VILNIUS UNIVERSITY MEDICAL FACULTY

The Final thesis

Subcutaneous automatic cardioverter-defibrillators

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2. ABBREVIATIONS

- VT ventricular tachycardia
- VF ventricular fibrillation
- SCD sudden cardiac death
- ICD implantable cardioverter-defibrillator
- S ICD subcutaneous implantable cardioverter-defibrillator
- CRT D cardiac resynchronization therapy-defibrillator
- CRT cardiac resynchronization therapy
- IAS inappropriate shock
- QT QT interval
- QTc corrected QT interval

3. SUMMARY

This thesis reviews the effectiveness and utility of subcutaneous implantable cardioverterdefibrillators compared to traditional transvenous implantable cardioverter-defibrillators in preventing sudden cardiac death in both primary and secondary prevention. The review includes literature review and a detailed clinical case to illustrate real-world utility of subcutaneous implantable cardioverter-defibrillators. The findings indicate that while subcutaneous implantable cardioverter-defibrillators have advantages in specific clinical scenarios, transvenous implantable cardioverter-defibrillators have preferance in cases involving complex cardiac conditions. Efficacy of the subcutaneous implantable cardioverter-defibrillators was also investigated, with data suggesting similar outcomes compared to those of transvenous implantable cardioverter-defibrillators in arrhythmia management. A clinical case illustrated the practical utility and effectiveness of subcutaneous implantable cardioverter-defibrillators in a pediatric patient with lead failure with transvenous system. This research highlights the importance of carefully considered treatment approach in cardiac care and points towards further investigation into patient-specific outcomes with subcutaneous implantable cardioverter-defibrillator installations.

4. SANTRAUKA

Šis baigiamasis darbas apžvelgia poodinio implantuojamo kardioverterio-defibriliatoriaus efektyvumą ir naudingumą, lyginant su tradiciniu transveniniu implantuojamu kardioverteriudefibriliatoriumi, siekiant užkirsti kelią staigiai širdies mirčiai, tiek pirminėje, tiek antrinėje prevencijoje. Baigiamasis darbas apima literatūros apžvalgą ir klinikinio atvėjo aprašymą, skirtą iliustruoti poodinių implantuojamų kardioverterių-defibriliatorių pritaikymą realiame pasaulyje. Išvados rodo, kad nors poodiniai implantuojami kardioverteriai-defibriliatoriai turi pranašumų tam tikrose klinikinėse situacijose, transveniniai implantuojami kardioverteriai-defibriliatoriai gali būti pranašesni situacijose, susijusiose su sudėtingomis širdies ligomis. Taip pat buvo išnagrinėtas poodinio implantuojamo kardioverterio-defibriliatoriaus efektyvumas lyginant su transveniniu implantuojamu kardioverteriu-defibriliatoriaus praktinį taikymą ir efektyvumą pediatriniam pacientui su transveninio kardioverterio-defibriliatoriaus laidų disfunkcija. Šis tyrimas pabrėžia individualizuotų gydymo metodų svarbą širdies ligų gydyme ir siūlo tolimesnius tyrimus, skirtus skirtingų pacientų grupių rezultatams tirti naudojant poodinį implantuojamą kardioverterį-defibriliatorių.

5. KEYWORDS

Subcutaneous ICD, Transvenous ICD, Defibrillation Efficacy, Cardiac Arrhythmias, Device Comparison, Clinical Case.

6. INTRODUCTION

Defibrillation serves as a highly effective intervention in terminating life-threatening ventricular arrhythmias, with ventricular fibrillation detected in nearly 70% of individuals experiencing cardiac arrest. If left untreated, this condition proves fatal within minutes (1). Defibrilation therapy can be delivered by a transvenous ICD, a subcutaneous implantable cardioverter-defibrillator, a wearable cardioverter-defibrillator, or an external defibrillator. These devices have guidelines for secondary and primary prevention therapy for sudden cardiac death. They monitor the heart rhythm continuously and deliver therapy in response to a tachycardia that meets the programmed settings (2). Implantable

cardioverter-defibrillators are considered the gold standard for sudden cardiac death prevention (3– 5).

