Multicenter Registry of Subcutaneous Cardioverter--Defibrillator Implantations: a preliminary report

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INTRODUCTION

Implantation of a subcutaneous cardioverter--defibrillator (S-ICD) is a well-established method for prevention of sudden cardiac death due to ventricular arrhythmias. It may be applied in patients with indications for an implantable cardioverter-defibrillator (ICD) not requiring permanent cardiac pacing nor antitachycardia pacing [1]. First implantation procedures in Poland were performed in 2014 [2, 3]. Due to the lack of clear rules for reimbursement of the procedure in the early days, the total number of implantations performed in Poland at that time was low. Reimbursement rules were changed in 2019 to the level allowing for complete coverage of the costs. It led to an increase in the number of implantations, but the total cumulative number of implantations in Poland has not yet exceeded 450.

Although the Heart Rhythm Section of the Polish Cardiac Society has published an expert opinion on the use of S-ICD in Poland, there is currently no report available that would summarize the Polish experience with S-ICD [4]. Therefore, the Executive Board of the Heart Rhythm Section appointed the Multicenter Registry of Subcutaneous Cardioverter-Defibrillator Implantations. The registry has been approved by Bioethical Committee at the Regional Medical Board in Rzeszow, Poland (decision number 35/B/2020), and launched on the 1st of May 2020.

METHODS

The Multicenter Registry of Subcutaneous Cardioverter-Defibrillator Implantations is an open registry run by the Heart Rhythm Section of the Polish Cardiac Society. Centers implanting S-ICD devices add data of consecutive patients undergoing implantation or exchange of the S-ICD system. Participation in the registry does not influence the clinical routine in any way. All data are introduced when the hospitalization is finished, and include age, gender, underlying disease, reasons for indications for S-ICD, electrocardiographic parameters, technique of implantation, and complications during the in-hospital period. The analysis included data reported between May 2020 and January 2021, regarding the periprocedural period, whereas follow-up data will be collected onwards and reported accordingly.

Statistical analysis

Continuous variables were reported as a range, mean and standard deviation, and categorical variables as numbers and percentages. Due to the type of our analysis, only descriptive statistics was used.

RESULTS AND DISCUSSION

During the initial 8 months, 15 centers reported 123 patients (Supplementary material, *Table S1*), 90 men, aged 15–79. Most patients were in NYHA II class. Left ventricular ejection fraction (LVEF) was 10%–80%. In 78 patients S-ICD was indicated for primary prevention. The most frequent underlying disease (54 patients, 44%) was nonischemic cardiomyopathy (Table 1). The most frequent reason for the choice of S-ICD (76%) was the patient's young age (Supplementary material, *Table S2*).

In 114 patients (93%) the reported procedure was the first-time implantation of S-ICD, and in the remaining 9 cases (7%) — device exchange. The procedure was performed most often by cardiologists and in general anesthesia — 89 procedures (72%). Local anesthesia was used in 19 cases (15%), and regional anesthesia or blockade — in 15 cases (12%). Three procedures (2%) were assisted by a cardiac surgeon. The 2-incision technique was slightly more prevalent (63 cases, 51%). The device pocket was intermuscular in all cases but one. In 102 cases, the defibrillation test was performed immediately following the surgical part of the procedure, and the 65 J shock was effective in all those patients. In 2 patients no sustained ventricular tachyarrhythmia could be induced. In the remaining 19 patients, the test was abandoned due to contraindications, specifically the risk of thromboembolic complications (10 patients) or extremely low LVEF (4 patients). The mean (SD) procedural time was 75 (32) minutes (range 18–150 min). Mean post-procedural hospitalization continued for 3 days. Complications were observed in 2 patients (pocket hematoma treated conservatively, and unilateral paresis of the lower limb with no apparent pathology on the CT and MRI scans).

