

# In-hospital and long-term prognosis in patients after implantation of implantable cardioverter-defibrillators and cardiac resynchronization therapy: 10-year results of the SILCARD registry

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## KEY WORDS

cardiac  
resynchronization  
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## ABSTRACT

**INTRODUCTION** During the last 20 years, there has been a considerable increase in the number of implanted implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT) devices. However, there have been only single reports on clinical events, including rehospitalizations, in the long-term follow-up.

**OBJECTIVES** We analyzed the baseline clinical characteristics, medical procedures used, and complications of patients with implantation of an ICD or CRT device. Moreover, we analyzed the causes of rehospitalization and the types of treatment used in the 12-month follow-up.

**PATIENTS AND METHODS** Out of 1208440 hospitalizations of patients with cardiovascular diseases included in the SILCARD registry, hospitalizations with an *ICD-9* code for an ICD or CRT device implantation between 2006 and 2016 were selected.

**RESULTS** The analysis included 12147 patients with an ICD or CRT device. The total number of hospitalizations was 14552. Over the years, a significant increase in the number of implanted devices and a higher percentage of CRT defibrillators was observed. Before the implantation, approximately 48.2% of patients underwent revascularization. In-hospital and 12-month mortality rates were 0.4% and 8.1%, respectively. Rehospitalizations due to cardiovascular causes were reported for approximately 40.3% of patients, with a significant reduction in the analyzed period. The most frequent cause of rehospitalization was heart failure (51.4%), while stable coronary artery disease and acute coronary syndromes constituted approximately 16% of the causes. In the 12-month follow-up, nearly every tenth patient was subjected to coronary angiography. Approximately 5% of patients required revascularization.

**CONCLUSIONS** The relatively high rates of hospital readmissions and their causes indicate the need for a comprehensive care of patients before implantation of ICD or CRT devices and after discharge.

**INTRODUCTION** In developed countries, heart failure (HF) is the main cause of hospitalizations and mortality.<sup>1</sup> The development of diagnostic

and treatment methods, including implantable high-voltage devices, resulted in a reduction of mortality due to HF.<sup>2</sup> Improvement in survival in

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the HF population in primary and secondary prevention of sudden cardiac death (SCD) was demonstrated in studies with implantable cardioverter-defibrillators (ICDs).<sup>3,4</sup> The use of resynchronization devices (cardiac resynchronization therapy [CRT]), both with and without the defibrillation function, has also been shown to reduce mortality rates.<sup>5</sup> The current guidelines of the European Society of Cardiology recommend implantation of an ICD or CRT defibrillator (CRT-D) as a class I treatment in selected HF patients.<sup>6</sup>

During the last 20 years, there has been a considerable increase in the number of implanted high-voltage devices. Therefore, epidemiological studies in this area are necessary. Registry studies of patients with these devices are conducted in the United States, Canada, and most of the Western Europe countries to analyze changes in clinical characteristics, methods of treatment, and prognosis.<sup>7,8</sup> However, there have been only single reports on clinical events, including hospital readmissions and medical procedures, in the long-term follow-up.<sup>9</sup> Therefore, we decided to use data from a large group of patients with implanted ICD or CRT devices who were included in the Silesian Cardiovascular Database (SILCARD) registry to analyze the baseline clinical characteristics, medical procedures used, and complications. We also evaluated the main reasons for rehospitalizations and types of treatment used in the 12-month follow-up.

**PATIENTS AND METHODS** The SILCARD registry was developed under the agreement between the Silesian Centre for Heart Diseases in Zabrze and Śląski Oddział Wojewódzki NFZ in Katowice (the Silesian branch of the Polish National Health Fund) to conduct epidemiological analyses and publish their results for the population of patients with cardiovascular diseases (CVDs) in Silesia Province. The design of and rationale for the SILCARD database were described previously.<sup>10</sup> The registry was approved by the local ethics committee, and the study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki.