The subcutaneous implantable cardioverter-defibrillator is a relatively new device placed outside the thoracic cage to avoid complications associated with transvenous leads (3,6,7). Yet, in the largest prospective investigation of the S-ICD to date, outcomes underscore the sustained safety and efficacy of the S-ICD over a five-year period, across a diverse cohort of recipients (8). While temporary post-shock pacing is an option, the subcutaneous ICD does not offer sustained pacing capabilities (3,7,9,10). The aim of this thesis is to evaluate the effectiveness and utility of subcutaneous implantable cardioverter-defibrillators (S-ICD) compared to traditional transvenous implantable cardioverter-defibrillators (ICD) in the prevention of sudden cardiac death.

7. IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS

7.1 Indications for the use of ICD

Secondary prevention of sudden cardiac death due to prior sustained VT, VF, or resuscitated SCD caused by VT/VF, excluding any reversible causes such as VT/VF limited to the first 48 hours after an acute myocardial infarction (2). The key point in selecting candidates for ICD implantation is evaluating total mortality and whether the therapy will result in meaningful survival over 1 year (11).

ICD therapy for the primary prevention of sudden cardiac death is most beneficial when the patient faces a high risk of death from ventricular arrhythmias and a low risk of nonarrhythmic death due to comorbidities and overall health status (2). It is crucial to assess the likelihood of meaningful survival exceeding one year (11).

7.2 Contraindications

Reversible causes (electrolyte imbalance, myocardial ischemia, etc.), incessant VT/VF, atrial arrhythmias with no concomitant VT/VF, patients with meaningful survival of less than one year, patients with NYHA class IV heart failure that are not candidates for heart transplantation and resistant to medical treatment, patients with normalized risk of sudden cardiac death after successful ablation, patients with active infection, patients with acute medical issues (2,11).

7.3 ICD components

An implantable cardioverter-defibrillator system consists of a pulse generator and one to three leads. The metal casing of the pulse generator is also called the "can". It protects the components inside from fluids and many external electrical sources. The main elements of the pulse generator are the battery and electronic circuitry (11). Battery longevity of each ICD device depends on how much therapy it performs (pacing and defibrillating), it can be more than eight years, and some models have expectancy of >10 years. For example, CRT-D devices can last for more than six years (12–14). Circuitry is the "brain" of the therapy, and the capacitors determine when and how pacing and defibrillation are delivered. Lead comprises multiple separated metal wires, encased in silicone rubber or insulated with polyurethane. This allows for a separate pathway to deliver shocks, also known as the "shock coil(s)". Defibrillation occurs across the heart between these coils and potentially the device itself. ICD leads may feature one or two shock coils, with one placed distally and, if a dual-coil lead is necessary, a second position in the superior vena cava (Figure 1). The number of pins varies based on whether additional defibrillation is required (in the case of a dual-coil lead). Still, the standard configuration includes two pins: one for sensing/pacing and the other for defibrillation (15). Recent DF-4 standard shock lead has up to four in-line contacts on one pin.

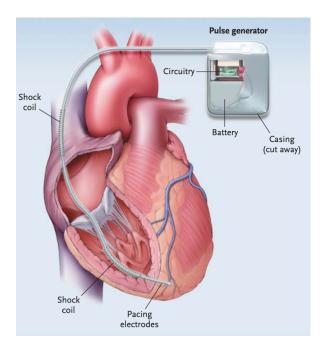


Figure 1. Components of a single chamber, dual coil lead transvenous ICD system (15).

7.4 Implantation

Before implanting an ICD, the healthcare provider must determine the optimal placement for leads and the pulse generator. Most current ICD systems utilize one or two transvenous leads inserted through the axillary, subclavian, or cephalic vein, connecting to a pulse generator located in the subcutaneous tissue of the infraclavicular anterior chest wall. An additional defibrillation lead can be placed in the azygos vein, coronary sinus, or subcutaneous tissue if needed to enhance defibrillation (16). Pulse generator implantations typically occur in the left pectoral region. One study revealed a twofold increase in mortality rates with right-sided implantations compared to left-sided ones, although the reason remains unclear (17,18). However, this does not preclude the use of right-sided implantation, particularly if left-side placement is contraindicated, as it has shown favorable clinical outcomes (11). Nonetheless, right-sided implantation presents technical challenges (17).

