Subcutaneous implantable cardioverter--defibrillators for the prevention of sudden cardiac death: five-year single-center experience

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Received: January 31, 2020.
Revision accepted: March 9, 2020.
Published online: March 17, 2020.
Kardiol Pol. 2020; 78 (5): 447-450
doi:10.33963/KP.15235

Introduction A totally subcutaneous implantable cardioverter-defibrillator (S-ICD) is an established method of treatment in patients at risk for sudden cardiac death (SCD). Both the American and European guidelines recommend its application as a class IIa recommendation, in case of indications for implantable cardioverter--defibrillator in patients who do not require permanent cardiac pacing or antitachycardia pacing.[1] The high cost of the device and limited reimbursement result in a relatively small number of patients treated with S-ICD and centers using that method in Poland. In this study we present the 5-year single-center experience with the use of S-ICD.

Methods The study group included 25 patients (13 women and 12 men) at the mean (SD) age of 49 (17) years (range, 13–70 years). One patient (number 1) had his device implanted abroad, and he underwent a pocket repair procedure in our center. The S-ICD was implanted for secondary prevention of SCD in 18 patients. The decision to choose S-ICD was based on additional clinical factors, and in many cases multiple factors were present (obstructed vascular access in 9 patients, high risk for infective complications in 6, young age in 8, and a history of failures of transvenous leads in 7; 1 indication in 9 patients [36%], 2 in 10 patients [40%], 3 in 4 patients [16%], 4 in 1 patient [4%], and 5 in 1 patient [4%]). Left ventricular ejection fraction was 15% to 66% (mean [SD], 48% [15%]). Detailed data are presented in TABLE 1.

The S-ICD implantation procedure was performed under general anesthesia. In the first 3 cases, the S-ICD pocket was subcutaneous, an in the remaining cases, intermuscular. In 21 patients, the defibrillation test was performed, and in 4 patients, it was abandoned due to contraindications (see Supplementary material, *Table S1*).

Only descriptive statistical methods were used.

Due to observational nature of the study, no additional patient consent was required.

Results and discussion No perioperative complications were observed.

Out of 21 patients in whom the defibrillation test was performed, in 20 cases, the first 65-J shock was effective. In one patient, the shock polarity inversion was required to achieve termination of ventricular fibrillation.

No late surgical complications were observed during the follow-up.

Subcutaneous implantable cardioverter-defibrillator interventions An adequate antiarrhythmic intervention of S-ICD was observed in one patient (4%, patient number 9). Ventricular arrhythmias occurred 5 times and they were terminated by the first 80-J shock. The patient died 9 months following the implantation due to progressive heart failure and pneumonia.

Inadequate interventions were observed in 5 patients (20%). In 2 cases (8%), they were related to atrial fibrillation (AF), in 1 case (4%) to an interaction between S-ICD and pacemaker, and in the remaining 2 cases (8%), the exact