Table 1. Clinical characteristics of the study group

General information	
Total number of patients	123 (100)
Age, years, mean (SD)	43 (15)
Gender: male	90 (73)
Sinus rhythm	114 (93)
LVEF, %, mean (SD)	40 (17)
NYHA class	
NYHA I	56 (46)
NYHA II	52 (42)
NYHA III	15 (12)
NYHA IV	0 (0)
Indication	
Primary prevention	78 (63)
Secondary prevention	45 (37)
Underlying disease	
NICM	54 (44)
ICM	34 (28)
HCM	5 (4)
LQTS	5 (4)
BrS	3 (2)
SQTS	2 (2)
Myocarditis	2 (2)
LVNC	1 (1)
CPVT	1 (1)
MAD	1 (1)
ToF	1 (1)
Primary VF	14 (11)

Data are presented as number (percentage) of patients unless indicated otherwise.

Abbreviations: BrS, Brugada syndrome; CPVT, catecholaminergic polymorphic ventricular tachycardia; HCM, hypertrophic cardiomyopathy; ICM, ischemic cardiomyopathy; LQTS, long QT syndrome; LVEF, left ventricle ejection fraction; LVNC, left ventricular non-compaction; MAD, mitral annular disjunction; NICM, nonischemic cardiomyopathy; SQTS, short QT syndrome; ToF, tetralogy of Fallot; VF, ventricular fibrillation

S-ICD systems have been implanted in Poland since 2014, but the total number of procedures remains relatively low, due to the high cost of the device and lack of clear rules for reimbursement during the early days of the method. Guidelines for S-ICD implantation in Poland and specified requirements for implantation centers, may potentially limit the access of patients to that method of treatment, but they enforce appropriate experience of implanting teams. Our analysis is based on the results of 123 patients, representing 90% of the total number of procedures performed in Poland between May 2020 and January 2021. According to the yearly report of the National Consultant in Cardiology, 9298 cardioverters-defibrillators were primarily implanted in Poland in 2019 (unpublished data, both ICD and CRT-D). Having taken into account the data from our eight-month period, it could be estimated that S-ICD represented about 2% of cardioverter-defibrillator implantations in our country.

In our study group, 73% of patients were men. That percentage is slightly higher than in other European centers (68.4%) but lower than in American groups (77%) [5, 6]. The mean age was 43 years, and it was lower in comparison with other studies [7].

Data concerning indications for S-ICD in our registry are also different from other reports. In our population, ischemic cardiomyopathy was diagnosed only in 28% of patients, whereas in other reports that percentage was definitely higher, reaching 48%–46% [7, 8]. The main reason for the choice of S-ICD in our study was concurrent with other studies, and it was young age in 76% of patients [9].

In clinical studies, S-ICD successfully terminated ventricular arrhythmias with 65 J test shock in over 90% of cases [10, 11]. In our population, the 65 J test shock was effective in 100% of the 102 tests performed. It may be related to the fact that the device pocket was dissected beneath the latissimus dorsi muscle in all cases of de novo implantations, which led to a dorsal final location of the can. Such a technique may be associated with higher efficacy of defibrillation test shock, due to the low impedance of defibrillation [12]. Implementation of the 2-incision technique in most cases (51%) and regional anesthesia in many

cases (28%) indicate the tendency to implement modern implantation techniques in Polish centers [13, 14].

The incidence of surgical complications of S-ICD implantation is currently estimated at approximately 3% during the first month [15]. In our study group, such complications have not been observed.

The most frequent reason for the choice of S-ICD was the patient's young age, similarly to other reports, but our observations revealed also some differences with regard to qualification for S-ICD implantation between Poland and other countries. High efficacy and lack of surgical complications in the post-operative period confirmed the appropriate selection of centers performing implantation procedures (according to the regulations issued by the National Health Fund, regarding requirements for reimbursement), and satisfactory level of training of implanting teams. The results of our study encourage further promotion of that modality of treatment in our country.

Article information

Conflict of interest: MK received consultancy fees from Boston Scientific. AP received lecturer's fees from Medtronic Polska, Biotronik Polska; consultancy fees from Medtronic Polska. KK received proctor/trainer and lecturer fees from Abbott Poland, Medtronic Poland and Boston Scientific Poland. PS received lecturer's fees from Abbott, Biotronik, Boston Scientific, Medtronic; consultancy fees from Biotronik, Boston Scientific. AS received consultancy agreement with Boston Scientific. MG received honoraria from Boston Scientific. DJ received honorarium from Boston Scientific for a lecture during Webinar. ST received a consultancy fee from Boston Scientific. The remaining authors declared no conflict of interest.

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