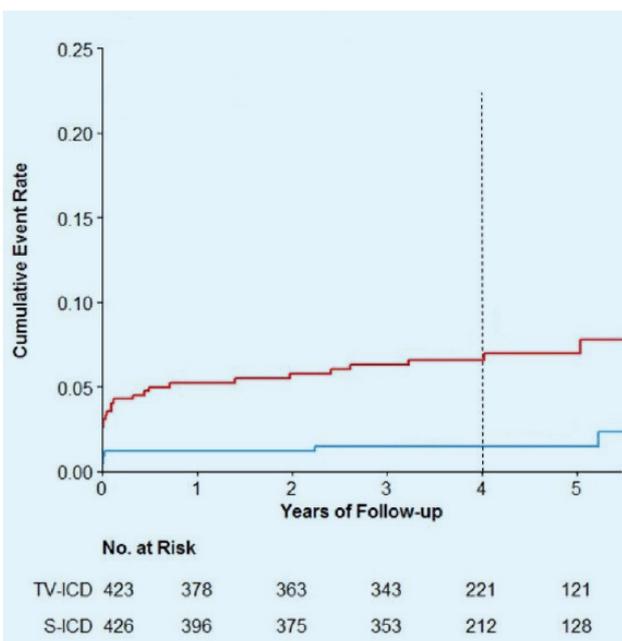
Figure 2

Patient-case: S-ICD situs from ventral. Note: suture sleeve fixation at lower sternal incision.

necessary qualification for participation in the German basketball young selection league (NBBL) was refused by the sport medicine practitioner and sport cardiologist in accordance to the ESC-guidelines (22). After judging the syncope as sudden cardiac arrest (SCA) of arrhythmogenic origin and since the implantation of S-ICD is better revisable and in contrast to TV-ICD, S-ICD leads can relatively easy be removed, the decision for implanting a S-ICD was taken and successfully carried out (Figure 2, 3). As a consequence of the now given effective prevention of arrhythmogenic sudden cardiac arrests during training and competition, qualification for participating in the German Young Basketball Selection league (NBBL) was given respecting the EAPC 4-D's (see below) in order to prevent >



**Figure 3**  
Patient-case: S-ICD device pocket frontal axillary line.



**Figure 4**  
Rate of lead-related complications. After four years: significant higher lead-related complications TV-ICD (6,6%; red line) vs. S-ICD (1,4%; blue line; Hazard ratio 0,24 (95% CI, 0,10-0,54) P=0,001). (Randomized PRAETORIAN-study (20) (courtesy of Boston Scientific Corporation, all rights reserved).

S-ICD-associated complications during exercise or competition. Seven months after the S-ICD implantation he is performing very well as competitive basketball player, without any events or sequelae i.e. no inappropriate shocks, lead- or device associated complications .

Discussion

Despite evidence in randomized studies are missing, S-ICD are highly likely the better ICD treatment in patients at a young age with an anticipated long-term need for defibrillation function without need for bradycardia pacing or those who likely benefit from anti-tachycardia pacing (ATP). Since lead complications are associated with movement and activity, S-ICD are probably the more suitable ICD-therapy in athletes with arrhythmic risk for sudden cardiac death with underlying structural or electrical pathological heart condition also in order to make physical activities and even participation in competitive sports possible.

According the European Association of Preventive Cardiology (EAPC) and the European Heart Rhythm Association (EHRA) physical activity and even competitive sport with ICD is highly recommended (22). Registry data revealed that shocks in the course of physical activity occur in 10-20% but more frequently during training (20%) as compared to competition (10%)(15). Several prominent soccer players participate successfully even in the highest European soccer leagues (e.g. Antony van Loo, Belgium; Daley Blind, AJAX Amsterdam) having a TV-ICD implanted like Christian Eriksen after his rhythmogenic sudden cardiac arrest during the European soccer championship 2021. Katharina Bauer participated the Tokyo-Olympics 2021 (pole vault) with a S-ICD implanted due to arrhythmogenic events.

According EAPC the 4-Ds (Danger, Disease, Device, Dysrhythmias) should be taken into consideration for athletes with ICD: Danger...no danger for the ICD-athlete and others (e.g. motorsports, diving, climbing). Disease...physical activity with ICD should not give reason to worsening of the underlying disease. Device...(e.g. no martial arts or boxing), contact-sports (i.e. Soccer, Handball, Basketball) should be carried out with external device protection measures (e.g. padding). Dysrhythmias...careful ICD-programming in order to prevent inappropriate shocks. ■

Conflict of Interest

The authors have no conflict of interest.

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