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Authors: Gerhard Hindricks, Radosław Lenarczyk, Zbigniew Kalarus, Michael Döring, Alireza Sepehri Shamloo, Nikolaos Dagres

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Prevention of sudden cardiac death by the implantable cardioverter-defibrillator.

Gerhard Hindricks[1], MD; Radoslaw Lenarczyk[2], MD; Zbigniew Kalarus[2,3], MD; Michael Döring[1], MD; Alireza Sepehri Shamloo[1], MD; Nikolaos Dagres[1], MD

[1] Department of Electrophysiology, Heart Center Leipzig at University of Leipzig, Leipzig, Germany

[2] Silesian Center for Heart Disease, Zabrze, Poland

[3] SMDZ in Zabrze, Medical University of Silesia, Katowice, Poland

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Address for correspondence:

Nikolaos Dagres

Strümpellstr. 39

04289 Leipzig, Germany

Tel: +493418651410

Email: dagresnikolaos@gmail.com

Abstract

Sudden cardiac death (SCD) is a leading cause of death. The advent of the implantable cardioverter-defibrillator (ICD) has revolutionized prevention of SCD in high-risk patients with underlying cardiac diseases. However, several challenges remain. Identification of patients at risk that should receive an ICD is suboptimal; sole criterion applied in clinical practice is a severely reduced left ventricular ejection fraction despite the fact that the majority of SCD cases occur in patients with preserved or mildly reduced ejection fraction. Additionally, the majority of patients that do receive the ICD will at the end not benefit from the device. Therefore, improved risk stratification approaches to guide selection of patients for ICD implantation are definitely needed. There are several novel features and developments in the field with the subcutaneous defibrillator being probably the most important one and having the potential to substantially influence clinical practice. The role of catheter ablation of ventricular tachycardia and particularly the potential to abolish the need for ICD implantation at least in selected patient groups needs to be further defined. Internists and general practitioners play a significant role in the management of ICD patients, from identification of candidates for ICD implantation up to early detection and appropriate treatment of complications.

Key words: catheter ablation; implantable cardioverter-defibrillator; subcutaneous defibrillator; sudden cardiac death; ventricular tachycardia

Sudden cardiac death (SCD) is a leading cause of death and continues to pose a significant challenge despite great successes in the last decades. In most cases, SCD occurs on the basis of an underlying cardiac disease, mostly coronary artery disease [1] and is, in the majority of cases, the result of ventricular tachyarrhythmias, i.e. ventricular tachycardia and/or ventricular fibrillation. More rarely, bradyarrhythmias such as asystole or complete atrioventricular block may also lead to SCD. With the development of the implantable cardioverter-defibrillator (ICD), a device has become available that can terminate life-threatening ventricular tachyarrhythmias very successfully and thus prevent SCD (Figure 1). Therefore, the identification of patients with a high risk for SCD that would benefit from the ICD has gained paramount importance. Apart from the selection of patients for ICD implantation, there are several other significant issues and dilemmas related to ICD therapy such as technical issues, novel developments, complications and their management as well as patient perception.

How to identify the patients that need to be protected

Obviously, a major goal in the context of ICD therapy is the identification of patients that are at high SCD risk and that would benefit from the ICD. A reduced left ventricular ejection fraction has been long identified as a risk factor associated with increased total mortality, cardiac mortality but also specifically SCD in patients with structural heart disease. Based on this observation, the efficacy of the ICD in this patient population, i.e. patients with severely reduced left ventricular ejection fraction, was tested in two landmark trials, the MADIT-II trial in patients with ischemic cardiomyopathy [2] and the SCD-HeFT trial in patients both with ischemic and non-ischemic cardiomyopathy [3]. Indeed, both trials demonstrated a significant survival benefit in patients receiving the ICD. Based on these results, current guidelines recommend prophylactic implantation of an ICD for primary prevention of SCD in patients with ischemic or non-ischemic cardiomyopathy and a severely reduced left ventricular ejection fraction ≤35% [4]. This strategy is currently implemented across different geographies and ICD implantation has become a cornerstone of daily clinical practice [5,6].

