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ORIGINAL ARTICLE

Initial experience with the subcutaneous implantable cardioverter-defibrillator with the real costs of hospitalization analysis in a single Polish center

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Abstract

Background: *The recent introduction of an entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) represents an important progress in the defibrillation technology towards a less invasive approach. This is a single-center observational study of S-ICD implantations in Poland.*

Methods: *The S-ICD was implanted in 11 patients with standard indications for an ICD. Patients in whom the device was implanted were evaluated for adverse events and device function at hospital discharge. All hospitalization costs were calculated and summed up for all patients. Costs were divided into following categories: medical materials, pharmaceuticals, operating theatre staff, cardiology department staff, laboratory tests, non-laboratory tests and additional non-medical costs.*

Results: *The mean age of patients was 51.6 ± 16.4 years, 9 were men and 2 were women. Four patients had atrial fibrillation as the basal rhythm, 1 patient had atrial flutter and 6 patients had sinus rhythm. All patients had at least one condition that precluded the use of a traditional ICD system or the S-ICD was preferred due to other conditions, i.e. a history complicated transvenous ICD therapy (18%), anticipated higher risk of infection (27%), lack or difficult vascular access (18%), young age and anticipated high cumulated risk of lifetime device therapy (36%). The mean duration of the implantation procedure was 2 h. One patient developed a postoperative pocket hematoma. Mean total time of hospitalization was 28 (6–92) days. Average cost of hospitalization per patient was 21,014.29 EUR (minimal = 19,332.71 EUR and maximal = 24,824.14 EUR).*

Conclusions: *S-ICD implantation appears to provide a viable alternative to transvenous ICD, especially for patients without pacing requirements.* (Cardiol J 2019; 26, 4: 360–367)

Key words: leadless, primary prevention, procedure cost, secondary prevention, subcutaneous implantable cardioverter-defibrillator, ventricular arrhythmias

Introduction

Sudden cardiac death (SCD) continues to be a major public health challenge, representing close to one-fifth of all mortality in industrialized countries and claiming about half of its victims not pre-viously diagnosed with heart disease [1]. In recent decades implantable cardioverter-defibrillators (ICDs) have become the treatment of choice in patients with a high risk of fatal ventricular arrhythmia [2]. A weak component of traditionally used ICD systems is the defibrillation lead, which is

placed through the venous circulatory system into the right ventricle. It was shown that the longevity of defibrillation leads have become substantially reduced, and risk of infection is significantly higher compared to pacing leads [3]. The subcutaneous implantable cardioverter-defibrillator (S-ICD) was developed in response to endovascular lead complications and represents important progress in defibrillation technology. After obtaining Conformité Européene (CE) marking in 2009 and United States (US) Food and Drug Administration (FDA) approval in 2012, there is growing clinical evidence regarding its safety and efficacy in prevention of SCD [4–11]. This novel technology seems promising and particularly beneficial in patients with conditions associated with higher risk of infections (dialysis, diabetes mellitus) or in those who had experienced previous complications related to transvenous (TV) leads. The clinical benefits of S-ICD therapy have been also documented in young patients facing a lifetime of device therapy [12, 13].

The availability of S-ICD therapy is limited in Poland due to a lack of reimbursement and the cost of the device itself is around 7-times higher than conventional transvenous single chamber ICD. Further advancements of this system and cost reduction will likely lead to the expansion of indications and widespread use of this technology. An analysis of the indications was performed, procedural data and the full costs of hospitalization of patients implanted with the S-ICD in single Polish center.

Methods

Procedure

The first four implantations were performed with the aid of three different international proctors who had sufficient experience in the procedure. Subsequent S-ICD implant surgeries were performed by two operators from Department of Cardiology of Central Teaching Hospital, Warsaw, Poland. All procedures were performed under general anesthesia. In nine cases, the pocket for the generator was created between the serratus anterior and the latissimus dorsi muscles. In the other 2 cases (case 2 and 3) subcutaneous device placement were used based on proctor advice. The lead was positioned in the subcutaneous tissue of the chest, parallel to and 1–2 cm to the left sternal midline followed by a perpendicular segment, at the level of the 6th rib, until it reached the pocket of the device. The lead had a 8-cm shock coil, flanked by two sensing electrodes — the distal one positioned close to the manubriosternal joint and the proximal one adjacent to the xiphoid process based on pre-procedural X-ray imaging. Immediately after implantation, the most suitable sensing vector (primary, secondary or alternate) was chosen automatically by the S-ICD. The detection was set for two zones (a conditional shock zone and shock zone depending on the patient's indication and condition). Duration of procedure as total implantation time (time from patient in to patient out) and in-hospital adverse events related to the procedure were evaluated.

