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Complications in recipients of cardioverter--defibrillator or cardiac resynchronization therapy: Insights from Silesian Center Defibrillator registry

Mateusz Tajstra, Elżbieta Gadula-Gacek, Anna Kurek, Elżbieta Adamowicz-Czoch, Dawid Olszowski, Mateusz Ostręga, Aneta Ciślak, Łukasz Pyka, Michał Hawranek, Andrzej Lekston, Lech Poloński, Mariusz Gąsior

3rd Department of Cardiology, Silesian Center for Heart Diseases, Medical University of Silesia, Zabrze, Poland

Abstract

Background: *Current real-life information from all-comers registries from middle and east Europe about the incidence and type of complications during long-term follow-up of patients with cardioverters-defibrillators (ICD) and cardiac resynchronization devices-defibrillators (CRT-D) is still insufficient. The aim of the study was to assess the incidence and determinants of short- and long-term complications related to implantable ICD and CRT-D.*

Methods: *We studied 1,105 recipients hospitalized in our center in 2009–2013, followed for a mean of 2.4 years (total of 2,652 patient-years). The independent association between ICD and CRT-D recipients' and implantation-procedures' characteristics with the incidence of complications was analyzed using multivariable Cox regression analysis.*

Results: *In 2-month post-procedural period, 124 (11.2%) patients developed complications. Independent predictors of short-term complications (within 2 months) were: atrial fibrillation, dual chamber ICD implantation, and use of antiplatelet therapy or coumarin. Twenty-seven (2.44%) patients experienced complications, mostly lead-related (n = 21). Independent predictors of long-term complications (2–12 months after implantation) were atrial fibrillation and dual chamber ICD implantation.*

Conclusions: *Despite significant technological progress and operators' experience, the occurrence of complications in ICD and CRT-D recipients is still substantial. Majority of complications are recorded in the early post-implantation phase. Analysis of independent predictors of complications seem to be essential in helping to reduce adverse events in the future and strongly supports the need for routine follow-up.* (Cardiol J 2017; 24, 5: 515–522)

Key words: cardioverter-defibrillator, cardiac resynchronization therapy, complications, registry, cardiac electronic implantable devices

Introduction

Indications for implantation of cardioverters-defibrillators (ICD) and cardiac resynchronization devices-defibrillators (CRT-D) widen after results of new trials and with updated guidelines [1, 2]. In Poland, the amount of patients with ICD implantations in 2007–2010 increased threefold — from 2,500 to 8,000/year [3]. These numbers are likely to increase in time as a result of quickly expanding group of patients with indications for implantation of ICD or CRT-D [4]. Results of randomized trials proved that cardiac implantable electronic devices (CIEDs) — ICD and CRT-D implanted in primary

Address for correspondence: Elżbieta Gadula-Gacek, MD, Silesian Center for Heart Diseases, ul. Szpitalna 2, 41–800 Zabrze, Poland, tel: +48 32 373 36 74, fax: +48 32 273 26 79, e-mail: egadulagacek@gmail.com

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and secondary prevention of sudden cardiac death are efficacious and prolong life [5, 6]. However, data assessing real-life, beyond clinical trials, functioning of patients with ICD or CRT-D, especially along with the technological development of the devices should be updated and geographical region of Europe should be taken into consideration and results compared with the ones available from registries from well-developed countries [7]. In everyday clinical practice, indications are sometimes off-label and population of patients is more heterogeneous [8]. Therefore, we created an all-comers Silesian Center Defibrillator registry of over 1,000 of subsequent patients with implantation of ICD/CRT-D and used data from hospitalizations, remote monitoring (RM) database and Polish National Health Fund (NHF) records to assess clinical characteristics, in-hospital complications, and 1-year mortality of the analyzed population. The registry can be important source of information complementary to data obtained from clinical trials.

