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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Polish single-centre follow-up of subcutaneous implantable cardioverter-defibrillator (S-ICD) systems implanted for the prevention of sudden cardiac death

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Abstract

Background and aim: Subcutaneous implantable cardioverter-defibrillator (S-ICD) is an effective and modern tool used to protect patients at risk of sudden cardiac death (SCD) from potentially life-threatening ventricular arrhythmias. The first S-ICD systems were implanted in Poland in 2014, but since that time the national experience with that therapy has been limited. Our analysis summarises the single-centre experience at the Department of Cardiology and Electrotherapy of the Medical University of Gdansk with the use of S-ICD from the year 2014 to 2017.

Methods and results: The S-ICD therapy was used in 12 patients (five male, seven female, mean age 57.2 ± 12.5 years), in eight of them for the secondary prevention of SCD. No surgical complications of implantation procedures were observed during the perioperative hospitalisation nor during follow-up. During the mean follow-up of 14 ± 13 months we observed the appropriate function of the systems and a ventricular fibrillation episode successfully terminated by the device in one patient, two cases of S-ICD sensing problems (one of which led to inadequate intervention of the device), and an episode of atrial fibrillation also leading to inadequate intervention in another patient.

Conclusions: S-ICD, being an effective and safe method used to treat patients at risk of SCD, may be safely and successfully introduced into clinical practice in centres new to that field. The number of complications during the initial experience and introduction of that method may be kept low if the operating team is experienced enough in cardiac electrotherapy.

Key words: subcutaneous implantable cardioverter-defibrillator, sudden cardiac death, electrotherapy complications

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INTRODUCTION

Subcutaneous implantable cardioverter-defibrillator (S-ICD) is an effective and modern tool used to protect patients at risk of sudden cardiac death (SCD) from potentially life-threatening ventricular arrhythmias [1, 2]. The history of the device dates back to the years 2001–2004, when the first attempts were made in humans to determine the appropriate location of the body of the S-ICD device and the lead. The first implantations of the system in the current setting were performed in the years 2008–2009 in New Zealand and Europe, in limited groups of patients (61 in total) [3]. Between 2010 and 2013, prospective clinical trials comprising 330 patients were conducted, and also some European centres were involved in that research [1]. The device acquired Food and Drug Administration approval in 2012 [4]. The first S-ICD systems were implanted in Poland in the year 2014 [5, 6]. The number of procedures is increasing slowly, due to the high cost of the device and difficulties with reimbursement from the Polish national healthcare fund. The number of centres undertaking the effort to introduce this new technology is limited as well. As a consequence, there are only a few reports presenting the results of S-ICD use in Poland, especially single-centre ones. Our publication is intended to summarise the single-centre experience with the S-ICD use during the period from 2014 to 2017.

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METHODS

At the Department of Cardiology and Electrotherapy of the Medical University of Gdansk, which is one of the referential centres in Poland, during the period from February 2014 to August 2017, S-ICD system therapy was used in 12 patients (five male, seven female, 34–69 years of age, mean age 57.2 ± 12.5 years). Three patients received the Cameron Health model 1010 SQ-RX system, and the remaining — the Emblem Boston Scientific system. The first S-ICD related procedure in our clinic was at the same time the first S-ICD related procedure performed in Poland, and it was a repair procedure in a patient with an S-ICD implanted abroad (in the USA). During the repair procedure, which was performed due to imminent pocket decubitus, the location of the pocket was changed from subcutaneous to submuscular. A detailed description of that procedure was published elsewhere [7]. In the remaining 11 cases, a de-novo S-ICD implantation was performed. Demographic and clinical data of those 12 patients are summarised in Table 1.