Patients

None of the patients had absolute indication for permanent pacing. Prior to the procedure patients were screened with a manual screening tool to assess the applicability of this technology. All the patients were informed of the characteristics of the new system, indications and potential complications. Informed consents were obtained.

Costs of hospitalization analysis

All costs of hospitalization were calculated and summed up for all patients. Costs were divided into following categories: S-ICD hardware (a device plus a defibrillation lead), medical materials excluding S-ICD (disposable materials related to the procedure, lead introducer), pharmaceuticals (oral drugs, antibiotics, disinfectants, analgesics), operating theatre staff (electrophysiologists, scrub nurse, personal costs of analgesia), cardiology department staff (cardiologists, nurses), additional laboratory tests, additional non-laboratory tests (echocardiography, X-ray), additional non-medical costs (materials and energy, linen, maintenance materials, office supplies, informatics and information technology, laboratory reagents, medical gases, electricity, heat, water, permanent foreign services, postage and telephone charges — non-medical indirect costs, management). Costs are in euro currency, using then current exchange rate (2017-10-06): 1 euro (EUR) = 4.24 Polish zloty (PLN).

Results

The S-ICD implantation was attempted in 11 patients with 100% success rate. All the patients had standard indications for ICD implantation that can be divided into two broad categories: secondary (45.5% of patients) and primary prophylaxis. For secondary prophylaxis, ICD placement was indicated as initial therapy in survivors of sudden cardiac arrest due to ventricular fibrillation (VF)

or hemodynamically unstable ventricular tachycardia (VT). For primary prophylaxis ICD placement was indicated as therapy in patients with low left ventricular ejection fraction (LVEF) ≤ 35% related do prior myocardial infraction or structural heart disease.

The mean age of the patients was 51.6 ± 16.4 years, 9 were men. Four patients had atrial fibrillation (AF) as the basal rhythm, 1 patient — atrial flutter (AFl) and 6 patients — sinus rhythm. One patient had previously implanted cardiac resynchronization therapy (CRT), that was removed during the hospitalization due to infective endocarditis. All patients had at least one condition that precluded the use of a traditional ICD system or had the condition that made the S-ICD more preferable, i.e. a history of previous complicated TV-ICD (18%), anticipated higher risk of infection (27%), lack or difficult vascular access (18%), young age and anticipated high cumulated risk of lifetime device therapy (36%). Patient characteristics and basic procedural data are summarized in Table 1.

The mean duration of the implantation procedure was 2 h. One patient developed a postoperative pocket hematoma treated conservatively. The same patient experienced severe gastrointestinal bleeding not directly associated with the procedure but related to oral anticoagulant treatment. The complication was treated with endoscopy accompanied with blood transfusion (8 units of packed red blood cells). Mean total time of hospitalization was 28 (6–92) days. The time from admission to the procedure ranged from 1 to 81 days (mean 18 days) and from procedure to discharge from 4 to 27 days (mean 10 days).

During follow-up (mean time 17.5 ± 9.6 months) all patients survived. There was no neither infection nor a need for battery replacement but 1 patient needed re-intervention due to in pocket device dislocation (case 3 with subcutaneous device placement). In 3 patients at least one appropriate therapy occurred and 1 patient had an episode of inappropriate therapies due to myopotentials.

The real costs of hospitalization for every patient are presented in Table 1. Average cost of hospitalization per patient was 21,014.29 EUR (minimal = 19,332.71 EUR and maximal = 24,824.14 EUR). Average costs for each category were as follows: 18,548.84 EUR for S-ICD, 142.66 EUR for medical materials excluding S-ICD; 142.87 EUR for pharmaceuticals; 157.14 EUR for operating theatre staff; 871.93 EUR for cardiology department staff; 399.33 EUR for laboratory additional tests, 221.13 EUR for non-laboratory additional tests; 521.65 EUR for additional non-medical costs.

Discussion

The S-ICD has recently entered into the clinical practice and represents a valid alternative for patients who have indications for ICD implantation, especially for those, whose clinical condition makes the risk of traditional TV-ICD implantation notably high. It becomes a less invasive option for patients in whom TV-ICD implantation is surgically impossible. It is estimated that up to 55% of patients in routine clinical practice needing an ICD are potential candidates for a subcutaneous device [14, 15]. However, to maximize clinical outcome and cost/benefit ratio, it is fundamental to choose candidates that can benefit most, taking into account both patient and device characteristics.