Methods

Study population and data sources

Data of 1,105 patients hospitalized in academic, high-volume CIEDs implantation center (an average of 1,000 implantations/year), in 2009–2013 with left ventricular (LV) ejection fraction (EF) ≤ 35% and who met current practice guidelines indications for implantation of ICD or CRT-D, and were included in Silesian Center Defibrillator registry were used. A group of 512 (46.3%) patients had active RM system and data transmitted were analyzed by qualified team consisting of electrophysiology nurse and in-training doctors under supervision of experienced cardiologists. Medical history, clinical data of the patients, collected during initial hospitalization were retrieved from prospectively recorded Electronic Database in our center by the attending physician. Furthermore, implantation procedure characteristics such as type of implanted ICD, which were also recorded to quantify its potential, added predictive value for subsequent complications. We obtained data regarding complications and mortality by linking registry records with NHF records, the only payer for medical procedures in Poland. All the hospitalizations after implantation procedures were analyzed with regard of the presence of complications related to index implantation procedure. Data concerning control visits in specialist outpatient clinics and primary health care were analyzed in a similar way. The data concerning the reported disease entities and procedures according to the ICD-10 and ICD-9 classifications were anonymized. Collecting the information concerning an individual patient was possible by tracking the hospital registration number and encoded PESEL (Personal Identification) number. The follow-up data with the accompanying exact dates of death were obtained from the official NHF records.

Due to retrospective character of the study, no approval from local bioethical committee was obtained.

Data analysis

The following variables were analyzed: gender, age, type of implanted CIED (single/dual chamber ICD, CRT-D), etiology of heart failure, functional class according to New York Heart Association (NYHA) score, co-morbidities, previous revascularization in case of coronary artery disease, 1-year mortality related to type of device implanted, echocardiography parameters, electrocardiographic parameters, atrial status and pharmacotherapy. All the patients underwent local antibiotic prophylaxis regimen pre-procedural single dose of cefazolin 1 g intravenously or prolonged 5-day antibiotic therapy in case of an implantation procedure lasting over 1 h or in patients with impaired immunity (diabetic, chronic kidney failure, neoplastic disease, over 75 years old). The primary end-point was analysis of the complications. The complications were defined according to well known and widely observed in daily practice: traumatic complications, lead-related complications, pocket and clinical complications, and problems with connection screw. We divided these complications into those occurring during the device therapy optimization and lead maturation phase (within 2 months after initial procedure of ICD/CRT-D implantation and likely related to the implantation procedure: short-term-2-month complications), and complications emerging during follow-up (long-term complications) [9, 10]. The incidence rate of complications is reported as the number of events and also as an incidence rate per 1,000 person-years. As patients could have > 1 complication recorded, multiple complications were not considered separately.

Statistical analysis

The incidence of short- and long-term ICD/CRT-D complications was assessed. Survival free time from any ICD/CRT-D complication was estimated using the Kaplan-Meier method [11]. The prognostic relevance of the various baseline variables on the occurrence of both short- and

long-term complications was assessed with Cox proportional hazards regression models with results expressed as hazard ratios (HR) and 95% confidence intervals (CI). We initially decided to include all clinical, demographic and type of implanted device data from medical history as potential predictors and all-cause mortality. All-cause mortality was determined to be considered a complication and it was taken into account in the Kaplan-Meier method and Cox proportional hazard regression model mentioned above. Our data come from a registry of high-energy implantable cardiac devices and, according to current European Society of Cardiology guidelines, only the patients with of at least 1-year life expectancy were qualified for ICD/CRT-D implantation. This is why it seems reasonable for all-cause mortality to be included in the analysis of complications as it was not an expected incident in this group of patients. Moreover, due to limitations of the registry, it is not possible to assess the cause of death, nor select deaths related to the procedure of ICD/CRT implantation.