The S-ICD system was implanted for the secondary prevention of SCD in eight patients, and primary prevention — in the remaining four patients. Additional factors favouring the decision to implant a subcutaneous system were: no vascular access due to unilateral or bilateral thrombosis of the subclavian vein (three patients), high risk of future infective endocarditis (IE; six patients), high risk of repeat failure of endocardial leads (three patients), previously implanted endocardial leads abandoned in the vascular system (three patients), and young age of the patient with long life expectancy (two patients). Clinical factors that were considered to put patients at high risk of IE comprised the following: the history of IE, dialysis, immunosuppression, and enterocutaneous stoma made in the course of oncological treatment, with a plan of further reconstructive procedures of the colon. The S-ICD system was the first system implanted in a given patient in five cases (of which in one patient the implantation of S-ICD was directly preceded by the implantation of a permanent epicardial VVI pacemaker during the same hospitalisation). In the remaining seven cases patients had had another device implanted previously — a transvenous ICD (T-ICD) (six patients) or a DDD pacemaker (one patient). Detailed indications for an S-ICD implantation are presented in Table 2.

All procedures were performed under general anaesthesia, and de-novo implantations were made with the use of the three-incision technique, with a subcutaneous device pocket in three patients and intramuscular pocket in the remaining patients (under the latissimus dorsi muscle). The decision to switch to the intramuscular pocket was associated with the growing experience of the implanting team, and personal opinion on the superiority of the latter location. In each case, limited fluoroscopy was used before the procedure to determine (and mark on the skin) the desired lead location, device location, and anatomical landmarks used to facilitate appropriate selection of incision sites. A single, 65 J defibrillation test was performed directly following the implantation, unless any contraindication was found. In one case, the defibrillation test was skipped because of high risk associated with severe heart failure, and in one other case the test was postponed due to persistent atrial fibrillation (AF) to the next day, and it was preceded by transoesophageal echocardiographic examination. In that case, the S-ICD defibrillation test resulted in conversion to sinus rhythm. In 10 cases the induced ventricular fibrillation (VF) was terminated by the 65 J shock. In one case the 65 J shock was ineffective, and the test was repeated with a reverse polarity shock, which successfully terminated VF. No surgical complications of implantation procedures were observed during the perioperative hospitalisation. Patients were discharged with a setting of two detection windows: conditional shock zone 180–230 bpm and non-conditional shock zone 220–240 bpm.

RESULTS

All patients are subject to post-operative periodic follow-up in our clinic. During the mean follow-up time of 14 ± 13 months (range: 1–41 months) we did not observe any abnormalities related to postoperative wounds, or any surgical complications (including lead or device migration) related to the implanted system. Follow-up device interrogation confirmed appropriate function of the systems. In one patient the device recorded four episodes of non-sustained polymorphic ventricular tachycardia (VT), with no shock and spontaneous termination of the arrhythmia into sinus rhythm. The analysis of data stored by the devices revealed a VF episode successfully terminated by the device in one patient, two other cases of S-ICD sensing issues in two separate patients (one of which led to inadequate intervention of the device), and one episode of AF in another patient, also leading to inadequate intervention. No incident of clinically significant bradycardia was observed during the follow-up.

Analysis of the episodes stored by the S-ICD devices

In patient JR we found a record of an inadequate intervention during the first 24 h post-implantation due to sensing disturbances (Fig. 1). The reason for those was probably air that was not squeezed out from the device connector at implantation, despite the fact that the lead was connected to the device according to the manufacturer's instructions (the torque wrench has to be inserted into the connector prior to the lead). Another possible explanation of that phenomenon was contact between the lead tip and the metal suture placed on the sternum during prior cardiac surgery. Because of the inability to determine the cause of the sensing issues (lead contact with metal sutures was excluded with high probability based on the X-ray analysis), after consultation with a representative of the manufacturer, we decided to change the detection vector from the initial setting of secondary to