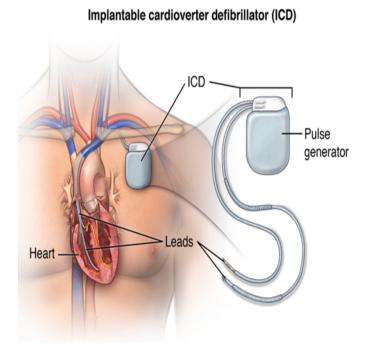


Figure 2. Implantation location diagram of transvenous implantable cardioverter-defibrillator components (20).

8. SUBCUTANEOUS IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS

8.1 Overview of the subcutaneous implantable cardioverter defibrillator system

Subcutaneous implantable cardioverter-defibrillator has extracardiac, extrathoracic, and subcutaneous electrodes. In between two sensing electrodes, lies an 8-centimeter-long defibrillation coil. The generator acts as the 3rd electrode for defibrillation and has an optional function for sensing (3). The most optimal device setup is a parasternal electrode paired with a left lateral thoracic pulse generator, demonstrating the same efficacy as a transvenous ICD in terminating induced ventricular fibrillation (3, 13, 14). Position of electrodes provides three potential sensing vectors (Figure 3). Unlike electrograms captured by closely positioned endocardial electrodes, recordings from the S-ICD show decreased amplitude and frequency content and are more sensitive to postural changes. They bear similarity to precordial surface electrocardiograms in representing the cardiac cycle, requiring software/algorithms to discern each component accurately. Pre-implant screening identifies individuals for whom processing based on QRS amplitude and QRS to T-wave ratio is unfeasible. Following S-ICD implantation, the device automatically selects the best vector to distinguish between the QRS complex and T wave, preventing double counting of cardiac events. A baseline template is stored using this optimal vector, which can also be manually selected by the operator if desired. Identifying specific components of the cardiac electrical cycle in the S-ICD signal can be influenced by factors such as atrial enlargement, ischemia, bundle branch block, depolarization abnormalities, anatomical variations, and posture (3,22). The initial S-ICD system's average battery life was 5.0 years (23). Following its authorization for use in the United States in March 2015, the EMBLEM subcutaneous implantable cardioverter-defibrillator was introduced. This system comprises the second and third-generation S-ICD models, designated as A209 and A219, respectively, with an anticipated lifespan of 7 years. Additionally, these models offer remote monitoring capabilities through the Boston Scientific Remote Patient Management System (LATITUDE) (24-26).

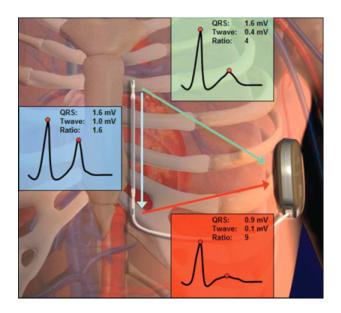


Figure 3. Illustration of the positioning of the subcutaneous implantable cardioverter-defibrillator and its sensing vectors. Two sensing electrodes at either end of the coil electrode and the generator. Additionally, diagrams of typically sensed electrograms for each vector are provided (27).

8.2 Indications for S-ICD implantation

For patients meeting ICD eligibility criteria but experiencing inadequate vascular access or facing a high risk of infection, and those not needing or anticipated to require pacing for bradycardia or VT termination or as part of CRT, a subcutaneous implantable cardioverter-defibrillator is recommended (28–37).