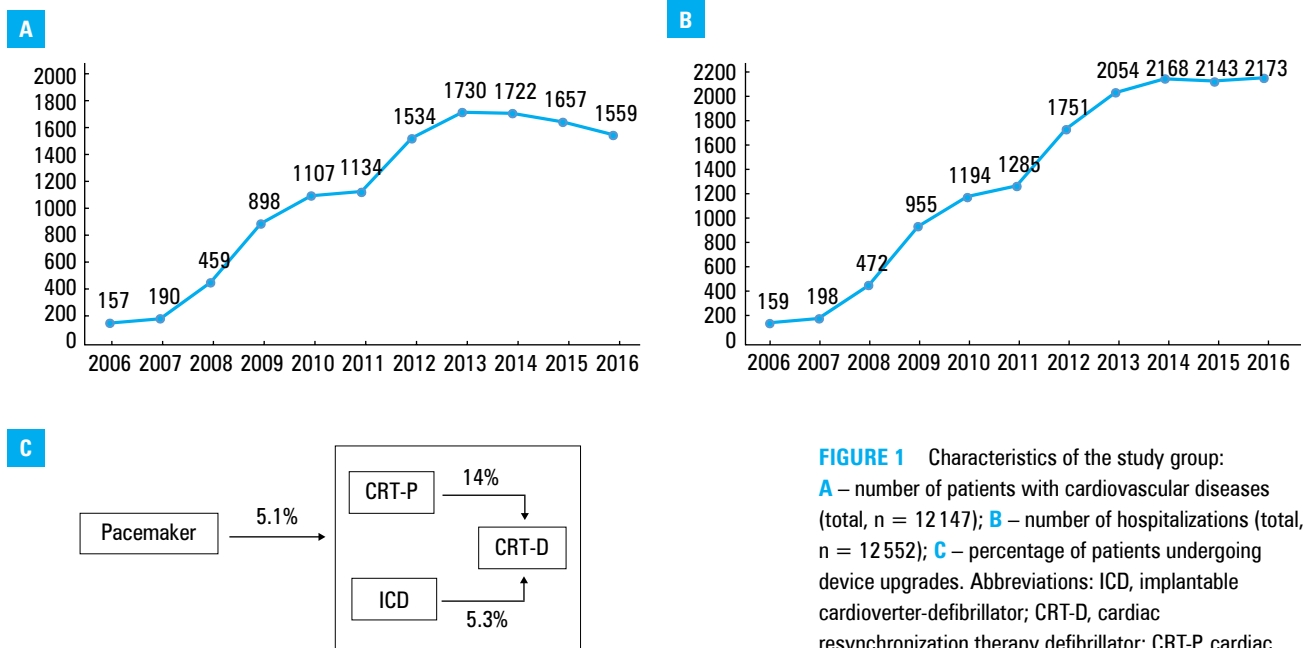
In the registry, all hospitalizations in cardiology, cardiac surgery, diabetes, or vascular surgery departments and all hospitalizations due to CVDs in internal medicine or intensive care departments were recorded between 2006 and 2016. Data on all diagnoses and medical procedures reported to the Polish National Health Fund were collected, including diagnostic and therapeutic procedures, hospital readmissions, and occurrence of myocardial infarction, stroke, or death. Data concerning outpatient visits (including general practitioner and other clinics) in previously hospitalized patients as well as on comorbidities and medical procedures performed before the ICD or CRT implantation were also collected.

In the present study, data for patients with an implanted ICD or CRT were demonstrated. We analyzed baseline clinical characteristics of

patients, history of medical procedures, complications, as well as prognosis and procedures reported in the 12-month follow-up after implantation. The data were presented for each calendar year separately. Out of 1 208 440 hospital stays of patients with CVDs included in the SILCARD registry, hospitalizations with an *International Classification of Diseases, Ninth Revision (ICD-9)* code for ICD or CRT implantation were selected (Supplementary material, *Table S1*). Other medical procedures were also distinguished according to ICD-9 codes. Comorbidities and diagnoses were reported according to ICD-10 codes (Supplementary material, *Table S1*).

**Statistical analysis** The hospitalizations of patients with an ICD or CRT implanted for the first time were included. In-hospital mortality, 12-month mortality, as well as the first hospital readmission in the 12-month follow-up were assessed according to the first hospitalization of a given patient. The other calculations were performed according to the analysis of all the hospitalizations. Descriptive statistics included means, numbers, and rates. Compilations were generated directly from the Oracle database using SQL Developer tool. A Microsoft Excel spreadsheet was used for graphic data development.