For both outcomes, all predictors were simultaneously included in the model. We used a p value of ≤ 0.3 in univariate analysis to include a variable in the multivariable analysis model [12]. A 2-sided p-value ≤ 0.05 was considered significant. The STATISTICA 10 software (StarSoft Inc., Tulusa, Oklahoma), MedCalc (MedCalc Software, Mariakerke, Belgium) and SPSS ver. 17.0.1 (SPSS, Inc., Chicago, Illinois) were used for all calculations.

Results

We analyzed population of 1,105 patients, followed for a mean of 2.4 years, resulting in a total of 2,652 patient-years. Mean age 60.3 ± 9.6 years and 900 (81.5%) patients were male. Mean LVEF was 25% and 956 (86.5%) patients fulfilled current indications for implantation of ICD or CRT-D in primary prevention. Most (40.9%) patients underwent implantation of a dual-chamber ICD. Some patients in the dual-chamber ICD group had dual-chamber pacemakers implanted previously and yet with lowered EF of 35% or below; others had dual-chamber ICD implanted according to current guidelines or out-of-label criteria. CRT-D criteria were met in 400 (36.2%) cases and single-chamber ICD in 253 (22.9%). At the time of qualification, 364 (33.9%) patients were in NYHA class II, 608 (55%) in NYHA class III, and 133 (11.1%) in ambulatory NYHA class IV. In most (63%) cases, the etiology of heart failure was ischemic. A group of 512 (46.3%) patients, beside regular visits in cardiology day clinic, activated remote monitoring system and were supervised by telemetric means. Twelve-month mortality in the entire group amounted to 7.5%. More details including basic clinical characteristics are shown in Table 1.

ICD/CRT-D-related complications

Figure 1 illustrates survival free from any ICD/CRT-D complication. The curve shows a steep slope in the first 5 months followed by a more stable decline, indicating a high incidence of ICD/CRT-D complications early after implantation.

Traumatic complications

According to their character, traumatic complications occurr mainly during the index procedure. The most frequently observed traumatic complication was pneumothorax in 13 (1.2%) patients and 5 of them had to be drained. All of the electrodes in this group of patients were implanted via subclavian vein puncture. Two of pneumothorax patients were earlier diagnosed with chronic pulmonary obstructive disease (COPD). Four (30.8%) patients in pneumothorax group were implanted with 1 electrode, 7 (53.8%) patients with 2 electrodes and 2 (15.4%) patients with 3 electrodes. Cardiac structure perforation during first 2 months of follow-up was rather a rare complication (0.1%). Pericardial infusion was seen in 4 (0.4%) patients and 1 person developed hemothorax treated with drainage. Only 1 patient, in whom ventricle defibrillation lead was implanted in the apex of right ventricle, experienced perforation treated by an uncomplicated pericardiocentesis.

Lead-related complications

The most frequent early lead-related complication was lead dislocation. However, that type of complication was also commonly recorded in late-term follow-up. Reposition due to electrode dislocation in 2 months was needed in 18 patients (5 atrial electrodes, 6 right ventricle and 7 electrodes placed over LV).

Pocket complications

The most common type of complication occurring in early period of the observation was pocket-related complication. Sixty-eight (6.1%) patients developed a pocket hematoma. Twenty-four (32.4%) patients with hemorrhagic complications were treated with acetylsalicylic acid (ASA), 21 (28.4%) with dual antiplatelet therapy (DAPT), 42 (56.8%) patients were on oral anticoagulants (OAC), 25 (33.8%) patients were treated with

Table 1. Baseline patient characteristics and 12-month all-cause mortality.