However, this strategy has important shortcomings. The most important shortcoming is the fact that the majority of SCD cases occur in patients with preserved or moderately depressed ejection fraction [7] and *not* in those with severely reduced ejection fraction. Thus, with our current strategy, we miss the majority of the patients that are at true risk and that we aim to protect. The second major shortcoming is the fact that among patients that do receive the ICD for primary prevention of ICD due to severely reduced ejection fraction according to current guidelines, only a minority will ultimately receive therapies by the device and derive benefit from it [8,9] but all of them will be subjected to the complication risk associated with ICD therapy.

It is important to notice that ICD implantation comes at a cost. Despite accumulated experience, there is still a considerable risk for complications and patients with a complex underlying substrate have an increased risk of complications [10]. These include both intraprocedural complications such as cardiac perforation with tamponade [11], pneumothorax [12] or pocket hematoma [13] but also the long-term risk of device infection [14–16] or lead malfunction [17]. Device infections occur in approx. 2-4% during long-term follow-up [18], are a serious condition that may be life-threatening [19] and are associated with significant cost for the healthcare systems [20]. Psychological distress of the patients caused by the ICD may also be a major concern. Interestingly, the ICD-related patient concerns themselves may have a bigger impact on psychological distress than the actual receipt of shocks [21]. Patients' preferences and needs are important in this regard since recent studies indicate unmet patient needs in clinical practice [22]. Additionally, the knowledge of the treating physicians about ICD treatment is also insufficient and needs improvement as recent studies demonstrate with over two thirds of the physicians rating their knowledge to be low [23].

For the reasons described above, there are intensive attempts to identify parameters that could assist in the prediction of the individual risk for SCD, refine the current strategy and guide the clinical decision for or against ICD implantation [24]. Clinical parameters may play a role in this regard. Data from the MADIT-II trial indicate that patients with a clinical profile of low to intermediate risk will probably derive a benefit from the ICD [25] whereas this may not be true for patients with a high-risk clinical profile. Indeed, a recent analysis of a large number of patients from

the Altitude database reported that with advanced age mortality increases, but the risk of ICD shocks decreases [26] possibly as a result of increasing competing risks. Other studies report findings that are in line with this observation [27]. Several clinical parameters and risk score systems have been proposed with the aim to improve risk stratification for SCD [28,29], but their utility in daily practice it is not clear [30] or not established yet, particularly since no randomized trial has been conducted to show that patients with a low predicted benefit from the ICD indeed do not benefit from the device. As long as this proof does not exist, it is difficult to refrain from current practice.

Apart from clinical characteristics, numerous other parameters and old or novel markers have been proposed as a tool for improved risk stratification such as ventricular ectopy, markers of the autonomic tone, ECG parameters, or invasive techniques such as electrophysiological testing [1,31–33]. Despite all these efforts, the ideal risk stratification approach that would provide an individualized risk assessment and would guide the decision for defibrillator implantation is unfortunately not available yet. The most promising tool seems to be imaging. Various traditional and novel imaging modalities have been proposed as tools that could contribute to risk stratification for SCD [34]. An established imaging modality that will most probably play a clinical role is cardiac magnetic resonance imaging. Detection of fibrosis by late gadolinium enhancement has been reported to predict SCD in patients with non-ischemic cardiomyopathy and mildly or moderately reduced left ventricular ejection fraction [35].

Another important aspect in the field of ICD therapy is the dramatic change of medical practice that has taken place in the last decades and the resulting impact on the risk-benefit ratio of the ICD. Indeed, since the time of the conduction of the major trials, many changes in clinical practice of patients with cardiac disease have occurred with the wider administration of protective therapies such as beta blockers or mineralocorticoid antagonists and the development of novel drugs such as angiotensin receptor neprilysin inhibitors [36]. In addition to these changes in pharmacological treatment, utilization of coronary revascularization has increase significantly, particularly in the setting of acute myocardial infarction. This may be important because coronary occlusion is reported to be associated with an adverse impact on long-term prognosis and ventricular arrhythmias [37,38].