**RESULTS** The present analysis included 12 147 patients with an implanted ICD or CRT device (ICD, 8604; CRT-D, 3056; CRT pacing [CRT-P], 487). The overall number of hospitalizations was 14 552. Over the years, an increase in the number of implanted devices until 2013 was observed, with a constant decrease in recent years (*FIGURE 1*) and a higher percentage of CRT-D (*FIGURE 2*). In the analyzed group, 5.1% of patients had a pacemaker before inclusion in the study. Upgrades from CRT-P to CRT-D were performed in 14% of patients, and from ICD to CRT-D, in 5.3% (*FIGURE 1*). The prevalence of concomitant diseases and medical procedures are shown in *FIGURE 3*. Before device implantation, approximately 48.2% of patients were subjected to revascularization. An increase in the percentage of percutaneous coronary interventions (PCIs) and coronary artery bypass grafting (CABG) was observed (24.2% in 2006 and 60% in 2016). Between 2006 and 2016 a significant decrease in the percentage of implanted devices for secondary prevention, older patient age, and shorter hospitalization were observed. The rate of implanted devices for secondary prevention in 2006 was 72.6%, and in 2016, 18.4% (mean, 28.7%) (*FIGURE 3*; Supplementary material, *Figure S1*). The periprocedural complications are shown in *FIGURE 4*. The mean in-hospital mortality rate after ICD or CRT implantation was 0.4% and decreased significantly over the study period. However, the mean percentage of deaths in the 12-month follow-up amounted to approximately 8% (*FIGURE 5*). Rehospitalizations due to cardiovascular causes were observed for



**FIGURE 1** Characteristics of the study group: **A** – number of patients with cardiovascular diseases (total,  $n = 12\,147$ ); **B** – number of hospitalizations (total,  $n = 12\,552$ ); **C** – percentage of patients undergoing device upgrades. Abbreviations: ICD, implantable cardioverter-defibrillator; CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker

approximately 40.3% of patients, with a significant reduction in the analyzed period (2006–2016). The most frequent cause of rehospitalization was HF (51.4%), while stable coronary artery disease and acute coronary syndromes constituted approximately 16% of the causes. In the 12-month follow-up, nearly every tenth patient underwent coronary angiography (9.2%). Approximately 60% of these patients required revascularization (PCI, 4.8%; CABG, 0.5%) (Supplementary material, *Figure S2*).

**DISCUSSION** There are many registries including patients with implanted ICD or CRT devices, mainly from Western Europe and North America.<sup>11–14</sup> In the present study, we analyzed data from the database including over 12 000 implanted ICD and CRT devices during the period of 11 years in a region inhabited by 4.5 million people. Our study is unique in that it focuses on medical procedures and reasons for hospital readmissions in the 12-month follow-up after ICD or CRT device implantation.

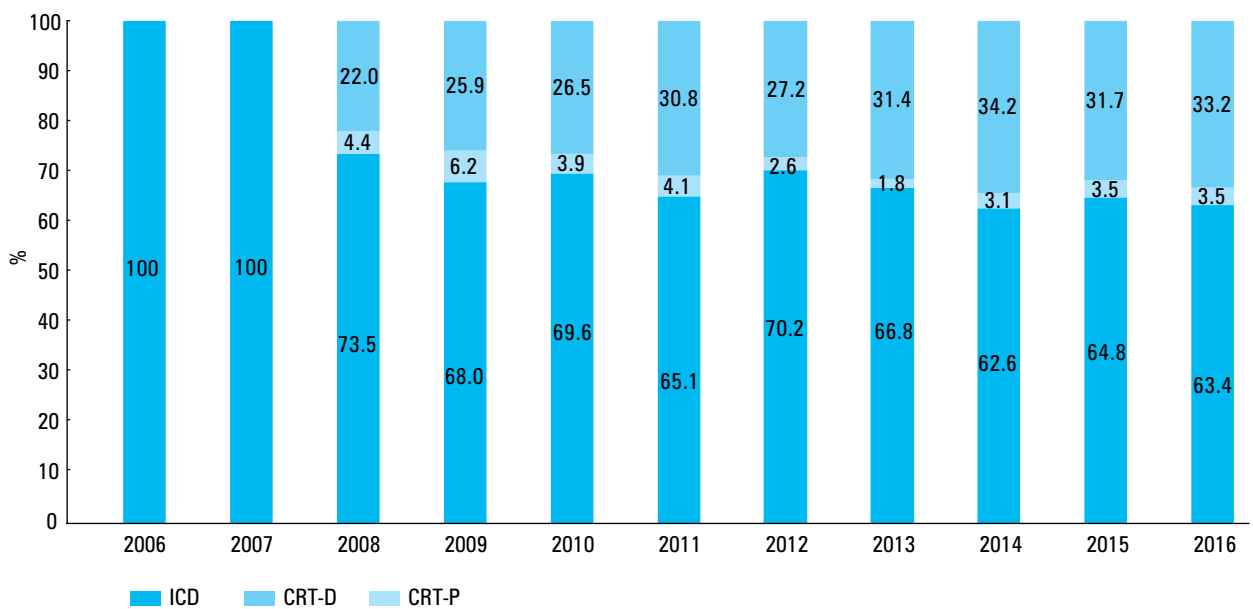
**Types of implanted devices and number of procedures**

