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Evolution of implantation technique and indications for a subcutaneous cardioverter--defibrillator over 7 years of experience in Poland

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Short title: 7 years of S-ICD evolution in Poland

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INTRODUCTION

Implantation of a subcutaneous cardioverter-defibrillator (S-ICD) may be used to prevent sudden cardiac death (SCD) due to ventricular arrhythmias in patients not requiring permanent cardiac pacing or antitachycardia pacing [1, 2]. That method of treatment was first applied in Poland in 2014 [3, 4]. But it took the S-ICD implantation procedure several years to become in 2019 reimbursed to the extent sufficient to cover the whole cost borne by the implanting centers. That in turn led to an increase in the number of procedures performed in Poland [5]. There is currently no report available on how that might have influenced the qualification procedure, implantation technique and results in comparison to the preceding period.

The aim of our analysis was to investigate, whether there was any change to indications for S-ICD implantation, operational technique and patient outcomes over 7 years of S-ICD utilization in Poland.

METHODS

We compared data collected in two registries in different time intervals: Registry A — September 2014 to December 2015, and Registry B — May 2020 to May 2021. Registry A was a multicenter query reporting data of 18 patients from 5 centers that pioneered S-ICD implantations in Poland [6]. Registry B is a nationwide initiative held by the Heart Rhythm Section of the Polish Cardiac Society [7], and 16 centers performing S-ICD implantations report data of subsequent patients undergoing implantation or exchange of the device. The analysis comprised only 144 patients from

Registry B undergoing first-time implantation of the system. We compared the data describing the general characteristics of patients, underlying diseases, implantation techniques, as well as reasons for choice of a subcutaneous instead of a transvenous cardioverter-defibrillator.

Statistical analysis

Continuous variables were presented as median and interquartile range (IQR) due to non-normal distribution confirmed with the Shapiro–Wilk test. The Mann–Whitney U test was used to compare continuous variables. Categorical parameters were presented as numbers and percentages, and Fisher's exact test was used for comparisons. A *P*-value of below 0.05 was considered statistically significant. Statistical analysis was performed with the use of Statistica 13.1 software (StatSoft, USA).

RESULTS AND DISCUSSION

Detailed data of the patients in both groups are presented in Table 1. Inter-group comparisons revealed that during the early period of S-ICD implementation in Poland it was less often implanted in primary prevention of SCD (22% vs. 65%; P <0.001), and dilated cardiomyopathy was less frequently the main underlying disease (17% vs. 47%; P = 0.02). Patients in the early group had higher left ventricular ejection fraction (LVEF) (median value, 52.5% vs. 35%; P = 0.005), whereas the main indications reasoning the choice of S-ICD were lack of venous access (44%) and high risk of infective complications (61%). In the more contemporary group, young age was the main reason for choice of S-ICD (76%). The change in operational technique over time was expressed as significant increase of the percentage of procedures performed without general anesthesia (0% vs. 26%; P = 0.01). 2-incision technique has become more frequently applied instead of the 3-incision one (11% vs. 56%; P <0.001), and the device pocket is now more frequently intramuscular than before (72 vs. 100%; P <0.001). Defibrillation test tends to be nowadays less frequently performed (100% vs. 83%; P = 0.08). In patients from Registry B, 3 cases of post-operative complications were reported: pocket hematoma treated conservatively, inadequate shock possibly due to air entrapment in the device connector or pocket, and unilateral lower limb paresis (with no changes found in imaging of the central nervous system).