The combination of these changes has led to a significant decrease of mortality of patients that are eligible for ICD implantation but also of SCD rates [39] with a presumable important impact on the benefit-risk ratio of the ICD. Thus, it is not surprising that rates of ICD shocks in contemporary cohorts of patients receiving the ICD for primary prevention are reported to be as low as 1% [8] further questioning the rationale for routine implantation of ICD based solely on the criterion of reduced left ventricular ejection fraction. In line with these observations, the recent large multicenter randomized DANISH trial that compared ICD therapy with optimal medical treatment in patients with non-ischemic cardiomyopathy reported no mortality benefit as a result of ICD therapy [18]. Although the guidelines for ICD implantation did not change after publication of the DANISH trial, it is interesting to notice that these findings had already a considerable influence on daily practice of ICD implantation in Europe [40] with many centers reporting a change of the indications for prophylactic implantation in their clinical routine towards more restrictive indications.

In the same context, a particularly challenging decision is whether to continue ICD therapy after an uneventful first battery life in patients that already carry an ICD when the battery has reached depletion, i.e. whether to replace the ICD. Current guidelines do not provide firm guidance in this setting and the great majority of physicians tend to routinely replace the ICD [41] although firm evidence is lacking.

A further context of particular debate is the need for ICD protection when a device for cardiac resynchronization therapy (CRT) is implanted. A CRT device is indicated in symptomatic patients with heart failure, reduced ejection fraction ≤35% and broad QRS complex [42] and is associated with relief of symptoms and reduction of mortality. The need for the defibrillator in patients receiving a CRT device is much less clear compared with patients without CRT because CRT reduces per se the risk for SCD [43]. Recent studies report very low rates of ventricular arrhythmias in CRT patients that show good response to this therapy [44] and numerous studies report conflicting results on the effect of adjunct defibrillator therapy (in the form of a CRT device with the capability of shock delivery called CRT-D) compared with CRT devices without the defibrillator component (called CRT-P) [18,45–52]. To shed more light in this important clinical issue, a large randomized trial, the

RESET-CRT trial [53], is currently conducted with the question whether patients undergoing routine implantation of a CRT device should receive a CRT-D or CRT-P.

Practical dilemmas around ICD implantation

When the decision for ICD implantation has been taken, there are several clinical dilemmas concerning the procedure. One of them is the choice between a single- and a dual-chamber defibrillator. Naturally, the main function of the device, i.e. termination of life-threatening arrhythmias by rapid ventricular pacing or, if necessary, shock depends on the ventricular lead. Only the minority of patients receiving an ICD have additionally an indication for cardiac pacing and in those, the selection of a dual-chamber device that can pace both the atrium and the ventricle is in most cases indicated. The dual chamber ICD system consists of the device, the right ventricular defibrillation and pacing lead as well as an atrial pacing lead. However, the majority of patients receiving the ICD do not have an additional indication for cardiac pacing. In those, addition of an atrial lead may have the advantage of better discrimination between ventricular and atrial arrhythmias through the device with the potential for minimization of inappropriate ICD therapies delivered for non-threatening arrhythmias. Real-life data however do not confirm this theoretical advantage. Single chamber ICDs are reported to have similar long-term outcome and similar rates of inappropriate therapies but lower complication rates compared with dual chamber ICDs [54,55] and are therefore increasingly considered standard in many centers.

A second practical question is the choice of a single- or dual-coil defibrillation lead. In systems with single-coil defibrillation lead, the ICD shock is delivered between the coil of the defibrillation lead and the device. In systems with dual coil leads, there are several options for the defibrillation vector, e.g. between the two coils of the defibrillation lead or the coils and the device. Clinical practice varies but contemporary data show similar long-term outcome with both lead types [56] in parallel with an increasing use of single coil electrodes (Figure 2).