The present registry included all patients with implanted ICD or CRT devices over the period from 2006 to 2016. Device replacements and upgrades were also considered. In other registries, only patients with one device type were enrolled, which hinders the direct comparison of the results. The percentage of upgrades cannot be unequivocally compared due to the lack of relevant information in the literature. This analysis shows an increase in the number of implanted devices until 2013, with a slight but constant decrease in the subsequent years (**FIGURE 1**). This is probably because the number of patients requiring de novo ICD or CRT implantation has been reduced. Of note, in the recent

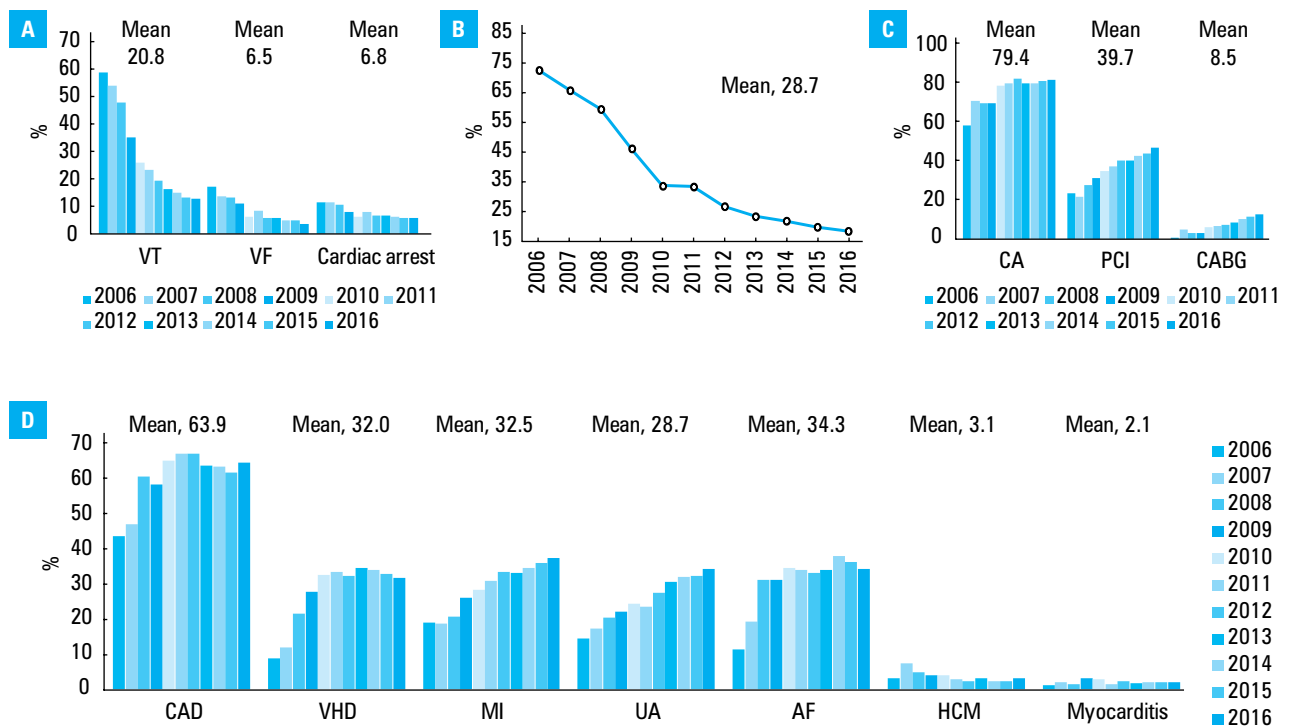
years, the number of implanted ICDs per million residents included in the SILCARD registry is comparable to that in Western European countries.<sup>11</sup> In SILCARD, the number of ICDs was 267 for 2013, 251.2 for 2014, 248.1 for 2015, and 235.8 for 2016. A trend towards an increased percentage of implanted CRT-Ds has been observed over the years (**FIGURE 2**), which is consistent with the reports of other authors.<sup>7</sup>