Based on recently released (2015) Clinical Practice Guidelines for the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC), the use of the S-ICD system may be useful, alternatively to the TV-ICD system, when venous access is difficult (especially due to congenital anomalies — writer's note), in young patients facing a lifetime of device therapy and in patients after the removal of a TV-ICD system for infection (Class IIb-C) [2]. Moreover, the device is recommended as an alternative to TV-ICDs when pacing therapy for bradycardia, cardiac resynchronization or antitachycardia pacing is not needed (Class IIa-C) [2]. In recent 2017 AHA//ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of SCD the use of S-ICD has become a Class I-B indication for the mentioned patient group [16]. Because the risk of infection appears to be lower, S-ICD may be preferred in patients who are at high risk of infection, such as those with a prior device infection, end-stage renal failure, diabetes mellitus, or those who are chronically immunosuppressed. This means that majority of ICD indicated patients (without pacing needs) should be considered for S-ICD according to Class IIa indication endorsed by recent guidelines [17]. Although according to above mentioned recommendations S-ICD can be used in most ICD candidates, due to cost issues in Poland it is possible to introduce this novel therapy only in very selected group of patients. This was reflected in the characteristics of the present study population and may be comparable to recently published data from a European survey showing the following main reasons favoring the use of an S-ICD: young

Table 1. Patient characteristics, implantation and cost data.

	PT 1	PT 2	PT 3	PT 4	PT 5	PT 6	PT 7	PT 8	PT 9	PT 10	PT 11
Initials	K.O.	J.M.	K.N.	R.M.	D.C.	D.P.	A.G.	D.K.	W.M.	A.P.	J.Sz.
Clinical characteristics											
Sex	Male	Male	Male	Male	Female	Male	Female	Male	Male	Male	Male
Age [years]	61	62	36	55	79	32	38	34	68	34	69
Concomitant conditions	Multiple MIs DM (DFS) CAD CKD stage 3	DM CAD PAD CKD stage 5 (dialysis)	PE ASD II correction Suspected congenital thrombophilia	MI CAD AVR HT	HCM MI TIA CKD stage 3 MDS Uterine cancer (chemiotherapy)	DCM	PPCM Hashimoto disease Acute myocarditis	Vasovagal syncope Thrombocytopenia	DM CKD CAD MVR TV repair	stage 4 DCM	Multiple MIs CABG Stroke CKD stage 4 AMAE SBS
Previous CRT	Yes	No	No	No	No	No	No	No	No	No	No
Indication for ICD (primary/secondary)	Primary	Secondary	Secondary	Secondary	Secondary	Primary	Secondary	Primary	Primary	Primary	Primary
Indication for ICD	LVEF = 30	VF	VT	VT	VF	LVEF = 27	VF	VT, BrS	LVEF = 22	LVEF = 14	VT
Absolute or relative contraindication for TV-ICD	CDRIE	High risk of infection	Lack of vascular access	CDRIE	High risk of infection	Young age	Young age	Young age	High risk of infection	Young age	Difficult vascular access
Basal rhythm	AF	SR	AF	AF	AF	SR	SR	SR	SR	SR	AFl
LVEF [%]	33	45	–	30	50	27	54	60	22	14	35
Total time of hospitalization [days]	92	55	17	7	7	14	69	6	9	6	29
Time from admission to implantation [days]	81	41	3	3	3	2	65	1	2	1	2
Time from implantation to discharge [days]	11	14	14	4	4	12	4	5	7	5	27
Implantation											
Total implantation time (time from patient in to patient out) [h]	2.5	2.0	1.5	1.5	2.5	2.5	2.0	1.33	1.75	2.0	1.5
Complications	No	Pocket hematoma	No	No	No	No	No	No	No	No	No
Costs of hospitalization analysis (in euro)											
S-ICD	18,594.34	18,248.69	18,594.34	18,568.61	18,568.61	18,568.61	18,568.61	18,568.61	18,568.61	18,594.08	18,594.08

Table 1 (cont.). Patient characteristics, implantation and cost data.