Table 1. Demographical and clinical data of the study group

Patient	Sex (M/F)	Age [years]	SCD prevention	Aetio-logy	Reasons for S-ICD choice	Previous T-ICD/PM	Abandoned leads	History of IE	Prior cardiac surgery	Dialysis	LVEF [%]	ECG rhythm	ECG intervals RR/PQ/QRS/QT [ms]
JD	M	40	Secondary	IVF	Young age	No	No	No	No	No	65	SR	900/160/100/360
WM	F	57	Secondary	IVF	Risk of IE Vein thrombosis	No	No	No	No	No	60	SR	900/210/80/400
JH	F	62	Primary	ICM	Risk of IE Vein thrombosis	No	No	No	No	Yes	30	SR	900/210/130/440
RZ	F	34	Secondary	ARVC	Risk of IE Vein thrombosis	T-ICD	No	Yes	No	No	50	SR	1000/160/100/480
JR	M	70	Secondary	ICM	Risk of IE	PM	Epi PM-VVI	Yes	Epi PM; AVR	No	40	SR	800/360/120/400
PS	M	39	Primary	HCM	Young age Abandoned leads	PM	Atrial, ventricular	No	No	No	60	SR	900/200/90/420
AM	F	60	Secondary	IVF	Abandoned lead	T-ICD	ICD lead	No	No	No	55	SR	960/166/98/419
ZR	M	60	Secondary	Toxic DCM	Abandoned lead Risk of repeat failure of endocardial lead	T-ICD	ICD lead	No	No	No	35	AF	720/-/90/400
BS	F	63	Secondary	LVNC	Risk of IE	T-ICD	No	Yes	No	No	25	AF	600/-/95/360
KR	F	68	Primary	ICM	Risk of repeat failure of endocardial lead	T-ICD	No	No	No	No	30	SR	960/190/180/460
ZL	M	65	Primary	ICM	Risk of repeat failure of endocardial lead	T-ICD	No	No	No	No	35	SR	1100/130/140/480
TZ	F	69	Secondary	IVF	Risk of IE	No	No	No	No	No	50	SR	760/140/140/460

AF — atrial fibrillation; ARVC — arrhythmogenic right ventricular cardiomyopathy; AVR - aortic valve replacement; DCM — dilated cardiomyopathy; ECG — electrocardiogram; Epi PM — epicardial pacemaker; F — female; HCM — hypertrophic cardiomyopathy; ICM — ischaemic cardiomyopathy; IE — infective endocarditis; IVF — idiopathic ventricular fibrillation; LVEF — left ventricular ejection fraction; LVNC — left ventricular noncompaction; M — male; PM — pacemaker; SCD — sudden cardiac death; S-ICD — subcutaneous implantable cardioverter-defibrillator; SR — sinus rhythm; T-ICD — transvenous implantable cardioverter-defibrillator

Table 2. Implantation and follow-up data of the study group

Patient	Procedure date	S-ICD model	Fluoro-scopy time [min]	Procedure duration [min]	S-ICD pocket	Defibrilla-tion test successful	Conditional shock zone [bpm]	Noncondi-tional shock zone [bpm]	Follow-up [months]	Sensing disturbances	Inadequate interventions	Adequate interventions
JD	17.12.2013	Cameron Health 1010SQ-RX	–	90	Intramuscular	Yes	210	230	41	No	No	No
WM	23.09.2014	Cameron Health 1010SQ-RX	1,07	120	Subcutaneous	Yes	210	230	34	No	No	No
JH	18.02.2015	Cameron Health 1010SQ-RX	0,29	90	Subcutaneous	Yes	190	220	29	No	No	No
RZ	22.10.2015	Emblem (Boston)	1,65	90	Subcutaneous	Yes	190	220	20	Yes	No	No
JR	17.05.2016	Emblem (Boston)	1,19	120	Intramuscular	Yes	200	220	13	Yes	Yes	No
PS	17.10.2016	Emblem (Boston)	1,06	120	Intramuscular	Yes	210	230	5	No	No	No
AM	28.10.2016	Emblem (Boston)	0,72	90	Intramuscular	Yes	220	240	5	No	No	No
ZR	01.12.2016	Emblem (Boston)	0,8	85	Intramuscular	Yes	200	220	8	No	Yes	No
BS	17.03.2017	Emblem (Boston)	1,62	100	Intramuscular	–	230	240	4	No	No	Yes
KR	30.03.2017	Emblem (Boston)	0,97	100	Intramuscular	Yes	190	220	4	No	No	No
ZL	14.04.2017	Emblem (Boston)	0,8	60	Intramuscular	Yes	180	220	3	No	No	No
TZ	05.06.2017	Emblem (Boston)	1,07	60	Intramuscular	Yes	190	220	1	No	No	No