**Clinical characteristics of patients** The baseline characteristics of patients enrolled to the study, including mean age and sex distribution (Supplementary material, *Figure S1*), were similar to those in other reports.<sup>7,12</sup>

The length of hospital stay for ICD or CRT implantation was reduced by more than 70% between 2006 and 2016 (Supplementary material, *Figure S1*), which is similar to the findings from other studies.<sup>7,12</sup> Most likely, this reduction results from the fact that operators and centers are becoming more experienced, and there is a lower percentage of periprocedural complications, which translates into the shortening of time from procedure to discharge. The prevalence of comorbidities and incidence of diagnostic and therapeutic procedures performed before the device implantation were analyzed (**FIGURE 3**). The prevalence of coronary artery disease, myocardial infarction, and atrial fibrillation was comparable to that in other reports.<sup>7–9,13,14</sup> A significant increase in the prevalence of stable and unstable coronary artery disease, myocardial infarction, valvular heart disease, and atrial fibrillation was observed between 2006 and 2010. After this time, the trend stabilized. However, since 2012, a decrease in the percentage of stable coronary artery disease was noted. In contrast, the prevalence of coronary artery disease and myocardial



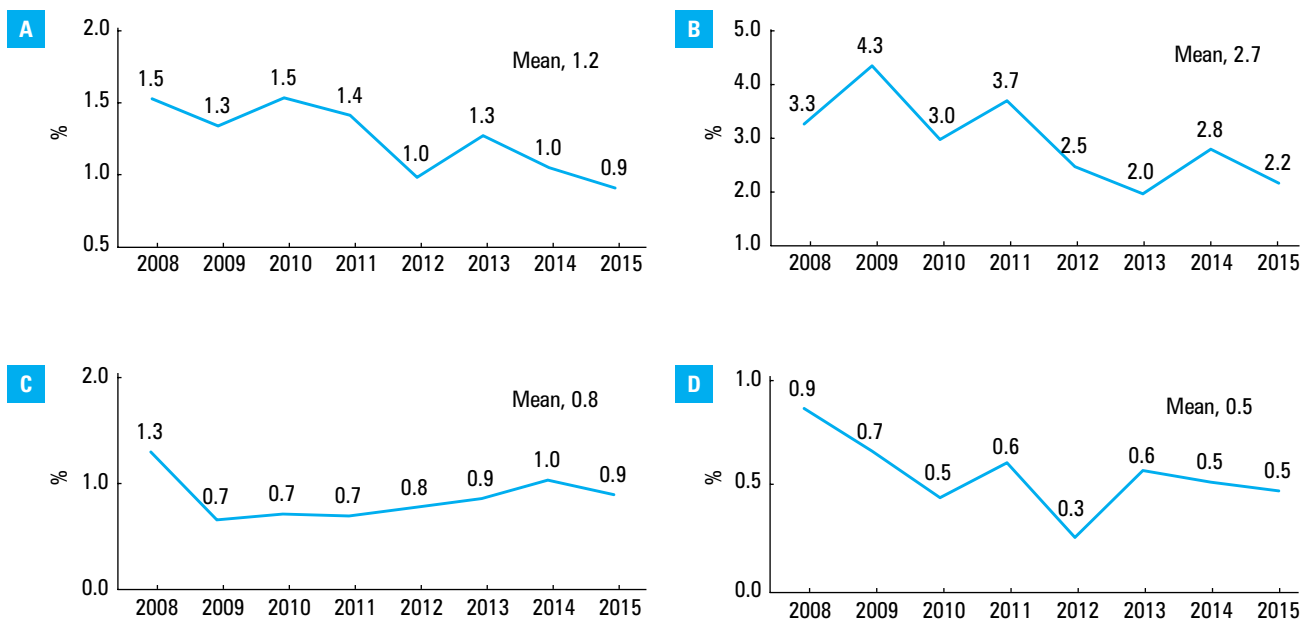
**FIGURE 2** Percentage of implanted devices in the years from 2006 to 2016  
Abbreviations: see **FIGURE 1**