	PT 1	PT 2	PT 3	PT 4	PT 5	PT 6	PT 7	PT 8	PT 9	PT 10	PT 11
Medical materials excluding S-ICD	163.54	160.22	45.16	38.72	38.72	38.72	447.74	38.72	447.74	38.72	111.23
Pharmaceutical	306.52	384.18	91.75	91.75	91.75	91.75	28.95	28.95	28.95	28.95	398.04
Operating theatre staff	157.14	157.14	157.14	157.14	157.14	157.14	157.14	157.14	157.14	157.14	157.14
Cardiology department staff	1,962.19	1,182.48	352.67	421.21	145.22	541.55	2,120.43	343.85	515.78	343.85	1,661.96
Laboratory test	1,054.95	1,223.11	137.26	127.59	127.59	99.29	714.39	111.32	137.50	101.89	557.78
Non-laboratory test	571.93	622.64	169.81	49.53	49.53	117.92	505.90	67.22	114.39	20.05	154.48
Additional non-medical	2,013.52	1,255.21	374.36	127.77	154.15	164.27	645.58	120.40	180.59	120.40	581.92
Total	24,824.14	23,233.67	19,922.50	19,582.32	19,332.71	19,779.26	23,273.85	19,436.21	20,150.70	19,405.07	22,216.73

AF — atrial fibrillation; AFI — atrial flutter; AMAE — acute mesenteric arterial embolism; ASD — atrial septal defect; BrS — Brugarda syndrome; AVR — aortic valve replacement; CAD — coronary artery disease; CDRIE — cardiac device-related infective endocarditis; CKD — chronic kidney disease; CRT — cardiac resynchronization therapy; DCM — dilated cardiomyopathy; DFS — diabetic foot syndrome; DM — diabetes mellitus; HCM — hypertrophic cardiomyopathy; HT — hypertension; LVEF — left ventricular ejection fraction; MDS — myelodysplastic syndrome; MVR — mitral valve replacement; PAD — peripheral artery disease; PPCM — peripartum cardiomyopathy; SBS — short bowel syndrome; S-ICD — subcutaneous implantable cardioverter-defibrillator; SR — sinus rhythm; TIA — transient ischemic attack; TV — tricuspid valve; TV-ICD — transvenous implantable cardioverter-defibrillator; PT — patient; VF — ventricular fibrillation; VT — ventricular tachycardia

age, lead-related complications, elevated risk or previous device infection, and also patient preference or active lifestyle [18]. In our population 2 patients with the history of cardiac device-related infective endocarditis (CDRIE), the S-ICD was implanted due to increased risk of infection related to the necessity of device re-implantation as well as increased levels of inflammatory parameters during the entire period of hospitalization. Additional risk factors for those patients were: advanced diabetes mellitus complicated by diabetic food syndrome in 1 patient and composite of CAD and heart valvular disease in the second one.

In 2 patients, TV-ICD implantation was prohibited by venous system anatomy, that made placement of a lead difficult or even impossible or the lack of vascular access associated with the need of intravenous nutrition. Recent studies show that venous abnormalities are not rare among patients requiring pacemaker or ICD therapy and presence of stenosis or obstruction of central veins (in absence of congenital anomalies) can be found in up to 7% of cases during pre-implant intravenous contrast venography [19], thus further development of this technology can make it first line option in these situations.

Finally, in 4 patients, S-ICD was chosen instead of TV-ICD due to long life expectancy. In those cases, implanting a TV-ICD with an endocardial lead system could put the patient at increased risk of serious systemic and potentially mortal complications such as CDRIE. Here it is worth mentioning that new reports confirmed safety and effectiveness of this system in children [20, 21] though implantation in patients with low body mass index should be carefully considered due to the relatively large and heavy generator. Channelopathies, hypertrophic cardiomyopathy (HCM), dilated cardiomyopathy (DCM), are very common problems among young people [22], which is in accord with this study, and those in whom the mechanism of SCD usually involves polymorphic VT or VF, and those with low risk of bradycardia and monomorphic VT requiring Anti Tachycardia Pacing (ATP) theoretically constitutes a group where S-ICD may be the preferable option. However, it should be noted that a higher rate of inappropriate shocks due to T-wave oversensing and double-counting has been recorded in these patients [23, 24]. For example, in patients with Brugada syndrome, although clinical efficacy of S-ICD has been demonstrated, the more recent experience in Europe suggests that S-ICD screening failure occurs in up to 13% of those patients [24]. Rate of inappropriate S-ICD

shocks ranges between 4% and 15%, [23, 25–27] that is not so different from TV-ICD [7, 24], but with a different mechanism: up to 80% is caused by T-wave oversensing (TWOS), especially in some patient populations (i.e. congenital heart disease, Brugada and long QT syndromes), while in TV-ICD TWOS is involved in about 20% of cases [4, 5, 25, 26]. This aspect is important because it underlies the importance of exercise testing shortly after the implantation, as well as adopting a detailed patient screening practice with selection of the optimal sensing vector in different positions to reduce the risk of TWOS [28, 29]. Careful screening, software updates and template selection has reduced the occurrence of inappropriate shocks with the current S-ICDs when compared with the earlier experiences [29].