For children and teenagers, S-ICD may offer similar survival benefit to transvenous ICD, with a decreased incidence of complications requiring reoperation. Given the lack of randomized trials, it is advisable to conduct prospective comparisons between S-ICD and transvenous ICD in large multicenter registries with similar follow-up durations. Considering the high likelihood of lead failures with transvenous systems over their lifetime, young patients may find S-ICD systems particularly advantageous. While numerous studies have demonstrated the safety of S-ICD systems, occurrences of inappropriate shocks are possible, albeit comparable to those seen in patients with transvenous ICDs (27,38,39).

8.3 Contraindications

Avoiding the use of the S-ICD is advisable in patients who have known monomorphic VT or conditions like sarcoidosis or arrhythmogenic right ventricular cardiomyopathy, which are likely to lead to VT amenable to antitachycardia pacing. Additionally, the presence of sinus node dysfunction, atrioventricular block, or an indication for cardiac resynchronization contraindicates the use of the S-ICD. This is because about 80% of spontaneous VT episodes respond to painless antitachycardia pacing (40).

A surface ECG manual screening tool has been created to reduce the occurrence of inappropriate shock (IAS) caused by T-wave oversensing errors (3,41–43). This tool identifies patients with large

or delayed T-waves compared to the QRS complex using three vectors resembling the device's sensing vectors. ECG screening is facilitated through automated software integrated into device programmers. Research indicates that approximately 8 to 15 percent of patients are deemed ineligible for an S-ICD due to susceptibility to T-wave oversensing, leading to a heightened risk of inappropriate shocks (3,42,43).

8.4 S-ICD efficacy

The S-ICD PAS, the largest prospective, multicenter trial for S-ICD to date, was conducted across 86 U.S. centers. Its objective was to evaluate the efficacy of the S-ICD over a 5-year period, focusing on safety and efficacy endpoints. With 1,643 patients enrolled and a median follow-up of 4.2 years, the study successfully met all prespecified safety and efficacy goals. Shock efficacy rates for ventricular tachycardia or ventricular fibrillation episodes were notably high at 98.4%, consistent across follow-up years. Furthermore, S-ICD-related complication-free rates were impressive at 93.4%, with electrode-related complications virtually absent at 99.3%. Remarkably, only 1.6% of patients required device replacement due to pacing needs. Despite a cohort with increased comorbidities compared to previous trials, cumulative all-cause mortality stood at 21.7%. These findings underscore the robust 5-year safety and efficacy profile of the S-ICD, making it a compelling choice for a diverse range of recipients (44).

In addition to assessing the efficacy of the S-ICD, predictive tools have been developed to forecast defibrillation success. One such tool is the PRAETORIAN score, designed to evaluate implant positioning and predict the likelihood of successful defibrillation. This scoring system integrates clinical knowledge and computer modeling insights to analyze factors influencing the defibrillation threshold, including sub-coil fat, sub-generator fat, and the anterior positioning of the S-ICD generator. Through the analysis of two distinct datasets, the PRAETORIAN score demonstrated high predictive accuracy. In a cohort of 181 S-ICD subjects and 321 patients from the S-ICD IDE trial, a positive predictive value of 51% was observed for intermediate or high PRAETORIAN scores in predicting failed conversion tests, while a low PRAETORIAN score predicted successful conversion in 99.8% of cases. These findings underscore the effectiveness of the PRAETORIAN score in identifying patients with elevated defibrillation thresholds and providing valuable feedback to implanters regarding S-ICD positioning (Figure 4) (45).

In a study, a novel method was developed to mitigate issues related to erosion, extrusion, and migration of the pulse generator (27,46–49), while also enhancing patient comfort and cosmetic outcomes (49). This involved implementing a two-incision implant technique with intermuscular placement between the anterior surface of serratus anterior and the posterior surface of latissimus dorsi to achieve optimal device positioning. The adoption of this technique showed promising results in improving device performance and reducing complications over the long term (43,49).