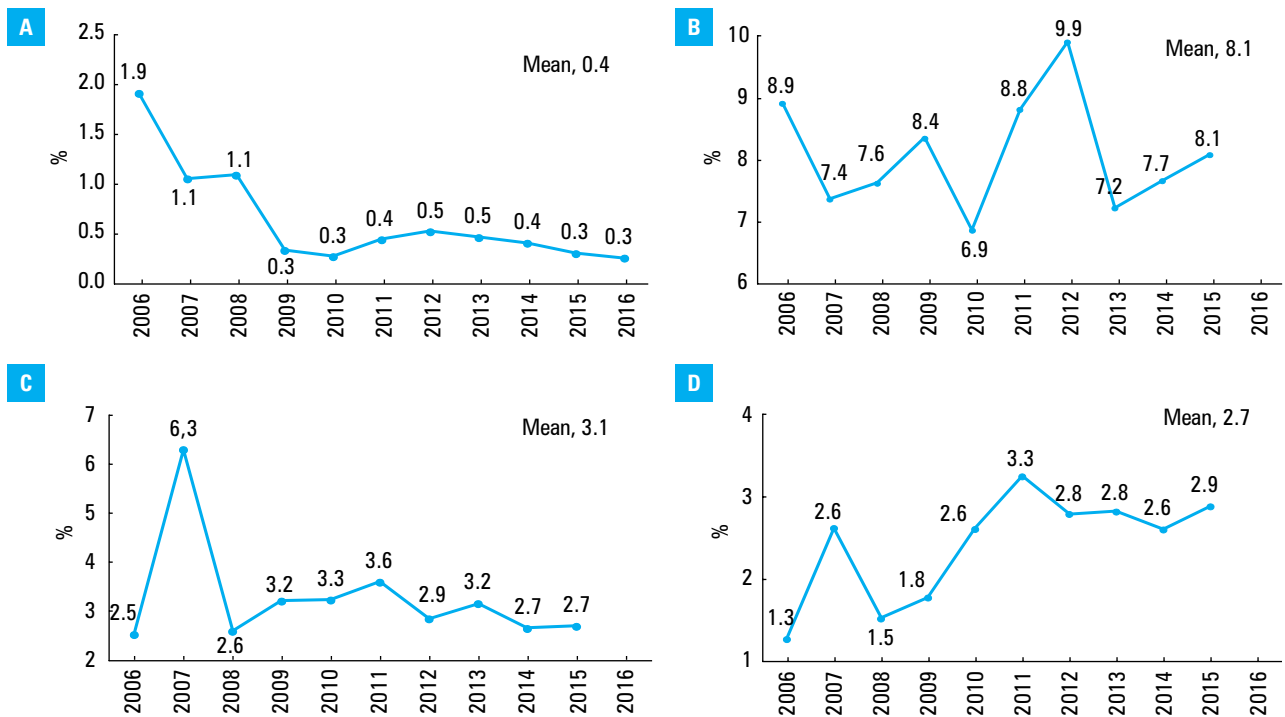
**FIGURE 3** Clinical characteristics of analyzed patients in the years from 2006 to 2016: **A** – prior ventricular tachycardia (VT), ventricular fibrillation (VF), cardiac arrest; **B** – secondary prevention; **C** – prior coronary angiography (CA), percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG); **D** – prior coronary artery disease (CAD), valvular heart disease (VHD), myocardial infarction (MI), unstable angina (UA), atrial fibrillation (AF), hypertrophic cardiomyopathy (HCM), and myocarditis