During the initial years of S-ICD use in Poland the number of implanting centers and procedures was limited. It resulted from the high cost of the system, and troublesome reimbursement procedure. Therefore, S-ICD implantation was reserved for secondary prevention of SCD and for patients not eligible for transvenous system (either with limited vascular access or high risk of infective complications), because only in such cases the implanting center would not have risked

incomplete reimbursement. Once the complete reimbursement had come into play, the method became more applicable in primary prevention of SCD and patient's young age might have become an indication for the choice of S-ICD. That selection factor became dominant, which brought Polish data closer to European reports [8]. Novel operational techniques reported in the literature, such as regional anesthesia, 2-incision technique and intramuscular pocket [9–12], have been introduced in Polish centers ever since. Those techniques have become dominant, and our results suggest that general anesthesia may be soon replaced by local and regional anesthetic techniques. Our analysis shows, that in many cases (17% in the Registry B) the defibrillation test is currently waived. It may result from the high efficacy of S-ICD in termination of ventricular fibrillation, that reached 100% of performed tests in both registries. Alternatively, it may be due to the concerns about the safety of inducing ventricular fibrillation in patients with more reduced LVEF, as a tendency to implant S-ICD in patients with more severe LVEF impairment was observed in Registry B compared to Registry A (median LVEF 35% vs. 52.5%, respectively). Of note, that did not significantly increase the complication rate, that remains below 2% in our data and is lower than reported by other groups [13].

Our analysis confirms the increasing role of S-ICD as a method of primary prevention of SCD in Poland. Recent administrative regulations resulted in a change of profile of patients qualified for the procedure. Currently, the main reason for choice of S-ICD is young age of a patient. A tendency to incorporate new operational techniques used in European centers is observed, with no increase of the perioperative complication rate. The influence of updated reimbursement regulations on the use of S-ICD in Poland suggests that other modern methods might be successfully introduced, if only clear regulations were introduced to cover all the costs borne by the implanting centers.

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Table 1. Comparison of clinical characteristics of patients in both registries. Registry A – September 2014 to December 2015, Registry B – May 2020 to May 2021. IQR, interquartile range; LVEF, left ventricular ejection fraction.

	Registry A	**Registry B**	***P***
General information			
Total number of patients	18	144	—
Age, years, median (IQR)	39 (32–62)	41 (31–55)	0.79
Male sex, n (%)	10 (56)	108 (75)	0.1
Sinus rhythm, n (%)	14 (78)	135 (94)	0.04
Primary prevention, n (%)	4 (22)	94 (65)	<0.001
LVEF, %, median (IQR)	52.5 (45–60)	35 (25–60)	0.005
Underlying disease			
Dilated cardiomyopathy, n (%)	3 (17)	68 (47)	0.02
Ischemic cardiomyopathy, n (%)	6 (33)	40 (28)	0.59
Hypertrophic cardiomyopathy, n (%)	2 (11)	7 (5)	0.26
Arrhythmogenic right ventricular dysplasia, n (%)	1 (6)	0	0.11
Long QT syndrome, n (%)	1 (6)	5 (3)	0.51
Brugada Syndrome, n (%)	1 (6)	3 (2)	0.38
Short QT syndrome, n (%)	0 (0)	2 (2)	1
Left ventricle non-compaction, n (%)	0 (0)	1 (1)	1

Catecholaminergic polymorphic ventricular tachycardia, n (%)	0 (0)	1 (1)	1
Mitral annular dysjunction, n (%)	0 (0)	1 (1)	1
Congenital heart disease, n (%)	1 (6)	2 (1)	0.3
Primary ventricular fibrillation, n (%)	3 (17)	15 (10)	0.43
Reason for choice of S-ICD vs. T-ICD			
Young age, n (%)	4 (22)	109 (76)	<0.001
Risk of infective endocarditis, n (%)	11 (61)	33 (23)	0.001
Recurrent lead failure, n (%)	1 (6)	10 (7)	1
Lack of venous access, n (%)	8 (44)	7 (5)	<0.001
Other, n (%)	1(6)	6 (4)	0.57
Implantation procedure			
General anesthesia, n (%)	18 (100)	107 (74%)	0.01
Intramuscular pocket, n (%)	13 (72)	144 (100)	<0.001
2-incision technique, n (%)	2 (11)	80 (56)	<0.001
Defibrillation test performed, n (%)	18 (100)	119 (83)	0.08
Defibrillation test successful, n (%)	18 (100)	119 (100)	—
Complications, n (%)	0 (0)	3 (2)	1