Variable	Analyzed group (n = 1105)
Age [years]	60.3 ± 9.6
Male	900 (81.5%)
LV ejection fraction [%]	25 ± 5.5
LV end-diastolic diameter [mm]	65.7 ± 9.15
LV end-systolic diameter [mm]	53.7 ± 10.5
LV end-diastolic volume [mL]	140 ± 77.9
LV end-systolic volume [mL]	190 ± 72.3
NYHA:	
Class II	364 (33.9%)
Class III	608 (55%)
Class IV	133 (11.1%)
Intrinsic QRS duration [ms]	122.5 ± 32.1
Telemonitoring	512 (46.3%)
Implanted device:	
Single chamber ICD	253 (22.9%)
Dual chamber ICD	452 (40.9%)
CRT-D	400 (36.2%)
Up-grade ICD to CRT-D	47 (4.3%)
Primary prevention indication for defibrillator	956 (86.5%)
Medical history:	
Ischemic cardiomyopathy	696 (63%)
Prior myocardial infarction	508 (46%)
Prior PCI	497 (45%)
Prior coronary bypass	176 (16%)
Stroke	55 (5%)
Hypertension	574 (52%)
Atrial fibrillation/flutter	353 (30.2%)
Diabetes	431 (39%)
Hyperlipidemia	464 (41%)
Renal insufficiency (class ≤ 3)	309 (28%)
Mean NT-proBNP [pg/mL]	2739.4 ± 234.4
Mean CRP [mg/dL]	15.1 ± 2.9
LBBB	222 (20.1%)
RBBB	45 (4.1%)
Drugs:	
Diuretic	928 (84%)
ACEI/ARB	917 (83%)
Beta-blocker	1060 (96.6%)
Aldosterone receptor blocker	939 (86%)
Calcium-channel blocker	66 (6.1%)
Digitalis	270 (24.4%)
Amiodarone	121 (11.6%)
Nitrate	124 (11.3%)
Statin	824 (74.6%)
Anticoagulant	531 (48.1%)
Aspirin	447 (40.5%)
Clopidogrel	286 (25.9%)
12-month all-cause mortality	83 (7.5%)

ACEI/ARB — angiotensin converting enzyme inhibitor/angiotensin receptor blocker; CRP — C-reactive protein; CRT-D — cardiac resynchronization therapy-defibrillator; ICD — implantable cardioverter-defibrillator; LBBB — left bundle branch block; LV — left ventricular; NT-proBNP — N-terminal pro-B-type natriuretic peptide; NYHA — New York Heart Association; PCI — percutaneous coronary intervention; RBBB — right bundle branch block

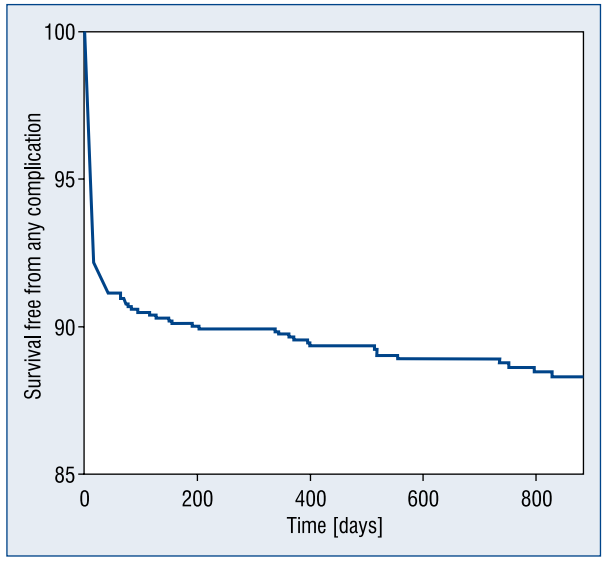

Figure 1. Survival free from implantable cardioverter-defibrillator/cardiac resynchronization therapy-defibrillator complications.

unfractionated heparin (UFH); 22 (29.7%) patients were on bridge therapy (either UFH or low-molecule weight heparin [LMWH]) and 19 (25.7%) patients were treated with both antiplatelet drugs and OAC. However, in only 6 (0.54%) patients blood transfusion was required. Only 1 (0.1%) patient in short-term follow-up, and 4 (0.4%) patients in long-term follow-up developed a pocket infection. Those numbers are much lower when compared to other trials or registries. The exact reason of such a low infection rate might be due to previous local policy of prolonged (up to 3–5 days) antibiotic therapy with cefazolin in case or prolonged implantation procedure (over 1 h) or in patients with impaired immunity (diabetic, chronic kidney failure, neoplastic disease, over 75 years old).