TABLE 1 Clinical and demographic data of the study group

Patient no.	Sex	Age, y	NYHA class	LVEF, %	Cardiac rhythm	Indication for S-ICD	SCD prevention	Prior CIED	Prior extraction of CIED	CIED present at S-ICD implantation	Indication for pacing	Indication for S-ICD[a]	Follow-up, mo
1	M	40	I	65	SR	IVF	Secondary	No	No	No	No	3	68
2	F	57	I	60	SR	IVF	Secondary	No	No	No	No	1, 2	61
3	F	62	I	30	SR	ICM	Primary	No	No	No	No	1, 2	56
4	F	34	I	50	SR	ARVC	Primary	ICD VR	Yes	No	No	1, 2, 3, 4, 5	48
5	M	70	II	40	SR	ICM	Secondary	Epicardial VVI	No	Epicardial VVI	Paroxysmal AVB III	2	41
6	M	39	I	60	SR	HCM	Primary	DDD	No	DDD (both leads inactive)	No	1, 3	38
7	F	60	I	55	SR	IVF	Secondary	ICD VR	Yes (only device can)	No (only abandoned lead)	No	1	36
8	M	60	I	35	AF	NICM	Secondary	ICD VR	Yes	ICD VR	No	1, 6	35
9	F	63	II	25	AF	LVNC	Secondary	ICD VR	Yes	No	No	2, 4, 5	9
10	F	68	I	30	SR	ICM	Primary	ICD VR	Yes	ICD-VR	No	1, 6	32
11	M	65	II	35	SR	ICM	Secondary	ICD VR	Yes	ICD-VR	No	1, 6	30
12	F	69	I	50	SR	IVF	Secondary	No	No	No	No	2	29
13	M	16	III	15	SR	NICM	Primary	DDD	No	DDD	LBBB, AVB I/II/III	1, 3	2 (followed by heart transplant)
14	F	59	I	35	SR	ICM	Secondary	ICD VR	Yes	ICD VR	No	1, 6	23
15	F	48	I	60	SR	LQTS	Secondary	ICD DR	Yes	ICD DR	No	1, 6	19
16	F	16	I	66	SR	LQTS	Secondary	No	No	No	No	3	18
17	M	45	II	43	SR	DCM	Primary	ICD VR	Yes	No	No	2, 3, 4, 5	18
18	F	38	I	50	SR	IVF	Secondary	ICD VR	Yes	ICD VR	No	1, 3, 6	18
19	F	48	I	62	SR	IVF	Secondary	No	No	No	No	3	15
20	M	13	I	60	SR	LQTS	Secondary	No	No	No	No	3	9
21	F	31	I	60	SR	IVF	Secondary	No	No	No	No	3	7
22	M	51	I	60	SR	IVF	Secondary	ICD VR	Yes	No	No	2, 4, 5	2
23	M	66	II	35	AF	ICM	Primary	No	No	No	No	1, 2	1
24	M	44	III	60	SR	ARVC	Secondary	ICD VR	Yes	No	No	2, 4, 5	1
25	M	58	I	60	SR	IVF	Secondary	No	No	No	No	2	0

a 1 – problematic vascular access; 2 – high risk of infection; 3 – young age; 4 – history of cardiac implantable electronic device infection; 5 – history of infective endocarditis; 6 – prior lead failure and transvenous lead extraction

Abbreviations: AF, atrial fibrillation; ARVC, arrhythmogenic right ventricular cardiomyopathy; AVB, atrioventricular block; CIED, cardiac implantable electronic device; F, female; HCM, hypertrophic cardiomyopathy; ICD, implantable cardioverter-defibrillator; ICM, ischemic cardiomyopathy; IVF, idiopathic ventricular fibrillation; LBBB, left bundle branch block; LQTS, long QT syndrome; LVEF, left ventricular ejection fraction; LVNC, left ventricular noncompaction; M, male; NICM, nonischemic cardiomyopathy; NYHA, New York Heart Association; SCD, sudden cardiac death; S-ICD, subcutaneous implantable cardioverter-defibrillator; SR, sinus rhythm; TLE, transvenous lead extraction

nature of interventions could not be determined. Patient 5 experienced inadequate interventions twice. The first one occurred during the early postoperative period. The analysis of recordings from the device memory (in cooperation with the manufacturer) did not result in any conclusive explanation of the nature of noise registered by the device.[2] The second inadequate intervention occurred in month 36 of the follow-up. It was due to inappropriate detection, most certainly resulting from the R-wave morphology change during permanent cardiac pacing delivered by a DDD pacemaker with epicardial leads. Repeated automated screening for S-ICD failed to confirm any possibility of appropriate sensing in that patient. As no ventricular arrhythmia was recorded during the follow-up period and the patient presented substantial improvement in left ventricular ejection fraction, a decision was made to switch the S-ICD device off.

Patient 6 experienced inadequate interventions 3 times while staying abroad. Due to the fact that no explanation for the noise that caused those interventions could be found by consulting electrophysiologists or manufacturer's representatives, the whole S-ICD system was replaced with a new one (new S-ICD) in a local hospital.

Patient 8 experienced inadequate interventions due to a sudden 2-fold increase of the ventricular rate of permanent AF. As a solution, the device settings were modified and rate-lowering treatment intensified.

Patient 17 had 5 episodes of AF with fast ventricular rate leading to inadequate interventions, and therefore pulmonary vein isolation was performed with good outcome.