Novel developments with significant potential impact for clinical practice: the subcutaneous defibrillator

In the last decades, the field of cardiac devices has been characterized by constant technical developments and advent of new features. While many of them have not influenced clinical practice in a significant way, one recent development seems to have the potential to do so. The subcutaneous defibrillator is a defibrillator system implanted entirely subcutaneously with no intravenous components [57–59] (Figure 3). This is particularly important due to the prevention of device-related endocarditis that, as described above, is the most feared frequent long-term complication of ICD therapy. Available data from large registries suggest satisfactory results of the subcutaneous defibrillator, even in challenging clinical settings [60–63]. Although this new technique is still not very widely, it seems to have the potential for much wider application in the future [58,64] and modifications of the implantation technique with the aim of reduced complications and improved cosmetic results have been reported [65]. Interestingly, the learning curve appears to be short with stabilization of performance reported after already 13 implantations [66]. A main limitation of the subcutaneous defibrillator compared with transvenous systems is the lack of pacing capability. Although preliminary data indicate safety and feasibility of a combined approach consisting of a subcutaneous defibrillator and a leadless pacemaker [67,68] for patients with pacing indication, patients with both an indication for pacing and for defibrillator should currently receive a transvenous ICD system [69].

Need for defibrillator therapy in light of increasing use of catheter ablation for ventricular tachycardia

Catheter ablation has become an established treatment modality for treatment of arrhythmias. This has been greatly facilitated by the advent of modern three-dimensional mapping systems [70] and irrigated ablation catheters [71]. In patients with recurrent episodes of ventricular tachycardia, catheter ablation can significantly reduce the arrhythmic burden and has a clear indication in patients with incessant ventricular tachycardia or electrical storm as well as in patients with

recurrent ICD shocks due to sustained ventricular tachycardia [4]. The feasibility of catheter ablation of ventricular tachycardia has been demonstrated in various clinical settings including higher-risk patients such as elderly [72], patients with complex underlying substrates [73–75], or polymorphic ventricular tachycardia originating from premature ventricular beats [76]. Ablation is also recommended with ischemic heart disease and an ICD after the first episode of sustained ventricular tachycardia [4]. Indeed, safety and feasibility of early ablation of ventricular tachycardia has been demonstrated in various clinical settings [73,77].

However, a main clinical question that remains unanswered question is whether patients that do not have an ICD and that undergo an apparently successful catheter ablation of ventricular tachycardia still need ICD implantation. For instance, do patients with a previous myocardial infarction and preserved left ventricular ejection fraction that present with a hemodynamically tolerated monomorphic ventricular tachycardia and undergo successful catheter ablation still need ICD implantation? Does this have any impact on mortality? There is currently no evidence to support any decision in this scenario. Thus, the role of the ICD in patients that are deemed to be candidates for successful treatment by catheter ablation still needs to be determined.

Role of internists and general practitioners in the management of ICD patients

Internists and general practitioners play a crucial role at all steps of management of ICD patients, from the initial assessment and identification of candidates for ICD implantation up to the management of complications due to their significant involvement in management of heart failure patients [78]. Although SCD may occur in different settings [79,80], the main bulk of patients in need of ICD implantation are patients with structural heart disease and heart failure. It is well demonstrated that a large proportion, probably the majority of heart failure patients are first seen by non-cardiologists, mainly general practitioners and internists [81]. Therefore, internists and general practitioners are very frequently the first physician group that will set the diagnosis of heart failure, identify patients that are eligible for ICD implantation and refer these patients to specialized centers for the procedure.

Furthermore, internists and general practitioners play a similar or even more important role in the recognition and management of complications, particularly of device infections. This is due not only to their prominent role in the follow-up of heart failure patients including ICD carriers but also due to the non-specific signs of device-related infections that lead most patients with this complication to an internist or general practitioner as initial physician contact. Therefore, awareness and timely consideration of device-related infection as cause of the symptoms reported by the patient is crucial for appropriate management, early initiation of therapy and avoiding of adverse outcome [16].

Conclusions

The advent of the ICD has revolutionized prevention of SCD in high-risk patients with underlying cardiac diseases. However, several challenges remain. Identification of patients at risk is suboptimal; sole criterion used in clinical practice is a severely reduced left ventricular ejection fraction despite the fact that the majority of SCD cases occur in patients with preserved or mildly reduced ejection fraction. Additionally, the majority of patients that do receive the ICD will not benefit from the device. Therefore, improved risk stratification approaches that may guide selection of patients for ICD implantation are definitely needed. There are several novel features and developments with the subcutaneous defibrillator being probably the most important one having the potential to substantially change clinical practice in this field.