Clinical complications such as cardiac arrest or pulmonary edema were all recorded during index hospitalization. All cardiac arrest cases were due to ventricular tachycardia/ventricular fibrillation and happened during the implantation procedure most likely due to mechanical irritation of endocardium by defibrillation lead and all were followed by a successful external defibrillation and resuscitation. The all-cause mortality data with the accompanying exact dates of deaths were obtained from official mortality records from the NHF. Unfortunately, it is impossible for us to state with certainty what were the reasons of deaths shown in Table 2 (cardiovascular or other), but all of them occurred after discharge from the hospital.

Table 2. Complication during first 2 months after implantation procedure and during long-term follow-up.

	Within 2 months	During follow-up	Rate (95% CI)[#]
All traumatic complications	23 (2.1%)	1 (0.1%)	9.26 (5.94–13.79)
Perforation of cardiac structure	1 (0.1%)	1 (0.1%)	0.77 (0.09–2.79)
Pneumothorax	13 (1.2%)	0 (0%)	5.02 (2.67–8.58)
Hemothorax	1 (0.1%)	0 (0%)	0.39 (0.01–2.15)
Pericardial effusion	4 (0.4%)	0 (0%)	1.54 (0.42–3.95)
Coronary sinus dissection	4 (0.4%)	0 (0%)	1.54 (0.42–3.95)
All lead-related complications	26 (2.35%)	21 (1.9%)	18.14 (13.3–24.3)
Lead damage	5 (0.45%)	10 (0.9%)	5.79 (3.24–9.55)
RA lead dislocation	5 (0.45%)	1 (0.1%)	2.32 (0.85–5.04)
RV lead dislocation	6 (0.54%)	1 (0.1%)	2.72 (1.09–5.57)
LV lead dislocation	7 (0.6%)	5 (0.45%)	4.63 (2.39–8.09)
Insulation problem	0 (0%)	0 (0%)	0.00
Infection	0 (0%)	4 (0.4%)	1.54 (0.42–3.95)
High defibrillation threshold requiring subcutaneous lead implantation	3 (0.3%)	0 (0%)	1.16 (0.24–3.38)
All pocket complications	72 (6.5%)	5 (0.45%)	29.72 (23.4–37.1)
Hematoma	68 (6.1%)	1 (0.1%)	26.64 (20.7–33.7)
Hematoma requiring blood transfusion	6 (0.54%)	0 (0%)	2.32 (0.85–5.04)
Difficult to control bleeding	3 (0.3%)	0 (0%)	1.16 (0.24–3.38)
Infection	1 (0.1%)	4 (0.4%)	1.93 (0.63–4.5)
Skin erosion	0 (0%)	0 (0%)	0.00
Clinical complications			
Cardiac arrest	4 (0.4%)	NA	1.54 (0.42–3.95)
Pulmonary edema	13 (1.2%)	NA	5.02 (2.67–8.58)
Death*	17 (1.53%)	180 (16.3%)	76.02 (65.8–87.4)
Others			
Problem with connection screw	3 (0.3%)	0 (0%)	1.16 (0.24–3.38)
Number of patients experiencing complications†	124 (11.2%)	27 (2.44%)	46.7 (41.2–53.8)

[#]Rate indicates the number of patients experiencing complication per 1,000 patient years at risk after implantation; *All-cause mortality; †Excluding clinical complications; CI — confidence interval; LV — left ventricle; NA — not available; RA — right atrial; RV — right ventricle

Table 3. Predictors of 2-month and long-term complications in multivariable analysis.