infarction was reported to decrease between 2006 and 2010 in the NCDR ICD Registry (National Cardiovascular Data Registry’s Implantable Cardioverter-Defibrillator),<sup>8</sup> unlike the prevalence of atrial fibrillation and atrial flutter. Such a difference may be explained by an increasing proportion of patients with an ischemic etiology of HF referred for ICD or CRT implantation in the United States. The prevalence of coronary

angioplasty performed before implantation was similar to that reported by Hamill et al.<sup>15</sup> However, in the SILCARD database, a significantly lower percentage of CABG procedures was observed. It may result from differences in the referral criteria for cardiac surgery procedures. Of note, during the follow-up, the number of PCIs and CABG procedures performed before the ICD/CRT implantation increased 2.5-fold.



**FIGURE 4** Percentage of complications in the 12-month follow-up in the years from 2008 to 2015: **A** – pocket revision; **B** – lead replacement/repositioning; **C** – lead extraction; **D** – infective endocarditis



**FIGURE 5** In-hospital and 12-month prognosis in the years from 2006 to 2016: **A** – in-hospital mortality; **B** – 12-month mortality; **C** – myocardial infarction in the 12-month follow-up; **D** – stroke in the 12-month follow-up

The prevalence of ventricular tachycardia (VT) before the ICD/CRT implantation in this study did not differ from that reported in other European registers,<sup>7,16</sup> but it was almost 2-fold higher than in American and Israeli registries.<sup>13,15</sup> In the National Cardiovascular Data Registry (NCDR), performed between 2006 and 2010, an increase in the percentage of patients with a history of VT was observed.<sup>17</sup> In the SILCARD registry, an almost 5-fold reduction in

the percentage of VT before the implantation was observed over the years. This may be associated with the increasing frequency of referrals for ICD in primary prevention.

In the SILCARD database, almost every third patient had the device implanted for secondary prevention of SCD (in the recent years, every fifth patient). This result is consistent with the available literature data (22.2%–41.9%).<sup>7,9,13,15,18</sup> In a Swedish registry, an increasing trend in

secondary prevention was observed before 2007, and then it reversed.<sup>7</sup> The possible explanation is that in the beginning of the ICD/CRT era, when the number of implanted devices was limited, mainly patients with the highest risk of SCD were referred for implantation. Over the years, the availability of devices increased, which enabled implantation also in primary prevention in patients with lower SCD risk.

**In-hospital and 12-month mortality** In the SILCARD database, the in-hospital mortality rate after ICD/CRT implantation was reduced over 6-fold between 2006 and 2016 (FIGURE 5). A lower in-hospital mortality (0.1%) was reported by Gadler et al,<sup>7</sup> but only in-hospital deaths associated with the implantation procedure were included. A similar 12-month mortality rate was observed by Buxton et al,<sup>19</sup> whereas higher rates were reported in the NCDR registry (6.8%–17.3%).<sup>8</sup> It should be emphasized that mortality rates presented in the SILCARD database are not only associated with a device implantation. In most cases, patients suffered from severe HF, and the risk of death was most probably associated with a primary disease. This may be confirmed by the results of the COMMIT-HF registry (COnteMporary Modalities In Treatment of Heart Failure), including patients with HF (including 41.1% of patients with an ICD and 20% of patients with a CRT-D), in which the 1-year mortality rate was 12.5%.<sup>20</sup>

**Rehospitalizations in the 12-month follow-up** As noted above, the analysis of hospital readmissions and medical procedures (coronary angiography, PCI, and CABG) performed during the 12 months after the ICD/CRT implantation may be considered as a unique and practical aspect of the SILCARD database (Supplementary material, Figure S2). In the literature, there have been few reports on the reasons for hospital readmissions after ICD/CRT implantation. In the German DEVICE registry, a considerably lower frequency of rehospitalizations due to CVDs in the 12-month follow-up was observed, namely, 13.8% to 23.1%, depending on the type of an implanted device and etiology of HF.<sup>9</sup> However, a comparable number of readmissions for CVDs in patients after CRT-D implantation (41.2%) was shown in the NCDR-ICD registry.<sup>8</sup> Moreover, the authors observed a relative reduction in the number of HF rehospitalizations by 13% in the 6-month follow-up after ICD implantation in primary prevention of SCD between 2006 and 2010.<sup>8</sup> In our study, in the same period, we showed a reduction in the number of hospital readmissions by one-third. In the following years, a plateau at the level of approximately 40% was observed. It may result from an improved medical treatment after discharge. Noteworthy, in the SILCARD database, HF was the reason for more than half of hospital readmissions due to CVD. In the vast majority of