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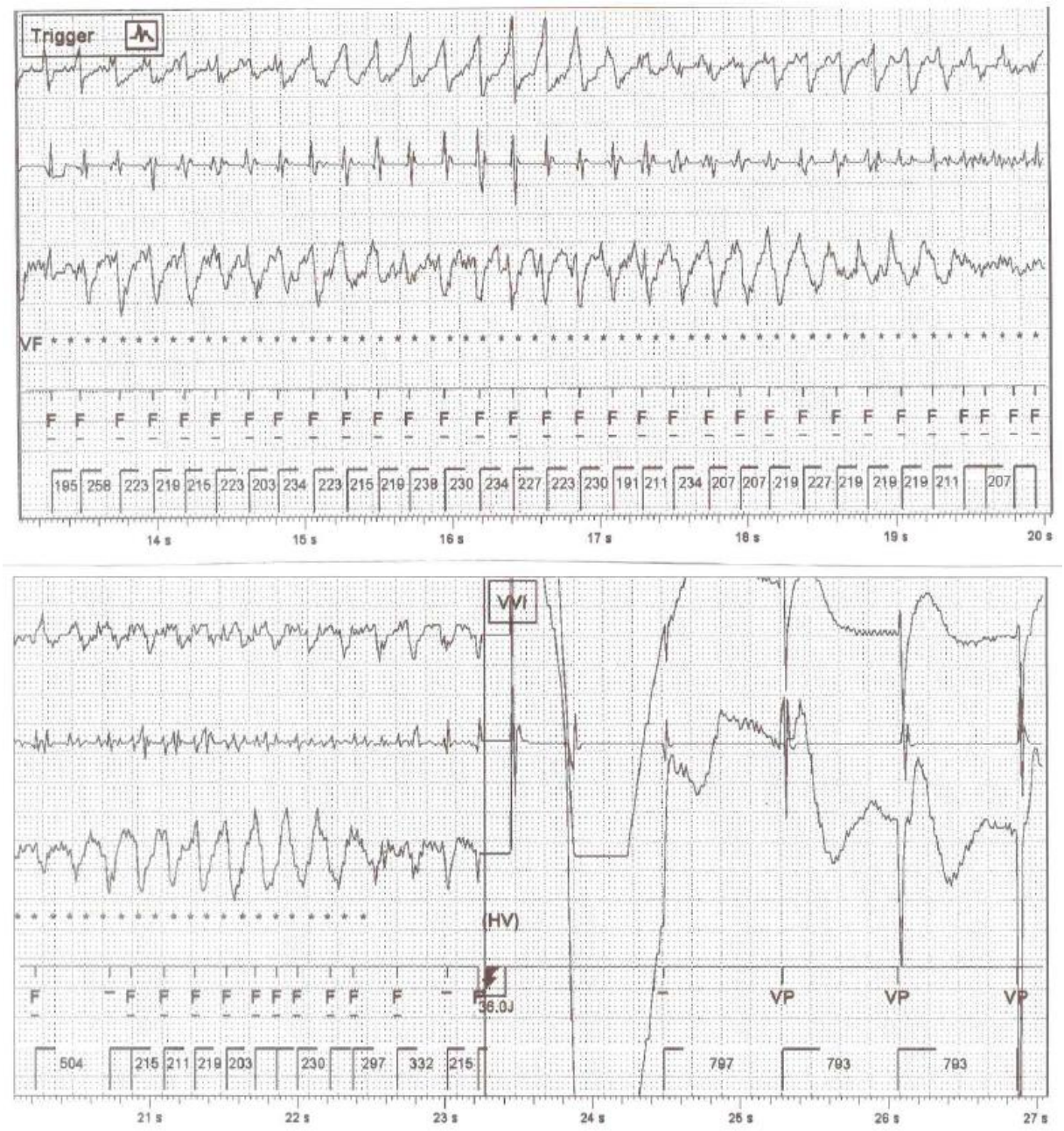

Figure 1 Example of ventricular fibrillation in a patient with dilated cardiomyopathy that carries an implantable cardioverter-defibrillator. Ventricular fibrillation is detected by the device and terminated by a life-saving shock.