S-ICD — subcutaneous implantable cardioverter-defibrillator

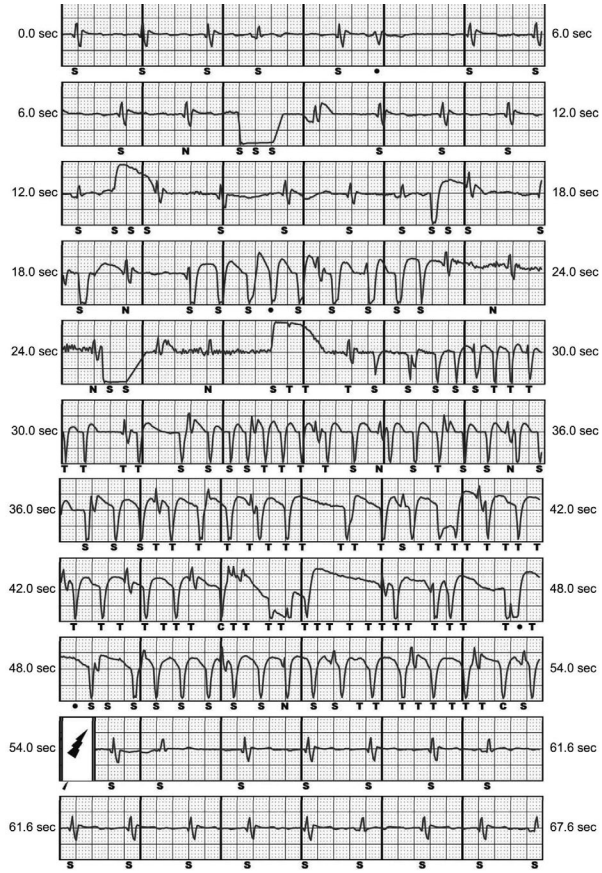

Figure 1. Episode of sensing disturbances with a following inadequate intervention of the subcutaneous implantable cardioverter-defibrillator

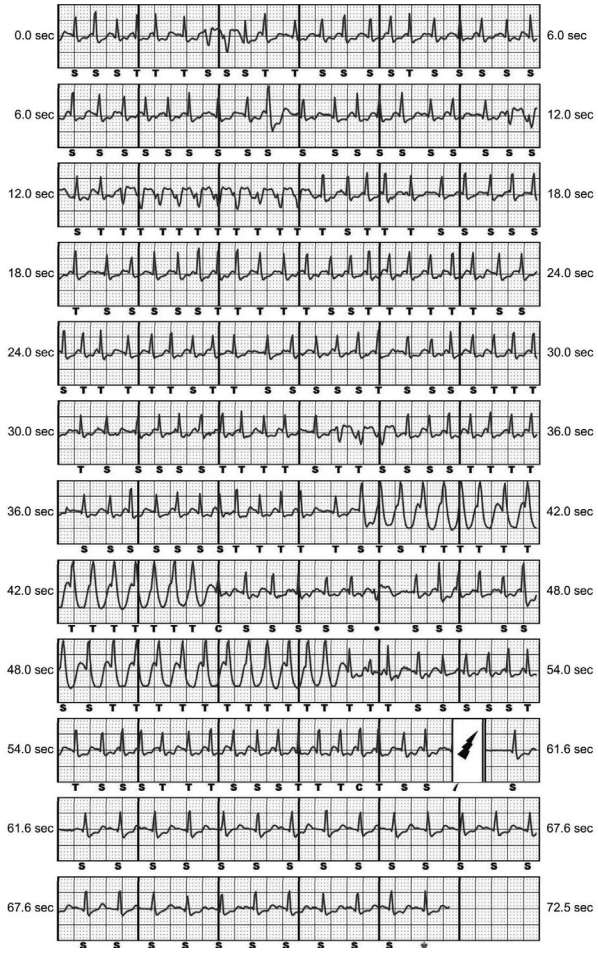

Figure 2. Inadequate subcutaneous implantable cardioverter-defibrillator intervention due to atrial fibrillation with fast ventricular rate

primary. No other sensing issues were observed during further 13-month follow-up of that patient.