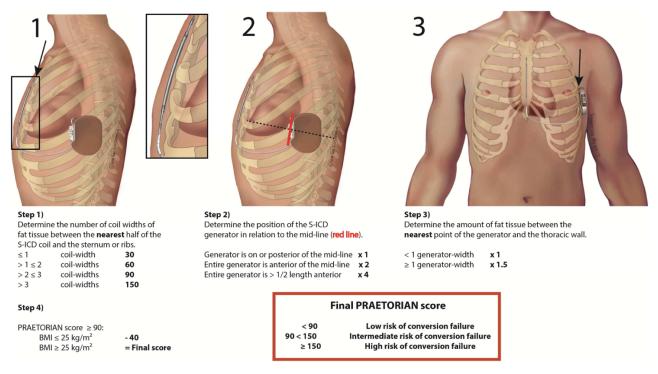


Figure 4. Illustration of the PRAETORIAN Score Steps (45).

9. COMPARISON OF SUBCUTANEOUS AND TRANSVENOUS DEFIBRILLATOR THERAPY

In a noninferiority trial, patients eligible for an implantable cardioverter-defibrillator but without pacing indication were randomly assigned to receive either a subcutaneous ICD or transvenous ICD. The trial aimed to assess the composite occurrence of device-related complications and inappropriate shocks, with a noninferiority margin set at 1.45 for the upper boundary of the 95% confidence interval for the hazard ratio (subcutaneous ICD vs. transvenous ICD). Secondary endpoints included mortality and occurrences of appropriate shocks. A total of 849 patients were included in the analysis, with 426 in the subcutaneous ICD group and 423 in the transvenous ICD group. Over a median follow-up duration of 49.1 months, primary endpoint events occurred in 68 patients in each group, with 48-month Kaplan–Meier estimated cumulative incidence rates of 15.1% and 15.7% for the subcutaneous

and transvenous ICD groups, respectively. The hazard ratio for the primary endpoint was 0.99 (95% CI, 0.71 to 1.39), indicating noninferiority with a p-value of 0.01, and 0.95 for superiority. Device-related complications were observed in 31 patients with subcutaneous ICDs and 44 patients with transvenous ICDs (hazard ratio, 0.69; 95% CI, 0.44 to 1.09), while inappropriate shocks occurred in 41 and 29 patients, respectively (hazard ratio, 1.43; 95% CI, 0.89 to 2.30) (Table 1). Mortality was recorded in 83 patients with subcutaneous ICDs and 68 patients with transvenous ICDs (hazard ratio, 1.23; 95% CI, 0.89 to 1.70), with appropriate shocks occurring in 83 and 57 patients, respectively (hazard ratio, 1.52; 95% CI, 1.08 to 2.12) (Table 2). In conclusion, the subcutaneous ICD demonstrated noninferiority to the transvenous ICD concerning both device-related complications and inappropriate shocks among patients eligible for an ICD without pacing needs (50,51).

End point	Subcutaneous ICD (N=426)	Transvenous ICD (N=423)	Hazard Ratio (95% CI)
Primary composite end point — no. (%)	68 (15.1)	68 (15.7)	0.99 (0.71–1.39)†
Components of primary end point			
Device-related complication — no. (%)	31 (5.9)	44 (9.8)	0.69 (0.44–1.09)
Infection — no.‡	4	8	
Bleeding — no.	8	2	
Thrombotic event — no.	1	2	
Pneumothorax — no.§	0	4	
Lead perforation — no.§	0	4	
Tamponade — no.	0	2	
Lead repositioning — no.∬	2	7	
Other lead or device complication — no.	19	20	
Lead replacement§¶	3	9	
Device malfunction	4	6	
Sensing issues	4	0	
Pacing indication	5	1	
Implantation failure	0	3	
Defibrillation test failure**	3	0	
Pain or discomfort	2	3	
Inappropriate shock — no. (%)††	41 (9.7)	29 (7.3)	1.43 (0.89–2.30)
Atrial fibrillation or supraventricular tachycardia — no.	11	27	
Cardiac oversensing — no.‡‡	24	2	
Noncardiac oversensing — no.∬	8	0	

Table 1. Primary Composite End Point (reproduced from the PREATORIAN Study (51)).