Another concern that has been raised is that there was no pacing capability (with the exception of 30" post-shock backup pacing) within S-ICD therapy which also means no possibility to deliver ATP for management of refractory monomorphic VT. This aspect was crucial in deciding on S-ICD implantation in the last patient in whom the benefits of S-ICD implantation (central venous circulation protection, avoidance of the lead related complications etc.) outweighed the lack of ATP function. The SCD-HeFT study showed that after almost 3 years of follow-up, only a third of patients with VT had more than one episode, which translated to 1.8% annual risk [30, 31]. In one cohort of patients it was shown that 55.5% (95% confidence interval 52.0–59.0%) of single or dual chamber ICDs recipients did not require pacing or receive ATP after 5 years and therefore could have been eligible to receive an S-ICD instead. The Pacing Fast Ventricular Tachycardia Reduces Shock Therapies (Pain-FREE Rx II) trial [32] showed that patients randomized to receive shock-only, 34% of fast VT episodes terminated spontaneously before therapy, suggesting that a considerable proportion of ATP intervention, which is delivered before a shock, may be unnecessary. Furthermore, ATP is not without risk; it is possible for ATP to accelerate VT to polymorphic VT or VF [33–35] which has been associated with a higher mortality risk [36]. In conclusion, the lack of ATP function in the S-ICD is a contentious one [37].

According to the latest reports of the current use of S-ICDs across a broad range of European centers, the most reported reasons for preferring an S-ICD over implantation of a TV-ICD are: an anticipated difficult vascular access (82% of the centers), a history of previous complicated TV-ICD (80% of the centers), young age (69%), an anticipated higher risk of infection (63%), the availability of the new generation S-ICD (53% of the centers), or a primary prevention indication (45% of the centers) [10]. In the present study the most common indication for S-ICD implantation was the young age of patients facing a lifetime of device therapy thus avoiding the lead-related complications (40% of patients), what can be explained by new reports demonstrated that lead failure rates are higher in younger patients [25, 38].

In the aforementioned study, more than one-fourth (n = 14, 27%) of the respondents have never implanted an S-ICD. The main reasons reported by these centers for the non-use of S-ICD include economic issues, such as lack of reimbursement (25% were not implanting centers), high cost of the device (25% of centers) and less often claimed issues were the lack of training (19% of centers), the complexity of the implantation procedure (6% of centers) [10]. Those results also reflect limitations in S-ICD implantation, that started in the documented hospital from 2015 [39]. Although implantation of TV-ICD is on the list of guaranteed services, total cost of S-ICD highly exceeds reimbursement level for this category, so individual financing was implemented for each patient and this paper depicts expenditures divided into range of categories. In the Honarbakhsh et al. [40] study, comparing efficacy, safety and costs of the S-ICD vs. TV-ICD, even though more expensive, S-ICD was associated with a relative risk reduction of device-related complication of 70% with a hazard risk of 0.30 (95% confidence interval 0.12–0.76; p = 0.01) compared to TV-ICDs. The total mean cost for each group, including the complication-related costs was £9967 ± 4511 ($13,639 ± 6173) and £12,601 ± 1786 ($17,243 ± 2444) in the TV-ICD and S-ICD groups respectively (p = 0.0001) [19]. It shows that despite the existing significant difference in unit cost of the S-ICD, overall S-ICD costs may be mitigated versus TV-ICDs over a longer follow-up period. If the incidence rate of TV-ICD-related complications [40] remains stable over the next years no cost difference between these two groups would be expected.

Until now, there is still relatively little data regarding long term performance of the S-ICD in a "real world" setting so larger experience and longer follow up are required, but initial results are encouraging [41, 42].

Limitations of the study

This single center experience was not randomized and shows the short term, initial experience of the present small group of patients. This implies that no real data on long-term performance of the device and its longevity were available. A low number of patients in the present cohort is the main limitation of the above analysis. However, the aim of the analysis was to present the initial experience of the operating team with the new treatment method in a single center and to present full hospitalization costs of "real-world" consecutive patients. Such data might be valuable for regional authorities to support decisions on reimbursement and for appropriate valuations of the procedure.

Conclusions

Current evidence suggests that S-ICD is a highly effective and safe modality with comparable defibrillation success rate to conventional ICDs. Thus, a wide range of patients without pacing requirements, and particularly younger patients, may benefit. Ongoing clinical studies will help establish the S-ICD system long-term safety and efficacy and better define target patient groups.

Conflict of interest: Marcin Grabowski, Andrzej Cacko and Marcin Michalak report receiving lecture honoraria from Boston Scientific.

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