Patient 13 experienced single inadequate shock in the postoperative period. The intervention was due to AAI pacing from the previously implanted permanent dual-chamber pacemaker with a first degree atrioventricular conduction block, which resulted in the overlay of paced P and T waves, and oversensing of that modified T-wave by the S-ICD. The settings for pacing of the pacemaker and detection of the S-ICD were reprogrammed. The problem was never observed again.

No other inadequate interventions were observed. Data concerning coexisting devices may be found in Supplementary material (*Table S2*).

The efficacy of S-ICD in defibrillation testing in clinical studies is estimated at over 90%,[3] and a need for surgical repositioning can occur in 5% of cases. In our population with 21 defibrillation tests performed, there was a need for shock polarity reversal only in 1 case (4.7%). In all the remaining cases, an impulse of 65 J proved effective. The device can was placed dorsally in relation to the midaxillary line, and such a location may promote lowering of the defibrillation threshold.[4] Our results seem to confirm that hypothesis (100% efficacy of the 65-J impulse).

Surgical complications of S-ICD implantation were reported to affect between 10% and 20% patients in the early years of the method. With increasing experience, the percentage of complications decreased to 3% in the first postoperative month.[5] In our cohort, we did not observe surgical complications in any of the de-novo implantations during the whole follow-up.

Inadequate interventions of S-ICD during the follow-up were observed in 5 patients (20%). In early-stage publications, the annual rate of inadequate interventions was between 7% and 13%, and has then been reduced to several percent due to improved detection and programming of 2 detection zones.[6] In our cohort, the inadequate intervention was caused by AF only in 2 cases. In the next 2 cases, inadequate therapies were due to interaction of a S-ICD with a coexisting pacemaker. In the last case, the cause of inadequate interventions could not be determined. In that patient, the whole system was replaced. In conclusion, inadequate interventions related to supraventricular arrhythmias were observed in 2 patients (8%), which is in line with the rates observed in other studies.

In our cohort, we observed 2 patients with a coexisting S-ICD and pacemaker. In both cases, inadequate interventions of S-ICD occurred due to the possible interaction between the devices. In patient 5, the possible cause of intervention was the decreased voltage of R-wave with concurrent myopotentials associated with physical activity. Permanent cardiac pacing from the DDD pacemaker as the reason for R-wave morphology change could neither be confirmed nor excluded. On repeated screening, none of the 3 electrocardiography vectors registered during pacing were appropriate for the use of S-ICD. The producer's representative suggested S-ICD system replacement, but with no guarantee that it would solve the problem. The decision was made to discontinue the S-ICD use, and the device was switched off.

The second patient requiring permanent cardiac pacing (patient 13) also experienced inadequate intervention, despite prior positive screening for S-ICD. It was caused by T-wave oversensing of the T wave changed in morphology due to overlay of P and T waves in the course of first-degree atrioventricular block. The problem was solved with pacemaker reprogramming.

As the S-ICD system cannot provide permanent cardiac pacing, the issue of possible interactions between a pacemaker and S-ICD is of paramount importance. Current guidelines state that S-ICD implantation is contraindicated in case of bradycardia requiring cardiac pacing.[1] Nonetheless, it may be expected that indications for permanent cardiac pacing may develop in some patients after the implantation of S-ICD. In populations of patients with S-ICD,

the absolute indication for pacemaker occurred in 2 patients out of 882 during 2 years (0.2%). In our cohort, both patients had the pacemaker implanted prior to S-ICD qualification, and the S-ICD system was implanted nonetheless, because no other therapeutic option was available in those patients. In no other case did we observe an indication for pacemaker develop after S-ICD implantation.

Summary The authors acknowledge that a small study group is the main limitation of the above analysis. Nonetheless, the aim of our report was to present our single-center results and troubleshoot specific real-life problems. A small number of patients with S-ICDs in our cohort is mainly caused by limited reimbursement of the system by the National Healthcare Fund in Poland. Our results confirm the efficacy of the treatment option and low risk of surgical complications, which suports its further more widespread application in Poland.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/kardiologiapolska.

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

HOW TO CITE Kempa M, Budrejko S, Zienciuk-Krajka A, et al. Subcutaneous implantable cardioverter-defibrillators for the prevention of sudden cardiac death: five-year single-center experience. Kardiol Pol. 2020; 78: 447-450. doi:10.33963/KP.15235

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