Predictors	Multivariable analysis: HR (95% CI); p	
	Within 2 months	During follow-up
Atrial fibrillation	2.15 (1.40–3.33); < 0.001	2.5 (1.58–3.94); < 0.001
Use of antiplatelet agent or coumarin	2.04 (10.1–4.13); 0.04	–
Dual-chamber cardioverter-defibrillator	2.01 (1.08–3.56); 0.045	2.08 (1.13–3.85); 0.019
Age at implantation*	1.01 (0.99–1.03); 0.09	1.03 (0.96–1.04); 0.15
CRT implantation	1.16 (0.62–2.16); 0.62	1.19 (0.64–2.19); 0.55
Use of heparin†	1.08 (0.63–1.82); 0.8	–
Body mass index[#]	0.49 (0.31–0.79); 0.002	0.52 (0.32–0.88); 0.002
Arterial hypertension	0.78 (0.50–1.20); 0.26	0.80 (0.53–1.22); 0.29
Ischemic cardiomyopathy	0.70 (0.42–1.18); 0.19	0.73 (0.32–1.28); 0.23

*Per 1-year increase; †Used < 24 h before and/or < 24 h after procedure; [#]Per 1-unit decrease; CI — confidence interval; CRT — cardiac resynchronization therapy; HR — hazard ratio

More details including clinical complications are presented in Table 2. Patient- and implantation-related predictors for short- and long-term ICD/CRT-D complications in multivariable analyses are shown in Table 3. Independent predictors for short-term ones (occurring within 2 months) were atrial fibrillation (AF; paroxysmal or fixed), dual chamber ICD implantation, and use of antiplatelet therapy or OAC. Independent predictors for long-term ICD/CRT-D complications (occurring after 2 months after implantation) were AF and dual chamber ICD implantation.

Discussion

The principal clinical implications from this investigation are the following. First — the study shows that despite current user-friendly and much smaller ICD/CRT-D devices and wide (including RM) possibilities for follow-up, the complication rate and associated morbidity remain significant and should be noted. Second — independent predictors for short-term complications (occurring within 2 months) were AF (paroxysmal of fixed), dual chamber ICD implantation, and use of antiplatelet therapy or OAC, whereas independent predictors for long-term ICD/CRT-D complications were AF (paroxysmal of fixed) and dual chamber ICD implantation. Third — data obtained in the study of Polish population may be of assistance when compared by other institutions with their local outcome and complication rate. Identification of high-risk patients would be useful for decreasing complication rate and help to adjust local procedures especially concerning venous access or bridge therapy. Moreover, the ability to predict patients at risk could lead to a more tailored allocation of resources with varying intensity of follow-up visits to the risk of the patient, thereby decreasing the heavy workload associated with device follow-up, which leads to more cost-effectiveness.

Data regarding in-hospital complications following "high voltage" device implantation should be frequently updated to help controlling complications rate and improve outcomes by implementing safer techniques and policies. Most available numbers are based on randomized controlled trials (RCT) results performed on selected groups of patients and therefore fewer complications may be observed than in an all-comers evaluation due to strict patient selection criteria and more experienced operators involved. In recent years, large, registry-based studies have emerged with more extensive estimates of complications, however, data available from many registries are restricted to in-hospital follow-up, leaving a large proportion of longer-term CIED complications unaccounted for [10]. Therefore, in this large Silesian Center Defibrillator registry, we analyzed baseline characteristic of patients included in the registry and the incidence and predictors of early and long-term ICD/CRT-D follow-up complications. We considered complications within first 2 months early ones as this is a generally accepted time period in which complications directly related to an initial surgical procedure as device implantation will have emerged [13]. The frequent practice of publishing only in-hospital complications may significantly underestimate true complication occurrence.