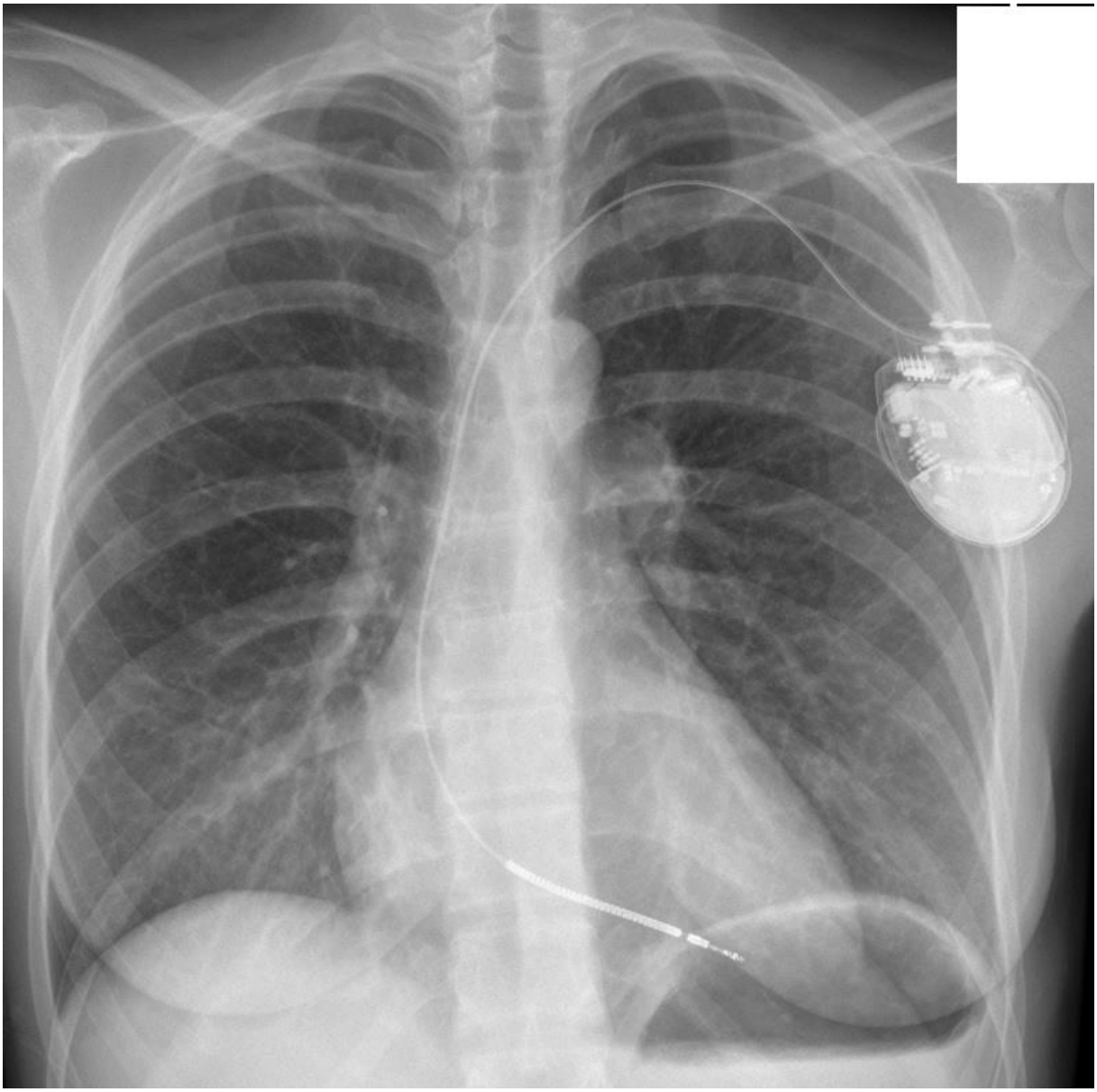

Figure 2 Chest X-ray of a single-chamber implantable cardioverter defibrillator in a patient with arrhythmogenic right ventricular cardiomyopathy that was implanted after an episode of sustained rapid ventricular tachycardia terminated with external shock. The defibrillation lead is a single coil lead.