In patient ZR an inadequate intervention was recorded during the third month post implantation, due to AF with a very fast ventricular rate, exceeding the detection rate of the non-conditional shock zone (220 bpm), and varying QRS morphology (Fig. 2). In that case we modified detection settings of the device from 200/220 bpm to 220/240 bpm and intensified the antiarrhythmic treatment. No other issues were recorded during the further five months of follow-up.

In patient RZ an episode of sensing disturbances was recorded in the 14th month after implantation, where a transient change of the QRS morphology resulted in reduction of the R-wave and increase of the amplitude of the T-wave (Fig. 3). Despite that abnormality, there was no intervention of the S-ICD. Transient bundle branch block was assumed to be the reason for the observed QRS morphology change. Such a phenomenon could not be re-induced during clinical observation (including body movements, S-ICD device movement, physical exercise), and thus, having consulted the patient with a manufacturer's representative, we did not change any of the detection settings of the device and left the standard gain and the secondary sensing vector. During the following five months of observation we did not record any further S-ICD sensing problems.

In patient BS, an episode of VF was recorded, adequately detected and treated by the device (Fig. 4).

In patient AM four episodes of non-sustained polymorphic VT (6–13 s) were recorded, which were appropriately detected by the device, and self-terminated without any high-voltage therapy (Fig. 5).

DISCUSSION

Subcutaneous ICD is a modern tool that is increasingly applied to treat patients at risk of SCD. According to the European Society of Cardiology guidelines, S-ICD is recommended as an alternative to T-ICD systems, when there is no need to introduce permanent cardiac pacing, resynchronisation therapy, or antitachycardia pacing. A specific subpopulation of patients who may benefit from S-ICD therapy according to the guidelines are patients with difficult vascular access, patients

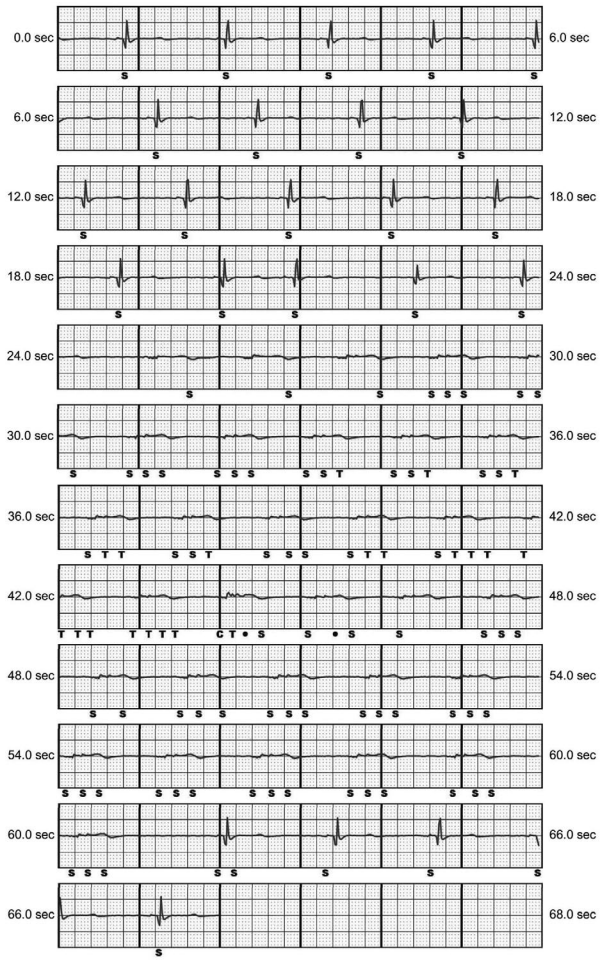

Figure 3. Sensing disturbances in the subcutaneous implantable cardioverter-defibrillator system resulting from the transient bundle branch block