Differences in definitions of complications resulting in a wide variance of outcomes as well as use of wide windows of time follow-up cause trouble with a valid comparison of published complication rates. However, clinical characteristics of patients in our registry, even though coming from still developing European country with smaller resources and experience, is similar to the ones analyzed in American or Western European clinical trials and registries, with main differences in type of implanted devices — most patients hospitalized included in this trial had a dual-chamber ICD (40.9%) implanted, while in available results of studies and registries most common devices were single-chamber ICD [9, 10]. In our opinion, the fact that more dual-chamber ICDs were implanted in the analyzed populations may be a due to the fact that the choice of the type of CIED was left at that time to the discretion of the operator or referring physician and more frequently off-label. Those numbers have been changing in favor of single-chamber ICD and CRT-D lately. Those results are in most aspects in-keeping with results from both prospective trials and registries, despite the fact the majority of implanted devices were dual-chamber ICD and CRT-D and amount of electrodes was higher. It is thought that CIED complications are more common than acknowledged and depend on certain patient-related (higher in female, underweight) and operator/hospital/device-related factors (center annual volume < 750 procedures, operator annual volume < 50 procedures, CRT-D over dual-chamber ICD, dual-chamber ICD over single-chamber ICD, upgrade or lead revision over new implantation or emergency, out-of-hours procedure). A new report based on meta-analysis of ICD complications in RCT and recent data from the largest international ICD registry, the United States National Cardiovascular Data Registry,

reported the overall ICD complication rate 9.1% over 16 months. Complications were divided to access-related, lead-related, generator-related and infection. Most frequent lead displacement, similar to our findings, was present in 3.1%, whereas access-related events were pneumothorax in 1.1% and hematoma in 1.4%. Interestingly, in-hospital complication rate from the RCT was 3-fold higher compared to ICD registry data (9.1% vs. 3.08%). Authors concluded that this fact may be associated with under-reporting of complications in registries [14]. Reporting of ICD complications in RCT and registries is variable and there is a need to standardize classification and time-window of evaluation of complications worldwide under the auspices of Heart Rhythm and Cardiac Societies allowing meaningful data collection, distribution, comparison, and practice-benchmarking.

Similar to our findings, the most often observed early complication is pocket hematoma. Its occurrence is reported in 2.9–9.5% of cases and it was usually treated conservatively. Evacuation of hematoma is required in 0.3–2% of implantation and related with a 15-fold increase in infection risk [13, 14]. Many hematomas can be avoided by substantial preparing the patient before surgery. It should contain especially careful evaluation of potential thrombotic- and bleeding-risk in patients with indication to antiplatelet and/or antithrombotic therapy. In comparison to untreated patients, ASA therapy is associated with 2-fold higher risk of bleeding, and the DAPT with a 4-fold increased risk of bleeding [15]. In most cases, antiplatelet therapy can be safely discontinued for a period of 5–7 days, especially when recommended for primary prevention [16, 17]. Additionally, the use of heparin (UFH or LMWH) as bridging therapy during interruption of OAC increased the risk of bleeding and some authors suggest performing implantation procedures without OAC therapy cessation [18, 19]. There are no data available regarding periprocedural treatment of patients treated previously with new OAC. Given the rapid onset and cessation of their activities, there is no need to use bridging therapy with LMWH, and after surgery this treatment should be resumed soon after reaching an effective hemostasis [20].

Limitations of the study

There are several limitations of our analysis. The retrospective nature of our analysis is a potential weakness. Even after data adjustment, the results could be biased by potentially important parameters that are not available in the registry, despite using the multivariable analysis. Another limitation is the duration of follow-up. Ideally, all patients would be followed until death or replacement of the ICD/CRT-D.

Conclusions

Despite significant technological progress in ICD/CRT-D therapy, complication occurrence is still substantial. Most complications are recorded in the early post-implantation phase. Analysis of complication type and frequency seems to be essential in helping avoid adverse events in the future and strongly supports the need of routinely performed follow-up.

To conclude: in modern practice, the incidence of complications related with ICD/CRT-D implantations remains considerable. Substantial part of complications occurs in early time-window after surgery. Thorough analysis of complication type and frequency seems to be essential in helping adjust local policies to lower the numbers of future adverse events and strongly supports the need of routinely performed follow-up.

Conflict of interest: None declared

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