cases, the cause was most probably decompensation of HF. Therefore, stabilization of the patient's condition during hospitalization, proper selection of pharmacotherapy, and patient education seem to be crucial.

One of the most important results of our study is that acute coronary syndrome and stable coronary disease accounted for 6.5% and 10% of CVD readmissions, respectively, in the 12-month follow-up. Almost 60% of patients with coronary angiography performed during follow-up had indications for coronary revascularization (PCI or CABG). This observation emphasizes the meaning of proper diagnosis and preparation of a patient before implantation of an ICD or CRT device, including the possibility of complete revascularization. Due to limited literature data on this subject, we were unable to compare our results with those reported by other authors. In the NCDR ICD registry, the number of hospital readmissions due to HF in the 6-month follow-up after the device implantation reached 12.2%.<sup>8</sup> Ranasinghe et al<sup>21</sup> reported the percentage of hospital readmissions due to HF, myocardial infarction, stable coronary artery disease, and stroke or transient ischemic attack to reach 38.1%, 0.2%, 10.5%, and 2.1%, respectively, in HF patients in the 30-day follow-up. However, it should be emphasized that their study group did not include only patients with an implanted ICD or CRT device. In the SILCARD registry, the percentage of myocardial infarction and stroke in the 12-month follow-up was 3.1% and 2.7%, respectively (FIGURE 5).

In our study, patients had a mean number of 3 outpatient visits in the 12-month follow-up (Supplementary material, Figure S2). At least 2 visits were related to a planned device control. Each patient had only one visit to a cardiology clinic on average. This may explain the high percentage of rehospitalizations for cardiovascular reasons.

**Complications** In the SILCARD database, a decreasing trend in the number of complications was observed (FIGURE 4). In comparison to other registries, a similar number of complications requiring reintervention and a significantly lower frequency of cardiac device-related infective endocarditis were observed.<sup>7,11,12,19</sup> Although ICD/CRTD implantation is associated with an increased risk of infectious complications, the number of complications in the SILCARD database may be considered as one of the lowest among the reported registries.<sup>22,23</sup>

**Limitations** Our study has several limitations. The principal diagnosis according to the ICD-10 classification reported to the National Health Fund most often reflects the real reason for hospitalization. However, the reporting systems are not standardized. The order and number of diagnoses are subjectively reported, so some disease entities can be omitted. Moreover, the classification often does not determine the subcategories

of individual diseases, which hinders precise determination of all the diagnoses. Similarly, data concerning clinical characterization, including concomitant diseases, are not obligatorily reported, so information on this subject cannot be completely reliable. There are also no detailed data on upgrades. We do not know if the leads have been removed or left during the procedure. Moreover, in the present report, due to the lack of direct information concerning the prevention of SCD, the appearance of VT or ventricular fibrillation or sudden cardiac arrest before the implantation of an ICD or CRT device was considered as secondary prevention, which also constitutes a limitation.

**Conclusions** In conclusion, the results of this study reflect the real-life practice in terms of referral criteria, as well as in-hospital and 12-month outcomes in patients with an implanted ICD or CRT device. The relatively high rates of hospital readmissions and their causes indicate the need for comprehensive care of patients before implantation of ICD or CRT devices and after discharge.

**SUPPLEMENTARY MATERIAL** Supplementary material is available with the article at [www.pamw.pl](http://www.pamw.pl).

**CONTRIBUTION STATEMENT** DP, JN, AK analyzed the data and wrote the manuscript. KG, KMS, ZG, ENK, WW, MT, MG revised the manuscript. MG created and designed the SILCARD register, revised the manuscript. All authors approved the final version of the manuscript.

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