* Percentages are 4-year cumulative incidences based on Kaplan–Meier estimates in time-to-first-event analyses. Multiple end points could occur in one patient; only the first end point was included in the estimation of the cumulative incidence. For all end points, the sample included all the patients in the trial group. The widths of the 95% confidence intervals have not been adjusted for multiplicity and therefore should not be used to infer definitive treatment effects.

† P=0.01 for noninferiority; P=0.95 for superiority.

- This category included lead-related infections in one patient in the subcutaneous ICD group and in five in the transvenous ICD group.
- [This end point was included in the composite end point "lead-related complications" (Fig. S2).
- In the subcutaneous ICD group, lead replacements were due to dislocation in two patients and to myopotential oversensing in one. In the transvenous ICD group, lead replacements were due to lead dysfunction in six patients and to lead dislodgement in three.
- In the subcutaneous ICD group, three patients received a pacemaker, one received a cardiac-resynchronization therapy device with a defibrillator (CRT-D), and one crossed over to transvenous ICD therapy all for pacing for the treatment of bradycardia. In the patient in the transvenous ICD group who had previously crossed over to subcutaneous ICD therapy, sick-sinus syndrome later developed, for which a pacemaker was implanted.
- ** This category included defibrillator test failures that led to surgical reintervention.

†† The subcutaneous ICD sensing filter (SMART Pass) was not activated or was unavailable in 78% of the first inappropriate shocks in the subcutaneous ICD group.

†‡ This category included T-wave and P-wave oversensing and includes shock on atrial fibrillation or supraventricular tachycardia below the detection limit in five patients in the subcutaneous ICD group.

 $\$ This category included myopotential and noise oversensing.

Table 3. Secondary End Points.*						
End Point	Subcutaneous ICD (N=426)	Transvenous ICD (N=423)	Hazard Ratio (95% CI)			
Death from any cause — no. (%)	83 (16.4)	68 (13.1)	1.23 (0.89–1.70)			
Sudden cardiac death — no.†	18	18				
Death from other cardiovascular causes — no.	34	28				
Death from noncardiovascular causes — no.	31	22				
Appropriate shock therapy — no. (%)	83 (19.2)	57 (11.5)	1.52 (1.08–2.12)			
Ventricular fibrillation — no.	32	22				
Ventricular tachycardia within therapy zone — no.	57	41				
Ventricular tachycardia below therapy zone — no. \ddagger	11	0				
Antitachycardia pacing — no. (%)∬						
Appropriate	6 (0.6)	54 (12.9)				
Inappropriate	1 (0.3)	30 (7.2)				
Major adverse cardiac event — no. (%)	64 (13.3)	80 (16.4)	0.80 (0.57–1.11)			
Hospitalization for heart failure — no. (%)	79 (17.4)	74 (16.1)	1.08 (0.79–1.49)			
Crossover to other study device — no. (%)	18 (4.3)	11 (2.7)	1.64 (0.77–3.47)			
Before initial implantation — no.	4	6				
During implantation or follow-up — no.	14	5				
Upgrade to CRT-D — no. (%)	16 (3.5)	21 (4.2)				

* Percentages are 4-year cumulative incidences based on Kaplan–Meier estimates in time-to-first-event analyses. For all end points, the sample included all the patients in the trial group. The widths of the 95% confidence intervals were not adjusted for multiplicity and therefore should not be used to infer definitive treatment effects.

† This category included death from unexplained causes.

These shocks were delivered on ventricular tachycardia below the programmed therapy limit with oversensing of cardiac signals. The sensing filter (SMART Pass) was not activated or was unavailable in 91% of the first occurrences of such events.

§ Patients who received antitachycardia pacing in the subcutaneous ICD group had previously crossed over to transvenous ICD therapy or had received a CRT-D.