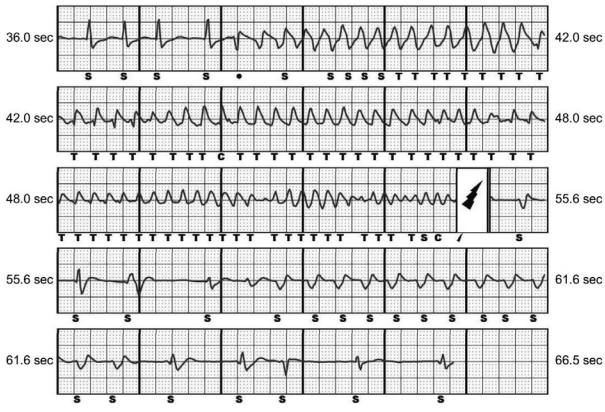

Figure 4. Episode of ventricular fibrillation adequately detected and treated by the subcutaneous implantable cardioverter-defibrillator system

after extraction of previous ICD systems due to infection, and young patients with long life expectancy [8]. In each patient

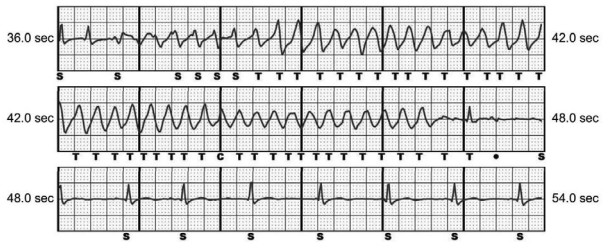

Figure 5. Episode of non-sustained polymorphic ventricular tachycardia. No therapy from the subcutaneous implantable cardioverter-defibrillator, the arrhythmia terminated by itself. Normal function of the device

in our cohort, at least one of the above guideline-derived indications was present. The efficacy and safety of S-ICD use was confirmed in prospective clinical trials [9, 10]. The results of those trials prove that the risk of implantation-related complications is low and equals approximately 1%, while the device-related complications occur in about 0.5% of patients during the first 30 days post-implantation. In our cohort of patients we did not observe any periprocedural surgical complications, and in one of the patients an inadequate S-ICD shock, as described above, was reported. Literature data concerning long-term follow-up show that during two years of follow-up the incidence of complications increases by up to 10% [9]. In late post-operative follow-up the only adverse event in our cohort of patients was an inadequate shock due to AF with fast ventricular rhythm, which occurred in one of the patients three months after implantation. This may be due to the very low incidence of adverse effects, given that fact that the experience of our centre is limited (to 12 patients). As a comparison, in the EFFORTLESS study population supraventricular tachycardias led to inadequate interventions in 1.5% of patients during the first year of follow-up, and that number increased to 2.3% during the following two years [11]. Other authors describing patient populations of a similar limited size, and a relatively short follow-up reported a higher percentage of complications, mainly of surgical nature, associated with delayed wound healing or local infection. This type of complications was not observed in patients primarily implanted in our centre, but we reported one such event in a patient with a system implanted in another centre [12, 13]. Based on the available data, the initial experience of any centre and the first dozen or so procedures is associated with increased risk of any complications, and only after 13 procedures the performance stabilises [14]. An interesting phenomenon caught in the act in our study was a transient S-ICD sensing problem in one of the patients, probably due to a transient bundle branch block. That phenomenon was described by Sousa et al. [15]. In our patient though, those sensing abnormalities could not be re-induced in a controlled clinical setting and therefore (because we could not confirm the nature of the problem) we did not change the settings of the device.

The low number of patients in our cohort and relatively short duration of follow-up of some of the patients are clear limitations of the above analysis. The aim of the analysis, however, was to present the initial experience of the operating team with the new treatment method in a single centre, and not to compare data with high-volume centres.

CONCLUSIONS

Subcutaneous ICD, being an effective and safe method used to treat patients at risk of SCD, may be safely and successfully introduced into clinical practice in centres new to that field. The number of complications during the initial experience and introduction of that method may be kept low if the operating team is experienced enough in cardiac electrotherapy.

Conflict of interest: *Maciej Kempa — consulting agreements with Boston Scientific.*

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