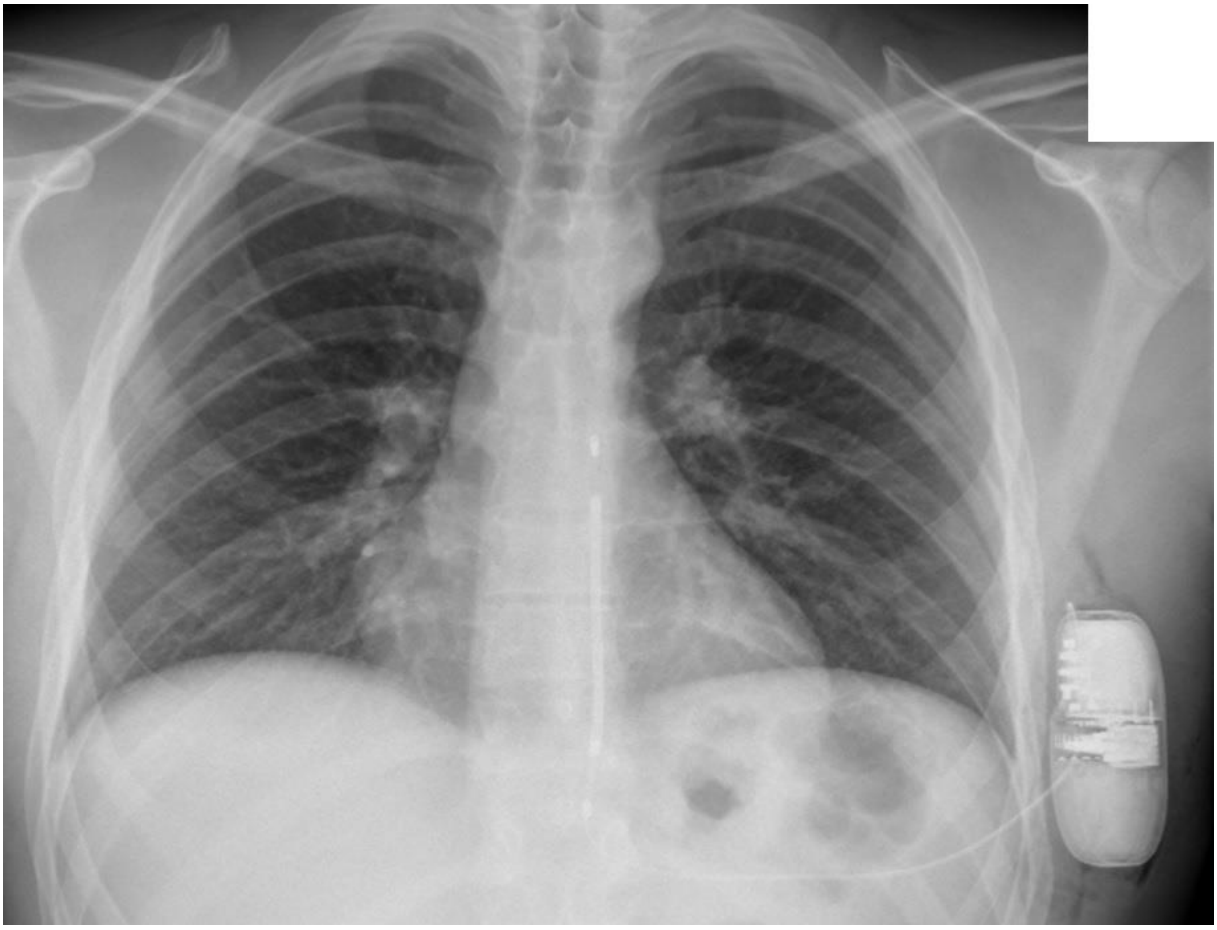

Figure 3 Chest X-ray of a subcutaneous defibrillator system. The system is entirely subcutaneously.