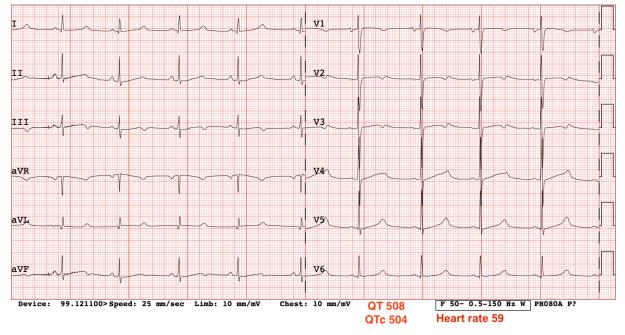
10. CLINICAL CASE

A 4-year-old child was taken to the emergency department after experiencing a syncopal episode lasting around 20 minutes. His relatives reported that this was not the first such incident and also mentioned that the child is deaf and mute. Medical evaluation suggested long QT syndrome as the likely cause of the syncope, indicated by a QT interval of 532 ms, a corrected QT (QTc) interval of 548 ms, and a heart rate of 64 beats per minute. Other tests did not reveal any significant findings. Following a consultation with cardiologists, the child was prescribed propranolol, and in subsequent months, a pacemaker was implanted. Post-implantation, with the medication switched to metoprolol, the child's QTc interval improved to 507 ms, QT interval to 426 ms, and heart rate normalized to 84-

88 beats per minute. Some time later the diagnosis was confirmed as long QT syndrome, specifically Jarvell and Lange-Nielsen syndrome.

Two years after the initial treatment, an implantable loop recorder was implanted to monitor heart activity. The device was removed a year afterward for analysis. The child's grandmother mentioned that there had been only one syncope episode post-implantation, and the boy remained active and symptom-free otherwise. Data from the implantable loop recorded showed episodes of ventricular tachycardia during the syncope and recorded instances of 2nd degree AV block. After consultation, it was recommended to implant a transvenous implantable cardioverter-defibrillator (ICD) and to increase the beta-blocker dosage. About a month later, the now 7-year-old patient underwent a dual-chamber transvenous ICD implantation in the left pectoral region.

Within six months of the procedure, the patient returned for a consultation where ICD pocket infection was discovered. Consequently, the patient was admitted to the hospital for the removal of the ICD.



Recorded ECG after the removal of the transvenous ICD.

The patient underwent antibiotic therapy for two weeks, after which a dual-chamber ICD was implanted in the right pectoral region. A few months later, the patient was admitted to the hospital due to intercostal muscle contractions, which led to a revision of the ICD. During the revision, it was

discovered that one of the leads had become disconnected from the generator. This issue was fixed on the same day, and the patient was discharged a few days later.

Around five years later, when the patient was 12 years old and shortly after his mother had died suddenly, he was hospitalized for a generator change due to its low battery life. During a consultation with electrophysiologists, it was discovered that the ICD leads were strained. Consequently, a corrective operation was scheduled for the following weeks in a hybrid operating room to ensure availability of cardiac surgeons if needed. The leads could not be removed intravenously, necessitating open-heart surgery with cardiopulmonary bypass, which was performed a few days later. The surgery successfully removed the obstructive and overgrown leads. However, it was not possible to implant a new transvenous ICD due to the increased risk to impair venous circulation on both sides.

In a subsequent consultation it was decided to implant a subcutaneous ICD on the left side of the chest, just below the armpit area, which was implanted in a couple of months. Five years later, the generator was replaced with no complications, due to low battery. Recently, the patient visited the clinic, with the device still showing 2-3 years of battery life remaining.

11. CONCLUSIONS AND PRACTICAL RECOMMENDATIONS

Based on the literature, when comparing the effectiveness of S-ICDs and traditional transvenous ICDs in preventing sudden cardiac death, S-ICDs have demonstrated significant safety and efficacy for patients without pacing needs and those at high risk for vascular complications. For pediatric patients, S-ICDs are an option due to the high likelihood of lead failures and complications with transvenous systems over their lifetime. A clinical case illustrates this situation and demonstrates the real-world utility of S-ICDs, highlighting the individual approach to each case. An individual approach is advised when choosing the defibrillation method, and further research should continue to clarify the outcomes of different patient groups in using S-ICD systems.

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